United States Air Force Aerospace Medicine Waiver Guide Compendium



Clinical • Environmental • Operational



January 1, 2023

The Aerospace Medicine Waiver Guide provides guidance for waivers relating to flying class and special duty personnel medical standards. The Aerospace Medicine Waiver Guide does not cover issues relating to general military accession or retention standards.

This document is guidance to be used by flight surgeons for aeromedical decision-making. It does not replace individualized clinical judgment, nor does it limit options for aeromedical disposition. While this document is not policy, it describes current USAF medical standards at the time of writing. This document does not supersede changes to evidence-based practice or updated medical standards outlined in DAFMAN 48-123, 8 Dec 2020 and the Medical Standards Directory. Flight surgeons may contact the MAJCOM/ SGP or AFMRA for further assistance.

Waiver guide reorganized into specialty categories with direct links to the waiver guide topics. For fastest access, use Google Chrome or another web browser to open file. The Search Function, accessed by <ctrl f>, will assist in locating and cross referencing diagnoses which may appear in other waiver guide topics.

Significant Updates: Crohn's Disease, Hypothyroidism, Salivary Gland Disorders, Sinusitis, Ulcerative Colitis and Urticaria, Angioedema, Anaphylyaxis Waiver Guide chapters updated

Cardiology

Aortic Aneurysm and Peripheral Arterial Disease Aortic Valve Disease Atrial Fibrillation and Atrial Flutter Cardiac Conduction Delay (Heart Block, Bradycardia) Cardiomyopathy Catheter Ablation of Tachyarrhythmias and Pre-Excitation (WPW) Congenital Heart Disease Coronary Artery Calcium Testing Coronary Artery Disease Coronary Artery Revascularization ECG Findings in USAF Aircrew, Disposition Ectopy, Supraventricular, and Ventricular and Pairing Hypertension Left Bundle Branch Block Mitral, Tricuspid, and Pulmonic Valve Disorders Mvocardial Infarction Pericardial and Myocardial Disorders, Including Pericarditis, Myopericarditis, and Myocarditis Supraventricular Tachycardia Syncope Valve Surgery, Replacement or Repair Ventricular Tachycardia Wolff-Parkinson-White (WPW) and Other Pre-Excitation Syndromes

Dermatology

Acne Eczematous Dermatitis (Eczema) and Atopic Dermatitis Psoriasis and Psoriatic Arthritis

Gastroenterology

Abnormal Liver Enzymes and Gilbert Syndrome Celiac Disease Chronic Viral Hepatitis Crohn's Disease Diverticular Disease of the Colon Eosinophilic Esophagitis and Other Eosinophilic Gastrointestinal Disorders Esophagitis and Gastroesophageal Reflux Disease (GERD) Hemochromatosis Hepatic Cirrhosis Irritable Bowel Syndrome Pancreatitis Peptic Ulcer Disease Ulcerative Colitis

Hematology

Anemia, Blood Loss, and Bone Marrow Donation
Congenital and Acquired Asplenia
Sickle Cell Disease/Trait and Heterozygous Sickling Disorders
Thalassemia and Other Disorders of Hemoglobin Synthesis
Thromboctopenia, Immunee Thrombocytopenic Purpura (ITP), and Thrombotic
Thrombocytopenic Purpura (TTP) Thrombocyosis
Venous Thromboembolism (VTE)

Internal Medicine

Ankylosing Spondylitis Diabetes Mellitus Gout Human Immunodeficiency Virus (HIV) Infection Hypercholesterolemia and Hyperlipidemia Hyperthyroidism Hypogonadism Hypothyroidism Kidney Disease, Chronic Lyme Disease Malaria and Antimalarial Medications Osteoarthritis Osteoporosis and Osteopenia Proteinuria and IgA Nephropathy Raynaud's Phenomenon **Rheumatoid Arthritis** PrEP, HIV Pre-Exposure Prophylaxis (PrEP) Systemic Glucocorticoid (Steroid) Treatment Urticaria, Angioedema, and Anaphylaxis

Malignancies / Cancers

Bladder Cancer Breast Cancer Cancers (Misc.) Cervical Cancer Colorectal Cancer Hodgkin Lymphoma Leukemia Malignant Melanoma Non-Hodgkin's Lymphoma Pituitary Tumors Prostate Cancer Testicular Cancer Thyroid Cancer

Neurology

Bell's Palsy
Chronic Low Back Pain
Guillain-Barré Syndrome (Acute Inflammatory Demyelinating Polyradiculoneuropathy)
Headache
Meningitis and Encephalitis
Multiple Sclerosis and Central Demyelinating Disorder
Seizures, Epilepsy, and Abnormal EEG
Stroke and Transient Ischemic Attack
Traumatic Brain Injury

Obstetrics and Gynecology (OB/GYN)

Birth Control Dysmenorrhea Endometriosis Polycystic Ovary Syndrome Pregnancy Uterine Fibroids (Leiomyomas)

Ophthalmology

Cataract, Capsular Opacifications, and Intraocular Lens Implant Central Retinal Vein Occlusion Central Serous Chorioretinopathy Color Vision Deficiencies Dry Eye Syndrome (Keratoconjunctivitis Sicca) Glaucoma and Ocular Hypertension Implantable Collamer Lens (ICL) Surgery Keratoconus, Abnormal Corneal Topography, and Corneal Collagen Crosslinking Lattice Degeneration Ocular Histoplasmosis Syndrome Optic Nerve Head Drusen **Optic Neuritis** Refractive Error, Excessive Refractive Surgery Retinal Holes, Retinal Tears, Retinal Detachment, and Retinoschisis Substandard Stereopsis (Formerly Defective Depth Perception) Uveitis

Orthopedics

Herniated Nucleus Pulposus (HNP) and Spinal Fusion Retained Orthopedic Device and Joint Replacement Spinal Curvature (Kyphosis, Scoliosis, and Lordosis) Spinal Fracture Spondylolysis and Spondylolisthesis

Otolaryngology (ENT)

Allergic Rhinitis Cholesteatoma Eustachian Tube Dysfunction Hearing Loss/Asymmetric Hearing Loss/Use of Hearing Aids Motion Sickness Otosclerosis/Stapedectomy Peripheral Vertiginous Disorders Sinusitis, Hypertrophic Sinus Tissue, and Nasal Polyps Salivary Gland Disorders Vestibular Schwannoma (Acoustic Neuroma)

Psychiatry / Neuropsychiatry

Adjustment Disorder Alcohol Use Disorders Anxiety Disorders Attention-Deficit/Hyperactivity Disorder (ADHD) Eating Disoders Learning Disabilities Mental Health Waiver Guide Checklist Mood Disoders: Depressive, Bipolar, and Related Disorders Other Condiions That May Be a Focus of Clinical Attention (V and Z Codes), and Miscellaneous Disorders Personality Disorders Post-Traumatic Stress Disorder (PTSD) Psychotic Disorders Somatic Symptom and Related Disorders (Formerly Somatoform and Factitious Disorders/Malingering) Suicide Attempt or Suicidal Behavior

Pulmonology

Asthma Pneumothorax Sarcoidosis Sleep Disorders

Urology

Benign Prostatic Hyperplasia (BPH) Congenital Urinary Anomalies Hematuria Prostatitis Renal and Ureteral Stones (Nephrolithiasis)

Other

Anthropometrics (Short Stature, Excessive Height, Weight, and Other Body Measurements) Decompression Sickness and Arterial Gas Embolism





Aortic Aneurysm and Peripheral Arterial Disease

Revised: Aug 2022 Authors/Reviewers: Col Eddie Davenport (ACS Chief Cardiologist) and Dr. Edwin Palileo (ACS Cardiologist); Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator); Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

Significant Changes: New waiver guide.

I. Waiver Consideration

Any arterial or aortic disease or disorder is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. These diseases and disorders include, but are not limited to, any history of the following: aneurysm, dissection, arteriosclerosis, collagen vascular disease, inflammatory conditions, infectious diseases, vasospastic diseases, and diabetic vascular disease. Any history of surgical repair or percutaneous intervention on these conditions is also disqualifying. Disqualifying arterial diseases and disorders include, but are not limited to, aneurysm, dissection, arteriosclerosis, collagen vascular disease, inflammatory conditions, infectious diseases and disorders include, but are not limited to, aneurysm, dissection, arteriosclerosis, collagen vascular disease, inflammatory conditions, infectious disease, and diabetic vascular disease.

In general, peripheral vascular (arterial or venous) disease is not disqualifying for ATC, GBO, or OSF personnel. However, any history of <u>symptomatic</u> peripheral or <u>central</u> vascular disease is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. These conditions include, but are not limited to, claudication, skin changes, stroke or central venous accident (CVA), transient ischemic attack (TIA), and any other peripheral or central vascular infarct. Furthermore, other concomitant factors may exist alongside aortic aneurysm and peripheral arterial disease. Please cross-reference the appropriate Air Force Waiver Guide chapters, the Medical Standards Directory, and DoDI 6130.03 vol 2. For example, arteriosclerosis of the coronary arteries is discussed in the chapters on *Coronary Artery Disease*. Percutaneous coronary artery interventions are addressed in the chapter on *Coronary Artery Revascularization*. For more information regarding aeromedical and operational waiver considerations for central nervous system vascular disease, please refer to the Aerospace Medicine Waiver Guide chapter on *Stroke and Transient Ischemic Attack*. Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Any history of disease or disorder of the aorta ¹	Yes AFRS/CMO	Yes
	Any history of peripheral arterial disease ²	Yes AFRS/CMO	Yes
FC II/III/SWA	Any history of disease or disorder of the aorta ¹	Yes MAJCOM ⁴	Yes
	Any history of peripheral arterial disease ²	Yes MAJCOM ⁴	Yes
ATC/ GBO/OSF	Any history of disease or disorder of the aorta ¹	Yes MAJCOM ⁴	Yes
	Any history of symptomatic peripheral arterial disease ³	Yes MAJCOM ⁴	Yes

Table 1: Waiver potential for Aortic Aneurysm and Peripheral Arterial Disease

1. May occur anywhere along the length of the aorta. Disqualifying conditions include, but are not limited to, aneurysm (or aortic enlargement over 4.0 cm in diameter), dissection, arteriosclerosis, collagen vascular disease, inflammatory conditions, infectious diseases, vasospastic diseases, and diabetic vascular disease. Any history of surgical repair or percutaneous intervention on these conditions is also disqualifying.

2. Disqualifying conditions include, but are not limited to, aneurysm, dissection, fistula, arteriosclerosis, collagen vascular disease, inflammatory conditions, infectious diseases, vasospastic disease, claudication, skin changes, erythromelalgia, and diabetic vascular disease.

In general, peripheral vascular (arterial or venous) disease is not disqualifying for ATC, GBO, or OSF personnel. However, any history of symptomatic peripheral or central vascular disease is disqualifying. Disqualifying conditions include, but are not limited to, claudication, skin changes, stroke or central venous accident (CVA), transient ischemic attack (TIA), and any other peripheral or central vascular infarct.

4. Certification authority for untrained assets is AFRS/CMO.

II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

NOTE: It is required that all original cardiac imaging and electrical tracings be submitted to ACS Cardiology for independent review. Electronic submission to the ECG Library is preferred. If electronic submission is not possible, electronic media can be sent via USPS or FedEx to the address below. Please include the service member's name, full social security number, date of mailing, and a POC at the submitting flight surgeon's office with all mailed materials. State in the AMS the date of submission.

Attn: Case Manager for [specify the appropriate MAJCOM] USAFSAM/FECI Facility 20840 2510 Fifth Street Wright-Patterson Air Force Base, OH 45433-7913

A. Initial Waiver Request:

- 1. Information to include in history:
 - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
 - b. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
 - c. List current medications with dosages.
 - d. Specify current activity level.
- 2. Consultation report from the treating specialist (e.g., cardiologist, vascular surgeon) and all subsequent consultation notes.
- 3. Results of any other testing performed in the course of diagnosis, evaluation, and management of aortic or peripheral arterial disease, including other laboratory studies, all imaging reports, and any other ancillary studies.
 - a. Include procedural reports from all surgical or percutaneous interventions that were performed, if applicable.
 - b. Include radiology reports from any imaging studies that were performed, if applicable (e.g., plain radiographs, ultrasound, CT, or MRI).
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
 - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
 - b. Summarize any interval evaluation and/or treatment.
 - c. List current medications with dosages.
 - d. Specify current activity level.
- 2. All interval consultation reports from the treating specialist (e.g., cardiology, vascular surgery), if applicable.
- 3. Results of any other testing performed in the course of diagnosis, evaluation, and management, including other laboratory studies, all imaging reports, all procedure reports, and any other ancillary studies.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

III. Aeromedical Concerns

Aeromedical and operational concerns related to aortic aneurysm and peripheral arterial disease include sudden incapacitation and sudden performance impairment resulting from acute vascular events, which may occur with little or no warning and be catastrophic or fatal without immediate definitive medical attention. Major events include acute aortic or arterial rupture or dissection, as

Aortic Aneurysm and Peripheral Arterial Disease

well as central venous accidents or transient ischemic attacks due to carotid or vertebral artery occlusion. Depending on the artery involved and the downstream perfusion, symptoms of arterial disease may include chest pain, back pain, the consequences of local mass effect (e.g., in the setting of an aneurysm), claudication, and systemic embolization (e.g., from a cardiac mural thrombus traveling to the brain or from an aortic thrombus traveling to the mesenteric arteries). The consequences may range from distraction and loss of attention on critical aviation or operational duties, to decrements in function that would compromise individual service member health and mission safety or effectiveness (e.g., loss of vision, concentration impairment, aphasia, severe pain, etc.).

Aortic aneurysm refers to a pathologic segment of aortic dilatation that expands and can eventually rupture. Aortic aneurysms are described by their size, location, morphology and cause. Aneurysms may be fusiform (more common) or saccular. Abdominal aortic aneurysms (AAA) occur in 3-9% of men older than 50 years and are the most common form of aortic aneurysms. AAA are five times more prevalent in males than in females and are strongly associated with age (mostly occurring in men over the age of 60 years), cigarette smoking (coveys a five-fold increase in risk over non-smokers), hypertension, and hyperlipidemia. Additionally, there is a 20% heritable component. Echocardiogram and either computed tomography (CT) with intravenous contrast or MRI of the entire aorta is required for all service members requesting a waiver for aortic aneurysm or dilation. Size should be corrected for body surface area (BSA). Repair with either an open or percutaneous approach should be pursued per published guidelines. Aircrew with a history of aortic aneurysm may be considered for a waiver. Waiver consideration after surgical repair will be on a case-by-case basis, and no sooner than six months after surgery.

Thoracic aortic aneurysms (TAA) have an estimated incidence of 5-10 per 100,000 person-years. Aortic root or ascending aortic aneurysms are the most common (60%) followed by aneurysms of the descending aorta (35%) and aortic arch (<10%). Thoracoabdominal (descending thoracic aneurysm extending distally to involve the abdominal aorta) represent another 10%. Causes of TAA include genetic (congenital) and degenerative (formerly known as atherosclerotic) disorders, mechanical, inflammatory, and infectious etiologies. Many genetic disorders preferentially involve the aortic root and ascending aorta. Cystic medial degeneration is often associated with Marfan syndrome and many other genetic TAAs. The association between bicuspid aortic valve (BAV) and dilatation of the aortic root and ascending aorta is well-established. Up to 20% of individuals with BAV will develop aortic aneurysms, and these individuals are at higher risk of aortic dissection and severe aortic enlargement. Due to abnormal aortic wall shear stress caused by the aortopathy of BAV disease, BAV results in turbulent blood flow even in the absence of a stenotic or regurgitant lesion.

Most TAAs are asymptomatic and discovered incidentally, but they may result in a variety of symptoms due to mass effect. The most serious complications are rupture and dissection. The thresholds for surgical repair vary depending on disease- and patient-specific factors and are outlined in published professional guidelines. Endovascular repair is now possible for many of these conditions. Echocardiogram and either computed tomography (CT) with intravenous contrast or MRI of the entire aorta is required for all service members requesting a waiver for aortic aneurysm or dilation. Size should be corrected for body surface area (BSA). Aircrew with

a history of TAA may be considered for a waiver limited to non-high performance airframes. For aortic root or ascending aorta dilation found incidentally on echocardiogram or CT scan, waiver is required if the diameter is over 4.0 cm, but flight restrictions may not be necessary.

Peripheral Artery Disease (PAD) refers to acute or chronic obstruction of the arteries of the upper or lower extremities. When severe, it can result in downstream ischemia, potentially leading to tissue necrosis or limb loss. PAD is most often caused by atherosclerosis; hence, the prevalence varies from 6% in persons 40 years and older to 15-20% in those 65 years and older. PAD correlates strongly with major adverse cardiovascular events, because it is frequently associated with coronary and cerebral atherosclerosis. Aircrew with PAD should undergo bilateral ankle brachial index (ABI) measurement, carotid ultrasound, and cardiac evaluation with ECG, echocardiogram, and exercise stress testing. CT coronary calcium scoring is also recommended, if available. Treatment is per published professional guidelines. Waiver may be considered for service members with non-flow-limiting PVD (generally <70% stenosis) and no or minimal claudication symptoms.

Peripheral Vascular Disease (PVD) is a less-specific term and can include other atherosclerotic disease, such as renal artery and carotid artery disease, as well as other vasculitides (e.g., vasospastic disease, venous thromboembolism, venous insufficiency, lymphatic disorders, etc.). More information regarding other specific disqualifying conditions can be found in other Aerospace Medicine Waiver Guide chapters.

Review of the AIMTWS database revealed a total of 48 total cases for aortic aneurism, peripheral vascular disease, and arterial embolism. The breakdown of the number of waivers and number of total cases are tabulated below. Of the disqualified waiver adjudications, 8 of 9 cases were related to aortic insufficiency or bicuspid aortic valves.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		(# of waivers / total # of cases)				
		IFC I/IA	FC II	FC III	GBO	ATC
I71.9	Aortic aneurysm, unspecified site, w/o rupture					
I71	I71 Aortic aneurysm and dissection		24/29	9/13	3/3	3/3
173.9	173.9 Peripheral vascular disease					
174	174 Arterial embolism and thrombosis					

IV. Suggested Readings

- Chaikof EL, Dalman RL, Eskandari MK, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg 2018;67:2-77. Available at https://www.jvascsurg.org/article/S0741-5214(17)32369-8/pdf. Accessed 11 March 2022.
- 2. Hiratzka LF, Bakris GL, Beckman JA, et al.; American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines; American Association for Thoracic Surgery; American College of Radiology; American Stroke Association; Society of Cardiovascular Anesthesiologists; Society for Cardiovascular Angiography and Interventions; Society of Interventional Radiology; Society of Thoracic Surgeons; Society for Vascular Medicine. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM guidelines for the diagnosis and management of patients with Thoracic Aortic Disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. Circulation 2010;121:e266-369. Erratum in: Circulation 2010;122:e410. Available at https://www.ahajournals.org/doi/epub/10.1161/CIR.0b013e3181d4739e. Accessed 11 March 2022.
- Rooke TW, Hirsch AT, Misra S, et al.; American College of Cardiology Foundation Task Force; American Heart Association Task Force. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA Guideline Recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013;61:1555-1570. Available at <u>https://www.sciencedirect.com/science/article/pii/S0735109713001770?via%3Dihub</u>. Accessed 11 March 2022.
- Guettler N, Nicol ED, d'Arcy J, Rienks R, Bron D, Davenport ED, Manen I, Gray G, Syburra T. Non-coronary cardiac surgery and percutaneous cardiology procedures in aircrew. *Heart*. 2019;105 (suppl 1);s70-s73. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6256296/pdf/heartjnl-2018-313060.pdf</u>

WAIVER GUIDE
Initial Version: Dec 2015
Supersedes Waiver Guides of Aug 2014 (Bicuspid Aortic Valve), Oct 2010 (Aortic Insufficiency), and Oct 2010 (Aortic Stenosis)
By: Dr Dan Van Syoc, Dr. Eddie Davenport (ACS Chief Cardiologist)

CONDITION: Aortic Valve Disease (Dec 2015)

I. Waiver Consideration.

All flying classes except are disqualified for aortic valve insufficiency (AI) greater than trace, any degree of aortic stenosis (AS), and bicuspid aortic valve (BAV) (regardless of degree of AI & AS).

ACS review is required for waiver consideration. ACS evaluation may be required, depending on the flying class or for specific concerns in an individual case. Waiver recommendations are primarily dependent on the presence and severity of associated AS and AI. FC I and IA will only be waiver eligible for BAV with \leq mild AI and no AS; any greater AI or any AS is not waiver eligible. FC II/III requires ACS evaluation for waiver consideration. ACS re-evaluations will be performed at 1-3 year intervals, depending on the degree of AI and/or AS and other related conditions such as chamber dilation, left ventricular function and left ventricular hypertrophy. As discussed above, the use of approved ACE inhibitors and nifedipine for afterload reduction is acceptable in aviators with BAV and asymptomatic moderate or severe AI.³ Waiver may be considered after surgery; please refer to the "Valve Surgery – Replacement or Repair" waiver guide. Table 2 is a summary of the clinical manifestations and most common requirements for the separate flying class (FC) duties for BAV, table 3 summarizes recommendations for AI in a structurally normal valve, and table 4 summarizes recommendations for AS in a structurally normal valve.

BAV and Associated Levels of	Flying Class	Waiver	Required ACS
Aortic Stenosis (AS) and/or		Potential	Review and/or
Aortic Insufficiency (AI)		Waiver	ACS Evaluation
nor de insumerency (m)		Authority	
BAV with no, trace or mild AI	FC I/IA	Yes	ACS review
(≤mild) and no AS	I C DIA	AETC	ACDICVICW
		ALIC	
BAV with >mild AI or any AS	FC I/IA	No	ACS review
Diff with and the of any ris		AETC	
	FC II, GBO	Yes	ACS review
	ATC, SWA	MAJCOM	
	,		
BAV with \leq mild AI and/or \leq	FC II/III**	Yes	ACS evaluation
mild AS		MAJCOM	
	ATC/GBO/SWA	Yes	ACS review
		MAJCOM	
BAV with moderate AI and/or	FC IIA (non-SHGA	Yes	ACS evaluation
greater than mild AS ⁺	only)	AFMRA	
		Yes	ACS evaluation
	FC III,	AFMRA	
	ATC/GBO/SWA		
	(low performance		
	only)		
BAV with severe AI only –	FC IIA only	Maybe*	ACS evaluation
asymptomatic and nonsurgical		AFMRA	
AI per guidelines			
	FC III (low	Maybe*	ACS evaluation
	performance only)	MAJCOM	
	ATC/GBO/SWA	Maybe	ACS Review
		MAJCOM	
BAV with \geq moderate AS [†] or	FC II/III	No	ACS review
with severe AI [‡] surgical by		AFMRA	
guidelines			
	ATC/SWA/GBO	Maybe	ACS review to
* W		AFMRA	confirm

Table 1. Summary of BAV and Associated Clinical Conditions and ACS Requirements.

* Waiver in untrained FC II and III individuals unlikely.
† Moderate to severe AS requires medical evaluation board (IRILO/MEB).

‡ Severe AI if symptomatic and associated with left ventricular dilation or dysfunction requires IRILO/MEB.

Table 2: Summary of waiver potential and required ACS evaluation for degrees of AI in aircrew.

Degree of Aortic Insufficiency (AI)	Condition	Flying Class	Waiver Potential/ Waiver Authority	Required ACS Review and/or ACS Evaluation
Trace	Trileaflet aortic valve	Qualifying for all classes	Not required (Normal variant)	ACS review to confirm
	Bicuspid aortic valve (BAV)	FC I/IA	Yes AETC	ACS evaluation
		FC II	Yes MAJCOM	ACS evaluation
Mild	Trileaflet or BAV***	FC I/IA	Yes AETC	ACS evaluation.
		FC II/III ATC/SWA/GBO	Yes MAJCOM	ACS evaluation
Moderate	Trileaflet or BAV	FC I/IA	No AETC	ACS review to confirm
		FC IIA	Yes* AFMRA	ACS evaluation
		FC III (low performance only)	Yes* MAJCOM	ACS evaluation
		ATC/GBO/SWA	Yes MAJCOM	ACS review
Severe – asymptomatic and nonsurgical per guidelines	Trileaflet or BAV	FC IIA only	Maybe* AFMRA	ACS evaluation
		FC III (low performance only)	Maybe* MAJCOM	ACS evaluation
		ATC/GBO/SWA	Yes MAJCOM	ACS review
Severe – symptomatic or surgical per guidelines†	Trileaflet or BAV	FC II/III	No MAJCOM	ACS review
		ATC/GBO/SWA	Maybe MAJCOM	ACS review

* Waiver in untrained FC II and III unlikely.

† Medical evaluation board (MEB) required.

** GBO, SWA, and ATC waivers for mild disease are very likely to be approved.

Associated Levels of	Flying Class	Waiver	Required ACS Review
Aortic Stenosis (AS)		Potential	and/or ACS Evaluation
		Waiver Authority	
Mild AS	FC I/IA	No AETC	ACS review to confirm
	FC II/III	Yes MAJCOM**	ACS evaluation
	ATC/GBO/SWA	Yes MAJCOM	ACS review to confirm
Mild-to-moderate AS (greater than mild not meeting all criteria for	FC IIA (low G- aircraft)	Yes AFMRA	ACS evaluation
moderate based on ACS review)	FC III (low G- aircraft)	Yes MAJCOM	ACS evaluation
	ATC/GBO/SWA	Yes AETC	ACS review to confirm
≥ Moderate AS*	FCI/IA, II, III	No	ACS review to confirm
	ATC/GBO/SWA	Maybe AFMRA	ACS review to confirm

Table 3: Summary of Degree of Aortic Stenosis and ACS Requirements.

* Medical evaluation board (MEB) required.

AIMWTS search in Dec 2015 for aortic valve disease revealed 372 cases. Breakdown of the cases revealed: 41 FC I/IA cases (8 disqualified), 227 FC II cases (23 disqualified), 89 FC III cases (20 disqualified), 6 ATC/GBC cases (1 disqualified), and 9 MOD cases (1 disqualified). There was significant overlap in these cases and the vast majority were mild and well controlled.

II. Information Required for Waiver Submission.

Aeromedical Consultation Service (ACS) review/evaluation is required for all classes of flying duties for BAV with or without AI/AS, as well as for AI or AS without BAV. No additional studies are routinely required prior to ACS evaluation. If however, the treating physician deems

it clinically necessary to perform additional studies, it is required that all studies be forwarded to the ACS for review. There is no minimum required non-flying observation period for waiver consideration for BAV, regardless of the presence or severity of AI or AS.

The aeromedical summary for <u>initial waiver</u> for aortic valve disease (initial ACS evaluation) should include the following:

A. List and fully discuss all clinical diagnoses requiring a waiver.

B. Complete history and physical examination – to include detailed description of symptoms, medications, activity level, family history, and CAD risk factors (positive and negative).

C. Copy of the local echo report and videotape or CD copy of the echo documenting BAV. (Notes 1 and 2)

D. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. Holter, treadmill, stress echocardiogram). (Notes 1 and 2)

E. Additional local cardiac testing is not routinely required but may be requested in individual cases.

F. Results of IRILO/MEB, if required.

The aeromedical summary of <u>waiver renewal</u> for aortic valve disease (ACS follow-up evaluations) should include the following:

A. Complete history and physical examination – to include detailed description of symptoms, medications and activity level.

B. Local follow-up cardiac testing is not routinely required prior to ACS re-evaluation. However, in asymptomatic individuals with mild or less AS/AI, it is common for the ACS to make a recommendation based on local AMS, ECG, and echocardiogram. This often will be specified in the report of the previous ACS evaluation.

C. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. Holter, treadmill, stress echocardiogram). (Notes 1 and 2)

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

To expedite the case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

Aortic valvular disease is relatively common in our aviation population. Previous waiver guides have separately addressed bicuspid aortic valve, aortic insufficiency, and aortic stenosis. As there is significant overlap of these conditions, this new waiver guide will discuss all three together.

Bicuspid Aortic Valve (BAV)

BAV occurs in 1-2% of the general U.S. population and is the most common congenital cardiac malformation, excluding mitral valve prolapse.¹ BAV and calcified aortic valve are the most common causes of chronic aortic regurgitation in the US and developed countries.² The prevalence of BAV is 0.6% in the United States Air Force (USAF) based on a database of over 20,000 Medical Flight Screening echocardiograms (echo) performed on pilot training candidates.^{3,4} Based on current ACS database review 84% of BAV subjects will develop some degree of aortic stenosis (AS) and/or aortic insufficiency (AI) during their lifetime. Additionally, 30-40% will require a replacement during their lifetime, predominantly after age 45.^{3,4} There is an association of BAV with aortopathy and thus CT angiography of the aorta is recommended if the morphology of aortic sinuses, sinotubular junction, or ascending portion cannot be assessed accurately or fully by echocardiography or when the aortic diameter appears greater than 4.0 cm on echocardiography.² There is some more recent published data that may support one evaluation of the ascending aorta via CT Aorta with contrast even without any signs or symptoms or aortopathy. Waiver criteria is largely based on degree of AI or AS as below, however even in the absence of AS or AI, waiver is still required given the high progression rates of BAV. Waiver for BAV with no or trace AI will typically be followed every three years with echocardiography

Aortic Insufficiency/Regurgitation

Aortic Insufficiency (AI), particularly in its milder forms, is usually asymptomatic for decades due to the compensation of the left ventricle to the volume overload produced by this condition. Symptoms generally do not become clinically apparent until some degree of left ventricular (LV) failure has occurred, usually after the fourth decade of life. AI is therefore most commonly associated with symptoms related to left ventricular failure, (e.g., exertional dyspnea, orthopnea, fatigue, and paroxysmal nocturnal dyspnea). Symptoms of angina are rare in the absence of coronary artery disease. The severity of AI is graded as trace, mild, moderate or severe. Trace AI is considered to be a physiologically normal variant in the absence of an accompanying AI murmur and with a structurally normal three-leaflet valve. The natural progression of AI varies based on symptoms and LV dysfunction as listed below. There is very little published data on the natural history of the progression of AI, particularly the mild to moderate types in a structurally normal valve. However, in an ACS review of 877 cases of Aortic Valve insufficiency followed over 10 years, progression rates from mild insufficiency to moderate was 8%, and progression rates from moderate to severe insufficiency was 23%. In a review of all cases of any valvular regurgitation, the aortic valve was most likely to have moderate or greater insufficiency on screening echocardiography, and the only valve in which mild insufficiency progression rates were >2%. Severe AI has a worse prognosis as seen below.

able 4. Natural History of Severe Autic Insufficiency				
Asymptomatic patients with normal LV systolic function				
Progression to symptoms and /or LV dysfunction <6%/year				
Progression to asymptomatic LV dysfunction	<3.5%/year			
Sudden death	<0.2%/year			
Asymptomatic patients with LV systolic dysfunction				

Table 4: Natural History of Severe Aortic Insufficiency⁵

Progression to cardiac symptoms	>25%/year
Symptomatic patients	
Mortality rate	>10%/year

Although there is a low likelihood of patients developing asymptomatic LV dysfunction, more than one fourth of the patients who die or develop systolic dysfunction will do so prior to the onset of any warning symptoms.

In a clinical population, AI is caused by aortic root or leaflet pathology. Root pathology is most commonly caused by dilatation associated with hypertension and aging. Other root pathologies include Marfan's syndrome, aortic dissection, ankylosing spondylitis and syphilis. Leaflet pathologies include infective endocarditis, bicuspid aortic valve and rheumatic heart disease. In the aviator population, the most common etiologies will be idiopathic AI with normal aortic valve and root and bicuspid aortic valve.

Theoretical concerns exist that extreme athletic activity or isometric exercise, or activities which include a significant component of such exercise, may promote progression of this condition and should therefore be discouraged. Examples of such activities would include the anti-G straining maneuver, weight lifting, and sprint running. Published guidelines for athletes with AI restrict activities for those with the moderate and severe types. Therefore, moderate AI and asymptomatic severe AI that does not meet guidelines criteria for surgery are restricted to nonhigh performance aircraft. Symptomatic severe AI and severe AI meeting guidelines criteria for surgery are disgualifying and waiver is not recommended. Moderate to severe AI should be followed closely, preferably by a cardiologist, for development of criteria for surgical intervention and to address the need for vasodilator therapy. Medications to reduce afterload, such as ACE inhibitors and nifedipine, have documented clinical benefit in chronic AI of moderate or greater severity especially if blood pressure is elevated. These medications can delay the need for surgery and improvement of surgical outcome. The use of approved ACE inhibitors and nifedipine is therefore acceptable in aviators with asymptomatic moderate and severe AI (although waiver still required).³ An echocardiogram with Doppler flow study easily diagnoses AI and is the mainstay of severity assessment. In addition, left ventricular function and chamber size impact the assessment of the severity of disease.

Aortic Stenosis

Aortic stenosis (AS) usually occurs at the level of the aortic valve. Supravalvular and subvalvular forms of AS exist but are unusual congenital defects less likely to present as a new diagnosis in adult military aviator/aircrew. These would be addressed aeromedically on a case-by-case basis. Valvular AS has several causes. In older adults the most common is senile AS, an aging-related calcifying, degenerative process. In the military aviator/aircrew population the most common cause will be associated bicuspid aortic valve. AS is still unusual in military aviator/aircrew with bicuspid aortic valve because this complication usually occurs in middle-aged or older patients.^{3, 4}

While the diagnosis may be suspected by careful auscultation, AS is primarily an echocardiographic (echo) diagnosis. On echo AS is graded by a combination of mean pressure

gradient across the stenotic valve and calculated valve area. Grading categories are mild, moderate and severe.^{1, 3, 4, 5} The prognosis of mild AS is good and essentially normal for at least five years after diagnosis however progression is common and thus disqualifying for all pilot candidates (FCI/IA). Once AS has progressed to moderate or severe, aeromedical and clinical concerns also include sudden cardiac death, syncope, angina and dyspnea. Angina may occur in the absence of significant coronary atherosclerosis while dyspnea may appear as a result of left ventricular dysfunction. Event rates are 5% and 10% per year for asymptomatic and symptomatic moderate AS, respectively. Event rates are considerably higher for severe AS. Mild-to-moderate AS has normal expected event rates for 1-3 years, but represents AS that is likely progressing toward moderate and later severe AS. At this level of stenosis, maintenance of normal cardiac output under +Gz load is a potential aeromedical concern, prompting restriction from high performance flying duties.

Antibiotic Endocarditis Prophylaxis for Aortic Valve disease

In early 2007, the American Heart Association published new infective endocarditis guidelines that are dramatically different from past recommendations.⁶ Subsequently endocarditis prophylaxis was recommended only for specified high risk groups, and only for dental procedures, respiratory tract procedures, and procedures on infected skin, skin structures or musculoskeletal tissue. The high risk group was limited to prosthetic cardiac valves, previous endocarditis, select congenital heart conditions and cardiac transplant patients with valvulopathy. Prophylaxis was no longer recommended for gastrointestinal or genitourinary procedures. Conditions commonly seen by most aerospace medicine practitioners were not included in the list of high risk conditions. Such common conditions no longer recommended for endocarditis prophylaxis include bicuspid aortic valve and aortic regurgitation with normal valve morphology.

IV. Aeromedical Concerns.

Aeromedical concerns include the development and progression of AS and/or AI. Risk of a sudden incapacitating event is very low and aeromedically acceptable in the absence of significant AS or AI. Aeromedical concerns include: related symptoms such as exertional dyspnea, orthopnea and paroxysmal nocturnal dyspnea. Also the progression of AI or AS to greater than mild and the impact of the anti-G straining maneuver or isometric/dynamic exercise on the degree of AI/AS which could result in reduced cardiac output and hypoperfusion of the brain are additional concerns. Any requirement for medical therapy, such as vasodilators are important concerns for aircrew with AI/AS. Waiver policies are thus primarily dependent on the presence and severity of associated AS and AI. AI and AS severity is graded by echo as: mild, moderate and severe (AI can also be trace).³ Asymptomatic BAV in USAF aviators was recently reviewed with 10 year progression rates of 10% for AS, 84% for AI, and 0.8% for endocarditis.⁷ Progression to severe AI or AS or symptoms requiring valvular replacement was 2%. Progression rates of moderate valvular regurgitation to severe is greater than 20% over 10 years.⁸ Aeromedical risks of aortopathy which can be associated with BAV include dissection and rupture and thus a one-time CT angiography of the aorta is recommended for aviators with BAV if not well visualized or dilated on echocardiography. Aeromedical concerns for AS include progression to significant stenosis and requirement for aortic valve replacement or repair. The

prognosis of mild AS is good and essentially normal for at least five years after diagnosis. Once AS has progressed to moderate or severe, aeromedical and clinical concerns also include sudden cardiac death, syncope, angina and dyspnea. Angina may occur in the absence of significant coronary atherosclerosis while dyspnea may appear as a result of left ventricular dysfunction. Event rates are 5% and 10% per year for asymptomatic and symptomatic moderate AS, respectively. Event rates are considerably higher for severe AS. Mild-to-moderate AS has normal expected event rates for 1-3 years but represents AS that is likely progressing toward moderate and later severe AS. At this level of stenosis, maintenance of normal cardiac output under +Gz load is a potential aeromedical concern, prompting restriction from high performance flying duties.³

ICD 9 codes for	ICD 9 codes for Aortic Valve Disease				
395.0	Rheumatic aortic stenosis				
395.1	Rheumatic aortic regurgitation				
395.2	Rheumatic aortic stenosis with aortic regurgitation				
395.9	Other and unspecified rheumatic aortic disease				
396.0	Mitral valve stenosis and aortic valve stenosis				
424.1	Aortic valve disorders				
746.4	Congenital insufficiency of aortic valve				

ICD 10 codes for Aortic Valve Disease				
I06.0	Rheumatic aortic stenosis			
I06.1	1 Rheumatic aortic regurgitation			
I06.2	Rheumatic aortic stenosis with aortic regurgitation			
I06.8	Other rheumatic aortic diseases			
Q23.1	Q23.1 Congenital insufficiency of aortic valve			
I35.8	Other non-rheumatic aortic valve disorders			

V. References.

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Atrial Fibrillation & Atrial Flutter (Jun 2020)

Reviewed: Lt Col Eddie Davenport (ACS chief cardiologist), Dr. Edwin Palileo (ACS cardiologist), Dr. Dan Van Syoc (ACS waiver guide coordinator, and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: Updated content and format

I. Waiver Consideration

History of atrial fibrillation (AF) and/or atrial flutter is disqualifying for all flying classes and retention. The one exception is a single episode of atrial fibrillation clearly associated with a reversible cause. Additionally, the use of maintenance medications for the treatment or prevention of major rhythm disturbances including atrial flutter or atrial fibrillation requires a waiver for retention and all flying classes. A history of catheter ablation is also disqualifying for all flying classes and is addressed in a separate waiver guide, Catheter ablation of Tachyarrhythmias. If hyperthyroidism is determined to be the cause of the AF, a waiver may be considered per policy after treatment of the hyperthyroidism (see hyperthyroidism waiver guide).

Flying	Condition	Waiver	ACS
Class		Potential	Review/Evaluation
		Waiver	
		Authority	
I/IA	Atrial fibrillation, single episode,	Maybe ¹	Yes
	without hemodynamic symptoms, no	AETC	
	medications, and including "holiday		
	heart" scenario. ⁶		
		No	No
	All other atrial fibrillation episodes,	AETC	
	with or without hemodynamic		
	symptoms.		
		No	No
		AETC	
	Atrial flutter, with or without		
	hemodynamic symptoms.		
II/III ⁵	Atrial fibrillation, single episode,	Yes ^{1, 2}	Yes
	without hemodynamic symptoms, no	MAJCOM	
	medications.		
		Yes ^{2, 3, 4}	Yes
	Atrial flutter and/or atrial fibrillation,	AFMRA	
	paroxysmal or chronic, without		
	hemodynamic symptoms, with or		
	without beta-blocker, with or without		
	radiofrequency ablation.		
		No	No
	Atrial flutter and/or atrial fibrillation	MAJCOM	
	not rate controlled and/or with		
	hemodynamic symptoms or		
	abnormal cardiac testing.		
ATC/GBO	Atrial fibrillation and/or atrial flutter,	Yes ^{4, 6}	Yes (review only)
SWA	paroxysmal or chronic, without	AFMRA	
	hemodynamic symptoms, with or		
	without beta-blocker, with or without		
	radiofrequency ablation.		
	(No waiver required for single		
	episode of AF with reversible cause,		
	without hemodynamic symptoms, on		
	no medications).		

 Table 1: Atrial fibrillation (lone), atrial flutter and waiver potential.

1. Waiver for single episode AF should not be submitted until at least 3 months after conversion to sinus rhythm, including a minimum of two months off antiarrhythmic medications. There is a minimum 6 months observation before submitting waiver for paroxysmal and chronic atrial fibrillation.

2. For untrained FC II individuals waiver is unlikely and for untrained FC III individuals, waiver will be considered on a case-by-case basis.

3. In cases of paroxysmal and chronic atrial fibrillation treated with or without beta-blocker, waiver will be restricted to low performance aircraft (IIA, III) and in case of pilots, with another qualified pilot at redundant controls (IIC). 4. If treated with radiofrequency ablation, see *Radiofrequency Ablation (RFA) of Tachyarrhythmias* waiver guide for

further guidance.

5. Initial FC II/III waiver authority is AETC.

6. "Holiday heart" refers to rhythm disturbances brought on by binge drinking episodes.

II. Information Required for Waiver Submittal

Aeromedical disposition and waiver submission should only be submitted after administrative and clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

A. Initial Waiver Request:

- 1. Complete history and physical exam to include description of any symptoms, blood pressure, medications, and activity level.
- 2. Cardiology consult. Copies of electrophysiology consultation report, electrophysiology study and catheter ablation reports

3. Electrocardiogram (ECG) during atrial fibrillation and if paroxysmal or cardioversion then repeat after conversion to sinus rhythm.

4. Report and digital images on CD of echocardiogram to the ACS (may also upload in PICOM), includes repeated studies if performed after conversion to sinus rhythm.

5. Lab testing to include Complete Blood Count (CBC), Complete Metabolic Panel (CMP) and Thyroid function test (TSH).

6. Report and representative tracings of Holter monitor performed in the final month of DNIF observation.

7. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, cardiac cath, cardiac CT or MRI).

8. Results of medical evaluation board MEB (worldwide duty evaluation), if required. FL4 with RTD and ALC status, if member did not meet retention status.

9. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

B. Renewal Waiver Request:

- 1 Complete updated history and physical exam to include description of any symptoms, medications, and activity level.
- 2 Electrocardiogram (ECG).
- 3 Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.
- 4 Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS.
- 5 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

All studies should be submitted electronically to the EKG Library. If this is not possible, items can be mailed via FedEx. If mailed, include patient's name, SSN and POC at base:

Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

Note 2: State in AMS when studies were sent to the ACS.

III. Aeromedical Concerns

Atrial fibrillation (AF) is the most common type of heart arrhythmia found in aircrew and seen in 0.4-1% of the general population with a lifetime incidence of 10% and can be found on 0.3% of asymptomatic screening ECGs. AF affects all ages and genders with a lifetime reported incidence of approximately 10% (although likely much higher). Aeromedical concerns include palpitations, dizziness, syncope, shortness of breath, hemodynamic instability, and stroke. A diagnosis of new atrial fibrillation should lead to immediate DNIF and cardiology consultation.

AF can be classified as paroxysmal if AF terminates <7 days (with or without intervention), persistent if AF >7 days in duration, long standing persistent if >12 months, and permanent AF when the patient and clinician make a joint decision to stop attempts to restore or maintain NSR. Etiologies of AF include electrolyte disorders, stimulant use, severe infection, excessive alcohol or caffeine intake, valvular heart disease, CAD, cardiomyopathy, HTN, hyperthyroidism, and/or respiratory disease, and in many cases is not identified (idiopathic). All aircrew with documented AF should undergo lab testing, chest imaging (CXR or CT), Holter monitor, echocardiogram, and cardiac stress test.

A single idiopathic episode of AF often has an identifiable precipitating cause, such as acute abuse of alcohol (holiday heart syndrome) and/or other stimulant use (heavy caffeine (including energy drinks), decongestant use, weight lifting supplements, surgery, electrolyte disturbance, or sepsis. A single episode of AF lasting less than 24 hours that converts either spontaneously or by medical intervention and there is a clearly identifiable precipitating cause may be recommended for waiver for return to unrestricted flight after correction of any underlying precipitating cause. Complete cardiac evaluation is still required and a waiting period of 3 months after restoration of NSR is recommended prior to return to flight. After ensuring there is no correctible etiology of the AF, one must then decide on rate vs rhythm control and stroke risk

Stroke risk should be estimated using the CHA₂DS₂VASc score. The annual risk of stroke for a score of 0, 1, 2, and 3 is <0.5%, 1.3%, 2.2%, and 3.2% respectively. According to the latest guidelines, scores greater than 2 in men and 3 in women should be placed on anticoagulation which should lower the stroke risk to less than 1% but confers a bleeding risk of approximately 1% thus disqualifying for all USAF aircrew. Rate vs Rhythm control should be managed in accordance with published guidelines although aeromedical implications exist for nodal blocking

agents and antiarrhythmics. Impaired atrial contraction in AF decreases ventricular cardiac output by up to 25% and additional therapy with nodal blockers such as beta-blockers and nondihydropyridine calcium channel blockers (verapamil and diltiazem) will further reduce cardiac output. Treatment with beta-blockers or calcium channel blockers therefore limits aircrew to non-high-performance aircraft. Similarly, many antiarrhythmics (especially Vaughan-Williams Class I & III) can affect cardiac output and also have side effect profiles and proarrhythmic risks such that they are not waiverable for any USAF aircrew. AF catheter ablation is becoming increasingly popular with success rates up to 85% in the young with paroxysmal AF, however success rates are as low as 40% in persistent AF. Repeat ablations do carry higher success rates.

Atrial flutter is often associated with atrial fibrillation but may occur as an isolated rhythm disturbance. It presents unique considerations as it is typically a right atrial macro-re-entrant tachycardia passing through the area between the inferior vena cava and tricuspid valve referred to as the cavo-tricuspid isthmus which can be a focus of ablation. Catheter ablation of typical atrial flutter has success rates over 90% although there is possibly increased atrial fibrillation risk. If NSR has been maintained for over 6 months off all medications regardless of treatment option then ACS evaluation with maximal stress testing can be done for return to flight status. For unrestricted flight in high performance airframes, a centrifuge study must also be completed. As of May 2020 there has been only 2 cases of Afib or Atrial flutter s/p ablation returned to unrestricted flight.

Aeromedical disposition of all aircrew with AF (paroxysmal, persistent, or permanent) and atrial flutter includes return to flight if not hemodynamically significant, rate controlled and low stroke risk with negative cardiac evaluation as above. Waiver will be limited to no single seat, high performance aircraft (unless single episode less than 24 hours with clear precipitant or >6 months after ablation maintaining NSR off all medications and s/p ACS evaluation with centrifuge testing as above).

A five-year review of AIMWTS through May 2020 revealed 76 cases of atrial fibrillation/flutter; there were 10 disqualified cases. Breakdown of the cases revealed: 42 FC II cases (2 disqualified), 23 FC III cases (6 disqualified), 8 GBO cases (2 disqualified), and 3 SWA cases. There is an ACS Atrial fibrillation working group with 168 cases being actively followed.

ICD-10 Codes for atrial fibrillation and flutter			
I48.91 Unspecified Atrial fibrillation			
I48.82Unspecified Atrial flutter			

IV. Suggested Readings

1. 2019 AHA/ACC/HRS Focused Update of the 2014 Guideline for the Management of Patients with Atrial Fibrillation. doi : 10.1026/j.jacc.2019.01.011

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Cardiac Conduction Delay (Heart Block, Bradycardia) (Jun 2020) Previously Atrioventricular Conduction Disturbances

Reviewed: Lt Col Eddie Davenport (chief ACS cardiologist), Dr. Ed Palileo (ACS cardiologist), Dr. Dan Van Syoc (ACS Waiver Guide coordinator, and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: New version and new title

I. Waiver Consideration

All ECGs done on USAF aircrew, even if normal, should be sent to the ECG library. All ECGs are reviewed, dispositioned, and archived by aerospace medicine trained cardiologists. Asymptomatic sinus bradycardia, sinus pause, junctional escape, accelerated idioventricular rhythm (AIVR), first degree AV block, and second degree type I (Wenckebach) AV block are generally considered normal variants and as such do not require a waiver (see aeromedical considerations below). Second degree type II AV block and third degree (complete) AV block are at high risk of hemodynamic symptoms and often recommended for permanent cardiac pacing thus waiver for these diagnoses is unlikely. The exception is atrioventricular block clearly associated with a reversible cause. Disqualifying diagnoses are per MSD H12-H17.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review/Evaluation
I/IA,	First degree AV block, Second degree type I	Not required – qualified ^{1, 2}	Yes ¹
II/III/ATC	(Wenckebach) AV block, Junctional rhythm, AIVR		
ATC/GBO			
SWA	Symptomatic bradycardia,	Yes	Yes ¹
	first-degree AV block with	AETC (FCI/IA)	
	PR >400ms, prolonged	AFMRA (all others)	
	sinus pause >3 sec, or		
	higher degree AV block		
	(Reversible & Resolved).		
	Mobitz II second degree	No	Yes ¹
	AV block and third degree	AETC (FCI/IA)	
	(complete) block.	AFMRA (all others)	
	Idiopathic, symptomatic and/or with pacemaker.		

 Table 1: Waiver potential for AV conduction disturbances.

1. ECG Library reviews all ECGs for all flying classes (includes USAFA, USAFSAM and AD sent by HQ AETC). 2. Must be asymptomatic and heart rate >39bpm without prolonged sinus pause/arrest (<3 sec) and PR interval for first degree AVB <400ms.

II. Information Required for Waiver Submittal

Aeromedical disposition and waiver submission should be done after administrative and clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

A. Initial Waiver Request:

- 1 Complete history and physical exam to include description of symptoms (positive and negative) as well as medications, treatments, and activity level.
- 2 Cardiology consult. (Not required in first degree block or Mobitz I second degree block, if ECG library does not request.)
- 3 Electrocardiogram (ECG), all ECGs if multiple.
- 4 Copies of reports and all tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI).
- 5 Electrophysiologist consultation if done, if electrophysiology study is done then procedure report should be submitted.
- 6 RTD and ALC status, if member did not meet retention status.
- 7 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

B. Renewal Waiver Request:

- 1 Complete updated history and physical exam to include description of any symptoms, medications, and activity level.
- 2 Electrocardiogram (ECG).
- 3 Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.
- 4 Local studies done since prior waiver or waiver renewal should be sent to ACS for review even if not requested by ACS. (e.g. stress test, echocardiogram, Holter monitor, cardiac cath, EP study, cardiac CT or MRI).
- 5 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

All studies should be submitted electronically to the EKG Library. If this is not possible, items can be mailed via FedEx. If mailed, include patient's name, SSN and POC at base:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

State in AMS when studies were sent to the ACS. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS.

III. Aeromedical Concerns

Aeromedical concerns of cardiac conduction disturbances include bradycardia-related hemodynamic symptoms, heart failure, syncope, and even sudden death. Joint guidelines were recently published by the American College of Cardiology, American Heart Association and Heart Rhythm Society regarding the management of bradycardia and conduction delay, and should be followed in all aircrew.

Fit aircrew may have resting heart rates lower than that of the general population and are also more likely to have junctional or ventricular escape rhythms. Evaluation is usually not indicated for asymptomatic **sinus bradycardia or junctional escape** rhythms for rates >39 bpm. The USAF Central ECG Library/ACS may request further local evaluation for unusual individual cases including first appearance of AV block at an older age (usually >40 years), **Marked sinus bradycardia (<40 bpm)** and **Prolonged sinus pause/arrest (>3 sec)**. Cardiac conduction delays occurring only during sleep may also require polysomnography study.

First degree AV block, defined as PR interval >200 ms, is common in athletes and has been found in approximately 1% of all USAF screening ECGs. If the airman is asymptomatic without evidence of structural heart disease then further evaluation is not necessary. There should be no limitations for flying or flying training and waiver is not required. However, if symptomatic or with **PR intervals >400ms**, there is increased risk of structural heart disease or more advanced conduction disease and therefore additional testing is required.

In Second degree type I block (Wenckebach) AV block there is a progressive delay between atrial and ventricular conduction and contraction which manifests as a prolonged PR interval with an eventual dropped beat (P wave not followed by QRS). Like first degree AV block, the site of block in second degree Mobitz type I AV block is at or above the AV node and thus likely secondary to increased Vagal tone. Second degree type one AV block was found in 0.1% of all screening USAF aircrew ECG. In most cases, Mobitz type I block does not produce any symptoms and further evaluation is not indicated unless symptomatic, very frequent, or not resolving with increased heart rates (exercise or atropine).

In **Second degree Mobitz AV type II block**, as with type I block, there is a dropped beat; however, in type II block the PR interval is fixed. The site of involvement for type II block is often below the AV node (His-Purkinje system) which puts the patient at a considerable risk for progression to complete heart block (third degree heart block). In third degree AV block there is complete AV dissociation and the atrial and ventricular rates are independent of each other. Second degree Mobitz type II and third degree heart block occurs in less than 0.004% of USAF aircrew screening ECGs. Second and third degree block require a complete cardiac evaluation including structural imaging and electrophysiologist referral. Aircrew should be grounded while undergoing workup. They generally are recommended for permanent pacemaker placement and disqualified for all flying classes. Second degree type II AV block and third degree heart block is also disqualifying for retention in the military. One final note. In athletes and young aircrew with high vagal tone there can be AV dissociation without block secondary to a junctional or ventricular pacemaker (accelerated idioventricular rhythm-**AIVR**) that is faster than the sinus node so on the ECG there will be more QRS complexes than P waves. However, careful examination of the ECG usually demonstrates intermittent ventricular capture of the P waves which excludes complete AV block. AIVR may be a benign arrhythmia in young, fit individuals, but also may be associated with underlying heart disease including cardiomyopathy and ischemic heart disease. If detected in aircrew, further assessment is recommended to include echocardiography, exercise ECG and Holter monitoring. Cardiac MRI may be appropriate in some cases. If asymptomatic with no underlying cause, no waiver is required.

A five-year review of AIMWTS through May 2020 revealed 10 cases of cardiac conduction delays. A breakdown of these cases revealed: one FC I case, two FC II cases (one disqualified), five FC III cases (three disqualified), one GBO case, and one SWA case.

ICD-,10 Codes for AV conduction disturbances		
I44.2	Atrioventricular block, complete	
I44.0	First degree atrioventricular block	
I44.1	Mobitz (type) II atrioventricular block	
I44.39	Other atrioventricular block	

IV. Suggested Readings

1. Kusumoto FM, Schoenfield MH, Barret C, et al. 2018 ACC/AHA/HRS Guideline on Bradycardia and Cardiac Conduction Delay. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol, 2019; 74(7): 933-983

2. Gray GW, Davenport ED, Nicol ED. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 5th ed. In press, pending publication 2020.

3. Strader JR, Jr, Gray GW, Kruyer WB. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 4th ed. Philadelphia: Lippincott Williams & Wilkins, 2008; 344-45.

4. Kruyer WB and Davenport ED. Cardiology. Ch. 2 in: *Rayman's Clinical Aviation Medicine*, 5th ed., Castle Connolly Graduate Medical Publishing, LTD, 2013; 75-79.

5. Guettler N, Bron D, Manen O, et al. Management of cardiac conduction abnormalities and arrhythmia in aircrew. Heart, 2019; 105: s38-49

6. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation, 2014; 130: 2071–2104.

7. Stevenson WG and Tedrow U. Preventing ventricular tachycardia with catheter ablation. Lancet, 2010; 375: 4-6.

Cardiomyopathy (Dec 2019)

Reviewed: Lt Col Kevin Alford, (RAM 21), Lt Col Eddie Davenport (ACS Cardiology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: Update to aeromedical concerns. Update to waiver considerations. Addition of Special Warfare to Table 1

I. Waiver Consideration

Cardiomyopathy is disqualifying for all classes of flying duties. It is disqualifying for retention purposes, and members with all but the most mild degrees of cardiomyopathy will only be considered for aeromedical waiver after the individual has been released to full unrestricted activity and found fit for continued military duty by a medical evaluation board (MEB). For the purposes of this waiver guide, cardiomyopathy includes any disease of the myocardium, reduction in left ventricular ejection fraction (<50%), or clinical diagnosis of heart failure. Heart failure is classified according to the New York Heart Association (NYHA) classes (class I or greater is disqualifying) and the American Heart Association (AHA) stages (stage B or greater is disqualifying). Heart failure also includes heart failure with preserved ejection fraction (HFpEF) when symptomatic. Waiver submissions should be made only after resolution of any acute episode, stabilization of the medical regimen, and release of the individual back to full unrestricted activities by the treating cardiologist. ACS review is required for initial waivers for cardiomyopathy to confirm the diagnosis. Mild cases of dilated cardiomyopathy (DCM) which resolve over time may be considered for waiver after ACS evaluation. Some secondary cardiomyopathies may be waiver eligible, based on policies for the underlying disorder and the impact of the secondary cardiomyopathy on overall prognosis. Typically, this will involve definitive therapy that results in an aeromedically acceptable outcome, including resolution of the cardiomyopathy. Resolution of tachycardia-induced cardiomyopathy and return of left ventricular and left atrial size and function to normal after successful surgical repair of severe mitral regurgitation are examples.

Flying Class (FC)	Condition	Waiver Potential	ACS
		Waiver Authority	Review/Evaluation
I/IA	DCM, HCM, RCM, ARVC/D,	No	Yes ²
	secondary cardiomyopathy	AETC	
II/III^1	DCM, HFrEF, HFpEF	Maybe	Yes ²
		MAJCOM	
	HCM, ARVC/D, and RCM	No	Yes ²
		MAJCOM	
	Secondary cardiomyopathy	Yes	Yes ²
		MAJCOM	
ATC^1	DCM, HFrEF, HFpEF	Maybe	Maybe ²
GBO^1		MAJCOM	
SWA^1			
	HCM, ARVC/D, and RCM	No	Maybe ²
		MAJCOM	
	Secondary cardiomyopathy	Yes	Maybe ²
		MAJCOM	

Table 1: Waiver potential for Cardiomyopathy³

DCM – Dilated Cardiomyopathy; HCM – Hypertrophic Cardiomyopathy; RCM – Restrictive Cardiomyopathy; ARVC/D – Arrhythmogenic Right Ventricular Cardiomyopathy/Dysplasia; HFrEF – Heart Failure with Reduced Ejection Fraction; HFpEF – Heart Failure with Preserved Ejection Fraction.

1. Initial training cases should all be treated similar to FC I/IA.

2. ACS review or evaluation for initial cases is at the discretion of the waiver authority.

3. Per AFI 48-123 6.4.1.3., AFMRA remains waiver authority for all initial waivers for conditions that do not meet retention standards, unless 6.4.1.4.1. applies.

II. Information Required for Waiver Submittal

Aeromedical disposition and waiver submission should only be submitted after administrative and clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary for the <u>initial waiver</u> for cardiomyopathy should include the following:

- 1. Complete history and physical exam to include description of symptoms before and after the acute episode, medications, and activity level.
- 2. Cardiology consult
- 3. Electrocardiogram (ECG).
- 4. Chest x-ray report.
- 5. Official report of all local echocardiograms. Also upload digitally or send CD/DVD copy of the images of the most recent echocardiogram to the ACS. (Notes 1 and 2)

- 6. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)
- 7. Results of medical evaluation board MEB (worldwide duty evaluation for ARC members).
- 8. If the local base is unable to provide all required items, they should explain why to the waiver authority.

The aeromedical summary for waiver renewal for cardiomyopathy should include the following:

- 1. Complete history and physical exam to include description of symptoms before and after the acute episode, medications, and activity level.
- 2. Electrocardiogram (ECG).
- 3. Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.
- Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac catheterization/angiography, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)
- 5. If the local base is unable to provide all required items, they should explain why to the waiver authority.

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is:

Attn: Case Manager for (member's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

For expediting the case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

III. Aeromedical Concerns

Cardiomyopathy is disease of the myocardium and can often result in functional cardiac deficits sufficient to affect aviation safety. Academically, the diagnosis of cardiomyopathy is distinct from the clinical syndrome of heart failure, which can be caused by disorders other than those of the myocardium. However, for the purposes of this waiver guide, cardiomyopathy includes any disease of the myocardium, reduction in left ventricular ejection fraction (<50%), or clinical diagnosis of heart failure. Heart failure is classified according to the NYHA classes (class I or greater is disqualifying) and the AHA stages (stage B or greater is disqualifying). Heart failure also includes heart failure with preserved ejection fraction (HFpEF) when symptomatic. The aeromedical concerns due to cardiomyopathy include the risk of sudden incapacitation, altered physiology secondary to the disease process, and the impact of medical treatment. The risk in these areas varies based on the cause of the cardiomyopathy, the severity of disease, and the

treatments used. Cardiomyopathy can be caused by primary disorders of the myocardium or result secondarily to systemic diseases. When a systemic disease is causative, aeromedical risk may be amplified by extra-cardiac manifestations of the disorder. While the natural history of most cardiomyopathies is to progress to more severe disease, some cardiomyopathies – particularly peripartum cardiomyopathy, tachycardia induced cardiomyopathy, and cardiomyopathy secondary to viral myocarditis – may resolve.

The risk for sudden incapacitation is increased in all members with cardiomyopathy due to an increased risk for ventricular arrhythmias. Certain types of cardiomyopathy result in proportionally higher risk for sudden incapacitation. For instance, individuals with Hypertrophic Cardiomyopathy (HCM) and Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) are at high risk for symptomatic and incapacitating arrhythmias. This hazard alone may exceed historical risk tolerances. All aviators in whom the diagnosis of cardiomyopathy is considered require an evaluation for ischemic heart disease, as those with ischemic cardiomyopathy also are at an increased risk for incapacitating ischemic events that can be modified with appropriate treatment. Importantly, the aviation environment may increase the risk for incapacitation. As an example, exposure to high $+G_zs$ may potentiate ventricular arrhythmias. [Also, those who are not acclimated to intermittent hypoxia may be at higher risk for cardiovascular complications.]

Alterations of cardiac function associated with cardiomyopathies increase the risk to aeromedical safety. Even if any cardiomyopathy associated heart failure is well compensated, aviators may experience decreased exercise tolerance that impairs execution in high-performance aviation. Furthermore, left ventricular dysfunction can reduce capacity to augment cardiac output during exposure to sustained acceleration increasing the risk for G-induced loss of consciousness. Finally, aviators with cardiomyopathy may more poorly tolerate the hypoxic environment of aviation than do their colleagues with normal cardiac function.

Treatments for cardiomyopathy can also have a deleterious effect on aviation safety. For instance, beta blocker (β B) therapy is recommended by published guidelines for treatment of those with reduced EF primarily to reduce risk of arrhythmia; beta blockers have also been shown to improve cardiac function in subsets of cardiomyopathy patients. [Of note, angiotensin converting enzyme inhibitors (ACE-i) and angiotensin receptor blockers (ARBs) are also recommended in heart failure with reduced EF.] Regardless of the indication, β Bs reduce tolerance for +G_z acceleration. Similarly, vasodilators such as nitrites and hydralazine, used for symptom management in heart failure would reduce G-tolerance. Medical devices are increasingly used in the management of cardiomyopathy. Those with sufficient cardiac dysfunction or risk of sudden cardiac death to warrant placement of an implantable cardioverter defibrillator (ICD), use of resynchronization therapy, or placement of more advanced devices such as left ventricular assist devices, are not suitable for military aviation.

In the USAF aviator and special operator populations, presumed diagnoses of cardiomyopathy are often identified after routine testing of an asymptomatic individual, such as with a screening EKG. However, young, athletic individuals can develop changes on cardiac testing that may appear similar to those identified in mild cardiomyopathies. For instance, EKG testing in athletic individuals may demonstrate first degree AV block, incomplete right bundle branch block, early

repolarization, or QRS voltage criteria for left ventricular hypertrophy in the absence of true pathology. Similarly, echocardiography may identify changes in the left ventricular size, mass, and wall thickness secondary to physical training that can appear similar to mild dilated or hypertrophic cardiomyopathies. These findings may be accompanied with borderline low left ventricular ejection fraction leading to a diagnosis of cardiomyopathy, but systolic function should appropriately augment under exercise testing in the athletic heart. In addition to properly supervised exercise testing, cardiac MRI (CMR) can help distinguish between pathology and changes related to physical fitness. These diagnostic challenges highlight the importance of ACS evaluation for aviators and special duty personnel with new aeromedical waiver requests for cardiomyopathy.

AIMWITS search in Dec 2019 for the previous five years revealed 41 cases listed as cardiomyopathy. Breakdown of the cases was as follows: 3 FC I/IA (1 disqualified), 18 FC II (1 disqualified), 1 RPA pilot, 14 FC III (4 disqualified), 1 special warfare airman, and 4 ATC/GBC (1 disqualified). All cases with a disqualification either had symptoms, were on a nonapproved medication or did not meet initial flying standards or radiographic evidence of cardiomyopathy.

ICD-9 Codes for cardiomyopathy		
425.4	Other primary cardiomyopathies (hypertrophic, restrictive, idiopathic, familial, not	
	otherwise specified, congestive, constrictive, obstructive, nonobstructive)	
425.9	Secondary cardiomyopathy, unspecified	
086.0	Chagas' disease with heart involvement	

ICD-10 Codes for cardiomyopathy		
I42.8	Other cardiomyopathies	
I42.9	Cardiomyopathy, unspecified	
B57.0	Chagas' disease with heart involvement	

IV. Suggested Readings

1. D'Arcy JL Manen O, Davenport ED, et. al. Heart Muscle Disease Management in Aircrew. Heart, 2019; 105:s50-s56.

2. Nicol ED, Rienks R, Gray G, et. al. An Introduction to Aviation Cardiology. Heart, 2019; 105:s3-s8.

3. Yancy CW, Jessup M, Bozkurt B, et. al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 2013; 128:e240–e327.

4. Maron BJ, Udelson JE, Bonow RO, et. al. Eligibility and disqualification recommendations for competitive athletes with cardiovascular abnormalities: Task Force 3: hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy and other cardiomyopathies, and myocarditis: a scientific statement from the American Heart Association and American College of Cardiology. Circulation, 2015; 132:e273–e280.

5. Yancy CW, Jessup M, Bozkurt B, et. al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136:e137–e161. DOI: 10.1161/CIR.00000000000509.

Catheter Ablation of Tachyarrhythmias & Pre-Excitation (WPW) (Jun 2020)

Reviewed: Lt Col Eddie Davenport (ACS Chief Cardiologist), Dr. Edwin Palileo (ASC Cardiologist), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) and Lt Col AFMSA David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes:

New format and updated references

I. Waiver Consideration

Ablation of cardiac tachydysrhythmias is a catheter based therapeutic intervention and thus disqualifying for flying classes (FC) I/IA, II, III and SWA (MSD H56). If catheter ablation is being performed only for aeromedical reasons and not for clinical indications, then ACS review and/or evaluation is highly recommended <u>before</u> procedure to assure that it is aeromedically indicated. The underlying diagnosis may also require a waiver or possible MEB. Refer also to the waiver guide for the underlying diagnosis for further details.

Flying Class	Condition Treated with	Waiver Potential	ACS
	catheter ablation	Waiver Authority ⁴	review/evaluation
I/IA	WPW ECG pattern only,	Yes ²	Yes
	WPW syndrome and	AETC	
	AVNRT		
	Other supraventricular	Yes ³	Yes
	tachycardias and RVOT	AETC	1.00
	ventricular tachycardia.		
	Atrial fibrillation,		
	Ventricular Tachycardia	No	No
	secondary to myocardial	AETC	
	infiltration or scar		
II, III, SWA	WPW ECG pattern only	Yes ¹	Yes
(including		MAJCOM	
untrained		2	
applicants)	WPW syndrome, RVOT	Yes ²	Yes
	tachycardia, and AVNRT	MAJCOM	
	Atrial fibrillation / Atrial	Yes ³	Yes
	Flutter	MAJCOM	
	Ventricular Tachycardia	No	No
	from infiltration/scar		

 Table 1: Waiver potential for catheter ablation cases

1. No observation post-ablation required prior to waiver submission.

2. Submit waiver no earlier than 4 months post-ablation.

3. Submit waiver 6 months post-ablation observation. Repeat EP study and/or centrifuge testing is required for FCI/IA and FCII high performance waivers.

4. Waiver authority is as listed for the ablation procedure itself. However, if underlying condition required an MEB, waiver authority is AFMRA for FCII, FCIII, ATC, and SWA.

II. Information Required for Waiver Submittal

Aeromedical disposition and waiver submission should only be submitted after administrative and clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations. See appropriate waiver guide for arrhythmia undergoing ablation for other possible requirements.

A. Initial Waiver Request:

- 1. Complete history and physical exam to include description of symptoms before and after ablation as well as medications and activity level.
- 2. Cardiology consult.
- 3. Official report of ablation and electrophysiologic study/studies (EPS).

- 4. Electrocardiogram (ECG) prior to ablation and at 2 months, 3 months and 4 months postablation for all tachyarrhythmias. A-fib requires an additional ECG at 6 months.
- 5. Copies of reports and all tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI).
- 6. RTD and ALC status, if member did not meet retention status
- 7. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

B. Renewal Waiver Request:

- 1 Complete updated history and physical exam to include description of any symptoms, medications, and activity level.
- 2 Electrocardiogram (ECG).
- 3 Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.
- 4 Local studies done since prior waiver or waiver renewal should be sent to ACS for review even if not requested by ACS. (e.g. stress test, echocardiogram, Holter monitor, cardiac cath, EP study, cardiac CT or MRI).
- 5 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided..

All studies should be submitted electronically to the EKG Library. If this is not possible, items can be mailed via FedEx. If mailed, include patient's name, SSN and POC at base:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

State in AMS when studies were sent to the ACS.

III. Aeromedical Concerns

Sudden cardiac death is the most compelling concern for any tachyarrhythmia; however, in many tachyarrhythmias this risk is low. The risk of recurrent sustained tachyarrhythmia and associated hemodynamic symptoms is the more likely aeromedical concern. To quantify these risks, the specific tachyarrhythmia, the presence or absence of hemodynamic symptoms, the presence or absence of associated structural heart disease and results of electrophysiologic studies and/or RFA must be considered. Careful review of the ablation procedure and corresponding electrophysiologic study is paramount, as this will provide details of the mechanisms and characteristics of the ablated pathway. These characteristics as well as response to ablation acutely will provide prognostic information necessary for aeromedical disposition. See individual waiver guides for more details on each specific diagnosis

Joint guidelines were recently published by the American College of Cardiology, American Heart Association and Heart Rhythm Society regarding the management of arrhythmias (supraventricular and ventricular). Detailed definitions and criteria for diagnosis of accessory pathways, supraventricular tachyarrhythmias and ventricular tachycardias are also addressed with treatment algorithms to include when ablation is indicated. These guidelines should be followed for all acute tachyarrhythmias in aviators. For long term therapies these guidelines should also be followed in regard to ablation and beta-blocker use, however antiarrhythmic medications and non dihydropyridine calcium channel blockers are rarely waiverable for ongoing flight duties. Ablation success rates and consequently aeromedical risks vary depending on ablation site and indication as follows:

1. Accessory pathways (AVRT, WPW pattern/syndrome) - Catheter ablation is potentially curative for accessory pathway tachyarrhythmias with an immediate success rate of 95-99%. Most recent guidelines consider catheter ablation as first line therapy and recommend catheter ablation particularly, if the accessory pathway has high risk features such as a short refractory period, retrograde conduction, or multiple pathways. The complication rate for ablation is low, but includes the possibility of complete heart block and subsequent requirement for permanent cardiac pacing. This risk is inherent to ablation performed on or near the anterior surface of the AV node. Approximately 5% to 10% of accessory pathways are located in this dangerous area; risk of complete heart block for such cases is 5% to 10%. Recurrence of a functional accessory pathway after ablation occurs in 1-5%, usually within 2-4 months after ablation. Late recurrence is rare. A nonflying observation period of 3 to 4 months is appropriate to get beyond the window of most clinical recurrences and to allow healing. The appropriate documentation of successful ablation is an important aeromedical decision. Based on USAF experience with consistently negative EPS and stress testing results, ambulatory ECG monitoring is the only test recommended 3 months after ablation and if negative then return to flight is supported. Annual follow-up with interval history, physical and ambulatory ECG monitor is recommended. Accessory pathways s/p ablation is waiverable for all flying classes.

2. Atrioventricular node reentrant tachycardia (AVNRT). AVNRT is the most common mechanism of SVT (about 60% of all SVT cases). It is caused by a reentry circuit within the AV node made possible by functional dissociation within the AV node with differential electrophysiologic properties creating 2 pathways with different conduction velocities and different refractory periods, a condition favorable for reentry phenomenon to occur). The published experience on catheter ablation for AVNRT is comparable to that of WPW ECG pattern and syndrome, with a success rate approaching 99% and a recurrence rate of 1-2% and thus waiverable for all flying classes. Ablation of AVNRT is typically performed on the posterior surface of the AV node; risk of complete heart block at this location is approximately 1%. Careful explanation of risks should be done with all aircrew prior to ablation and the procedural electrophysiology/ablation study reports should be carefully reviewed prior to return to flight. Annual follow-up with interval history, physical and ambulatory ECG monitor is recommended.

3. Other supraventricular tachycardias. The remaining 10% of SVTs are due to a variety of uncommon mechanisms. These may include reentrant pathways, such as around the

sinus node (sinus node reentry) or around a surgical scar (intra-atrial reentry post-congenital heart disease repair) and automatic foci, such as focal atrial tachycardia and paroxysmal junctional tachycardia. Published experience of ablation regarding these rhythm disturbances is limited. Waiver will be recommended on a case-by-case basis with careful review of EP study by ACS.

4. Atrial flutter. Atrial flutter is most often due to a macro- reentry circuit within the right atrium including the atrial septum and the right atrial free wall and incorporating a narrow isthmus of atrial tissue between the tricuspid valve and the inferior vena cava (commonly referred to as cavo-tricuspid isthmus) which offers an accessible target for ablation to interrupt the reentry circuit. Curative ablation is very feasible, with success rates >90% approaching those of accessory pathways and AVNRT. However, atrial flutter can be atypical not following usual circuit and all atrial flutter can be associated with atrial fibrillation. Therefore, a 6-month period of observation is recommended for atrial flutter s/p ablation prior to return to flight. Careful review of actual electrophysiologic testing, ablation procedure, and chart review by ACS is necessary for prognostication and aircrew disposition. Repeat EP study and/or centrifuge testing may be necessary to FCI/IA and high performance FCII aircrew.

5. Atrial fibrillation (AF). Ablation of atrial fibrillation is less successful both immediately after the procedure and at follow-up. The success of atrial fibrillation ablation depends on the type (ex. paroxysmal, long-term, persistent, or permanent) as well as the presence of absence of structural heart disease and the degree of severity of atrial fibrosis. Overall success rates of 60% to 90% have been reported, with reoccurrences mostly within 3 to 6 months of the procedure. Specific procedures for atrial fibrillation ablation are continuously under development and refinement, however there still is an approximately 25% recurrence rate which often require repeat ablation procedures. Late recurrence is also more likely than for ablation of other mechanisms. An extended observation period of 6 months is therefore recommended in all aircrew. Graded exercise testing, 24-hour ambulatory monitoring, and echocardiography are recommended prior to return to flight. In high performance aircrew repeat EP study (with provocation, which may be done immediately after ablation during initial EP procedure) and centrifuge testing is required. Of note, recurrent AF after ablation does not necessarily mean the ablation was not successful; the member may have decreased symptoms, better rate control, and/or the ability to decrease or stop medications thus allowing for return to non-high performance flight.

Although Stroke risk decreases after successful ablation, recent data shows that those who have recurrent AF after ablation may be at an even higher risk of stroke such that the overall risk of stroke is not necessarily changed by undergoing the ablation procedure. Therefore, CHA2DS2VASc score is still used and if elevated risk then anticoagulation is recommended regardless of ablation and waiver is not recommended.

6. Ventricular Tachycardia and Ventricular Ectopy (PVC). Most published experience with ablation for VT deals with ablation performed for sustained VT or hemodynamically symptomatic nonsustained VT, often in the setting of prior myocardial infarction with ischemic scar tissue or other infiltrative or idiopathic cardiomyopathy. Ablation is often performed after

failure of one or more antiarrhythmic medications to prevent VT recurrences. Recurrence rates post-ablation varies in the clinical literature from 0% to 30% within 1-2 years. In many reports control of VT after ablation with continued use of antiarrhythmic medications is considered an ablation cure, this is not so in aircrew. Long-term success, outcomes, recurrence rates and late adverse consequences depend on the type of VT mechanism and the underlying heart disease. Most published success rates range between 50% and 75% at 6 to 12 months but very little is known beyond this time frame and thus wavier is not recommended. Ablation may be done in conjunction with AICD implantation, which is permanently disqualifying.

Specific types of VT can occur in relatively healthy individuals without other structural heart disease. This includes foci in the ventricular outflow tracts, mainly the RVOT but can also be from the LVOT or the area of the fascicles of the left bundle. These are mostly amenable to RF with success rates over 90% and thus low enough risk to allow return to unrestricted flight. Ventricular ectopy (PVC) ablation appears to have lower success rates however there is little risk of increased arrhythmia after the procedure and the PVCs either resolve or decrease in frequency. If the PVCs are idiopathic (not secondary to structural or coronary heart disease) and the indication for PVC ablation is either only high burden and/or symptoms, then return to unrestricted flight following ablation may be reasonable after an observation period.

AIMWTS review in late May of 2020 for cases receiving catheter ablation in the past five years revealed the following results. There were 31 FC I/IA cases (five disqualifications), 147 FC II cases (two disqualifications, 104 FC III cases (18 disqualifications), six ATC cases, 31 GBO cases (two disqualifications), and 13 SWA cases.

ICD-10 Codes for radiofrequency ablation procedure		
93650	Radiofrequency ablation	
93653		
93654		
93656		

ICD-10 Codes for conditions requiring catheter ablation		
I45.89	Anomalous atrioventricular excitation (Wolff-Parkinson-White	
I45.6	syndrome)	
I47.1	Paroxysmal supraventricular tachycardia	
I47.2	Ventricular tachycardia	
I48.91	Atrial fibrillation	
I48.82	Atrial flutter	

IV. Suggested Readings

1. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia: Executive Summary. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol, 2016; 67(13): 1575-1623.

2. Gray GW, Davenport ED, and Nicol ED. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 5th ed. In press, pending publication 2020.

3. Strader JR, Jr, Gray GW, Kruyer WB. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 4th ed. Philadelphia: Lippincott Williams & Wilkins, 2008; 344-45.

4. Kruyer WB and Davenport ED. Cardiology. Ch. 2 in: *Rayman's Clinical Aviation Medicine*, 5th ed., Castle Connolly Graduate Medical Publishing, LTD, 2013; 75-79.

5. Guettler N, Bron D, Manen O, et al. Management of cardiac conduction abnormalities and arrhythmia in aircrew. Heart 2019; 105:s38-49.

6. Davenport, ED and Kruyer WB. Clinical and Aeromedical Guidelines for Wolff-Parkinson-White. Presented at the Aerospace Medical Association 81st Annual Scientific Meeting, May 2010. Abstract published Aviat Space Environ Med. Mar 2010; 81(3): 272.

7. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circulation, 2014; 130: 2071–2104.

8. Stevenson WG and Tedrow U. Preventing ventricular tachycardia with catheter ablation. Lancet, 2010; 375: 4-6.

9. Packer DL, Mark DB, Robb RA, et al. Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients with Atrial Fibrillation: The CABANA Randomized Clinical Trial. JAMA, 2019; 321(13):1261-1274.

WAIVER GUIDE Updated: Feb 2015 Supersedes Waiver Guide of Sep 2011 By: Dr Dan Van Syoc, Lt Col Steven Gore and Maj Eddie Davenport (ACS chief cardiologist),

CONDITION: Congenital Heart Disease (Feb 2015)

I. Waiver Consideration.

Congenital heart defects, uncorrected or corrected by surgical or catheter-based procedures, are disqualifying for flying class (FC) I/IA, II, and III. Congenital and structural anomalies of the heart that are not normal structural variants, other than PFO are not qualified for retention, so ATC, SWA, and GBO personnel would need a waiver, as they require an MEB. In addition, any history of cardiac surgery or catheter-based therapeutic intervention (including closure of PFO) is disqualifying for all flying classes. ASD, VSD and PDA successfully corrected by surgery or catheter-based techniques, especially in childhood, may be favorably considered for waiver for all classes of flying duties, as may uncorrected, but hemodynamically insignificant ASD and VSD. Because the appropriate treatment of hemodynamically insignificant PDA is unsettled, uncorrected small PDAs will be considered on a case-by-case basis. Coarctation of the aorta will also be considered on a case-by-case basis.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review/Evaluation
I/IA	Hemodynamically insignificant ASD, VSD, PDA	Yes AETC	Yes
	Hemodynamically significant ASD, VSD, PDA (uncorrected)	No AETC	No
	Hemodynamically significant ASD, VSD, PDA (corrected)	Yes# AETC	Yes
	Coarctation of aorta	Maybe*# AETC	Yes
	PFO surgically closed	Maybe AETC	Yes
	PFO asymptomatic/incidental finding	N/A (not DQ)	No
II/III and initial GBO/ATC/SWA	Hemodynamically insignificant ASD, VSD, PDA	Yes MAJCOM	Yes
	Hemodynamically significant ASD, VSD, PDA (uncorrected)	No MAJCOM	No
	Hemodynamically significant ASD, VSD, PDA (corrected)	Yes# MAJCOM	Yes
	Coarctation of aorta	Maybe# MAJCOM	Yes
	PFO surgically closed	Maybe*# MAJCOM	Yes
	PFO asymptomatic/incidental finding	N/A (Not DQ)	No
ATC/GBO/SWA	Any congenital heart defect	Maybe MAJCOM	No

Table 1: Waiver potential for congenital heart defects**

Must wait at least six months after surgery before submitting waiver.

* Not waiverable if PFO closed due to TIA or CVA episode. See TIA/CVA Waiver Guide.

** Per AFI 48-123 6.4.1.3, AFMRA remains waiver authority for all initial waivers for conditions that do not meet retention standards, unless 6.4.1.4.1 applies.

AIMWTS search in Feb 2015 revealed 96 aeromedical summaries with a diagnosis of ASD, VSD, PFO, PDA, or coarctation. Breakdown of the cases revealed: 12 FC I/IA cases (2

disqualified), 32 FC II cases (4 disqualified), 45 FC III cases (12 disqualified), 3 ATC/GBC cases (no disqualifications), and 4 MOD cases (1 disqualified). Only 5 of the 19 disqualified cases were disqualified specifically for the congenital abnormality.

II. Information Required for Waiver Submission.

The aeromedical summary should only be submitted after administrative and clinical disposition have been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary for initial waiver should contain the following information:

A. Complete history and physical exam – to include description of any symptoms, treatment, medications, and activity level.

B. Cardiology consultation.

C. Electrocardiogram (ECG).

D. Official report of all local echocardiograms. Also send videotape/CD copy of the images of the most recent echocardiogram to the ACS [if recent surgery, echocardiogram should be done close to six months after surgery]. (Notes 1 and 2)

E. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)

F. Operative report, if recent surgery.

G. Results of medical evaluation board (MEB) (worldwide duty evaluation for ARC members), if congenital abnormalities not satisfactorily treated by surgical correction.

The aeromedical summary for <u>waiver renewal</u> should contain the following information: A. Complete history and physical exam – to include description of any symptoms, treatment, medications, and activity level.

B. Electrocardiogram (ECG).

C. Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.

D. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

Congenital heart disease (CHD) is estimated to involve up to 1% of live births in the US.^{1, 2} CHD in adults includes common and uncommon defects, with and without correction by surgery or catheter-based interventions. Consideration of waiver for continued military flying duties or training require normal or near-normal cardiovascular status, acceptably low risk of aeromedically pertinent events, and no significant residua. Since the advent of reparative surgery for congenital cardiac defects, it is estimated that 85% of affected children survive into adulthood.³ In 2010, researchers estimated there are approximately 1.1 million Americans over the age of 18 with congenital heart disease.¹² Longitudinal studies estimate that approximately 20% of individuals with CHD will experience tachyarrhythmias during their lifetime which can possibly become an aeromedical concern.²

Bicuspid aortic valve is discussed in the Bicuspid Aortic Valve Waiver Guide. Otherwise, the most common congenital disorders that will require aeromedical consideration are the atrial septal defect (ASD), ventricular septal defect (VSD), and patent foramen ovale (PFO) with/without associated atrial septal aneurysm (ASA). Patent ductus arteriosus (PDA) and coarctation of the aorta may also be seen. Hemodynamically significant defects are likely to be detected and corrected during infancy or childhood, especially VSD and PDA. Other, more complicated congenital disorders will be very unusual because most will be detected in infancy or childhood and, even if corrected, will be unacceptable for entrance into military service.

ATRIAL SEPTAL DEFECT (ASD)

There are three types of ASD; ostium secundum (75%) [failure of the septum primum to cover the fossa ovalis], ostium primum (15%) [inadequate development of the endocardial cushion, thus failing to close the ostium primum], and sinus venous (10%) [abnormal embryologic evolution of the sinus venous and sinus valves]. ASDs allow shunting of blood flow from the left to right atrium, with resultant right-sided volume overload and enlargement of the right atrium and ventricle. Presence and time course of symptom development depends on the magnitude of the shunt with shunts greater than a 1.5 pulmonary to systemic flow ratio (Qp:Qs) generally producing significant volume overload with resultant symptoms, including easy fatigue, dyspnea, and arrhythmias, especially atrial fibrillation. Straining, coughing, Valsalva, anti-G straining maneuvers or positive pressure breathing may cause the blood flow to reverse, which could serve as conduit for embolic material. Moderate and even large sized ASDs may not be detected until adulthood. Many patients are minimally symptomatic during the first three decades of life although more that 70% became somewhat impaired by the fifth decade.⁴ Prognosis after successful and uncomplicated closure of significant secundum and sinus venosus ASD is normal if accomplished before age 25.⁵⁻⁷ Closure later in life increases the risk of atrial fibrillation, stroke, and right heart failure.

VENTRICULAR SEPTAL DEFECT (VSD)

Hemodynamically significant defects are likely to be detected and corrected during infancy or childhood. Hemodynamically insignificant VSDs will also likely be detected in infancy or childhood due to the very characteristic murmur but may not be recommended for closure

because of insignificant shunting and a high likelihood of spontaneous closure over time. VSDs repaired before age 2 have a good long-term prognosis.⁷

PATENT DUCTUS ARTERIOSUS (PDA)

PDAs classically produce a prominent continuous "machinery" murmur heard at the second left intercostal space. Small PDAs may escape detection until adolescence or adulthood but are unusual. In the past, even small PDAs were often recommended for surgical or catheter-based closure due to anticipated long-term risks of heart failure, endocarditis and pulmonary hypertension. Recently, a trend has developed to follow small PDAs, especially silent PDAs, without correction/closure. The proper course of therapy for small PDAs is not yet established and there is disagreement among experts as to the theoretical increased risk of endocarditis in small and silent PDAs.

COARCTATION OF THE AORTA

Coarctation of the aorta results in elevated blood pressure in the upper limbs, with normal or low pressure in the lower limbs. Associated abnormalities with coarctation include bicuspid aortic valve, congenital aneurysms of the circle of Willis, and aortic aneurysms. Unrepaired coarctation with a resting gradient ≥ 20 mm Hg between the upper and lower extremities carries an increased risk for progressive left ventricular hypertrophy and subsequent left ventricular dysfunction, persistent systolic hypertension, and premature atherosclerotic cerebrovascular and coronary heart disease. Coarctation of the aorta is usually diagnosed in childhood, but up to 20% of cases are reportedly not detected until adolescence or adulthood. Long-term prognosis is related to the age of repair, with the best outcome for correction being before age 9.⁸

PATENT FORAMEN OVALE (PFO) and ATRIAL SEPTAL ANEURYSM (ASA)

Patent foramen ovale (PFO) and atrial septal aneurysm (ASA) are anatomic anomalies of the interatrial septum. PFO occurs in 25-30% of the general population. At that prevalence, it can be considered a normal variant. ASA is present in about 1-2% of the general population. PFO and ASA may be present alone or may occur together. Asymptomatic PFO and/or ASA are typically incidental findings discovered on echocardiogram evaluation performed for unrelated indications. Aeromedically, these are considered normal anatomic variants and therefore are qualifying for all classes of flying duties including initial training.

Despite these defects being considered normal anatomic variants for aeromedical evaluation, PFO and ASA, alone or in combination, have been associated with possible paradoxical embolic events, notably stroke and transient ischemic attack. Although the relative risk for such an event may be increased, the absolute risk is low. The 2010 published CLOSURE trial showed no decrease in recurrent stroke after PFO closure (via percutaneous device) and a possibly significant vascular complication rate and increased risk of atrial fibrillation after PFO closure.⁹ Additionally, there was still a 3.1% stroke rate in both the medical and PFO closure arms of the trial. More recently, the 2013 published PC and RESPECT trials both found that device closure of a PFO did not offer a significant benefit over medical therapy for the prevention of recurrent ischemic stroke.^{14, 15} Therefore, asymptomatic and hemodynamically insignificant PFO by itself is considered a normal variant and does not require waiver UNLESS it has been surgically (to include percutaneously) closed. TIA/CVA is not usually waiverable. Aeromedical concerns and

recommendations for PFO and/or ASA associated with stroke or transient ischemic attacks are also discussed in the Transient Ischemic Attack (TIA) and Stroke (CVA) Waiver Guide. All aeromedical instructions in this waiver guide regarding PFO associated with CVA/TIA apply equally to ASA associated with CVA/TIA.

II. Aeromedical Concerns.

Aeromedical concerns for all congenital heart disease are primarily related to the long-term effects of shunting with volume overload. These include atrial and ventricular dilation and dysfunction, tachydysrhythmias, endocarditis or endarteritis. For those treated surgically, favorable results need to be well demonstrated.

ICD-9 Cod	ICD-9 Codes for congenital heart diseases		
745.4	Ventricular septal defect		
745.5	Patent foramen ovale and ostium secundum atrial septal defect		
745.6	Ostium primum atrial septal defect		
745.9	Unspecified defect of septal closure		
747.0	Patent ductus arteriosus		
747.1	Coarctation of aorta		

ICD-10 Co	ICD-10 Codes for congenital heart diseases		
Q21.0	Ventricular septal defect		
Q21.1	Atrial septal defect, patent foramen ovale, ostium primum atrial septal defect,		
	and ostium secundum atrial septal defect		
Q21.9	Congenital malformation of the cardiac septum, unspecified		
Q25.0	Patent ductus arteriosus		
Q25.1	Coarctation of aorta		

V. References.

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4. Marelli AJ. Congenital Heart Disease in Adults. Ch. 69 in *Goldman's Cecil's Medicine*, 24th ed., Saunders, 2011.

5. Kruyer WB and Davenport ED. Cardiology. In: *Rayman's Clinical Aviation Medicine*, 5th ed., New York: Castle Connolly Graduate Medical Publishing, LTD, 2013; 106-15.

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8. Webb GD, Smallhorn JF, Therrien J, and Redington AN. Congenital Heart Disease. Ch. 62 in *Mann: Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine*, 10th ed. Saunders Elsevier, 2014.

9. Furlan AJ, Reisman M, Massaro J, et al. A Prospective Multicenter, Randomized Controlled Trial to Evaluate the Safety and Efficacy of the STARflex Septal Closure System Versus Best Medical Therapy in Patients With a Stroke or Transient Ischemic Attack Due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale. Stroke, 2010; 41: 2872-83.

10. Furlan AJ, Reisman M, Massaro J, et al. Closure or Medical Therapy for Cryptogenic Stroke with Patent Foramen Ovale. NEJM, 2012; 366: 991-99.

11. Johnston SC. Patent Foramen Ovale Closure – Closing the Door Except for Trials. NEJM, 2012; 366: 1048-50.

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15. Carroll JD, Saver JL, Thaler DE, et al. Closure of Patent Foramen Ovale versus Medical Therapy after Cryptogenic Stroke. N Eng J Med, 2013; 368: 1092-1100.





Coronary Artery Calcium Testing

Revised: Aug 2022

Reviewed: Lt Col Jeffrey Kinard (RAM 22), Col Eddie Davenport (Chief ACS Cardiologist), Dr. Edwin Palileo (ACS Cardiologist); and Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: This edition includes updated waiver authorities, submission requirements, AIMWTS data, aeromedical concerns, and updated suggested readings.

I. Waiver Consideration

Any degree of coronary artery disease is disqualifying for all flying classes, to include ATC, GBO, and SWA personnel. Coronary Artery Calcium Scores (CACS) of 10 or greater are considered abnormal and requires waiver submission. For the purpose of aeromedical disposition, scores of 0-9 are considered normal and therefore meets standards for all classes of flying duties. A positive CACS is a non-invasive assessment of the presence of CAD, therefore even if additional cardiac testing is negative, waiver and ongoing follow-up are still necessary. Aviators who received a CACS test as part of a local evaluation for symptoms suggestive of CAD should complete their evaluation as directed by the local cardiologist.

CAC	Flying Class	Waiver Potential	Required ACS Review and/or ACS
Score	• •	Waiver Authority	Evaluation
0-9	FC I/IA/II/ III	No waiver necessary ¹	No
10-	FC I/IA	No	No
99		AFRS/CMO	
	II, GBO, ATC,	Yes	Yes - evaluation initially and every 1-4
	SWA and III	MAJCOM	years thereafter ^{2, 3}
100-	FC I/IA	No	No
399		AFRS/CMO	
	II, GBO, ATC,	Yes	Yes - evaluation initially and then every
	SWA, and III^4	MAJCOM	1-3 years ^{2, 3}
400+	FC I/IA	No	No
		AFRS/CMO	
	II, GBO, ATC,	Yes	Yes - evaluation initially with mandatory
	SWA, and III^4	MAJCOM	coronary angiography; re-evaluation
			annually ²

Table 1: Waiver Potential for Coronary Artery Calcium Testing

1. Reminder: All cardiology tests (e.g., Holter, CAC testing, echocardiogram, ECG, treadmill, cardiac catheterization) on all flying classes must be sent to the ECG library.

2. Need for coronary angiography will be based on Astro-CHARM calculation and results of non-invasive testing

3. If coronary angiography is accomplished (invasive or CT coronary angiography) then follow Coronary Artery Disease waiver guide. All images regardless of outcome need to be sent to ECG library / ACS for review.

4. Waiver for untrained FC II and FC III unlikely.

II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and practice recommendations.

A. Initial Waiver Request:

- 1. Complete history and physical examination to include detailed description of any symptoms, exercise history, and CAD risk factors (positive and negative). *Include the reason the CAC test was obtained.*
- 2. Report of the CAC score and images if available. Please also include all reports, images, and tracings of any other cardiac tests performed locally for clinical assessment (e.g. echocardiography, treadmill, Holter, or angiography). (Notes 1 and 2)
- 3. All CACS 10 require imaging stress testing (stress echocardiogram or nuclear stress test), and fasting lipids to calculate an ACC/AHA and Astro-CHARM 10 year risk score (Astro-CHARM includes CACS in the scoring). (Note 3)
- 4. Additional local cardiac testing is not routinely required but may be requested in individual cases.
- 5. Alternatively, for all CACS 10, CT coronary angiography can be done in addition to or in place of all other testing.
- B. Renewal Waiver Request:
 - 1. History brief summary of previous CT results and findings at ACS. Address interim cardiac symptoms (including negatives), exercise/activity level, coronary artery risk factors, and all medications.
 - 2. Local follow-up cardiac testing is not routinely required prior to ACS re-evaluation. If requested for individual cases, it will have been specified in the report of the previous ACS evaluation.
 - 3. Copies of reports and tracings of any other cardiac tests if performed locally for clinical assessment (e.g. echocardiography, treadmill, Holter, or angiography). (Notes 1 and 2)

Note 1: All original cardiac imaging and electrical tracings must be submitted to ACS Cardiology for independent review. Electronic submission to the ECG Library is preferred. If electronic submission is not possible, electronic media can be sent via USPS or FedEx to the address below. Please include the service member's name, full social security number, date of mailing, and a POC at the submitting flight surgeon's office with all mailed materials. State in the AMS the date of submission.

Attn: Case Manager for [specify the appropriate MAJCOM] USAFSAM/FECI Facility 20840 2510 Fifth Street Wright-Patterson Air Force Base, OH 45433-7913

<u>Note 2</u>: Include the shipping tracking number(s) and when studies were sent to ACS in the aeromedical summary. <u>Note 3</u>: The Astro-CHARM Calculator (<u>http://astrocharm.org/calculator-working/</u>) and ACC/AHA 10-Year ASCVD Calculator (<u>https://tools.acc.org/ascvd-risk-estimator-plus/#!/calculate/estimate/</u>) are available online. <u>Note 4</u>: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

III. Aeromedical Concerns

Coronary artery calcium (CAC) testing has emerged as a helpful tool in cardiac risk stratification, prevention, and shared decision making regarding initiation of statin therapy. The presence of any amount of coronary artery calcium confirms the presence of atherosclerotic coronary artery disease. As such, CAC-testing is simply a non-invasive assessment of the presence of coronary artery disease. It is important to note that while the presence of CAC confirms the diagnosis of coronary artery disease, the converse is not true: it is possible to have coronary atheromas that have not calcified and thus are not detected by this type of testing.

The MESA (Multi-Ethnic Study in Atherosclerosis) trial demonstrated a strong and graded association between CAC scores and 10-year ASCVD risk. For every doubling of CAC scores, the 10-year ASCVD risk rose 14% in this prospective study that followed patients for an average of 10.2 years. Higher CAC scores indicate detection of greater amounts of calcium and larger overall burden of coronary artery disease. The reported CAC score is a total CAC burden, the sum of the scores of all individual calcium deposits.

Even minor amounts of detectable coronary artery calcium result in significant coronary event rates, while more substantial CAC results in higher event rates. This predictive value of CAC testing is particularly useful for younger, asymptomatic populations with low to moderate risk score profiles (such as Framingham). In particular, the Prospective Army Coronary Calcium (PACC) project noted that in a healthy cohort of roughly 2,000 active-duty army personnel, the presence of any amount of detectable coronary artery calcium increased coronary heart events by nearly 12-fold. All the events in this cohort occurred in personnel between ages 40 and 50 years old with a Framingham risk score less than 10%, and with CAC scores as low as 10.

In addition to the ACC/AHA 10-year ASCVD Pooled Cohort Equation, the Astronaut Cardiovascular Health and Risk Modification (Astro-CHARM) includes CAC scoring in the risk calculation. Astro-CHARM also incorporates family history of CAD as well as optional high-sensitivity C-reactive protein (CRP) lab results. Unlike other risk scores, Astro-CHARM was validated utilizing data from a cohort resembling military aircrew. Astro-CHARM is validated for individuals' 40-years old and older.

Screening aircrew with CACS if not low risk (>6-10% ten-year cardiovascular event rate) using a validated risk score is appropriate based on international aerospace cardiology consensus and many published guidelines. The aeromedical concerns surrounding abnormal CAC tests are the same as those for individuals with angiographically proven asymptomatic CAD. The major aeromedical concerns are myocardial ischemia presenting as sudden cardiac death, acute myocardial infarction, stable or unstable angina, or ischemic dysrhythmias; any of which could cause sudden incapacitation or significantly impair flying performance or mission completion. Additional concerns surround the need for invasive cardiac procedures and revascularization, frequent contact with cardiac specialists, and comprehensive medication regimens. At present, there is no reliable method of detecting asymptomatic progression of CAD short of frequent noninvasive monitoring, combined with periodic invasive testing. Review of AIMWTS data from August 2011 through September 2021 revealed a total of 20 waiver packages for CACS only. The breakdown of the number of waivers and number of total cases are tabulated below.

Please use only this ICD-10 code		(# of waivers / total # of cases)				
for AIMWTS coding purposes		IFC I/IA	FC II	FC III	GBO	SWA
Z13.6	Encounter for screening for cardiovascular disorders	0	11/13	4/4	1/1	1/2

IV. Suggested Readings / References

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- Lloyd-Jones D, Lewis C, Schreiner P, Shikany J, Sydney S, Reis J. The Coronary Artery Risk Development In Young Adults (CARDIA) Study. JACC. 2021 Jul, 78 (3) 260-277. <u>https://www.jacc.org/doi/epdf/10.1016/j.jacc.2021.05.022</u>

WAIVER GUIDE Updated: Dec 2015 Supersedes Waiver Guide of Mar 2012 By: Lt Col Hui Ling Li (RAM 16) and Dr Dan Van Syoc Reviewed by: Lt Col Eddie Davenport, Chief ACS Cardiologist

CONDITION: Coronary Artery Disease (Dec 2015)

I. Waiver considerations.

Coronary Artery Disease (CAD) is disqualifying for all classes of flying duties to include GBO, ATC, and SWA personnel. CAD is disqualifying for retention if associated with myocardial infarction, major rhythm disturbances, congestive heart failure, angina, silent ischemia or for maintenance on any medication for prevention of angina, CHF or rhythm disturbance. Waiver is not recommended for FC I/IA or for unrestricted FC II/III duties. Severity of disease is defined below and categorized as Luminal irregularities only (LI), Mild or minimal (MinCAD), Moderate (MODCAD) or Severe (SCAD). Depending on the severity and extent of disease, waiver may be considered for categorical FC II/III duties (restricted to low performance aircraft defined as <2.5 sustained +Gz). Waiver may be considered for Initial FC II for Flight Surgeons, but will be similarly restricted. The only exception is that luminal irregularities (LI) only may be considered for unrestricted FC II/III duties. Additionally, modifiable risk factors **must** be acceptable, including but not limited to no use of tobacco products, no diabetes, controlled hypertension (per ACC/AHA guidelines), acceptable lipid profile (treated or untreated per ACC/AHA guidelines), acceptable lipid profile (treated or untreated per ACC/AHA guidelines), and compliance with medications. These risk factors **must** be acceptable to both gain **and** maintain the waiver. Degree of coronary

CAD Category Classification	Flying Class	Waiver Potential	Required ACS Review and/or ACS
		1 oventuar	Evaluation
		Waiver	
		Authority	
Luminal irregularities	FC II/III	Yes	ACS evaluation
(LI) only (no graded	ATC/GBO/SWA	MAJCOM	initially and four years
% stenoses) \$*			later, then every two years**
MinCAD\$#	FC IIA rated aviators	Yes	ACS evaluation
Aggregate <50%		AFMRA	initially and annually
No left main disease			
	GBO	Yes	ACS evaluation
	ATC	MAJCOM	initially and
	SWA		annually**
	Restricted FC III		
ModCAD\$+@	FC IIC pilots	Yes	ACS evaluation
Aggregate \geq 50% and	FC IIA navigators & flight	AFMRA	initially and annually
<120%, and/or any	surgeons		
gradable left main	Restricted FC III		
disease			
	GBO/ATC	Yes	ACS evaluation
	SWA	MAJCOM	initially and annually
SCAD\$∫	All Flying Classes	No	N/A
Aggregate $\geq 120\%$ or		AFMRA	
max lesion >70% or			
left main ≥50%			
Any CAD	FC I and FC IA	No	N/A
	Initial FC II/III, SWA,	AETC	
ψτ · 1 · 1 ·, 1 ·	ATC, and GBO		

Table 1: Summary of CAD Categories and ACS Requirements

* Luminal irregularity only is eligible for unrestricted FC II/III waiver.

** ACS annual evaluation not required for LI or MinCAD for ATC/GBO/SWA personnel unless requested by waiver authority.

MinCAD is eligible for FC IIA waiver.

+ ModCAD is eligible for FC IIC waiver for pilots, limited to low performance aircraft with another qualified pilot. For navigators and flight surgeons, waiver is FC IIA.

@ MinCAD and ModCAD are eligible for restricted FC III waiver, limited to low performance aircraft.

 \int SCAD (aggregate \geq 120%) is disqualifying without waiver recommended. SCAD with a maximum lesion >70% (SCAD>70) and CAD with a left main coronary lesion \geq 50% are also disqualifying without waiver recommended. \$\$ No indefinite waivers

Individuals with a waiver for LI only will be reevaluated at the ACS four years after diagnosis, then every two years thereafter. Individuals with a waiver for MinCAD and ModCAD will be reevaluated at the ACS annually. Successful modification of cardiac risk factors must be demonstrated for LI only, MinCAD and ModCAD. Additional criteria for waiver of LI only and

MinCAD include, but may not be limited to: no history suggestive of ischemic symptoms, no prior cardiac events (e.g. unstable angina, myocardial infarction) and normal left ventricular function. Repeat coronary angiography will not be required for LI only or for MinCAD in the absence of any suggestion of CAD progression or symptoms suggestive of ischemia. Additional criteria for waiver of ModCAD include, but may not be limited to: only one lesion of 50-70% stenosis, normal nuclear stress imaging study in the distribution of the 50-70% lesion, no history suggestive of ischemic symptoms, no prior cardiac events (e.g. unstable angina, myocardial infarction) and normal left ventricular function. Follow-up coronary angiography will be performed for ModCAD every five years routinely, or sooner depending on degree of risk factor improvement, complexity of disease, or for symptoms suggestive of ischemia or deterioration in noninvasive testing.

AIMWTS review in Dec 2015 revealed a total of 246 cases with known coronary artery disease. This total includes those with MI and revascularization as well. Breakdown of cases was as follows: 160 FC II cases (56 disqualifications), 75 FC III cases (29 disqualifications), 6 ATC/GBC cases (2 disqualifications), and 5 MOD cases (2 disqualifications). Of the total of 89 disqualified cases, the vast majority were disqualified primarily for cardiac disease.

II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial waiver</u> for coronary artery disease should contain the following information: A. Complete history and physical exam – to include description of any symptoms, blood pressure, medications, and activity level.

B. Cardiology consult.

C. Electrocardiogram (ECG).

D. Report and CD copy of coronary angiography to the ACS. (Notes 1 and 2)

E. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)

F. Results of MEB or worldwide duty evaluation (for ARC members), if required (e.g. on medications or MI, etc.).

The AMS for waiver <u>renewal</u> should contain the following information:

A. Complete history and physical exam – to include description of any symptoms, medications, and activity level.

B. Electrocardiogram (ECG).

C. Additional local cardiac testing is not routinely required for re-evaluation cases followed at the ACS but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.

D. Copies of reports and tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is: Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

For expediting case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

This waiver guide addresses only <u>asymptomatic</u> coronary artery disease that has <u>not</u> been treated by revascularization (e.g. stent, bypass surgery). Refer to the Coronary Artery Revascularization waiver guide for revascularization cases.

Coronary artery disease (CAD) is the result of coronary artery plaque development, reducing oxygen supply to the myocardium.¹ It is the leading cause of death and premature, permanent disability of American males and females.^{2, 3} It accounts for approximately 16% of all deaths each year.⁴ In spite of tremendous progress regarding CAD therapy, about 50% of initial and recurrent acute events continue to be fatal. Risk factors included older age, male sex, hypertension, hyperlipidemia, diabetes, obesity, smoking, and sedentary lifestyle.^{5, 6} Initial symptoms may include incapacitating angina, dyspnea, arrhythmia with altered consciousness or sudden death. Heat stress, hypoxia, high +Gz maneuvers and other features of the unique military cockpit/aircraft environment may provoke ischemia in individuals with pre-existing coronary artery lesions. CAD is the leading cause of disqualification for aviators.⁷

Coronary angiography is the golden standard for determining the presence and extend of CAD.⁶ Clinically, significant CAD is defined as one or more lesions with \geq 50% stenosis (diameter reduction) by coronary angiography.⁷ In the clinical literature, such disease is nearly always symptomatic, since it would rarely be identified otherwise. When treated medically, patients with this degree of disease are reported to show >5% per year annual cardiac event rates in favorable prognostic subgroups. Although the term significant coronary artery disease (SCAD) has historically also been applied to aviators discovered to have a maximal stenosis \geq 50%, event rates encountered in the clinical population may not accurately predict prognosis in the younger and relatively healthier aviator population with *asymptomatic* CAD.

To evaluate the actual risk associated with asymptomatic CAD, the Aeromedical Consultation Service (ACS) analyzed initial and long-term follow-up data from approximately 1,500 asymptomatic military aviators with coronary angiography. For aviators with SCAD as defined above, average annual cardiac event rates exceeded 2.5% per year at 2, 5 and 10 years of follow-

up. To further stratify risk, the SCAD group was divided into two subsets of SCAD severity, SCAD50-70 (worst lesion 50-70%) and SCAD>70 (worst lesion >70%). Detailed examination of the SCAD50-70 subset revealed that extent of disease (aggregate of lesions) at the time of index coronary angiography could further be stratified into a low-risk versus high-risk subjects. This new stratification used an aggregate of lesions defined as the arithmetic sum of all graded lesions, e.g. 60% lesion + 20% lesion + 30% lesion = aggregate of 110%. Aggregate <120% identified a lower-risk SCAD50-70 subgroup with an average annual event rate <1% per year at ten years of follow-up. Subsequent analysis of the group with minimal coronary disease (MCAD, defined at that time as maximal stenosis <50%) also showed that aggregate was significantly predictive of events albeit low.

Because aggregate successfully stratified cardiac risk, all groups with any CAD (combined SCAD and MCAD) with a maximal lesion \leq 70%, was submitted to a similar analysis. In this combined group, aggregate was highly predictive of event-free survival (p<0.00004). Specifically, aviators with an aggregate \leq 50% showed an average annual event rate of 0.6% per year, while those with an aggregate \geq 50% but <120% had an average annual event rate of 1.1% per year. (Although a rate of 1.1% slightly exceeds the 1%/year threshold, the data reviewed predated the routine use of lipid-lowering therapy for secondary prevention, which would be expected to reduce events by an additional 30-40%).

By way of comparison, clinical literature reports annual cardiac event rates of about 0.5% per year in general population studies of apparently healthy asymptomatic males aged 35-54 years. Similarly, follow-up studies of male subjects with normal coronary angiography, who in most cases presented with a chest pain syndrome, report annual cardiac event rates of 0.2-0.7% per year. Annual cardiac event rates in apparently healthy USAF aviators have been reported by the ACS as $\leq 0.15\%$ per year for males aged 35-54 years although more recent data approaches the expected 0.5% per year rate.

From this database analysis, the current aeromedical classification of asymptomatic CAD is based on aggregate, with minimal CAD (MinCAD) defined as an aggregate <50%, and moderate CAD (ModCAD) defined as an aggregate $\geq50\%$ but <120%. Significant CAD is now defined as an aggregate $\geq120\%$. A demonstrated maximum lesion >70% is also considered SCAD.

Graded lesions in the left main coronary artery are treated more cautiously due to the unfavorable prognosis associated with left main disease. Left main coronary artery lesions <50% stenosis are defined as ModCAD, assuming that other criteria for that classification are met. Left main lesions \geq 50% stenosis are considered SCAD.

An additional category of CAD was more recently identified from the ACS database – luminal irregularities (LI) only. LI only describes coronary angiography with irregular arterial edges due to atherosclerotic plaque but less than gradable 10-20% stenosis (diameter reduction). LI only represents a subset of CAD with event rates higher than those with truly normal coronary angiography (smooth arterial edges). A review of the ACS database showed that aviators with LI only on coronary angiography had no events in the first five years after diagnosis. However, between 5 and 10 years follow-up, cardiac event rates were 0.54% per year compared to 0.1%

per year for those with truly normal coronary angiography. This represents a risk similar to MinCAD in the first five years of follow-up.

IV. Aeromedical Concerns.

The aeromedical concern is myocardial ischemia presenting as sudden cardiac death, acute myocardial infarction, stable or unstable angina or ischemic dysrhythmias, any of which could cause sudden incapacitation or significantly impair flying performance. At present, there is no reliable method of detecting asymptomatic progression of CAD short of frequent noninvasive monitoring, combined with periodic invasive testing.⁸

Because cardiac catheterization of asymptomatic aviators with abnormal noninvasive testing is only recommended if the risk of CAD exceeds a predetermined threshold, local catheterization of asymptomatic aircrew for aeromedical indications alone is strongly discouraged. Where catheterization is indicated for <u>clinical</u> reasons, then of course the aviator should be managed as any other clinical patient would be.

ICD 9 Codes	ICD 9 Codes for Coronary Artery Disease		
414	Other forms of chronic ischemic heart disease		
414.0	Coronary atherosclerosis		
414.8	Other specified forms of chronic ischemic heart		
	disease		
414.9	Chronic ischemic heart disease, unspecified		

ICD 10 Codes for Coronary Artery Disease		
I25.89	Other forms of chronic ischemic heart disease	
I25.10S	Atherosclerotic heart disease of native coronary	
	artery without angina pectoris	
I25.9	Chronic ischemic heart disease, unspecified	

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WAIVER GUIDE Updated Jun 2016 Supersedes Waiver Guide of Aug 2012 By: Lt Col (Dr.) Paul De Florio, Lt Col (Dr.) Eddie Davenport (ACS Chief Cardiologist) and Dr. Dan Van Syoc

CONDITION: Coronary Artery Revascularization (Jun 2016)

I. Waiver Considerations.

Coronary artery disease and coronary artery revascularization are disqualifying for all classes of flying duty and retention. The events triggering revascularization are critical, as there is greatly increased morbidity and mortality in the setting of MI. If there is evidence of myocardial infarction (ECG changes, or cardiac enzymes elevation) then they must meet criteria for the myocardial infarction waiver policy. In general, revascularization should not be done for asymptomatic coronary artery disease. ACS review and evaluation is required for waiver consideration. Waiver restricted to low performance aircraft may be considered for all flying classes. Coronary artery revascularization is also disqualifying for ATC/GBO/SWA duty as well as for retention purposes, and MEB and waiver is required before return to duty.

Waiver for pilots, limited to FC IIC (low performance aircraft with another qualified pilot) was approved by the Aerospace Medicine Corporate Board in 2008. Criteria for waiver consideration for all aviators include (must meet all of the below):

- A. Normal left ventricular wall motion and systolic function,
- B. Complete revascularization; all lesions with \geq 50% stenosis successfully treated,
- C. The sum of all remaining stenosis should be less than 120%,
- D. No reversible ischemia on noninvasive testing (off cardioactive medicines),
- E. For PCI, no restenosis over 50%,
- F. Successful risk factor modification,
- G. A minimum DNIF observation period of six months post procedure.

ACS evaluation for initial waiver consideration will include complete noninvasive testing and follow-up coronary angiography. If waiver is recommended and granted, waiver will be valid for one year with annual ACS re-evaluation required for waiver renewal consideration. In addition, routine serial coronary angiography *is required at five year intervals*. Follow-up coronary angiography may be recommended sooner if indicated by symptoms, noninvasive test results, or failure to control risk factors.

Flying Class	Waiver Potential	ACS
	Waiver Authority	Review/Evaluation
I/IA	Not Waiverable	NA
II (unrestricted)	Not Waiverable	NA
IIA (flight surgeon)	Yes*	Yes, Annual
IIC (pilot)	AFMRA	
III	Yes*	Yes, Annual
	MAJCOM**	
ATC/GBO/SWA	Yes*	Review possible***
	MAJCOM**	

Table 1: Coronary Artery Revascularization and Waiver Potential

* Must meet following criteria for consideration: 100% revascularization, <50% single lesion, <120% aggregate, normal LVEF, no wall motion abnormality. Adequate medical management may include statin, aspirin, nitroglycerin, and/or ACE inhibitor, as clinically appropriate. Additionally, patient must have controlled hypertension, no diabetes, no other significant co-morbidities, and controlled risk factors. Low performance aircraft defined as <2.5 sustained G, with another qualified pilot. No altitude restriction in low performance aircraft. ** AFMRA is the waiver authority for all initial waivers.

*** Annual testing may be done locally and sent to ACS for review at the request of the MAJCOM, alternatively all testing and follow-up can be done during annual ACS evaluations.

AIMWTS review through Jun 2016 revealed 143 submitted cases with a history of revascularization. There were 0 FC I/IA cases; 89 FC II cases (39 disqualified), 48 FC III cases (18 disqualified); 4 ATC/GBC cases (disqualified); and two MOD cases (one disqualified).

II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for the <u>initial waiver</u> for coronary artery revascularization should include the following:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. A complete discussion of the history of CAD and procedures.

C. Consultation notes from a cardiologist.

D. Imaging: Copy of the cardiac catheterization report and copy of the images (CD,

cineangiogram or videotape); copy of the revascularization procedure report (CABG or PCI) and for PCI copy of the images (CD, cineangiogram or videotape); copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. electrocardiogram, treadmill, nuclear myocardial stress perfusion imaging).

E. Additional local cardiac testing is not routinely required, but may be requested in individual cases. Copies of reports of any such testing will be required.

F. Results of MEB returning member to worldwide duty.

The AMS for <u>waiver renewal</u> for coronary artery revascularization should include the following:

A. Interval history since last waiver.

B. All applicable and imaging tests and reports that have been completed since last waiver/renewal. If annual ACS evaluation is required, no local testing is required unless clinically indicated as follow-up testing will be done at annual ACS evaluation.C. Consultation (any follow-up exams) from local cardiologist.

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is: Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

For expediting case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

Coronary artery revascularization addresses occlusive coronary artery disease (CAD) via either coronary artery bypass graft (CABG) surgery or percutaneous coronary intervention (PCI), which most commonly includes the catheter-based techniques of angioplasty and stent placement. Because these techniques are palliative, not curative, any new cardiac events 6-12 months after successful revascularization are primarily caused by progression of disease.¹

Two large trials with long term follow up were designed to compare outcomes of PCI versus CABG.²⁻³ With a median follow up of 4.6 years, the BEST trial measured a primary end point of death, myocardial infarction (MI), and target-vessel revascularization. The PCI group rate was 15.3%, and the CABG rate was 10.6% at 4.6 years.³ The SYNTAX trial reported five year event data, with a composite end point of death, MI, stroke, and repeat revascularization. Their PCI group suffered events at a rate of 37.3%, with the CABG group reported as 26.9%.² For both trials revascularization drove the primary endpoint and neither death nor MI were independently significantly different with MI and mortality rates of approximately less than 2% per year. Kaplan-Meier curves in both trials also showed an early spike in complication rates, with a more linear curve after 6-12 months, which reinforces historical waiver guide recommendations that patients only be assessed after a minimum of six months post-procedure. Although both trials favor CABG over PCI, it is important to note this was driven by target vessel revascularization and reinforces policy that either CABG or PCI can be done in aviators. Data with newer-generation drug-eluting stents is ongoing.

The applicability of these and similar trials to the military aviator is very limited, as they universally study older patients with high rates of comorbidities. In addition, they also record post-intervention complications that fall within the first 6-12 months, which would not be applicable to military aviators. In an attempt to address these shortcomings, one older study re-examined the large post-CABG database and extracted a "simulated aviator population" of males

under 60 with no history of cardiovascular comorbidities and no major complications within 12 months. Of these, the two youngest cohorts (ages 20-39 and 40-49) best resemble the military aviator population. Their five year cardiac event-free rate was found to be $94 \pm -3\%$ and $91 \pm 2\%$ respectively.⁴

A retrospective review of ACS data studied 122 former military aviators with no prior cardiac events who underwent coronary artery revascularization.⁵ About half the group had CABG and the other half had PCI, primarily angioplasty. There were no cardiac deaths within five years and only two myocardial infarctions, both beyond two years follow-up. After excluding repeat revascularization within six months of the index revascularization, cardiac event rates at one, two, and five years were 1.0%, 2.7% and 3.6% per year respectively. Individuals meeting the below waiver criteria have estimated cardiac event rates of 2-3% per year for up to five years after revascularization.

Recently a selected group of 30 aviators that presented to ACS (2000-2008) while on active duty, after having had coronary revascularization, were chosen for a retrospective study to determine the time to event and resulting annual event rate. Out of these, only two progressed requiring revascularization.⁶ There were no deaths and no MIs. The annual event rate was 2.1% (CI 1.2% - 3.0%). The event free survival was 97% at two years and 88% at 5 years. Both of these patients needing repeat intervention would likely have been identified during the annual ACS reevaluation as required by policy. Neither would have manifested as an incapacitating event.

IV. Aeromedical Concerns.

The aeromedical concern is myocardial ischemia presenting as sudden cardiac death, myocardial infarction, angina or ventricular dysrhythmias, all of which may cause sudden incapacitation or seriously impact performance of flight duties. Detecting the asymptomatic progression of CAD reliably without frequent invasive testing or noninvasive monitoring is the aeromedical challenge.

ICD-9 Codes for coronary artery disease	
414.00	Coronary artery disease
36.10	Coronary artery bypass graft (CABG)
36.06	Coronary artery stent placement
36.09	Coronary artery angioplasty

ICD-10 Codes for coronary artery disease	
I25.10	Coronary artery disease without angina
Z95.1	Coronary artery bypass graft (CABG)
Z98.61	Coronary artery angioplasty with or
	without stent placement

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ECG Findings in USAF Aircrew, Disposition of (Jan 2019)

The following guidelines standardize the aeromedical evaluation and recommendations for 12lead electrocardiographic (ECG) findings of individuals who must qualify for any class of flying duties. One goal is to streamline the local evaluation and minimize testing and travel to the Aeromedical Consultation Service (ACS). Aircrew with normal or normal variant ECG findings **as reviewed by the ECG Library** require no further evaluation or follow-up and no waiver action. Additional local studies or an ACS evaluation may be requested by the ECG Library on all individuals with borderline or abnormal ECG findings which are new or not previously evaluated. Originals of all ECGs and any other cardiovascular studies (even if normal) must be forwarded to the ECG library for review and image storage per AFI.

If additional studies are performed at the local level and reviewed through the ECG Library as normal or normal variant, no further workup is needed. If the additional studies are reviewed as borderline or abnormal, further evaluation will be directed through the ECG Library. Unless specified otherwise, borderline and abnormal ECG findings that require additional local workup do not require waiver if the additional workup is reviewed by the ECG Library as acceptable (normal/normal variant). If ACS evaluation or AFMOA/MAJCOM waiver is required for any of the findings, the ECG library will indicate this in its correspondence. **Unless indicated clinically, only the tests requested by the ECG library need to be performed.**

In general, these recommendations are intended to guide the aeromedical evaluation of the asymptomatic aviator with an electrocardiographic finding. The aviator who presents with symptoms, signs or findings of potential clinical significance must first be managed locally as a clinical patient. These ECG guidelines are based on historic ACS data as well as the 2017 International criteria for ECG interpretation in athletes. *denotes new aircrew disposition guidelines based on published and ACS data since the last ECG disposition guide.

Electronic submission of cardiac studies to the ECG library is preferred with average disposition time in less than 24 hours. Upload studies at https://acspacs.area52.afnoapps.usaf.mil/PicomCloud/Default. You may contact the ECG library to gain access or for any questions at USAFSAM.FECIECGLib@us.af.mil.

Normal or Normal Variant ECG Findings

The following are considered normal or normal variants in our aviator population. No further evaluation or follow up is needed for these findings IF ISOLATED (two or more normal variant or borderline findings requires additional testing after ACS ECG library disposition).*

- 700. Normal ECG
- 002. Sinus bradycardia (30 to 50 beats per minute) Note: Aeromedically, normal sinus rhythm is defined as 50-100 bpm

- 007. Sinus arrhythmia
- 028. Ectopic atrial rhythm
- 040. Accelerated junctional rhythm
- 080. Supraventricular rhythm at a rate of less than 100 bpm
- 085. Wandering atrial pacer
- 104. Second degree AV block, Mobitz Type I (Wenckebach)
- 121. Incomplete right bundle branch block
- 123. Terminal conduction delay (S wave in the lateral leads \geq 40 msec)
- 132. Nonspecific intraventricular conduction delay, $QRS \ge 100$ but < 120 msec
- 204. ST segment elevation due to early repolarization

221. Persistent juvenile T-waves (T wave inversions in V1-3 in an otherwise normal ECG that have been present on all previous ECG's)

- 737. Indeterminate QRS axis
- 743. S1, S2, S3 pattern (S waves in the inferior limb leads)
- 744. S1, S2, S3 pattern with RSR' pattern in V1 or V2 with QRS < 120 msec

755. R > S in V1 without other evidence of right ventricular hypertrophy

- 764. RSR' pattern in V1 or V2 with QRS < 120 msec
- 721. Right ventricular hypertrophy (R wave in V1 plus S wave in V5 or V6 > 10.5mV1)

Abnormal or Possibly Abnormal ECG Findings

The following are abnormal or possibly abnormal ECG findings with brief explainations and disposition. Each disposition if based on the associated finding <u>in isolation</u> (two or more abnormal findings requires ACS ECG library review).

Marked Sinus Bradycardia: Sinus bradycardia refers to heart rate less than 60 bpm with marked sinus bradycardia heart rate less than 30bpm. Marked sinus bradycardia is usually the result of athletic conditioning with increased vagal tone and is not associated with an adverse prognosis. Past evaluation of this finding in asymptomatic aviators by the ECG Library has consistently failed to uncover evidence of sinus node dysfunction unless heart rate is less than 30bpm. Further evaluation should be pursued as clinically indicated and/or requested by the ECG Library and commonly includes verification of increased heart rate with exercise.

A02. Marked sinus bradycardia (<30 bpm)*

Sinus Tachycardia: Sinus tachycardia may be transient and due to anxiety, fever, pain, etc. It may occasionally be an indicator of underlying heart disease or a metabolic abnormality. If sinus tachycardia is noted on an ECG, a repeat ECG should be obtained. If this is a persistent finding on the repeat ECG, a Holter monitor should be obtained while the aviator remains on flying status (no DNIF). If sinus tachycardia persists on the Holter, further evaluation should be pursued as clinically indicated and/or requested by the ECG Library.

001. Sinus tachycardia (resting heart rate > 100 bpm)

Short PR Interval:

Short PR interval (PR < 120 msec) may be a normal variant but is occasionally evidence for a bypass tract, even without an accompanying delta wave. Before diagnosing short PR interval, one must assure that it is truly sinus rhythm with sinus origin P waves, rather than ectopic atrial or other rhythm. For a PR interval between 100 and 120 msec, it is most likely a normal variant, but could represent a bypass tract. For these cases, a thorough history should be obtained locally with specific questions aimed at the detection of tachyarrhythmias, to include palpitations, rapid heart beat sensations, lightheadedness or syncope. If the history is unremarkable with no suggestion of a possible tachyarrhythmia, then no further evaluation is indicated and the finding should be considered a normal variant. For a PR interval less than 100 msec, the possibility of a bypass tract is much greater and further evaluation should be pursued as clinically indicated and/or requested by the ECG Library

029. Short PR interval (PR interval < 120 msec in all leads)

Wolff-Parkinson-White:

Ventricular Pre-excitation to include Wolff-Parkinson-Whitepattern on ECG requires ACS evaluation/review. The aviator/aircrew should be placed DNIF pending ACS evaluation/review. See the *Wolff-Parkinson-White (WPW) and Other Pre-excitation Syndromes* Waiver Guide for further details.

- 704. Wolff-Parkinson-White pattern
- 705. Lown-Ganong-Levine pattern

Prolonged QT Interval:*

Perform a repeat fasting ECG on a separate day and submit both ECGs to the ECG Library with a list of any prescription or over-the-counter medications and supplements used. Electrolytes to include potassium, magnesium, and calcium should also be checked. Further guidance will follow ECG Library review of this information. Per new ECG guidelines in athletes, corrected prolonged QTc duration has increased from prior guidelines.

215. Prolonged QT defined as a QTc >470 msec in males or >480 msec in females.

Atrial Enlargement/Abnormality:*

The following are nonspecific as isolated ECG findings in isolation. Additional testing (echocardiogram +/- stress test) is necessary only when accompanied by axis deviation, fasicular block, or bundle branch block. Further testing necessary is based on clnical indications by the interpreting physician at the ECG Library.

- 500. Left atrial enlargement
- 501. Right atrial enlargement
- 503. Biatrial enlargement

Ventricular Hypertrophy: An echocardiogram is required for evaluation of all ventricular hypertrophy with the exception of isolated right ventricular hypertrophy. If the echocardiogram is normal or normal variant by ECG Library review, no further workup is necessary. Since the specificity of these findings on ECG is poor, the aviator does not need to be DNIF pending our interpretation of the echocardiogram. For any left ventricular hypertrophy also provide a detailed exercise and blood pressure history for the past 6-12 months.

720. Left ventricular hypertrophy by voltage criteria with associated ST segment abnormalities

727. Biventricular hypertrophy

729. Left ventricular hypertrophy by voltage alone (sum of the S wave voltage in V1 or V2 plus the R wave voltage in V5 or V6 > 55 millivolts for individuals 35 years old or younger or > 45 millivolts for individuals older than 35 years of age).

First Degree AV Block:

First degree AV block is most often the result of athletic conditioning with increased vagal tone. This finding is common and not associated with an adverse prognosis. Past evaluation of this finding by the ECG Library has consistently failed to uncover evidence of conduction system disease. Therefore, evaluation of this finding is only required if requested by the interpreting physician or for very prolonged PR interval (>400ms).*

100. First degree AV block. (PR interval \geq 220 msec.)

Second Degree Mobitz Type II, and Third Degree AV Block:

The following abnormalities, if confirmed by the ECG Library or local consultant, are disqualifying for flying duties and waiver is not recommended. ACS evaluation is not required. Local medical evaluation and management is mandatory. Mobitz Type I second degree AV block (Wenckebach block) is considered a normal variant and is listed as such above.

105. Second degree AV block, Mobitz Type II

108. Complete heart block. This must be differentiated from A-V dissociation due to sinus bradycardia with a competing junctional rhythm, which may be a normal variant finding.

Right Bundle Branch Block:

This recommendation includes new complete right bundle branch block or complete right bundle branch block that has progressed from previous incomplete right bundle branch block. An echocardiogram is required for evaluation. If a previous echocardiogram is on file at the ACS, it may be acceptable per judgment of the ECG Library physician. The aviator does not need to be DNIF during this evaluation. Reminder - incomplete right bundle branch block in isolation is a normal variant and does not require evaluation.

120. Right bundle branch block with normal QRS axis.

Left Bundle Branch Block:

Left bundle branch block requires ACS evaluation and waiver. The aviator/aircrew should be placed DNIF pending ACS evaluation. The primary physician should insure that the aviator is clinically stable prior to arranging an ACS evaluation. See the *Left Bundle Branch Block* Waiver Guide for further details.

124. Left bundle branch block

Fascicular blocks and Axis Deviation:

Isolated Axis deviation is a normal variant unless accompanied by any other abnormal, borderline, or even normal variant ECG finding (such as complete or incomplete RBBB, atrial enlargement, or ventricular enlargement) then further evaluation should be pursued as requested by the ECG Library.* Fascicular blocks require echocardiogram at all ages and if age >35 then exercise stress. Waiver is no longer required unless the echo or stress test are abnormal after ACS/ECG library review.

The diagnostic criteria and evaluation of hemiblocks and left axis deviation are as follows:

	126.	Left anterior fasicular block (LAFB): Displacement of the mean QRS axis in the frontal plane to between -45°
and -90)°, and	
and		A qR complex in leads I and AVL, an rS complex in leads II, III and AVF,
		normal or only slightly prolonged QRS duration.
	128.	Left posterior fasicular block (LPFB):
and +1	80°, an	
and		An rS complex in leads I and AVL, a qR complex in leads II, III and AVF,
		normal or only slightly prolonged QRS duration
	735.	Left axis deviation (LAD):
		QRS axis -30° or more negative without full criteria for LAH as above.
	736.	Right axis deviation (RAD) QRS axis +120° or more positive without criteria for left posterior
hemibl	ock	

Supraventricular and Ventricular Ectopy and Pairing: Holter monitor is required for one or more paired premature beats and for two or more isolated premature beats on a single page of ECG paper, 12- lead or rhythm strip, regardless of the age of the aviator/aircrew.* Further evaluation should be pursued as clinically indicated and/or requested by the ECG Library after holter monitor review.

023. Premature atrial beat (PAC), two or more on a single page of ECG paper, 12- lead or rhythm strip

043. Premature junctional beat (PJC), two or more on a single page of ECG paper, 12-lead or rhythm strip

083. Premature supraventricular beat, two or more on a single page of ECG paper, 12-lead/rhythm strip

063. Premature ventricular beat (PVC), two or more on a single page of ECG paper, 12- lead/rhythm strip

032. Paired atrial premature beats, one or more pairs on a single page of ECG paper

046. Paired junctional premature beats, one or more pairs on a single page of ECG paper

072. Paired ventricular premature beats, one or more pairs on a single page of ECG paper

Supraventricular Tachycardias & Arrhythmias:

Any individual with documented supraventricular tachycardia (three or more supraventricular premature beats in a row at a rate exceeding 100 bpm) or multifocal tachycardia requires holter monitor. Member need not routinely be placed DNIF if there are no associated hemodynamic symptoms. Atrial fibrillation and atrial flutter require cardiology evaluation and DNIF.

- 021. Atrial tachycardia
- 026. Atrial fibrillation
- 027. Atrial flutter
- 036. Multifocal atrial tachycardia (MAT)
- 041. Junctional tachycardia (> 100 bpm)
- 081. Supraventricular tachycardia

Ventricular Tachycardia: An aviator/aircrew with asymptomatic nonsustained ventricular tachycardia should be placed DNIF. One 24 hour Holter monitor should be obtained. ACS review/evaluation is required for waiver consideration of any ventricular tachycardia.

061. Ventricular tachycardia (three or more ventricular beats in a row at a rate > 100 bpm)

Ventricular Fibrillation and Ventricular Flutter: The following abnormalities are disqualifying for continued flying duties. Waiver is not recommended, and ACS evaluation is not required.

- 066. Ventricular fibrillation
- 067. Ventricular flutter

Findings Suggestive of Myocardial Infarction:

ECG findings diagnostic for or very suggestive of myocardial infarction are disqualifying for continued flying duties pending further evaluation. The individual should have a cardiology evaluation to insure that he is clinically stable. If a true myocardial infarction is confirmed, this is disqualifying for flying duties but may be waiver eligible after ACS evaluation (see waiver guide).

All 600 series codes. Myocardial infarction

The aviator may remain on flying status during evaluation of the following more nonspecific findings:

739. Non-diagnostic Q waves. No further evaluation is required unless directed by the ECG Library.

759. Poor R wave progression. This finding may be due to incorrect chest lead placement or can be a normal variant. It can also be seen in myocardial infarction. Evaluation consists of repeat ECG with attention to chest lead placement and other testing as directed by the ECG Library. Echocardiogram may be requested to rule out wall motion abnormalities.

18. ST Segment and T Wave Abnormalities:

The following diagnoses may be normal variants, or may be findings associated with myocardial ischemia, cardiomyopathy and other disorders. The nonfasting state may cause nonspecific ST-T wave changes on ECG. If these findings represent a serial change and persist after repeat <u>fasting</u> ECG, a treadmill exercise tolerance test and echocardiogram should be performed on aviators aged 35 or older. For aviators younger than 35 years, an echocardiogram should be performed. If a previous screening echocardiogram is on file at the ACS, it may be acceptable per judgment of the ECG Library physician. Since mild ST segment and T wave abnormalities are not very specific, the aviator does not need to be DNIF during this evaluation. However, judgment should be exercised in aviators with more than mild changes or compelling coronary risks.

200. Low T waves less than 2 mm in chest leads V3-V6 or less than 0.5 mm in limb leads I and II.

- 201. Nonspecific T wave abnormalities
- 203. Nonspecific ST segment depression

19. Cardiac Inflammation (Pericarditis and Myocarditis):

If pericarditis or myocarditis is clinically present, the aviator should be placed DNIF and should be treated as indicated by the clinical condition. Confirmation should be done locally and studies sent to ACS ECG library for review. If asymptomatic, ECG confirmation can be done throught ECG library and further evaluation pursued as clinically indicated and/or requested by the ECG Library

- 706. Compatible with pericarditis
- 707. Compatible with myocarditis

Miscellaneous

Treadmill Test Results:

In order to insure a consistent interpretation of all studies and to attain the highest sensitivity, the following criteria were established for classifying treadmill exercise tolerance test results. The ST segment depression will be read at 80 msec after the J point irrespective of ST segment slope. The PQ segment will be used as the baseline. Tests showing less than 0.5 mm of ST segment depression are considered normal. Tests showing 0.5 to 0.9 mm of ST segment depression are considered borderline. Tests showing 1 mm or more of ST segment depression are abnormal. Any studies considered to be abnormal by review at the ECG Library will require an ACS evaluation.

Treadmill testing may also be suggestive of organic heart disease due to findings other than ST segment depression. These may include exercise-induced chest discomfort, hypotensive blood pressure response to exercise, chronotropic incompetence with decreasing heart rate at peak exercise or exercise-induced dysrhythmias. Exercise-induced dysrhythmias should be treated as described in the appropriate sections of this document and corresponding waiver guide.

The treadmill test should be performed in the fasting state. Baseline ECGs should be obtained supine, standing, and after hyperventilation. If ST segment depression is present on any baseline ECG, 1 mm of additional ST segment depression beyond the baseline ST segment will be required to be considered abnormal. The **raw unprocessed tracings and interpreted report** must be forwarded to the ECG Library for review.

Holter Monitor Findings:

A Holter monitor is generally performed to evaluate rhythm or conduction disturbances found on physical exam or 12-lead ECG or subjective complaints of palpitations. It might be requested by the ECG Library or ordered by a local provider. The following discussion assumes no associated hemodynamic symptoms and addresses the aeromedical disposition of isolated ectopy and ectopic pairs. Disposition of other findings, such as supraventricular tachycardia, are discussed in appropriate sections of this document.

By ECG Library review, if isolated ectopic beats on the Holter are frequent or less ($\leq 10\%$ of total beats) and if ectopic pairs are occasional or less (10 total pairs or fewer), no further testing is required and the findings are aeromedically acceptable without waiver.

If ectopic beats are very frequent (>10% of total beats) and/or ectopic pairs are frequent (>10 pairs total), a treadmill test and echocardiogram should be performed with appropriate reports and tracings/images referred to the ECG Library for review. The aviatior does not need to be DNIF during this assessment.

Echocardiograms:*

Actual echocardiogram images must be sent to the ACS for review. Reports without images are not accepted. Echocardiograms must include at minimum M-mode, 2-dimensional and Doppler studies. Studies should be saved in a digital format and preferably uploaded into the ECG library system as above. VHS studies are no longer accepted. CD/DVD studies can be mailed only if unable to upload into ECG library and this can delay processing time by as much as two weeks.

Published by the US Air Force Aeromedical Consultation Service Central Electrocardiographic Library Last updated: Nov 2017 (Note: This reference is published as a guide only, final ECG disposition recommendations are determined by the ECG Library as per AFI 48-123.) WAIVER GUIDE Updated: Sep 2015 Supersedes Waiver Guide of Mar 2011 By: Dr Dan Van Syoc Reviewed by Lt Col Eddie Davenport, Chief ACS Cardiologist

CONDITION: Ectopy, Supraventricular and Ventricular, and Pairing (Sep 2015)

I. Waiver Consideration.

Symptomatic ectopy which is significant enough to interfere with satisfactory performance of duty or requiring any medication for control is disqualifying for all flying classes as well as retention. For asymptomatic ectopy, waiver is not required if further evaluation specified by and reviewed by the ECG Library discloses no other disqualifying conditions.

Table 1: Policy for asymptomatic supraventricular and ventricular ectopy and pairing				
Findings on 24-hour	Additional Local Testing	Flying Class/ Waiver Required	ECG Library makes final	ACS Review/
Holter		Waiver Authority#	determination	Evaluation
PACs/PVCs ≤10% and/or 1-10 pairs	None	FC I/IA No AETC	Yes	No
		FCII/III and ATC/GBO/SWA No MAJCOM	Yes	No
PACs/PVCs >10% and/or >10 pairs	Echocardiogram and treadmill test*	FC I/IA, II/III No (if normal studies) AETC	Yes	Yes
		ATC/GBO/SWA No (if normal studies) MAJCOM	Yes	No

Table 1: Policy for asymptomatic supraventricular and ventricular ectopy and pairing

* Studies to be submitted to the ECG library, if found aeromedically acceptable no further work-up required.

AIMWTS search in Sep 2015 revealed 155 cases carrying a diagnosis of supraventricular and ventricular ectopy and pairing. There were 22 cases that were disqualified. Breakdown of the cases revealed: 4 FC I/IA cases (3 disqualified), 102 FC II cases (13 disqualified), 42 FC III cases (4 disqualified), 6 ATC/GBC cases (2 disqualified), and 1 MOD cases. Most of the disqualifications were due to other cardiac diagnoses.

II. Information Required for Waiver Submission.

None, unless other disqualifying findings are found on further evaluation performed clinically or as specified by the ECG Library. In those cases, refer to the applicable waiver guide and/or as directed by the ECG Library. For symptomatic ectopy/pairing that is significant enough to interfere with satisfactory performance of duty, ensure MEB results are included in AMS.

III. Overview.

This waiver guide discusses isolated ectopy and paired ectopy (pairs, couplets) and assumes no associated hemodynamic symptoms. Supraventricular and ventricular tachyarrhythmias are discussed in separate waiver guides. Ectopy and pairs include premature supraventricular and premature ventricular contractions (PVCs). In this discussion, the term ectopy will refer to both supraventricular and ventricular ectopy unless otherwise specified. Supraventricular ectopy includes premature atrial contractions (PACs) and premature junctional contractions (PJCs). The term PAC will be used to refer to all supraventricular ectopy.

Ectopy is quantified as a percentage of total beats on a Holter monitor and is graded as rare (<0.5%), occasional (0.5% - 1%), frequent (>1%), and very frequent (>10%). Pairs are similarly graded as rare, occasional, or frequent by total number of pairs on a Holter monitor. Aeromedical disposition is determined by the grading of ectopy and pairs on a Holter monitor. Typically, Holter monitor will have been requested to evaluate ectopy on a 12-lead electrocardiogram, ectopy appreciated during physical examination, or to evaluate subjective complaints of palpitations.

On 12-lead electrocardiogram (ECG), PACs have been reported in about 0.6% of aviators and 0.4%-3.0% of civilian populations. PVCs have been reported in about 0.8% of aviators and 2.0%-7.0% of various civilian populations. Evaluating ectopy on 12-lead ECG is thus not a problem of large numbers but is nevertheless made difficult by the significant frequency of ectopy reported on 24-hour Holter monitors performed on apparently healthy subjects. Holter findings were reported on 303 male military aviators with no structural heart disease and no referral diagnoses of arrhythmia; only 12% had no ectopy. Rare and occasional PACs and PVCs occurred in about 75% and 50%, respectively. Frequent PACs and PVCs only occurred in about 2.5% and 3.5%, respectively. PAC pairs occurred in about 15%. Otherwise, more complex ectopy was unusual.

The presence of more than one PAC and/or PVC in 10 seconds (standard 12-lead ECG page) requires additional evaluation with a 24-hour Holter as outlined in the following table. DNIF is not required pending the 24-hour Holter.

ECG/Rhythm Strip	24-hour Holter Required ¹
PACs, $PJCs < 2$	No
PACs, PJCs ≥2	Yes
Paired PAC, PJC or PVC	Yes

Table 2: Guide to necessity for Holter monitor

¹ Holter monitor results to include interpreted report summary, representative tracings, and patient diary must be forwarded to ECG library.

In summary, Holter monitor is required for two or more isolated premature beats and for one or more paired premature beats on a standard (10-second) single page of ECG paper, 12- lead or rhythm strip, regardless of the age of the aviator/aircrew. Holter monitor is no longer required for one isolated atrial, junctional or ventricular premature beat on a single page of ECG paper, 12- lead or rhythm strip.

The results of the 24-hour Holter will determine requirement for further work-up. IAW AF policy, waiver for isolated and paired ectopy is not required for any class of flying duties if local evaluation specified by and reviewed by the ECG Library discloses no other disqualifying findings. By ECG Library review, if isolated ectopic beats on the Holter are frequent or less (< 10% of total beats) and if ectopic pairs are occasional or less (10 total pairs or fewer), no further testing is required and the findings are aeromedically acceptable and considered normal variant. If ectopic beats are very frequent (>10% of total beats) and/or ectopic pairs are frequent (>10 pairs total), a treadmill test and echocardiogram should be performed with appropriate reports and tracings/images referred to the ECG Library for review. The aviator does not need to be DNIF during this assessment.

IV. Aeromedical Concerns.

If isolated or paired ectopy itself causes hemodynamic symptoms, then aeromedical disposition is determined by the symptoms as well as by the presence and severity of underlying heart disease. In the absence of hemodynamic symptoms, there are three basic aeromedical concerns. One, does the ectopy represent a risk for sustained tachydysrhythmias? Two, does the ectopy represent a risk for cardiac events? And three, does the ectopy predict underlying cardiac disease?

In an ACS database of 430 aviators evaluated for nonsustained or sustained supraventricular tachycardia (SVT), frequent PACs, PAC pairs and nonsustained SVT were not predictive of hemodynamically symptomatic SVT or of recurrent sustained SVT. In a similar database of 193 aviators with nonsustained ventricular tachycardia, neither frequent PVCs nor PVC pairs predicted sustained ventricular tachycardia or associated hemodynamic events. These data suggest that frequent isolated ectopy and paired ectopy do not present an increased risk for tachyarrhythmic events in the absence of structural heart disease.

The predictive value of ectopy for underlying cardiac disease is less clear. The considerable frequency and variability of ectopy in normal subjects makes it difficult to determine its predictive value for disease. PACs may occur in association with some disease states, such as mitral valve prolapse, but prognosis is not related to the PACs. On the other hand, frequent and complex PVCs in the presence of coronary and some other heart diseases clearly confer a poorer prognosis. This is true in clinical populations with significant, usually symptomatic disease. It may be less so in asymptomatic populations such as aircrew. However, some ACS databases do suggest increased prevalence of cardiac disease in the presence of significant ectopy.

ICD-9 C	ICD-9 Codes for Supraventricular and Ventricular Ectopy And Pairing		
427.60	427.60 Premature beats unspecified		
427.61	Supraventricular premature beats		
427.69	9 Other premature beats		

ICD-10	ICD-10 Codes for Supraventricular and Ventricular Ectopy And Pairing		
I49.4	I49.4 Unspecified premature depolarization		
I49.1	Atrial premature depolarization		
I49.2	Junctional premature depolarization		
I49.49	I49.49 Other premature depolarization		

V. References.

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Hypertension (Apr 2020)

Reviewed: Lt Col Michael Crowder (RAM 21), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), Lt Col Eddie Davenport (chief ACS cardiologist), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: New Format, Table 1 changes to reflect special warfare and RPA. Addressing multi-agent therapy.

I. Waiver Consideration

Hypertension that is not controlled with a single approved agent or with lifestyle changes is disqualifying for FC I/IA, FC II, FC III, and ATC/GBC personnel. Aviators with hypertension responsive to lifestyle modifications should have serial BP rechecks quarterly to semi-annually during the first year to assure success of the lifestyle modifications. Failure to achieve blood pressure control with lifestyle modifications, or an initial blood pressure average exceeding 160 mmHg systolic or 100 mmHg diastolic, requires initiation of pharmacotherapy. The rated or non-rated aviator (to include ATC/GBO personnel) with a history of isolated HTN who remains normotensive using lifestyle modifications or one of the following approved medications as monotherapy (thiazide, with or without triamterene, ACEi [lisinopril or ramipril], or ARB [losartan or telmisartan]) does not require a waiver. The aviator requires a minimum of seven days grounding after initiation of pharmacotherapy. Their BP should be controlled below 140/90 mmHg (or below 150/90 mm Hg if 60 years of age or older), and they should be free of medication side effects prior to return to full duty; this includes all subsequent dose adjustments. For retention purposes, hypertensive cardiovascular disease is disqualifying for all classes to include ATC/GBO/SWA personnel.

Table 1: Waiver potential for anti-hypertension medications and waiver authority Waiver Potential ACS Review				
Flying Class (FC)	Medication(s)	Waiver Authority	or Evaluation	
I, IA	HTN, if controlled with a thiazide ¹	Waiver not required	N/A	
,	(HCTZ or chlorothiazide), lisinopril,	1		
	ramipril ² , losartan or telmisartan			
	1 /			
	HTN, if controlled on other medication	No		
	than listed above and/or in combination.	AETC		
II	HTN, if controlled with a thiazide ¹	Waiver not required	N/A	
	(HCTZ or chlorothiazide), lisinopril,	-		
	ramipril ² , losartan or telmisartan			
	HTN, if controlled on HCTZ combined	Yes ^{4, 5}	Up to 3 years	
	with lisinopril, ramipril ² , losartan or	AFMRA	op to 5 years	
	telmisartan; atenolol ³ alone or in			
	combination; nifedipine (coat-core or			
	GITS) alone or in combination; or			
	amlodipine alone or in combination			
	HTN, if controlled with a thiazide ¹	Waiver not required	N/A	
III/ATC	(HCTZ or chlorothiazide), lisinopril,	1		
	ramipril ² , losartan or telmisartan			
	HTN, if controlled on HCTZ combined	Yes ⁵	Up to 3 years	
	with lisinopril, ramipril ² , losartan or	MAJCOM	op to 5 years	
	telmisartan; atenolol ³ alone or in			
	combination; nifedipine (coat-core or			
	GITS) alone or in combination; or			
	amlodipine alone or in combination			
SWA/GBO	HTN, if controlled on medical therapy	Waiver not required	N/A	
	including combination therapy. Waiver			
	required only if evidence of end organ			
	damage.			
	HTN with associated end organ damage			
	(outlined below); controlled on HCTZ			
	combined with lisinopril, ramipril ² ,	Yes	Up to 3 years	
	losartan or telmisartan; atenolol ³ alone	MAJCOM		
	or in combination; nifedipine (coat-core			
	or GITS) alone or in combination; or			

Table 1: Waiver potential for anti-hypertension medications and waiver authority

Note: Uncontrolled hypertension is disqualifying for all aircrew, wavier eligible only if controlled.

1 With or without triamterene. If potassium is added, a waiver will be required.

2 Ramipril restricted to dosages of 5 mg to 20 mg.

3 Third line drug, used after all others failed or were not tolerable. For aviators not required to fly in high-G aircraft.

4. FC II aviators on these medications can be waived, but only for FC IIA.

5. Waiver authority for initial FC II and FC III is AETC

II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations. Waiver is required for hypertension only if pharmacotherapy involves more than one medication (with the exception of HCTZ and triamterene) or the use of one of the following (alone or in combination with another approved medication): atenolol, amlodipine, and nifedipine.

A. Initial Waiver Request:

- 1. List and fully discuss all clinical diagnoses requiring a waiver.
- 2. History summary of blood pressures, risk factors/co-morbidities including negatives [diet (especially, alcohol and sodium intake), botanicals/supplements, cigarette smoking/tobacco use, physical activity level, family history of premature cardiovascular disease, dyslipidemia, diabetes mellitus, sleep apnea (snoring, observed apneas)], symptoms including negatives (flushing, headaches, nocturia, chest pain, and claudication), previous treatments, medications and side effects. Any consultation reports, including follow-up notes with examination findings after disease resolution.
- 3. Physical weight (BMI), fundus for hypertensive retinal changes, thyroid, heart, lungs, auscultation for carotid, abdominal, and femoral bruits, abdominal exam for enlarged kidneys, masses, and abnormal aortic pulsation, lower extremity exam for edema and pulses and neurological assessment. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 4. Labs hematocrit/hemoglobin, fasting glucose, serum electrolytes, serum calcium, blood urea nitrogen (BUN), serum creatinine (Cr), lipid profile, thyroid stimulating hormone (TSH), and urinalysis.
- 5. Resting electrocardiogram (ECG).
- 6. 3-day blood pressure check demonstrating BP stable at goal at least one week after medication initiated.
- 7. FL4 with RTD and ALC status, if member did not meet retention status.
- 8. If the local base is unable to provide all required items, they should explain why to the waiver authority.

B. Renewal Waiver Request:

- 1 Interval history summary of the intervening blood pressure control, symptoms related to coronary artery disease or medications, diet (e.g., alcohol and sodium intake) and supplements, cigarette smoking/tobacco use, physical activity level, other co-morbid medical conditions since last waiver granted.
- 2 Physical blood pressure readings over the course of the previous waiver, weight changes, hypertensive retinal changes, auscultation for carotid, abdominal, and femoral bruits, heart and lungs, abdominal exam for enlarged kidneys, masses, and abnormal aortic pulsation, lower extremity exam for edema and pulses, and neurological assessment.
- 3 Labs for all medications a renal panel (to include Cr and potassium) annually.
- 4 3-day blood pressure check.

5 If the local base is unable to provide all required items, they should explain why to the waiver authority.

III. Aeromedical Concerns

Hypertension is almost never a risk factor for sudden incapacitation, particularly if it is controlled. However, the secondary complications of hypertension are of aeromedical significance. The long-term vascular complications of HTN are an increased risk of cardiovascular events such as myocardial infarction and stroke, potentially resulting in sudden incapacitation, or death. Hypertension in aircrew should be diagnosed and treated per the most recent ACC/AHA guidelines, with a strong preference to monotherapy². Because lifestyle modifications are considered first line interventions and are associated with negligible aeromedical side effects, each aviator should be individually evaluated for potential benefit from lifestyle modifications, used alone or in combination with medication(s). While numerous medications are effective in lowering BP, some drugs have modes of action that may adversely affect the flyer. Medications that act via direct vasodilatation or autonomic vasoregulation are avoided in favor of those that work via volume reduction, such as diuretics, or via the reninangiotensin axis, such as angiotensin converting enzyme inhibitors (ACEi), or angiotensin receptor blockers (ARB). Medications that affect cognitive capacity (e.g., central α -adrenergic agonists) should also be avoided.

The classes of antihypertensive agents available to USAF aviators include diuretics (thiazides, with or without triamterene), ACEi (lisinopril or ramipril) and ARB (losartan or telmisartan). These drugs are effective as monotherapy and when used as such do not require a waiver as long as the blood pressure is controlled and there are no adverse effects from the medication. All other medications will require a waiver. Recent society guidelines after JNC 8 recommend multi-agent therapy as initial therapy in certain instances, but this is not recommended for special duty personal covered by this guide given hypotension can be more acutely problematic in aircrew. However, if multi-agent therapy is needed, the combination of diuretic with ACEi or ARB is synergistic and usually very effective at lowering BP and waiver often granted restricted to non-high-performance aircraft. Calcium channel antagonists (specifically coat-core and GITS [Adalat CC® and Procardia XL®, respectively] and amlodipine [Norvasc®]) are also approved in aviators; whether used alone or in combination, they are restricted to non-high-performance aviators. Beta-blockers are often poorly tolerated in aviators due to decrease in heart rate (chronotropy) and stroke volume (inotropy) which limits high performance flight and can manifest as fatigue, reduced exercise capacity, and impotence. Beta-blockers should only be used for a specific indication and whether used alone or in combination, waiver is required and will be restricted to non-high-performance aviators.

AIMWTS review in Apr 2020 for the previous five years revealed 445 members with a disposition containing the diagnosis of hypertension. Fifty of these cases resulted in a disqualified disposition. Breakdown was a follows: 2 FC I/IA cases, 172 FC II cases (15 disqualified), 210 FC III cases (30 disqualified), 37 GBO cases (3 disqualified), 21 ATC cases (2 disqualified) and 3 Special Warfare cases. All of the disqualified cases were due to other medical issues or to use of a non-approved medication.

ICD-9 codes for hypertension		
401.0	Malignant essential hypertension	
401.1	Benign essential hypertension	
401.9	Unspecified essential hypertension	
405.0	Malignant secondary hypertension	
405.1	Benign secondary hypertension	
405.9	Unspecified secondary hypertension	

ICD-10 codes for hypertension		
I10	I10 Essential (primary) hypertension	
I15.8	Other secondary hypertension	
I15.9 Secondary hypertension, unspecified		

IV. Suggested Readings

1. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC8). JAMA, 2013; published online 18 Dec 2013.

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WAIVER GUIDE

Updated: May 2017 Supersedes Waiver Guide of Dec 2013 By: Lt Col Robert McCoy (RAM 18) and Dr. Dan Van Syoc Reviewed by Dr. Edwin Palileo & Lt Col Eddie Davenport (Chief Cardiologist ACS)

CONDITION: Left Bundle Branch Block (May 2017)

I. Waiver Consideration.

Left Bundle Branch Block (LBBB) is disqualifying for all classes of flying duties, to include ATC, GBO and SWA duties. It may be waiver eligible for any class of unrestricted flying duties after evaluation. All flyer cases that are being considered for a waiver MUST be seen at the Aeromedical Consultation Service (ACS). Angiography is preferably done during the ACS evaluation. If coronary angiography is normal, waiver is usually recommended for unrestricted flying duties. If angiography is abnormal, waiver status will be determined primarily by the extent of CAD and the CAD waiver policy. Re-evaluations for LBBB without CAD are typically at three-year intervals and are primarily to follow for the possible development of cardiomyopathy.

Flying Class (FC)	Waiver Potential	ACS Review/Evaluation
	Waiver Authority	
I/IA	Yes	Yes
	AETC	
II/III	Yes	Yes
	MAJCOM	
ATC/GBO/SWA	Yes	Yes
	MAJCOM	

 Table 1: Waiver potential for Left Bundle Branch Block

AIMWTS search in Jan 2017 revealed a total of 72 cases carrying the diagnosis of LBBB with 8 total disqualifications. Breakdown of the cases was as follows: 8 FC I/IA cases (1 disqualified), 40 FC II cases (4 disqualified), 23 FC III cases (3 disqualified), and 1 ATC/GBC case. Of the disqualified cases, only two were disqualified for a cardiac reason; one for cardiomyopathy and the other for valvular disease.

II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations. All aircrew with LBBB require ACS evaluation prior to waiver consideration.

The AMS for the initial waiver for LBBB should include the following:

- A. List and fully discuss all clinical diagnoses requiring a waiver.
- B. History of symptoms along with a good time line of events.
- C. List all treatments (medications if any) attempted with response.
- D. Original copy of the 12-lead ECG or other ECG tracing documenting LBBB.
- E. Reports of any local consultations.
- F. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. electrocardiogram, treadmill, stress nuclear imaging).

The AMS for waiver renewal for LBBB should include the following:

- A. Interim history since last waiver submission to include symptoms.
- B. Treatments current medications for the condition, if any.
- C. Recent 12-lead ECG.
- D. Reports of any local consultations.

III. Overview.

LBBB is a pattern seen on electrocardiogram (ECG) when there is delayed conduction throughout the ventricles with characteristic ECG appearance. The normal heart's electrical impulse originates in the sinus node, spreads across the atria, and travels through the atrioventricular node. The impulse penetrates into the ventricles via the His bundle where it then enters the two bundle branches. Soon after, the right and left bundle branches transmit the electrical impulse to the right and left ventricle, respectively. This entire process of ventricular depolarization is completed within about 100 msec, and thus the normal width of the QRS complex is less than 100 msec. In a normally functioning heart, the ventricles contract nearly simultaneously.¹ LBBB usually reflects intrinsic intraventricular impairment of conduction in the left bundle system. The electrical impulse is transmitted through the right bundle branch and myocardium normally while activation of the left ventricle is delayed primarily within the myocardium and occurs after most of the right ventricle has been activated. The impairment can be chronic or transient. It may also appear only when the heart rate exceeds some critical value (rate- or acceleration-dependent LBBB) likely secondary to imbalance in the refractory periods between the two bundle branches. A much less common type is bradycardia-dependent LBBB, in which LBBB occurs only at low heart rates; the responsible mechanism for this seemingly paradoxical situation is not known.² Careful examination of the ORS complex and axis (or expert consultation) should be made as an accessory pathway with aberrant ventricular conduction (not a LBBB) can cause a widened QRS complex occurring only at lower heart rates.

The total time for left ventricular depolarization is prolonged with LBBB and leads to prolongation of the QRS interval and sometimes to alterations in the QRS vector. The ECG patterns most commonly seen in LBBB are the characteristic monophasic R wave in I, aVL, and V6 (sometimes M-shaped), and QS (sometimes W-shaped) QRS complex in lead V_1 .⁴ The degree of prolongation depends upon the severity of the impairment.³ A QRS interval greater than or equal to 120 msec is considered a complete LBBB while incomplete LBBB has a shorter 100 – 120 msec interval.

Unlike right bundle branch block, LBBB is more often a sign of organic heart disease. LBBB is often a marker of one of four underlying conditions: advanced coronary heart disease, long-standing hypertension (with or without left ventricular hypertrophy), aortic valve disease, or cardiomyopathy. More than one contributing factor may be identified.⁴ In military aviators we found 10% of those with LBBB had significant CAD on coronary angiography, 2% had dilated cardiomyopathy, and 1% required permanent pacemaker. Over 16 years of follow-up, another 8.5% developed CAD, and 5% developed cardiomyopathy with no additional pacemaker requirements. This increased risk of CAD was also seen in The Women's Health Initiative which followed women with asymptomatic LBBB over a fourteen year time span and showed a hazard ratio of CHD death of 1.43 (95% confidence interval 1.11 to 1.83, p<0.01).⁵ In a report from the HOPE trial looking at patients with LBBB over a 4.5 year time period, patients with LBBB compared to those without LBBB, were older, had higher systolic blood pressure and were more likely to be female.⁶ Thus LBBB is an important clinical consideration as it may be the first clue to previously undiagnosed, but clinically important abnormalities.

The incidence of LBBB increases with age.⁷ It has been reported in 0.01%-0.1% of healthy military aviators versus 0.2%-0.7% of various civilian populations, increasing to over 2% of those over age 75 and over 5% prevalence over age 80 suggestive of a degenerative disease of the conduction system.^{8,9} In the non-aviator population, there was an incidence rate of 7/1000 in men and women developing a LBBB before the age of 60.¹⁰ Rate- or acceleration-dependent LBBB has also been shown to be associated with a greater degree of underlying coronary artery disease.¹¹

IV. Aeromedical Concerns.

The prognosis of isolated LBBB in young men is generally benign.¹² Traditionally, there have been two major aeromedical concerns for LBBB. First, does LBBB increase the risk for progressive conduction system disease? And second, is LBBB predictive of current or future underlying cardiac disease? The risk of progressive conduction system disease for newly diagnosed LBBB has not been shown to be increased in otherwise apparently healthy young males.¹³ However, acquired LBBB may be the result of advanced and advancing coronary artery disease (CAD).¹⁴ A study in 2012 demonstrated that adjusted mortality rates for patients with new onset LBBB were similar to patients with ST-segment elevation myocardial infarction.¹⁵ In the USAF male aviator population aged 35-55 years, estimated background prevalence of significant CAD is about half that of those with LBBB (5% vs. 10%).⁸ Thus LBBB has a twofold increase in risk of underlying significant CAD. Many studies have shown increased major adverse cardiovascular event and increased mortality when LBBB is accompanied by any structural heart disease, congestive heart failure, or coronary artery disease. Thus echocardiography and an ischemic evaluation is absolutely necessary for all cases of LBBB. However, considering the possibility of underlying coronary heart disease and the inaccuracy of many noninvasive tests in the presence of LBBB, invasive coronary angiography might be warranted for definitive diagnosis, especially in older or high-risk aviators.¹⁶ Noninvasive coronary angiography (i.e. CT coronary angiography) is aeromedically acceptable to exclude coronary heart disease for age under 35 as the risk of significant CAD in this population is well less than 5%. In the absence of underlying cardiac disease, return to unrestricted flying is

acceptable. Finally, more recent data suggests there may be structural and functional changes in contractility with increased ventricular dyssynchrony as seen in LBBB and therefore even without CAD or valvular disease, echocardiography at regular intervals is recommended to ensure absence of cardiomyopathy.

ICD-9 code for Left Bundle Branch Block				
426.3 Left bundle branch block				
ICD-10 code for Left Bundle Branch Block				

	ICD-10 coue for Left Bunule Branch block			
I44.7 Left bundle branch block, unspecifie		Left bundle branch block, unspecified		

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WAIVER GUIDE Initial Version: Jan 2016 Supersedes Waiver Guides of Aug 2014 (Mitral Regurgitation), Jul 2014 (Mitral Valve Prolapse), and Feb 2011 (Misc. Valvular Heart Disorders) By: Dr Dan Van Syoc and Lt Col Steven M. Gore Reviewed by: Lt Col Eddie D. Davenport, ACS Chief Cardiologist

CONDITION: Mitral, Tricuspid, and Pulmonic Valve Disorders (Jan 2016)

I. Waiver Consideration.

Per Air Force Instruction, any history of valvular heart disease to include mitral valve prolapse, mitral, pulmonic, and tricuspid valve regurgitation with a severity greater than mild, and any degree of valvular stenosis is disqualifying. ACS evaluation is required for waiver consideration. For most aircrew, moderate to severe mitral regurgitation of any etiology is disqualifying if symptomatic or associated with subnormal ejection fraction. Symptomatic MVP requiring treatment is also disqualifying.

A. Mitral Regurgitation:

1. Moderate MR may be eligible for an unrestricted FC II, FC III, ATC/GBO/SWA waiver.

2. Asymptomatic severe MR that does not meet ACC/AHA guideline criteria for surgery may be considered for a waiver restricted to low performance aircraft.

3. Asymptomatic severe MR that meets ACC/AHA guideline criteria for surgical repair/replacement and symptomatic severe MR are disqualifying without waiver recommendation.⁹

ACS re-evaluations will typically be performed at 1-3 year intervals, depending on the degree of MR and other associated findings such as cardiac chamber dilation and left ventricular dysfunction. The use of approved ACE inhibitors for afterload reduction is acceptable in aviators with moderate or asymptomatic severe MR. Waivers may be considered after surgery. Refer to the "Valve Surgery – Replacement or Repair" waiver guide. For further details of waiver criteria for MR, see Table 1.

B. Mitral Valve Prolapse (MVP):

1. MVP with MR mild or less in severity is eligible for FC I/IA waiver.

2. MVP with MR moderate or less in severity is eligible for unrestricted FC II, ATC/GBO/SWA or FC III waiver.

3. MVP with MR that is severe, but asymptomatic, and does not meet ACC/AHA guideline criteria for surgery may be considered for a waiver restricted to low performance aircraft.⁹

4. MVP with MR that is either "severe and symptomatic" or "severe and asymptomatic", but meets ACC/AHA guideline criteria for surgical repair or replacement, is disqualifying without waiver recommendation.²

ACS re-evaluations will be performed at 1-3 years intervals, depending on the degree of MR and other associated findings such as cardiac chamber dilation and left ventricular dysfunction. The use

of approved ACE inhibitors for afterload reduction is acceptable in aviators with MVP and moderate or asymptomatic severe MR. For further details of waiver criteria for MVP, see Table 2.

C. Miscellaneous Heart Valve Disorders:

For retention purposes, severe valve or sub-valvular pulmonic stenosis is disqualifying in addition to most cases of symptomatic mitral stenosis. Table 3 summarizes disposition recommendations for several of these valve disorders. Due to the rarity of these valve disorders in our population, they will also be considered on a case-by-case basis.

Additional findings considered in waiver recommendations, include but are not limited to, normal atrial and ventricular size, normal ventricular function, no prior thromboembolic events, no associated tachydysrhythmias and no symptoms attributable to the specific valve disorder. Waivers may be considered after surgery. Refer to the "Valve Surgery – Replacement or Repair" waiver guide.

Degree of Primary Mitral	Flying Class (FC)	Waiver	ACS Review and/or
Regurgitation (MR) Graded on		Potential	Evaluation
Echocardiogram			Required
		Waiver	
		Authority	
Trace or mild MR (normal variant)	FC I/IA/II/GBO	Qualified* N/A	ACS review
	FC III, ATC/SWA	Qualified* N/A	No ACS review required
Moderate MR	FC I/IA	No AETC	ACS review
	FC II/III	Yes MAJCOM	ACS evaluation
	ATC/GBO/SWA	Yes MAJCOM	ACS Review
Severe MR – asymptomatic and nonsurgical per guidelines	FC I/IA	No AETC	ACS review
	FC IIA only	Maybe AFMSA	ACS evaluation
	GBO	Maybe MAJCOM	ACS evaluation
	FC IIIC (low performance only)	Maybe AFMRA	ACS evaluation
	ATC/SWA	Yes MAJCOM	ACS evaluation
Severe MR – symptomatic or surgical per guidelines &	FC I/IA	No AETC	ACS review
	FC II/RPA Pilot/III	No AFMRA	ACS review
	ATC/GBO/SWA&	Maybe AFMRA	ACS evaluation

Table 1: Summary of Associated Clinical Conditions and ACS Requirements for Mitral Regurgitation

*Qualified means no waiver required, however, for FC I/IA/II/RPA Pilot individuals, echos read locally as trace or mild MR require ACS review via the ECG Library. The report and a CD/videotape copy are required for confirmation and to exclude underlying pathology such as MVP.

**No waiver required if member asymptomatic and has a normal ejection fraction.

[&] Successful mitral repair with preservation of ejection fraction, no need for anticoagulants or anti-arrhythmics may be waived if exercise tolerance is normal, but DAWG review (with MEB/IRILO as appropriate) must precede surgery.

Table 2: Waiver Potential for MVP			
MVP and Associated	Flying Class	Waiver Potential	Required ACS Review
Levels of Mitral		Waiver	and/or ACS Evaluation
Regurgitation (MR)		Authority†	
Documented by			
Echocardiogram			
MVP with mild or less MR	FC I /IA	Yes AETC	ACS evaluation
	FC II/III	Yes* MAJCOM	ACS evaluation
	ATC/GBO?SWA	Yes AFGSC	ACS review
MVP with moderate MR	FC I/IA	No AETC	ACS review
	FC II//III	Yes* MAJCOM	ACS evaluation
	ATC/GBO/SWA	Yes MAJCOM	ACS review
MVP with severe MR - asymptomatic and nonsurgical MR per	FC I/IA	No AETC	ACS review
guidelines	FC IIA only	Maybe* AFMSAAFMRA	ACS evaluation
	FC IIIC (low performance only)	Maybe* AFMSA	ACS evaluation
	ATC/GBO/SWA	Maybe MAJCOM	ACS review
MVP with severe MR – symptomatic or surgical MR per guidelines	FC I/IA	No AETC	ACS review
Lot Paraciulos	FC II//III	No MAJCOM	ACS review
	ATC/GBO/SWA	Maybe MAJCOM	ACS review
MVP: clinical (auscultation) only without a positive echo	FC I/IA/II/III ATC/GBO/SWA	Yes MAJCOM	After 3 ACS evaluations/reviews without a positive echo, an indefinite waiver is recommended

Table 2: Waiver Potential for MVP

* Waiver in untrained FC II and III individuals unlikely.

Table 3: Summary of Associat Type and Degree of	Flying Class	Waiver Potential	ACS Review/Evaluation
Valvular Disease	v e		Required
Graded on		Waiver Authority	•
Echocardiogram		L L	
Trace or mild PI and TR	FC I/IA	Qualified N/A	ECG Library review
	FC II/III ATC/GBO/SWA	Qualified N/A	FC II - ECG Library review, FC III, ATC/GBO/SWA not required
Moderate PI and TR	FC I/IA	Maybe AETC	ACS evaluation
	FC II//III ATC/GBO/SWA	Maybe MAJCOM	ACS evaluation#
Severe PI and TR – asymptomatic and nonsurgical per	FC I/IA	No AETC	ACS review
guidelines	FC IIA only	Maybe* AFMRA	ACS evaluation
	FC IIIC (low performance only)	Maybe* AFMRA	ACS evaluation
	ATC/GBO/SWA	Maybe* MAJCOM	ACS evaluation#
Congenital mild PS	FC I/IA	Yes AETC	ACS evaluation
	FC II/III ATC/GB)/SWA	Yes MAJCOM	ACS evaluation
Any degree of mitral or tricuspid valve stenosis	FC I/IA	No AETC	ACS review
	FC II RPA Pilot//III	No MAJCOM	ACS review
	ATC/GBC MOD	Maybe MAJCOM	ACS review

 Table 3: Summary of Associated Clinical Conditions and ACS Requirements

*Waiver for untrained FC II and III individuals unlikely.

#ACS evaluation not required for ATC/GBC personnel and waiver may be recommended based on ACS review.

AIMWTS search in Jan 2016 revealed 304 Air Force members with a waiver disposition for mitral valve, tricuspid valve, or pulmonic valve disorders. There were 41 disqualifications (one was

eventually given an ETP – FC III). Breakdown of the cases revealed 19 FC I/IA cases (4 disqualified), 162 FC II cases (13 disqualified), 113 FC III cases (21 disqualified), 5 ATC/GBC cases (1 disqualified), and 5 MOD cases (2 disqualified). Approximately 50% of the disqualified cases were due in part to the valvular disease.

II. Information Required for Waiver Submission.

ACS review/evaluation is required for diagnosis confirmation and aeromedical disposition. The aeromedical summary should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

ACS review/evaluation is required at least once for all classes of flying duties for moderate or severe MR with waiver renewals recommended based on local studies. No additional studies are routinely required prior to ACS review/evaluation. If the treating physician deems it clinically necessary to perform additional studies, it is required that all studies be forwarded to the ACS for review. There is no minimum required nonflying observation period for ACS review/evaluation.

For <u>initial</u> ACS evaluation the aeromedical summary should contain the following information:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. Complete history and physical examination – to include detailed description of symptoms, medications, activity level and CAD risk factors (positive and negative).

C. Formal report and complete tracings (videotape or CD) of the echo documenting the findings. (Notes 1 and 2)

D. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. holter, treadmill, stress echocardiogram). (Notes 1 and 2)

E. Additional local cardiac testing is not routinely required, but may be requested on a case by case basis.

F. Medical evaluation board (MEB) reports and narrative if applicable.

For <u>follow-up</u> ACS evaluations (re-evaluations) the aeromedical summary should contain the following information:

A. Complete history and physical examination – to include detailed description of symptoms, medications, activity level, and interval history

B. All applicable labs and imaging tests as required in the initial aeromedical summary.

C. Local follow-up cardiac testing is not routinely required prior to ACS re-evaluation. If requested for individual cases, it will have been specified in the report of the previous ACS evaluation.

D. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. holter, treadmill, stress echocardiogram). (Notes 1 and 2)

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is: Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI, Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

For expediting the case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in the aeromedical summary when studies were sent to ACS.

III. Overview.

This waiver guide will combine three previous guides; mitral regurgitation, mitral valve prolapse, and miscellaneous valve disorders, which comprises disorders of the tricuspid and pulmonary valves as well as mitral stenosis.

A. <u>Mitral Regurgitation</u> - Abnormalities of the mitral valve annulus, the valve leaflets, the chordae tendinae, or the papillary muscles can cause mitral regurgitation (MR). In assessing a patient with mitral regurgitation, it is important to distinguish between primary (degenerative) MR or secondary (functional) MR. In primary MR, the pathology of ≥ 1 of the components of the valve (leaflets, chordae tendinae, papillary muscles, annulus) causes valve incompetence with systolic regurgitation of blood from the left ventricle to the left atrium. Younger populations usually present with severe myxomatous degeneration with gross redundancy of both the anterior and posterior leaflets and chordal apparatus. Older populations present with fibroelastic deficiency in which lack of connective tissue leads to chordal rupture.

In the United States and much of the Western world, the most common cause of MR is mitral valve prolapse (MVP), accounting for as much as one-half to two-thirds of cases. In the aircrew population, clinically significant MR is also most commonly associated with MVP/myxomatous mitral valve disease. Other causes of primary MR include rheumatic heart disease, infective endocarditis, collagen vascular disease, and cleft mitral valve and radiation heart disease. Causes of secondary MR include ischemic and idiopathic myocardial disease leading to a dilated cardiomyopathy.^{1,2} Aeromedical considerations for all etiologies of MR will be addressed by the underlying disease process in this waiver guide. Symptom manifestation depends on the etiology and severity of MR. Moderate or less MR should not cause symptoms. Symptoms due to chronic MR are related to progressive volume overload resulting in pulmonary congestion and left ventricular dysfunction. Symptoms of severe MR include reduced exercise tolerance, chronic weakness, fatigability, exertional dyspnea, dyspnea at rest, and orthopnea. However, some subjects with severe MR and associated left ventricular dysfunction may be asymptomatic, with symptom onset being insidious and not appreciated by the patient. A careful history is important to elicit subtle symptoms or lifestyle changes due to the patient "slowing down" or "not being in shape". Atrial fibrillation may be a resultant complication associated with severe MR.^{1,2}

In the aircrew population, MR is typically diagnosed by an echocardiogram (echo) ordered for murmur evaluation or for a variety of other clinical or aeromedical indications, such as an abnormal electrocardiogram. MR is graded on echo as trace, mild, moderate or severe. MR graded on echo as trace or mild is considered to be a normal variant (not disqualifying) and no waiver is required.

For FC I/IA/II/RPA Pilot individuals, echocardiogram studies read locally as trace or mild MR require Aeromedical Consultation Service (ACS) review via the ECG Library. The formal report and a CD/videotape copy are required to confirm the local read and to exclude underlying pathology such as MVP. ACS review for trace to mild MR is optional for FC III, and can be requested by the local flight surgeon or the waiver authority if desired. A waiver is required for all classes of flying duties when MR is graded moderate or severe.

B. <u>Mitral Valve Prolapse (MVP)</u> - The prevalence of MVP is reported to be 2-5% in the general U.S. population. The prevalence of MVP utilizing data from the USAF database of Medical Flight Screening (MFS) echocardiograms performed on pilot training candidates, was about 0.5% in males and females.^{1, 2} The lower prevalence seen in the USAF database may be due to the young age of this population and elimination of some of the more obvious cases during the examination process. MVP may be diagnosed or suggested by the typical auscultatory findings of a mid-systolic click with or without a late systolic murmur, but is more typically diagnosed by echocardiography (echo) evaluation. The current echocardiographic definition of MVP is billowing of any portion of the mitral leaflets \geq 2 mm above the annular plane in a long axis (parasternal or apical 3-chamber) view.⁴ Echo criteria have evolved over the years, but current standards are widely accepted and unlikely to significantly change in the near future. These criteria have been followed by the ACS for over a decade since their earliest acceptance by the academic cardiology community, but many civilian cardiologists may not adhere to the currently defined strict criteria. Therefore, verification of a local MVP diagnosis needs to be completed by the ACS in all cases.

Historically, there have been reports of a possible association between panic disorder or social anxiety disorder and MVP. The purported relationship between these conditions is most likely a matter of chance and the result of a confluence of factors.⁷ Additionally, other symptoms to include palpitations, dyspnea, exercise intolerance, dizziness, numbness or tingling, skeletal abnormalities, and abnormal resting and exercise electrocardiograms have been attributed to MVP. Recent investigations into these associations have not conclusively shown a direct link between and reassurance about the benign nature of MVP is usually enough to reduce the severity of associated symptoms.⁸

Progressive mitral regurgitation is one of the primary clinical and aeromedical concerns with MVP due to morphologic changes of the valve leaflets and chordae tendinae. In the aircrew population, clinically significant MR is commonly associated with mitral valve prolapse/myxomatous mitral valve disease. Given the progression rates, all MVP requires waiver for flight duties even if no associated regurgitation or stenosis. Despite some risk of progression to severe MR, most aviators with MVP can be reassured the condition (and associated MR) is not life threatening.⁶

C. Misc. Valvular Heart Disorders

- 1. Regurgitation/insufficiency of the tricuspid (TR) and pulmonic (PI) valves
- 2. Mitral stenosis (MS), Tricuspid stenosis (TS) and Pulmonic stenosis (PS)

These disorders are commonly asymptomatic and thus found incidentally during echocardiography evaluation for other reasons. The natural history and progression of disease depends on the underlying cause.^{9, 10} These valve disorders will be rarely, if ever, seen in our aviator population. The most common pathology seen in the AIMWTS database search is TR with the majority being graded as trace to mild in severity, thus considered a normal variant.^{1, 2}

In the aircrew population, regurgitation/insufficiency or stenosis of these cardiac valves will typically be diagnosed by an echocardiogram (echo) ordered for cardiac murmur evaluation or a variety of other clinical or aeromedical indications, such as an abnormal electrocardiogram. As with mitral regurgitation, tricuspid and pulmonic regurgitation is graded as trace, mild, moderate or severe. In the absence of morphologic valve pathology, tricuspid and pulmonic valve regurgitation graded as trace or mild are considered normal variants. They are not disqualifying and a waiver is not required. Conversely, any degree of mitral, tricuspid or pulmonary valve stenosis is considered abnormal.^{1, 2}

For FC I/IA/II/RPA Pilot individuals, echocardiograms interpreted locally as trace or mild TR and/or PI (i.e. normal variants) require review and confirmation via the Aeromedical Consultation Service (ACS) ECG Library. The formal report and a CD/videotape copy are required for confirmation in order to exclude underlying pathology such as valve prolapse. If ACS ECG Library review confirms trace or mild PI and/or TR with no valve pathology, a letter to this affect will be sent and incorporated into the patient's medical record. The individual is considered medically qualified and no waiver or further work-up is required. If ACS ECG Library review determines TR and/or PI severity is worse than trace or mild, a letter will be sent directing the need for a waiver. ACS ECG Library review of trace to mild TR and/or PI is optional for FC III, but may be requested by the local flight surgeon or the waiver authority if desired. Locally interpreted echocardiograms with moderate or greater TR and/or PI and any degree of mitral, tricuspid, or pulmonic stenosis, will require ACS evaluation. The formal report and a CD/videotape copy are required for confirmation.

In early 2007, the American Heart Association published new infective endocarditis guidelines that are dramatically different from past recommendations.³ Endocarditis prophylaxis is recommended only for specified high risk groups, and only for specified dental procedures, respiratory tract procedures, and procedures on infected skin, skin structures or musculoskeletal tissue. The high risk group was limited to prosthetic cardiac valves, previous endocarditis, select congenital heart conditions and cardiac transplant patients with valvulopathy. Prophylaxis was no longer recommended for gastrointestinal or genitourinary procedures. Conditions commonly seen by most aerospace medicine practitioners were not included in the list of high risk conditions. Common conditions no longer recommended for endocarditis prophylaxis included, but are not limited to, mitral valve prolapse, bicuspid aortic valve, mitral or aortic regurgitation with normal valve morphology and uncorrected small defects of the atrial and ventricular septum.

IV. Aeromedical Concerns.

A. <u>Mitral Regurgitation and Mitral Valve Prolapse (MVP)</u>: Two categories of aeromedical events must be considered with MVP and moderate or severe MR. First, events which might occur abruptly and impact flying performance include sudden cardiac death, cerebral ischemic events, syncope, presyncope and sustained supraventricular and ventricular tachydysrhythmias. Second, progression to severe MR, requirement for surgical mitral valve repair or replacement, other thromboembolic events and non-sustained tachydysrhythmias are of aeromedical concern.

ACS experience with moderate and severe primary MR is very limited. However, a review of the ACS experience with 404 trained aviators with MVP is applicable.^{11, 12} This review yielded event rates of 1.5% per year for all aeromedical endpoints examined. Most of these could be readily

tracked by serial evaluations and represented a low risk for sudden incapacitation. For events which might suddenly impact flying performance, the rate was only 0.3% per year. The majority of the MVP subjects in this review had less than moderate or severe MR. The primary aeromedical concern of moderate to severe MR would be the development of symptoms and progression to severe MR that meets guideline criteria for surgical repair or replacement of the mitral valve. Fortunately, surgical criteria can be tracked and followed by serial echocardiogram studies and patients who are followed closely will usually be identified before symptom onset and elective surgery can be scheduled.

In general, exercise produces no significant change or a mild decrease in MR because of reduced systemic vascular resistance. However, patients with elevation of heart rate or blood pressure as a result of static or isometric exercise may manifest increased MR and pulmonary capillary pressures. Static exercises that increase arterial pressure are potentially deleterious. Ejection fraction usually does not change or decreases slightly with exercise. However, the ejection fraction response may be completely normal in younger asymptomatic subjects. These latter concerns may be more theoretical than clinically relevant, but nonetheless result in a recommendation for restricting static exercise in competitive athletes with significant MR.⁹ In the aeromedical environment, "pulling Gs" is a similar situation and reduced +Gz tolerance and +Gz-induced tachydysrhythmias are of concern with severe MR. In an ACS MVP database review, 95 aviators had a monitored centrifuge assessment. Non-sustained supraventricular tachycardia and non-sustained ventricular tachycardia each occurred in one individual (1/95, 1%). G-loss of consciousness occurred in two individuals (2/95, 2%) without an associated cardiac dysrhythmia in either case. These occurrences are less than previously reported for apparently healthy centrifuge subjects or trainees.¹³ Notably, a slight reduction in +Gz tolerance has been reported for MVP, but was operationally nonsignificant.¹⁴⁻¹⁷ Therefore, monitored centrifuge assessment is no longer required for MVP or primary MR, but may be used on a case by case basis as deemed necessary by the ACS. An unrestricted waiver may be considered for moderate MR, but waiver consideration for severe MR is limited to low performance aircraft.

Medications that reduce afterload, such as ACE inhibitors, have a documented clinical benefit in acute MR and chronic aortic insufficiency. However, no studies have shown a clinical benefit for MVP or chronic primary MR. Although some studies have shown hemodynamic improvement and relief of symptoms, medication use has not been shown to delay the need for surgery or improve surgical outcome, in contrast to that seen for severe aortic insufficiency. Use of afterload reducing medications in symptomatic MR is appropriate, but at this stage, the aviator should be disqualified and aeromedical disposition should be secondary to clinical disposition regarding proper timing of valve surgery. The use of approved ACE inhibitors is acceptable in aviators with asymptomatic moderate or severe MR.¹

B. <u>Miscellaneous Heart Valve Disorders</u>: In general, aeromedical concerns for these various valve disorders include progression of the regurgitation and/or stenosis, requirement for surgical or catheter-based valve repair or replacement, underlying or associated disease processes, thromboembolism and arrhythmias.^{1, 2, 9, 10}

ICD-9 codes for mitral valve and misc. valve disorder	
394.0	Mitral Stenosis
394.1	Rheumatic mitral insufficiency
394.9	Other and unspecified mitral valve disease
397.0	Diseases of the Tricuspid Valve
397.1	Rheumatic diseases of the Pulmonary Valve
424.0	Mitral valve disorders
424.2	Tricuspid Valve disorders, specified as non-rheumatic
424.3	Pulmonary Valve disorders
742.02	Congenital Pulmonary Stenosis
746.02	Stenosis of Pulmonary Valve
746.6	Congenital mitral insufficiency

ICD-10 codes for mitral valve and misc. valve disorder	
I05.0	Rheumatic Mitral Stenosis
I05.1	Rheumatic mitral insufficiency
I07.8	Other rheumatic tricuspid valve diseases
I09.89	Other specified rheumatic heart diseases
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.8	Other nonrheumatic mitral valve disorders
I36.9	Other nonrheumatic tricuspid valve disorders
I37.7	Other nonrheumatic pulmonary valve disorders
Q23.2	Congenital mitral stenosis
Q23.3	Congenital mitral insufficiency

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WAIVER GUIDE Updated Jun 2016 Supersedes Waiver Guide of Aug 2012 By: Capt Ashley Franz (RAM 17), Lt Col Eddie Davenport (ACS chief cardiologist) and Dr Dan Van Syoc

CONDITION: Myocardial Infarction (Jun 2016)

I. Waiver Considerations.

Myocardial infarction is disqualifying for all classes of flying duty as well as retention. ACS review and evaluation is required, in all cases, for waiver consideration. Waiver is restricted to low performance aircraft (defined as < 2.5 sustained +Gz) and may be considered for all trained aircrew; for pilots, the waiver is additionally restricted to flying with another qualified pilot. Waiver for trained aircrew was approved by the Aerospace Medicine Corporate Board in 2008. Myocardial infarction is also listed specifically as disqualifying for ATC, GBO, and SWA duties.

For aviators, criteria for waiver consideration include, normal left ventricular systolic function at rest and exercise (normal ejection fraction), adequate medical management (lipids, ASA use, HTN control, no diabetes), restricted to low performance aircraft (<2.5 Gz and with another qualified pilot), patent infarct-related artery, no noninvasive testing evidence of reversible ischemia off cardioactive medications at rest and at peak stress, and successful risk factor modification at initial ACS evaluation and at each re-evaluation. If revascularization has been performed, they must meet criteria for the coronary artery revascularization waiver policy. Initial minimum DNIF observation period is six months post-MI. ACS evaluation for initial waiver consideration will include complete noninvasive testing and coronary angiography. If waiver is recommended and granted, waiver will be valid for one year with annual ACS re-evaluation required for waiver renewal consideration. In addition, routine serial coronary angiography is required at five-year intervals. This is based on a review of ACS database of repeat angiography, which shows no recurrent disease at three years following coronary revascularization. This is also consistent with recommendations in the current literature for repeat coronary angiography following revascularization. Follow-up coronary angiography may be recommended sooner if indicated by symptoms, noninvasive test results or failure to control risk factors.

Flying Class	Waiver Potential	ACS
	Waiver Authority	Review/Evaluation
I/IA	No	NA
Untrained II and III	AETC	
II	No	NA
IIA (flight surgeon,	Yes	Yes, Annual Visit
navigator)*	AFMRA	
IIC (pilot)*		
III*	Yes	Yes, Annual Visit
	AFMRA	
ATC/GBO/SWA	Yes	Review possible**
	AFMRA	

Table 1: Myocardial infarction and Waiver Potential

* Aircrew must meet all of the following criteria for consideration: normal LVEF, no wall motion abnormality, adequate medical management (including statin, ASA, nitroglycerine (PRN), ACE inhibitor and/or β blocker as clinically appropriate), controlled hypertension, no diabetes or other co-morbidities. Low performance aircraft defined as <2.5 sustained G with another qualified pilot. No altitude restriction in low performance aircraft. ** Annual testing may be done locally and sent to ACS for review at the request of the MAJCOM, alternatively all

testing and follow-up can be done during annual ACS evaluations.

AIMWTS review in May 2016 revealed 76 submitted cases with a history of myocardial infarction. There were 0 FC I cases, 37 FC II cases (21 disqualifications), 32 FCIII cases (23 disqualifications), 6 ATC/GBC cases (2 disqualifications), and 1 MOD case (0 disqualifications).

II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations, and the MEB has recommended return to duty.

The AMS for the initial waiver for myocardial infarction should include the following:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. Complete history of the event, emergency care rendered, testing done to include all results.

C. Copy of the cardiac catheterization report and copy of the images (CD, cineangiogram or videotape).

D. Additional local cardiac testing is not routinely required but may be requested in individual cases.

E. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. electrocardiogram, treadmill, nuclear myocardial stress perfusion imaging).

F. Results of MEB returning member to worldwide duty.

The AMS for <u>waiver renewal</u> for myocardial infarction should include the following: A. Interval history since last waiver – any history of chest discomfort, shortness of breath, or fatigue.

B. Recent ECGs and any other applicable cardiac testing.

Note 1: The address to send videotape/CD and reports not attached in AIMWTS is: Attn: Case Manager for (patient's MAJCOM) USAFSAM/Aeromedical Consultation Service 2510 5th Street, Bldg. 840 WPAFB, OH 45433

For expediting case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

Myocardial infarction (MI) is a common problem in the United States, especially in the general population. Each year, approximately 735,000 Americans have an MI; for 525,000 of these people, it is their first event. Importantly, an estimated 20% of people have "silent" MIs and do not even know that they suffered from an incident.¹

In the military, and the flying community in particular, MIs are far less common than in the general population. In this population, MI presents as it does in the general population; as an acute, symptomatic event or as a silent event. Such events are often discovered as a result of cardiac testing performed for other indications, such as evaluation of an asymptomatic aircrew with new Q waves on ECG. Post-MI outcomes are similar in these two scenarios and depend primarily on residual left ventricular function, severity of coronary artery disease (CAD), and classic risk factors.²

ACS cardiology staff members published a recent study regarding military aviators who have cardiac disease and an MI. This study shows that annual "cardiac event" rates in presumed healthy USAF aviators are 0.15% for males aged 35-54 years. Of particular note, for those aviators who eventually require revascularization, 34% had the MI at initial presentation. Tests designed to screen for MI in the presumed healthy aviator population yield a positive predictive value of 13%. Thus, the screening tests are not good predictors of the risk for MI in the aviator population. Fortunately, the aviators tend to have a much better outcome post CAD diagnosis than does the general population.³

There is increasing US Air Force experience with MI in aircrew since a policy change in 2008 allowing waivers for that condition. Policy previously did not allow for a waiver, but an analysis of the Aeromedical Consultation Service (ACS) coronary angiography database provides outcome data in former US Air Force aircrew. Between 1971 and 1999, 1487 asymptomatic male military aviators had an occupational coronary angiogram, and were followed for the cardiac end-points of cardiac death, nonfatal MI and coronary artery revascularization. During the follow-up, 57/1487 aviators (3.8%) had an MI as their first cardiac event. Their MI date was defined as the index date, and post-MI events were calculated at one, two and five year intervals. The events considered

were: cardiac death, non-fatal second MI or first revascularization. No cardiac deaths or second MIs occurred within the 5 years of follow-up; all events were revascularizations. The calculated event rates were 4.0% per year at one year, 2.3% per year at two years and 2.4% per year at five years.⁴

The experience in the medical literature with MI in young populations is very sparse and therefore unreliable. It is also not very generalizable because of high variance in selected groups in term of baseline medical conditions (diabetes, dyslipidemias, HTN) and different degrees of physical fitness. Despite these limitations, the rate of cardiac events is similar to the ACS experience. Batalla published a 2003 follow-up study of 229 male patients younger than 50 years old after their initial MI. The mortality at 3 years was 5% (annual rate of 1.6%) and for a repeat MI at 3 years was 4% (annual rate of 1.3%).⁵

Lopes published a 2008 study reporting on a cohort of 825 patients followed at a large medical center, comparing outcomes in patients with single vessel disease (SVD), two vessel disease (2VD) and three-vessel disease (3VD). All patients had preserved left ventricular ejection fraction (LVEF) and optimal medical therapy (ASA, nitrates, β blockers, ACE inhibitors, statins and low fat/cholesterol diet). The patients with SVD, which are closer to the intended AF population, had a mortality of 1.2% per year and a new MI-rate of 1.3% per year.⁶

In summary, the post-MI event rate in the medical literature is about 2-3% per year in aeromedically appropriate populations. Low risk outcomes are attained by patient selection: absence of premorbid conditions like diabetes, no significant myocardial scars with normal left ventricular systolic function and no significant dysrhythmias following MI, aggressive reduction of risk factors (HTN, lipids, complete smoking cessation, weight control, dietary changes and regular physical activity).

IV. Aeromedical Concerns.

The aeromedical concern is recurrent myocardial ischemia presenting as sudden cardiac death, second myocardial infarction, angina or ventricular dysrhythmias, all of which may cause sudden incapacitation or seriously impact performance of flight duties. Detecting the asymptomatic progression of CAD reliably without frequent invasive testing or noninvasive monitoring is the aeromedical challenge.

ICD-9 Code for myocardial infarction	
410	Acute myocardial infarction

ICD-10 Codes for myocardial infarction		
I21.09	Acute myocardial infarction	
I21.3	ST elevation (STEMI) MI of unspecified site	
I21.4	Non- ST elevation (STEMI) MI	

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Pericardial and Myocardial Disorders, Including Pericarditis, Myopericarditis, and Myocarditis (Jan 2021)

Authors/Reviewers: Lt Col Eddie Davenport and Dr. Edwin Palileo (ACS Cardiology); Dr. Christopher Keirns, Maj Laura M. Bridge and Lt Col Amy Hicks (Technical Editors)

Significant Changes: Content updated and revised to reflect current standards of care and to include information pertaining to COVID-19 myocarditis.

I. Waiver Consideration

Any history of pericarditis, myocarditis, or myopericarditis is disqualifying for all flying classes and SWA duties. Chronic pericarditis or myocarditis with degeneration of the myocardium is disqualifying for all flying classes, GBO, ATC, and SWA duties, as well as for retention. Any history of heart surgery or pericardial procedure is disqualifying for all flying classes, GBO, ATC, and SWA duties, as well as for retention. Disqualifying procedures include, but are not limited to, pericardial drainage, pericardiotomy, pericardial window, or pericardiectomy. DNIF/DNIC/DNIA is required at the onset of symptoms of pericardial/myocardial disease. Appropriate medical management follows established national or international guidelines under the care of a local specialist (e.g., cardiologist). Generally, a waiver will be considered once the inflammatory process and resulting pericardial/myocardial injury are resolved, treatment is complete, and recovery of normal physiology and operational functionality is demonstrated by local testing (see II.A.4.).

For pericarditis, first line treatment includes the combination of a non-steroidal anti-inflammatory medication (NSAID) and colchicine. NSAID therapy is typically continued for at least 7 days after symptom resolution. Colchicine is continued for a total of at least 3 months from initiation of treatment. Premature discontinuation of therapy results in increased risk for recurrence and will not be considered favorably for waiver. For myocarditis, a waiver will not be entertained until completion of a structured rehabilitation program, which should not begin until after a 3-6 month period of complete activity and exercise restriction. Earlier return to activity or more aggressive activity progression than is clinically warranted will not be considered favorably for a waiver due to the increased risk of detrimental health and operational outcomes.

Flying Class	Condition ¹	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Uncomplicated acute idiopathic/viral pericarditis, off all medication and ≥ 3 months from initiation of treatment	Yes AFRS/CMO	Yes
	Complicated pericarditis, including pericarditis with effusion and myopericarditis, off all medication for ≥ 6 months from initiation of treatment	Yes AFRS/CMO	Yes
	Myocarditis ^{2,3}	Yes AFRS/CMO	Yes
FC II/III/SWA	Uncomplicated acute idiopathic/viral pericarditis ⁴	Yes MAJCOM	Yes
	Complicated or chronic pericarditis, including pericarditis with effusion and myopericarditis ^{2,3}	Yes MAJCOM	Yes
	Myocarditis ^{2,3}	Yes MAJCOM	Yes
ATC/GBO	Uncomplicated acute idiopathic/viral pericarditis or myocarditis	N/A	N/A
	Complicated or chronic pericarditis, including pericarditis with effusion and myopericarditis ²	Yes MAJCOM	No
	Complicated myocarditis	Yes MAJCOM	No

Table 1: Waiver potential for pericardial and myocardial disorders

1. Waiver will not be considered for any untrained asset if there is evidence of persistent cardiac dysfunction, residual symptoms, or evidence of chronic inflammation.

2. Waiver may be submitted after the necessary recovery period (3-6 months, depending on severity of illness).

3. Cardiac MRI is <u>required</u> for FCI/IA applicants. For all other waiver classes, submission of a cardiac MRI will facilitate the waiver review process and is highly recommended.

4. For a trained asset with acute, uncomplicated idiopathic or viral pericarditis treated with NSAIDs and colchicine, treatment should be continued for at least <u>12 weeks (3 months)</u>, but a waiver request may be submitted as soon as 1 month following complete resolution of symptoms.

II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

NOTE: It is required that all original cardiac imaging and electrical tracings be submitted to ACS Cardiology for independent review. Electronic submission to the ECG Library is preferred. If electronic submission is not possible, electronic media can be sent via USPS or FedEx to the address below. Please include the service member's name, full social security number, date of mailing, and a POC at the submitting flight surgeon's office with all mailed materials. State in the AMS the date of submission.

Attn: Case Manager for [specify the appropriate MAJCOM] USAFSAM/FECI Facility 20840 2510 Fifth Street Wright-Patterson Air Force Base, OH 45433-7913

A. Initial Waiver Request:

- 17. Information to include in history:
 - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
 - b. Medical history, medications, and activity level prior to onset of symptoms.
 - c. Summary of disease course, including list of all treatments administered.
- 18. Consultation report from the treating cardiologist and all subsequent consultation notes.
- 19. Results of all testing performed to establish the diagnosis of pericarditis, myopericarditis, or myocarditis (see note above).
- 20. Results of current local testing to confirm recovery from pericarditis, myopericarditis, or myocarditis (see note above). The below-listed studies must be included. *For the diagnosis* of myocarditis, restriction from exercise for at least 3 months is required prior to completion of follow-up testing.
 - a. Electrocardiogram (ECG)
 - b. Echocardiogram
 - c. Exercise stress test
 - d. Additional requirements for myocarditis or myopericarditis:
 - i. Ambulatory heart monitor (e.g., 24-hour Holter monitor)
 - ii. Troponin level
 - iii. Cardiac MRI (required for FC I/IA; will expedite review process for all other waiver classes and is highly recommended)
- 21. Any other ancillary test results pertinent to the diagnosis or management of pericarditis, myopericarditis, or myocarditis (e.g., coronary artery catheterization, cardiac CT scan, endocardial biopsy, etc.) (see note above).

- 22. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 23. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
 - 11. Updated AMS with interval history, including:
 - a. Complete updated history and physical examination.
 - b. Complete list of current medications with dates of initiation, doses, and all adverse effects.
 - c. Documentation of medication adherence.
 - d. Report of any new subjective symptoms.
 - e. Documentation of current activity level, to include most recent Air Force Physical Fitness Assessment (AF PFA) score with explanation of any component exemptions.
 - 12. Current ECG.
 - 13. All interval consultation reports from all treating providers.
 - 14. Additional local cardiac testing is not routinely required for re-evaluation but may be requested in individual cases based on prior abnormal testing. If so, the previous ACS evaluation/review will specify details regarding the necessary local testing. Exercise testing is not required if AF PFA was accomplished without exemption in the interval following the previous waiver recommendation. However, the waiver package must include any and all interval laboratory and ancillary test results pertinent to the diagnosis of myopericarditis that were obtained in the course of clinical care (e.g., cardiac stress test, echocardiogram, ambulatory heart monitor, coronary artery catheterization, electrophysiology study, cardiac CT, cardiac MRI) (see note above).
 - 15. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
 - 16. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

III. Aeromedical Concerns

The aeromedical concerns associated with diseases of the pericardium and myocardium relate to the symptoms of the condition itself, complications or sequelae arising from the inflammatory process, and adverse effects of treatment. Symptoms that may adversely affect duty performance in the aviation or operational environment include chest pain, fatigue, or decreased exertional capacity. Examples of complications of aeromedical importance include heart failure and arrhythmia, which may lead to performance decrement, incapacitation, or sudden cardiac death.

Pericarditis and Myopericarditis

Pericarditis is an inflammatory process affecting the pericardium, which is typically either idiopathic or associated with a trigger such as vaccination or viral illness. Symptoms include pleuritic chest pain, and respiratory involvement is also possible. At a minimum, these symptoms can be distracting in an aviation or operational setting. While severe symptoms can cause incapacitation, most cases of acute pericarditis resolve within several days to weeks with the use of

anti-inflammatory medications. Treatment with an NSAID or aspirin plus colchicine is first line for uncomplicated acute disease. In certain specific situations, systemic glucocorticoids may be indicated, although this class of medication is not routinely used due to the association with an increased incidence of recurrent events. All of these medications used to treat pericarditis can cause adverse effects of aeromedical significance. In some instances, these adverse effects may be severe. Careful long-term monitoring after recovery from acute pericarditis is vitally important due to the high rate of disease recurrence. An estimated 15-30% of individuals will develop recurrence, and the most common risk factor is premature cessation of treatment. Therefore, NSAID therapy should continue for at least 7 days after complete resolution of symptoms, and colchicine should be continued for a total of at least 3 months. Refer to established guidelines and local cardiology recommendations for specific management decisions.

In the setting of pericarditis complicated by significant pericardial effusion or myocardial inflammation, the aeromedical risks increase due to the impact on myocardial cellular function and cardiac output. Myopericarditis is a condition in which the inflammation of the pericardium spreads to the underlying myocardial tissue. It is characterized by elevated blood levels of cardiac enzymes. Myocardial wall-motion abnormalities may be detected on dynamic imaging studies, although the left ventricular systolic function is typically preserved. Myopericarditis typically resolves with anti-inflammatory therapy. It is important to distinguish primary myocarditis from myocarditis secondary to pericarditis, because the clinical and aeromedical implications of these two distinct entities differ. Myocarditis is more likely to be associated with global hypokinesis and/or impaired LV systolic function, either of which portend a poorer prognosis and heightened risks in the aviation or operational environment.

Myocarditis

Myocarditis is an inflammatory process of the myocardium that results in myocyte degeneration and non-ischemic necrosis. The morbidity and mortality of myocarditis is much higher than pericarditis. For example, heart failure stemming from myocarditis is one of the most frequent precipitators of heart transplantation. Most commonly, myocarditis arises in the setting of either an acute infection or a post-infectious auto-immune response. Non-infectious etiologies include drug-induced hypersensitivity, giant cell myocarditis, and systemic autoimmune diseases. Any infection may trigger myocarditis. Viral pathogens are the most common, and it is estimated that myocarditis complicates approximately 1% of severe viral infections. Interestingly, early studies of the novel coronavirus SARS-CoV-2 demonstrate myocardial involvement in 7-15% of diagnosed individuals. Among those with COVID-19 of sufficient severity to warrant hospitalization, the observed rate of myocardial involvement may surpass 20%. Myocardial injury is detected in 80% of COVID-19 fatalities. Myocardial injury related to SARS-CoV-2 can also occur without cardiopulmonary symptoms or other signs of myocardial inflammation. These findings underscore that cardiac screening is often indicated in the setting of SARS-CoV-2 infection. (For guidance, refer to the comprehensive return to duty and return to flight guidelines following SARS-CoV-2 infection and the DoD Clinical Practice Guideline for COVID-19, which are listed in the "Suggested Readings" section.)

In addition to viral pathogens, bacterial, fungal, protozoal, rickettsial, or helminthic infections can also precipitate myocarditis. In the case of post-infectious myocardial inflammation, the antecedent illness may have been subclinical or asymptomatic and gone unnoticed by the infected individual. Up to 8% of the cases of exertional sudden cardiac death in athletes are attributed to myocarditis, making this disease of particular relevance to a military population. Almost exclusively, sudden cardiac death in athletes due to myocarditis occurs without prior knowledge of the condition. The mechanism of sudden death in these cases is presumably malignant arrhythmias. Arrhythmias occur in more than one third of patients with myocarditis and is one of the leading causes of prolonged recovery. These arrhythmias may manifest even after resolution of inflammation and structural abnormalities. For this reason, an assessment of cardiac electrical activity is required for waiver consideration. At a minimum, this assessment includes ambulatory monitoring (e.g., 24-hour Holter monitor) and exercise stress testing.

Endomyocardial biopsy (EMB) is NOT necessary or recommended for waiver consideration. Echocardiographic imaging is sufficient to exclude concomitant endocarditis, pericarditis, or effusion and to ensure normal systolic and diastolic cardiac function, chamber sizes, wall thickness, and regional wall motion. The most recent medical literature suggests that cardiac MRI (also referred to as cardiovascular MRI or CMR) is the best prognostic assessment following myocarditis. In addition, cardiac MRI can differentiate between and exclude other causes of chest pain with elevated troponin, such as infarction, cardiac muscle spasm, or embolism. Therefore, it is preferred over the classic gold standard EMB. Cardiac MRI is required for all FC I/IA applicants and is highly recommended in all other service members. Given the limitations of EMB, which include sampling error, inter-observer variability, and peri-procedural risks of cardiac tamponade or death, this procedure is NOT recommended in aircrew unless otherwise indicated based on published guidelines.

Regardless of the underlying trigger for myocarditis, up to one third of individuals may experience long-term complications, including arrhythmias. Therefore, initial waivers for myocarditis are typically limited to a duration of one year, and annual non-invasive testing is a requirement for renewal consideration (e.g., ECG and functional assessment such as AF PFA or exercise stress test). Additional testing may be clinically warranted, and it is recommended that long-term follow-up be overseen by a local primary cardiologist. After a period of demonstrated stability, waivers of longer duration may be recommended, and those assessed as being at lowest risk may be considered for an indefinite waiver. Some individuals may experience residual cardiac dysfunction following an episode of myocarditis; in this situation, a waiver may be considered on a case-by-case basis.

Review of AIMWTS data from October 2015 through October 2020 revealed a total of 118 waiver packages involving pericarditis and myocarditis. Of that total, 14 were FC I/IA (1 disqualified), 58 were FC II (1 disqualified), 30 were FC III (1 disqualified), 2 were ATC (0 disqualified), 5 were GBO (2 disqualified), and 9 were SWA (0 disqualified).

Please use <i>only</i> these ICD-10 codes for AIMWTS coding purposes		
I30.9Acute, uncomplicated pericarditis		
I31.9	Chronic and/or complicated pericarditis	
I40.9	I40.9 Myocarditis	

IV. Suggested Readings

 Return to Flight Status Following COVID-19 Illness. Department of the Air Force Memorandum from HAF/SG3P. Available at <u>https://kx.health.mil/kj/kx4/FlightMedicine/Documents/Policy/2020/RTFS%20post%20COVID%20guidance%20</u>

<u>memo.pdf</u>. Accessed 28 October 2020. NOTE: To access this document, the user must first log into the USAF Knowledge Exchange at <u>https://kx.health.mil</u>.

- Return to Flight and Special Operator Duty Guidance Post SARS-CoV-2 Infection. Available at https://kx.health.mil/kj/kx4/FlightMedicine/Documents/Policy/2020/ACS%20RTFS%20Post-COVID-19%20Guidance%20%20(3%20Sep%2020).pdf. Last accessed 28 October 2020. NOTE: To access this document, the user must first log into the USAF Knowledge Exchange at https://kx.health.mil/kj/kx4/FlightMedicine/Documents/Policy/2020/ACS%20RTFS%20Post-COVID-19%20Guidance%20%20(3%20Sep%2020).pdf. Last accessed 28 October 2020. NOTE: To access this document, the user must first log into the USAF Knowledge Exchange at https://kx.health.mil.
- 3. Department of Defense COVID-19 Practice Management Guide. Available at https://www.milsuite.mil/book/docs/DOC-760845. Accessed 6 October 2020.y
- D'Arcy JL, Manen O, Davenport ED, et al. Heart muscle disease management in aircrew. Heart 2019;105:s50-s60. Available at <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6256300/pdf/heartjnl-2018-313058.pdf</u>. Accessed 28 October 2020.
- Pellicia A, Solberg EE, Papadakis M, et al. Recommendations for participation in competitive and leisure time sport in athletes with cardiomyopathies, myocarditis, and pericarditis: position statement of the Sport Cardiology Section of the European Association of Preventive Cardiology (EAPC). Eur Heart J 2019;40:19-33. Available at https://academic.oup.com/eurheartj/article/40/1/19/5248228. Accessed 28 October 2020.
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- Kociol RD, Cooper LT, Fang JC, et al. Recognition and Initial Management of Fulminant Myocarditis: A Scientific Statement From the American Heart Association. Circulation 2020;141:e69-e92. Available at https://www.ahajournals.org/doi/10.1161/CIR.000000000000745. Accessed 28 October 2020.
- Maron BJ, Udelson JE, Bonow RO, et al. Eligibility and Disqualification Recommendations for Competitive Athletes With Cardiovascular Abnormalities: Task Force 3: Hypertrophic Cardiomyopathy, Arrhythmogenic Right Ventricular Cardiomyopathy and Other Cardiomyopathies, and Myocarditis: A Scientific Statement From the American Heart Association and American College of Cardiology. Circulation 2015;132:e273–e280. Available at https://www.ahajournals.org/doi/10.1161/CIR.00000000000239. Accessed 28 October 2020.
- Caforio ALP, Pankuweit S, Arbustini E, et al. Current state of knowledge on aetiology, diagnosis, management, and therapy of myocarditis: a position statement of the European Society of Cardiology Working Group on Myocardial and Pericardial Diseases. Eur Heart J 2013;34:2636-2648. Available at <u>https://academic.oup.com/eurheartj/article/34/33/2636/408735</u>. Accessed 28 October 2020.

WAIVER GUIDE Updated: Jan 2018 Supersedes Waiver Guide of Dec 2013 By: Dr. Dan Van Syoc Reviewed by: Dr. Edwin Palileo and Lt Col Eddie Davenport (Chief Cardiologist ACS), and AFMSA staff

CONDITION: Supraventricular Tachycardia (Jan 2018)

I. Waiver Considerations.

Per MSD H9, SVT is disqualifying for all classes of flying duties and for retention in the Air Force (this covers those individuals in the ATC, GBO and OSD programs). An ACS evaluation may be required, depending on the aviation duty, SVT characteristics or specific concerns in an individual case. SVT associated with hemodynamic symptoms will typically not be considered for waiver, unless successful ablation has been performed. Palpitations are not considered to be a hemodynamic symptom. A single episode of asymptomatic nonsustained SVT of 3-10 beats duration will typically be recommended for indefinite waiver for all aviation classes after ACS review. For recurrent episodes of asymptomatic nonsustained SVT or a nonsustained SVT episode longer than 10-beats duration, an ACS evaluation will be required, with expectation of waiver for FC II/III and RPA pilots. Waiver for FC I/IA and untrained FC II/III will be considered on a caseby-case basis depending primarily on characteristics of the nonsustained SVT. A single episode of sustained SVT without hemodynamic symptoms may be considered for FC II, III, or GBO waiver without ablation, on a case-by-case basis. Recurrent sustained SVT is disqualifying without waiver unless successful ablation is performed. SVT treated with antiarrhythmic medication for suppression is disqualifying without waiver. Table 1 is a summary of the clinical manifestations and most common requirements for the separate flying class (FC) duties. Most cases of SVT for ATC, GBO, and SWA personnel will likely be recommended for a waiver unless there is significant hemodynamic compromise. For cases where ablation is part of treatment, please also refer to waiver guide on "Radiofrequency Ablation (RFA) of Tachyarrhythmias".

SVT (symptoms refers to	Flying Class	Waiver	Required ACS
hemodynamic symptoms)		Potential/	Review and/or
		Waiver	ACS Evaluation
		Authority	
Asymptomatic, single episode of	FC I/IA/initial FC	Yes [#]	ACS review
3-10 beats duration	II/GBO/ATC, & ATC	AETC	
5-10 beats duration		ALIC	
	FC II/III, & ATC	Yes [#]	
		MAJCOM	ACS review
		MAJCOW	ACSIEVIEW
	GBO/SWA	Yes [#]	
	GDO/SWA	AFMSA	ACS review
		AINISA	ACSIEVIEW
Asymptomatic, recurrent	FC I/IA/initial FC II/	Maybe	ACS evaluation
nonsustained SVT or single	GBO/ATC	AETC	
episode nonsustained SVT >10	ODO/ITTC	ALIC .	
beats duration	FC II/III & ATC/GBO	Yes*	ACS evaluation
	& SWA	MAJCOM	
	a swa		
Asymptomatic sustained SVT	FC I/IA/initial FC II/	No	ACS review
(>10 minutes duration), single	GBO/SWA	AETC	
episode, no ablation [†]	GDO/DWII	71LTC	
	FC II/III & ATC/GBO	Maybe	ACS evaluation
	& SWA	MAJCOM	
Recurrent sustained SVT or any	FC I/IA/initial FC	No‡	ACS review
degree of SVT associated with	II/GBO/ATC/SWA	AETC	
hemodynamic symptoms, no			
ablation	FC II/III &	No‡	ACS review
uoiution	ATC/GBO/SWA	MAJCOM	
Any degree of SVT requiring	FC I/IA/II/III/ &	No	ACS review
antiarrhythmic medication for	ATC/GBO/SWA	MAJCOM	
suppression			
Indefinite waiver possible for all asymptot		- <u>flaga (kan 10 ka</u>	

Table 1. Summary of Supraventricular Tachycardia (SVT) and ACS Requirements.

suppression "Indefinite waiver possible for all asymptomatic, single episodes of SVT of less than10 beats duration.

* Waiver in untrained FC II, III, and RPA individuals is on a case-by-case basis.

‡ Waiver is possible after successful ablation - refer to "Radiofrequency Ablation (RFA) of Tachyarrhythmias" waiver guide.

If the disease process appears mild and stable, waiver for all classes of flying duties will generally be valid for three years with ACS reevaluation/review at that time for waiver renewal. Each waiver recommendation will specify requirements and timing for waiver renewal.

A query of AIMWTS in Jan 2018 revealed 398 individuals with waivers including a diagnosis of SVT. The breakdown of the cases is as follows: 21 FC I/IA cases (2 disqualified); 222 FC II cases (23 disqualified); 121 FC III cases (23 disqualified); 5 RPA pilots (0 disqualified); 22 ATC/GBC cases (2 disqualified); and 7 MOD cases (0 disqualified. The majority of the waived cases were for nonsustained single episode of SVT, followed by recurrent non-sustained SVT and then SVT treated with radiofrequency ablation.

II. Information Required for Waiver Submission.

ACS review/evaluation is required for all classes of flying duties for SVT. One 24-hour Holter monitor should be obtained. If the initial SVT is found on a Holter, then that Holter will suffice and repeat Holter is not warranted unless requested by the ACS/USAF Central ECG Library. If the evaluation reveals only one isolated run of SVT of 3- to10-beats duration, no further testing is typically required. If however, the treating physician deems it clinically necessary to perform any additional studies, it is required that all studies be forwarded to the ACS for review. Aeromedical disposition will be recommended after the studies are forwarded to the ACS for review and confirmation. If more than one run of SVT is present, or if a single run is more than 10-beats in length, ACS evaluation is required. No additional studies are routinely required prior to ACS evaluation. There is no minimum required nonflying observation period for waiver consideration for SVT, unless ablation is performed. Ablation of all SVT mechanisms is addressed in the "Radiofrequency Ablation (RFA) of Tachyarrhythmias" guide.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

For <u>initial waiver</u> (ACS review or evaluation) the AMS should contain the following information: A. Complete history and physical examination – to include detailed description of symptoms, medications, activity level and CAD risk factors (positive and negative).

B. Original or legible copy of the tracings documenting SVT (ECG, rhythm strip, Holter, treadmill, etc.). (Notes 1 and 2)

C. Copy of the report and representative tracings of the Holter, if not provided under B. (Notes 1 and 2)

D. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. Holter, treadmill, echocardiogram). (Notes 1 and 2)

E. Additional local cardiac testing is not routinely required but may be requested in individual cases.

For <u>renewal waivers</u> [ACS follow-up evaluations (re-evaluations)] the AMS should contain the following information:

A. Complete history and physical examination – to include detailed description of symptoms, medications and activity level.

B. Local follow-up cardiac testing is not routinely required prior to ACS re-evaluation. If requested for individual cases, it will have been specified in the report of the previous ACS evaluation.

C. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. Holter, treadmill, echocardiogram). (Notes 1 and 2)

<u>Note 1</u>: All studies should be submitted electronically to the EKG Library. To expedite the case, recommend sending via FedEx. Include patient's name, SSN and POC at base. The address to send videotape/CD and reports not attached in AIMWTS is:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

Note 2: State in AMS when studies were sent to ACS.

III. Overview.

Supraventricular tachycardia (SVT) is defined as 3 or more consecutive supraventricular premature beats at a heart rate of 100 beats per minute (bpm) or faster. The term supraventricular usually refers to a narrow QRS complex (<120ms) however there are cases of delayed ventricular activation (referred to as aberrant conduction) that can lead to a widened QRS complex, most often in the setting of a functional or permanent bundle branch block. The two most common forms of pathologic SVT are atrial fibrillation and atrial flutter.¹ These two are covered in a separate waiver guide "Atrial Fibrillation and Atrial Flutter" and will not be discussed in this waiver guide. SVT associated with ventricular pre-excitation with bypass tract is addressed in a separate waiver guide "Wolff-Parkinson-White (WPW) and Other Pre-Excitation Syndromes."

For the remainder of SVTs, the spectrum ranges from an asymptomatic three-beat run that is unnoticed by the individual to a sustained arrhythmia with hemodynamic symptoms such as syncope or very rarely, sudden cardiac death. Approximately 60% of these SVTs are due to a reentry mechanism within the AV node termed an AV node reentrant tachycardia (AVNRT), while 30% of SVTs are associated with a bypass tract. The other 10% of SVTs are a variety of mechanisms, including automatic foci in the atria causing focal atrial tachycardia, multifocal atrial tachycardia and sinus node reentrant tachycardia.² Ablation of all SVT mechanisms is addressed in the "Radiofrequency Ablation (RFA) of Tachyarrhythmias" waiver guide. This waiver guide addresses SVT caused by mechanisms other than bypass tracts and includes symptomatic, asymptomatic, sustained (over 30 seconds or with symptoms) and paroxysmal (intermittent with abrupt onset and offset).

In a 1992 Aeromedical Consultation Service (ACS) review of 430 military aviators evaluated for nonsustained or sustained SVT there were no deaths caused by or related to SVT. Forty-two (10%) had symptoms of hemodynamic compromise with syncope, presyncope, light-headedness, chest discomfort, dyspnea or visual changes and an additional 21 (5%) had recurrent sustained SVT without hemodynamic symptoms.³ Palpitations are not considered to be a hemodynamic symptom. Recurrent is defined as any recurrence, i.e. more than one run of SVT. For this review, sustained SVT was defined aeromedically for the Air Force as SVT lasting greater than 10 minutes. Neither frequent PACs, PAC pairing, nor nonsustained SVT was predictive of hemodynamically symptomatic SVT or of recurrent sustained SVT.^{3, 4} The study thus documented that most individuals with asymptomatic SVT remained healthy and symptom free for many years. In those with symptomatic SVT, 90% initially presented with these symptoms. The remaining 10% who

later developed symptoms presented with either sustained or recurrent sustained episodes of SVT. Of the multiple factors examined, only presentation with recurrent sustained SVT, hemodynamic symptoms or WPW ECG pattern were at higher risk for future events. Overall, in the above ACS review, of those initially presenting with asymptomatic nonsustained SVT, only 0.9% experienced sustained SVT during the follow-up period, none with associated hemodynamic symptoms. Of those presenting with one or more episodes of sustained SVT, recurrence of sustained SVT was still only 1-2% per year. Civilian population-based studies report recurrence up to 10% per year.³

Accepted treatment of acute AVRNT include vagal maneuver, adenosine, or cardioversion. Medications that can be used both acutely and chronically include beta-blocker, nondihydropyridine calcium channel blockers and/or antiarrhythmics (the latter two are not approved in aircrew). A similar approach is taken for focal atrial tachycardia. For multifocal atrial tachycardia (MAT), most clinicians utilize IV metoprolol or verapamil to treat the acute arrhythmia. For junctional tachycardia, IV beta blockers or IV calcium channel blockers are an appropriate approach to treatment.⁵ These interventional approaches are generally safe unless there is a recognized contraindication to use them.⁶

A recent meta-analysis of the efficacy and safety of ablation for the treatment of supraventricular tachycardia shows that this is a safe and effective procedure for our aviators who truly have symptomatic episodes of SVT. There is a greater than 95% success rate with the first ablation treatment for SVT with a rate of adverse events of less than 3%.^{7, 8}

IV. Aeromedical Concerns.

The aeromedical concerns associated with SVT include hemodynamic symptoms associated with any degree of sustained or non-sustained SVT, recurrent episodes of sustained SVT and associated cardiac disease.

Various antiarrhythmic medications may be used clinically to attempt suppression of SVT. Medication concerns include side effect and safety profiles of the medications, proarrhythmic effects and patient compliance in taking the medication every day. Acceptable control with medication is often not achieved with tolerable side effects, and one must accept that the arrhythmia may "break through" and recur on medication. SVT that is otherwise disqualifying would thus still be disqualifying on antiarrhythmic medication. Many antiarrhythmics have a proarrhythmic effect, meaning that they also precipitate tachyarrhythmias, usually ventricular tachyarrhythmias. Given the current high success and low complication rates of ablation, SVT that previously required suppression will now preferentially be referred for ablation.

ICD-9 code for supraventricular tachycardia		
427.0	Paroxysmal supraventricular tachycardia	

ICD-10 code for supraventricular tachycardia		
I47.1	Paroxysmal supraventricular tachycardia	

V. References.

1. Link MS. Evaluation and Initial Treatment of Supraventricular Tachycardia. N Engl J Med, 2012; 367: 1438-48.

2. Strader JR, Gray WG, and Kruyer WB. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in *Fundamentals of Aerospace Medicine*, 4th ed., Philadelphia: Lippincott Williams & Wilkins, 2008.

3. Richardson LA and Celio PV. The Aeromedical Implications of Supraventricular Tachycardia. In The Clinical Basis for Aeromedical Decision Making, AGARD Conference Proceedings 553. Hull (Quebec), Canada, Canada Communication Group, Sep 1994; 25-1 to 25-5.

4. Kruyer WB and Davenport ED. Cardiology. Ch. 2 in *Rayman's Clinical Aviation Medicine*, 5th ed., New York: Castle Connolly Graduate Medical Publishing LTD, 2013.

5. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AJA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia. J Am Coll Cardiol, 2016; 67(13): e27-115.

6. Al-Khatib SM and Page RL. Acute Treatment of Patients with Supraventricular Tachycardia. JAMA Cardiol, 2016; 1(4): 483-85.

7. Spector P, Reynolds MR, Calkins H, et al. Meta-Analysis of Ablation of Atrial Flutter and Supraventricular Tachycardia. Am J Cardiology, 2009; 104: 671-77.

8. Helton MR. Diagnosis and Management of Common Types of Supraventricular Tachycardia. Am Fam Physician, 2015; 92(9): 793-800.

Syncope (Mar 2019) Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Edwin Palileo (ACS Cardiologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

Significant Changes:

Restructuring of Waiver Guide, Updated Table 1 and References

I. Waiver Consideration

Air Force aviators with recurrent vasodepressor syncope or symptomatic orthostatic hypotension are disqualified for all flying classes. Careful evaluation is necessary before consideration of aeromedical waiver. Waiver consideration is limited to cases in which the risk of recurrence is low and/or the underlying condition or triggering factor can be adequately controlled. Benign syncope limited to predictable settings may be recommended for waiver if there is negligible risk of recurrence in the aviation environment. If a treatable etiology for syncope is found, then correction of the underlying condition may allow a return to flying status. However, certain conditions (e.g., arrhythmia) and/or medications may pose unacceptable risks of recurrence or side effects that could preclude waiver suitability. If the etiology of syncope remains unknown despite extensive diagnostic evaluation, then a clinical judgment based on careful consideration of all available information must be made before allowing a flyer to return to the cockpit. Unexplained or recurrent syncope is disqualifying for retention, and a Medical Evaluation Board is indicated in such cases.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes	AETC	Yes
FC II/III	Yes	MAJCOM	Yes
ATC/GBO/SWA	Yes	MAJCOM	At discretion of waiver authority

Table 1: Waiver potential for syncope

II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

A. Initial Waiver Request:

1. Complete history and physical exam, including orthostatic blood pressure/pulse readings, cardiovascular exam assessing pulses for rate, rhythm and differences between extremities and auscultation for murmurs or abnormal heart sounds, and neurologic exam assessing mental status, cranial nerves, motor and sensory function, reflexes, plantar reflexes, coordination, gait and Romberg test. The history is the most important component and should include: a complete description of the syncopal episode to include posture, presyncopal symptoms, duration, pre- or post-syncopal amnesia, convulsive accompaniments; any precipitating factors such as venipuncture, medical procedure or standing in formation; other contributory factors (dehydration, inadequate nutrition, strenuous exercise, fatigue, recent illness, etc.) and documentation of any previous syncopal or near-syncopal episodes. Reports from witnesses and first responders are important to obtain and review. A history of

previous episodes or any other features exceeding the parameters described above, require a waiver. To the extent possible, details of the syncopal episode such as pre-and post-syncopal appearance and behavior, duration of loss of consciousness, post-syncopal posture and any convulsive accompaniments should be based on reliable witness observations. If the episode was unwitnessed, then duration and other details of the syncopal episode cannot be verified.

- 2. If possible, the flight surgeon should interview witnesses personally and the AMS should indicate which elements of the history were provided by witnesses. Past medical history, medications, allergies, and family history (especially of sudden death, arrhythmia or epilepsy) should be documented.
- 3. Reports of consultations and diagnostic testing. Cardiology consultation is required if cardiac etiology is suspected or etiology is unknown. If clinically indicated, tertiary testing such as echocardiogram, Holter or event monitor, tilt-table testing, stress-test, electrophysiology studies, etc. may be necessary. Neurology consultation should be obtained if the LOC cannot be attributed to syncope and/or neurologic deficits are identified or suspected. If clinically indicated, tertiary testing such as neuroimaging or EEGs, etc. may be necessary. Psychology or psychiatry consultation should be obtained if psychogenic factors are suspected. Documentation should include the ECG and results of any laboratory or imaging studies, cardiodiagnostic testing, and neurologic tests such as imaging or EEGs. For cases sent to the ACS for review or evaluation, original images, tapes, etc. will be required. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

B. <u>Renewal Waiver Request:</u>

- 1 Interval history and level of symptom resolution.
- 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical and neurologic exam findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

III. Aeromedical Concerns

Syncope is a common clinical problem, and has been estimated to account for 3-5 percent of emergency room visits and 1 percent of hospital admissions. Any underlying condition that predisposes an aviator to suffer syncopal attacks could lead to incapacitation and loss of aircraft control. For this reason, loss or disturbances of consciousness, symptomatic orthostatic hypotension, or recurrent vasodepressor syncope are all disqualifying. Careful evaluation is required to determine the etiology, risk for recurrence, or long-term complications. Unfortunately, even after thorough evaluation, the cause of syncope remains unknown in many cases. Any aviator being treated with beta blockers, scopolamine, paroxetine, fludrocortisone, or alpha-agonists will not be eligible for a waiver as these medications are not approved for aviation duties in the US Air Force. The evaluation for G-LOC has additional requirements. In-flight G-LOC must be reported as a physiologic event. Evaluation should include a description of the sequence of events and

careful video tape recorder (VTR) review for adequacy of anti-G straining maneuver. Cases in which G-LOC continues to occur despite correction of underlying factors and/or additional and training conducted by an aerospace physiologist are managed IAW AFI 11-4-4, Centrifuge Training for High-G Aircrew.

Review of AIMWTS in Jan 2019 revealed a total of 509 waivers submitted with the diagnosis of syncope. Of this total, 61 were FC I/IA (19 disgualified), 158 were FC II (25 disgualified), 21 were RPA pilots (1 disqualified), 200 were FC III (77 disqualified), 46 were ATC/GBC (21 disqualified), and 23 were MOD (4 disqualified). There were a total of 100 disqualifications. Most of the DQ cases were for issues related to syncope – some were on beta blockers, others had unexplained etiologies and others had ongoing issues with syncope. About 20 percent of the DQ cases were disqualified for issues other than syncope.

ICD-9 code for syncope		
780.2 Syncope and collapse		
IC-10 code	e for syncope	

IV. Suggested Readings

1. Benditt D. Syncope in adults: epidemiology, pathogenesis and etiologies. UpToDate, Nov 15, 2018. Link: https://www.uptodate.com/contents/syncope-in-adults-epidemiology-pathogenesisand-

etiologies?search=syncope&source=search result&selectedTitle=5~150&usage type=default&disp lay rank=5

2. Benditt D. Syncope in adults: management. UpToDate, Mar 6, 2019. Link:

https://www.uptodate.com/contents/syncope-in-adults-

management?search=syncope&source=search result&selectedTitle=6~150&usage type=default&d isplay rank=6

3. Benditt D. Syncope in adults: clinical manifestations and diagnostic evaluation. UpToDate, Sep 24, 2018. Link: https://www.uptodate.com/contents/syncope-in-adults-clinical-manifestations-anddiagnostic-

evaluation?search=syncope&source=search result&selectedTitle=1~150&usage type=default&dis play rank=1

4. Cheshire WP. Syncope. Continuum (Minneap Minn) 2017; 23(2):335-358.

5. Ropper AH, Samuels MA, Klein JP (Ed). Faintness and syncope. Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education, 2014:383-394.

6. Kuriachan V, Sheldon RS, and Platonov M. Evidence-based treatment for vasovagal syncope. Heart Rhythm 2008; 5(11):1609-1614.

7. Link MS and Estes M. How to Manage Athletes with Syncope. Cardiol Clin 2007; 25:457-66.

WAIVER GUIDE

Updated: May 2017 Supersedes Waiver Guide of Jan 2011 By: Lt Col Cindy Harris Graessle (RAM 2017) and Dr Dan Van Syoc Reviewed by: Dr. Edwin Palileo and Lt Col Eddie Davenport (Chief Cardiologist ACS)

CONDITION: Valve Surgery - Replacement or Repair (May 2017)

I. Waiver Consideration.

Cardiac valve replacement or repair by surgery or catheter-based technique is disqualifying for all classes of flying duties as well as retention in most cases. ACS review/evaluation is required for initial and renewal waiver considerations. The ACS will make recommendations based on the successfulness of the procedure/surgery and residual valve hemodynamics and cardiac function.

	tential for various valve replace		1.00
Flying Class	Condition	Waiver Potential	ACS
(FC)		Waiver Authority	Evaluation/Review
I/IA	Mitral valve, aortic valve and	No	No
	tricuspid valve surgery	AETC	
	Pulmonic valvuloplasty	Maybe	Yes
		AFMRA	
II/III	Mitral valve prosthetic	No	No
	(mechanical or biological)	AFMRA	
	Mitral valve annuloplasty or	Maybe	Yes
	repair	AFMRA	
	1		
	Aortic valve (mechanical)	No	No
	``````````````````````````````````````	AFMRA	
	Aortic valve (biological)	Maybe	Yes
		AFMRA	
	Other procedures or valves	Maybe	Yes
	1	AFMRA	
III*	Mitral valve prosthetic	No	No
ATC/GBO/SWA*	(mechanical or biological)	AFMRA	
	Mitral valve annuloplasty or	Maybe	Yes
	repair	AFMRA	
	Aortic valve (mechanical)	No	No
		AFMRA	
	Aortic valve (biological)	Maybe	Yes
		AFMRA	
	Other procedures or valves	Maybe	Yes
	1	AFMRA	

Table 1: Waiver potential for various valve replacements and repairs.

*Waiver authority for all initial certification is AETC.

## II. Information Required for Waiver Submission.

Complete MEB prior to waiver submission. Prior to waiver submission for valve replacement or repair there is a minimum nonflying observation period of six months. After the six-month observation period, submit an aeromedical summary (AMS) with the following information:

A. Complete history and physical exam – to include description of symptoms before and after surgery, cardiovascular risks (family history, smoking status, lipids, and history of rheumatic disease), medications, and activity level.

B. Copy of pre- and post-procedure local echocardiogram reports. For all FC II and RPA Pilots and for FC I and III individuals requiring ACS evaluation, send digital copy/CD copy of the echocardiographic images to the ACS. (Notes 1 and 2)

C. Copy of the formal operation/procedure report and follow-up progress notes by the attending cardiovascular specialists.

D. Copies of reports and tracings of any other cardiac tests performed locally for clinical assessment (e.g. electrocardiogram, treadmill, Holter monitor). For all FC II and RPA Pilots and for FC I and III individuals requiring ACS evaluation if reports or tracings not attached in AIMWTS then send to ACS. (Notes 1 and 2)

E. Results of medical evaluation board MEB) (worldwide duty evaluation for ARC members).

F. Additional local cardiac testing is not routinely required but may be requested in individual cases.

<u>Note 1</u>: Electronic submission of cardiac studies to the ECG library is preferred, please contact ECG library at <u>USAFSAM.FECIECGLib@us.af.mil</u> for access.

The address to send digital imaging/CD and reports not electronically submitted is:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

For expediting case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

## III. Overview.

Replacement or repair of a cardiac valve is a complicated aeromedical subject and disposition consideration.¹⁻⁴ This is largely considered a surgical procedure; however, catheter-based techniques are presently being performed in certain cases.^{5, 6} In the military aviator/aircrew population valve replacement or repair will usually be for severe regurgitation of the aortic or mitral valve.⁷⁻⁸ In the older aviator population with bicuspid aortic valve, significant aortic valve stenosis is an unusual possibility. Procedures for mitral stenosis and tricuspid valve disease are very rare. One occasional consideration in candidates for initial flying training may be balloon valvuloplasty of congenital pulmonary valve stenosis performed during childhood. Due to the broad spectrum of procedures, types of valve prostheses and other considerations, valve replacement/repair considered for waiver must be evaluated by the Aeromedical Consultation Service (ACS) (See Table 1). Information in this waiver guide will thus be very general.

## **IV. Aeromedical Concerns.**

Aeromedical concerns include thromboembolic events, anticoagulation and/or antiplatelet medications, infective endocarditis, dysrhythmias, residual or progressive post-procedure valvular regurgitation and/or stenosis, and short- and long-term durability of the procedure, especially prostheses. The etiology of the underlying valve disease is also a consideration as it may affect procedure outcomes (e.g. repair of severe mitral regurgitation (MR) due to myxomatous disease has a much better prognosis than severe MR due to rheumatic disease).

Prosthetic valves are of two basic types, mechanical (primarily metal) and biological (human and nonhuman tissue).⁹ Regardless of valve type, valve prostheses in the mitral position have higher thromboembolic rates than those in the aortic position and are thus unacceptable for military aviation. Mechanical valves have higher thromboembolic rates than biological valves and require chronic anticoagulation therapy, with associated risk of major hemorrhage.¹⁰ The combined risk is considered unacceptable for military aviation. Biological valve prostheses are of several tissue types and designs and do not require chronic warfarin therapy unless there is some other indication, such as chronic atrial fibrillation.¹¹⁻¹³ These valves in the aortic position may be a consideration for waiver. Mitral valve repair and annuloplasty for severe MR due to a myxomatous valve (i.e. mitral valve prolapse) also may be favorably considered for waiver. Valve prostheses with residual regurgitation or other concerns regarding long-term durability will likely be restricted to low performance aircraft. Select architecturally intact valves with no residual regurgitation may be considered for unrestricted waiver on a case-by-case basis.

## V. References.

1. Bonow RO, Carabello B, DeLeon AC, et al. ACC/AHA guidelines for the management of patients with valvular heart disease. A report of the American College of Cardiology/American Heart Association task force on practice guidelines (committee on management of patients with valvular heart disease). J Am Coll Cardiol, 1998; 32: 1486-1588.

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10. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol, 2014; 63(22): e57-e185.

11. Peltz M. Surgery for Valvular Heart Disease. Ch. 46 in *Cardiovascular Therapeutics: A Companion to Braunwald's Heart Disease*, 4th ed., Saunders, 2012.

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#### Ventricular Tachycarhia (Dec 2019)

Reviewed: Capt Mitchell Radigan (RAM 20), Lt Col Eddie Davenport (ACS Cardiology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator, and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

## Significant Changes:

Updated content and format

## I. Waiver Consideration

Ventricular tachycardia (VT) is the most malignant of arrhythmias which can degenerate into ventricular fibrillation and sudden death; therefore immediate DNIF is required in all documented VT until a complete investigation can be completed. VT may be symptom of structural heart disease, ischemia, infarction, cardiomyopathy, or channelopathy. A history of symptomatic or asymptomatic ventricular tachycardia is disqualifying for all classes of flying duties. VT is defined as 3 or more consecutive complexes originating in the ventricles at a rate of >100bpm and can be sustained (>30 sec or requiring termination due to hemodynamic compromise) or non-sustained (terminating spontaneously) and monomorphic (stable morphology) or polymorphic (changing or multiform QRS from beat to beat). VT is considered significant and disqualifying if associated with hemodynamic symptoms, an underlying cardiac disorder, is longer than 11 beats, or when there are more than 4 episodes of VT in a single exercise stress test or during a 24 hour Holter monitor. VT that can be treated via aeromedically approved medications or ablation is waiverable for all flying classes in asymptomatic aircrew with a structurally normal heart. Given the complexity of cases, ACS review is recommended in all VT waivers. FC I, FC II and FC III waivers for VT require ACS evaluation/review.

Table 1 summarizes the current approved aeromedical policy.

Flying Class	Disease/Condition	Waiver Authority	ACS Review/
(FC)		Waiver Potential	Evaluation
I/IA	Nonsustained idiopathic VT (max	Maybe	Yes
Untrained II,	duration $\leq 11$ beats, $\leq 4$ episodes per	AETC	
RPA pilot,	study)		
and III			
	Nonsustained idiopathic VT (max	Maybe	Yes
	duration >11 beats, >4 episodes per	AETC	
	study) or sustained VT after ablation		
	Nonsustained VT with underlying	No	No
	cardiac disorder ¹	AETC	110
		ALIC	
	Sustained VT or any duration VT with	No	No
	associated hemodynamic symptoms	AETC	
	not treatable with ablation.		
II/III	Nonsustained idiopathic VT (max	Yes	Yes
	duration $\leq 11$ beats, $\leq 4$ episodes per	MAJCOM	
	study)		
	Nonsustained idiopathic VT (max	Maybe	Yes
	duration >11 beats, >4 episodes per	MAJCOM	105
	study) or sustained VT after ablation		
	Nonsustained VT with underlying	Maybe	Yes
	cardiac disorder ¹	MAJCOM	
	Sustained VT or any duration VT with	No	No
	associated hemodynamic symptoms	MAJCOM*	
	not treatable with ablation.		
ATC	Any sustained VT with or without	Yes	Yes
GBO	medical treatment or ablation	MAJCOM	
SWA			
	Any Nonsustained VT	Yes	At the
			discretion of
			the waiver
1 Candia dia adam			authority

Table 1: Waiver potential for Ventricular Tachycardia

1. Cardiac disorders that are unlikely to be waived include moderate and significant coronary artery disease, hypertrophic or dilated cardiomyopathy, and electrical or ion-channel abnormalities (unless potentially curable with ablation).

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment, including:
  - a. Detailed description of VT and of symptoms before and after the acute episode
  - b. Medications, lab values
  - c. Activity level
  - d. CAD risk factors (positive and negative)
  - e. Electrophysiology Reports if performed

There is no minimum required nonflying observation period for waiver consideration for nonsustained VT.

- 2. Reports of any pertinent laboratory studies and actual ECG tracings and images (as indicated). Include diagnostic tests and procedures performed to include EKG, ambulatory ECG monitor, treadmill test, echocardiogram, cardiac MRI/CT, EP studies etc. No additional studies are required, unless specifically requested on a case by case basis, prior to ACS evaluation. If however, the treating physician deems it clinically necessary to perform additional studies, it is required that all studies be forwarded to the ACS for review.
- 3. Any consultation reports, including follow-up notes with examination findings after disease resolution.
- 4. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 5. Current physical examination findings.
- 6. FL4 with RTD and ALC status, if member did not meet retention status
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## B. Renewal Waiver Request:

- 1 Summary of interim course and treatment including:
  - a. Change in symptoms
  - b. Medications
  - c. Activity level
  - d. CAD risk factors (positive and negative).
- 2 Reports of any pertinent laboratory studies or cardiac imaging studies that have been done since initial waiver. No additional studies are required, unless specifically requested on a case-by-case basis, prior to ACS evaluation. If however, the treating physician deems it clinically necessary to perform additional studies, it is required that all studies be forwarded to the ACS for review.
- 3 Any follow-up or new consultation reports.
- 4 Documentation of degree of physical activity, including specific comments regarding any activity limitations.
- 5 Current physical examination findings.

6 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

<u>Note 1</u>: All studies should be submitted electronically to the EKG Library. If this is not possible, items can be mailed via FedEx. If mailed, include patient's name, SSN and POC at base:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913 Note 2: State in AMS when studies were sent to the ACS.

## **III. Aeromedical Concerns**

Ventricular tachycardia is second only to ventricular fibrillation as the most common cause of sudden cardiac death. In rare instances, VT can be associated with treatable electrolyte abnormalities and/or electrical re-entry which can be ablated and therefore waiverable. However, more often VT is the result of structural heart disease, ischemia, infarction, cardiomyopathy or channelopathy that in not compatible with ongoing flight duties given risk of hemodynamic symptoms that may render an individual incapable of remaining in control of an aircraft or supporting the flying mission. Though sudden cardiac death related to sustained VT would be an obvious and dramatic explanation for such an event, a less dramatic near syncopal episode is also likely to result in sudden incapacitation or interference with duty performance. Permanent disqualification for aircrew is recommended for VT, which is sustained or symptomatic, if antiarrhythmics are necessary for control, with AICD implantation, if associated with underlying myocardial disease, or when ablation is done for failed medical therapy in prior infarct/scar related VT.

When there is no underlying cardiac disease or other obvious etiology, the arrhythmia is termed *idiopathic VT*. Cardiac literature does support a benign prognosis for infrequent episodes of shortduration asymptomatic VT in structurally normal hearts. In USAF aviators with asymptomatic idiopathic non-sustained VT, the annual event rate for sudden cardiac death, syncope, presyncope, or sustained VT was less than 0.5% per year during a mean follow-up of approximately 10 years with the majority having VT runs of only three beats' duration and only one VT episode per 24hour ambulatory ECG recording. Only 10% had more than four episodes of non-sustained VT per 24-hour ambulatory recording and only 3% had VT episodes longer than ten beats duration. International consensus is that asymptomatic VT with a duration of 11 beats or less and no more than 4 runs in a 24 hour period is acceptable for return to flight duties in otherwise structurally normal hearts. Idiopathic VT that responds well to antiarrhythmic therapy is limited by the side effect profile, pro-arrhythmic, and hemodynamic effects of antiarrhythmics. The only antiarrhythmic approved in aircrew is beta-blocker use in non-high performance airframes.

Review of AIMWTS waiver submissions for ventricular tachycardia in Nov 2019 for the previous 5 years showed 33 waivers submitted. Breakdown of the cases was as follows: 1 FC I/IA case (0 disqualified), 16 FC II cases (0 disqualified). 12 FC III cases (2 disqualified), 3 ATC/GBC cases (0 disqualified), and 1 SWA case (0 disqualified). There were a total of 2 submissions that resulted in

a disqualification. These were complex cases. One was associated with significant heart defects and the other had multiple comorbidities.

ICD-9 codes for Disease/Condition		
427.1 Paroxysmal ventricular tachycardia		
ICD-10 codes for Disease/Condition		
I47.2	Ventricular tachycardia	

#### **IV. Suggested Readings**

1. Kruyer WB and Davenport ED. Cardiology. In: Rayman 's *Clinical Aviation Medicine*, 5th ed. New York: Castle Connolly Graduate Medical Publishing, LTD, 2013; 81-7.

2. Guettler N, Bron D, Manen O, et al. Management of cardiac conduction abnormalities and arrhythmia in aircrew. Assessing aeromedical risk: a three-dimensional risk matrix approach. Heart 2019;105:s38–s49

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8. Hoffmayer KS and Gerstenfeld EP. Diagnosis and Management of Idiopathic Ventricular Tachycardia. Curr Probl Cardiol, 2013; 28: 131-58.

9. Olgin J and Zipes DP. Specific Arrhythmias: Diagnosis and Treatment. Ch. 39 in *Bonow: Braunwald's Heart Disease – A Textbook of Cardiovascular Medicine*, 9th ed., 2011, Saunders.

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## Wolff-Parkinson-White (WPW) and other Pre-Excitation Syndromes (Aug 2020)

Reviewed: Lt Col Eddie Davenport (ACS Chief Cardiologist), Dr. Edwin Palileo (ACS cardiologist), Dr. Dan Van Syoc (ACS waiver guide coordinator), and Lt Col Ric Speakman (AFMRA Physical Standards Development Chief)

## Significant Changes:

Updated content and format

## I. Waiver Consideration

Per MSD H14, WPW pattern is disqualifying for all classes of flying duties in the US Air Force.

Flying Class (FC)	Waiver Potential	ACS Evaluation/Review
	Waiver Authority	
I/IA	Yes ¹	Yes
	AETC	
II/III	Yes ¹	Yes
	MAJCOM	
ATC/GBO/SWA	Yes ¹	Yes
	MAJCOM	

#### Table 1: Waiver potential for WPW and related syndromes

1. FCI candidates will require EP study; all others will require Holter monitor and treadmill testing.

## **II. Information Required for Waiver Submittal**

Aeromedical disposition and waiver submission should be done after administrative and clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

## A. Initial Waiver Request:

1. Complete history and physical exam – to include description of symptoms (positive and negative) as well as medications, treatments, and activity level.

- 2. Cardiology consultation
- 3. Electrocardiogram (ECG), all ECGs if multiple.
- 4. Copies of reports and all tracings/images of any other cardiac tests performed locally for clinical assessment (e.g. treadmill, Holter monitor, cardiac cath, cardiac CT or MRI).
- 5. Electrophysiologist consultation if done, if electrophysiology study and/or catheter ablation is done then procedure report(s) should be submitted.
- 6. RTD and ALC status, if member did not meet retention status.
- 7. If the local base is unable to provide all required items, they should explain why to the waiver authority

B. <u>Renewal Waiver Request:</u>

- 1 Complete updated history and physical exam to include description of any symptoms, medications, and activity level.
- 2 Electrocardiogram (ECG).
- 3 Additional local cardiac testing is not routinely required for re-evaluation but may be requested in individual cases. If so, the previous ACS evaluation/review will specify details regarding any requested local testing.
- 4 Local studies done since prior waiver or waiver renewal should be sent to ACS for review even if not requested by ACS. (e.g. stress test, echocardiogram, Holter monitor, cardiac cath, EP study, cardiac CT or MRI).
- 5 If the local base is unable to provide all required items, they should explain why to the waiver authority

All studies should be submitted electronically to the EKG Library. If this is not possible, items can be mailed via FedEx. If mailed, include patient's name, SSN and POC at base:

Attn: Case Manager for (patient's MAJCOM) USAFSAM/FECI Facility 20840 2510 Fifth Street WPAFB, OH 45433-7913

State in AMS when studies were sent to the ACS. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS.

## **III. Aeromedical Concerns**

Aeromedical concerns with WPW (Pattern and Syndrome) involve the risk of recurrent arrhythmia with symptoms that range from palpitations that would adversely affect flying performance to sudden cardiac death. Fortunately, WPW is often successfully treated with ablation which decreases risk to less than 1% and thus eligible for unrestricted waiver.

## WPW Syndrome vs Pattern Only

WPW pattern (also commonly referred to as ventricular pre-excitation) is characterized on the ECG by a short PR interval (less than 0.12 seconds) due to more rapid AV conduction through an accessory pathway AND a prolonged QRS complex (> 0.12 seconds) due to a slow initial phase due to ventricular muscle to muscle conduction (often referred to as a delta wave) followed by more rapid ventricular activation via the His-Purkinje fibers. WPW Pattern is the term often used to indicate the presence of ventricular pre-excitation on EKG in the absence of any symptoms consistent with tachydysrhythmias. WPW Syndrome, on the other hand refers to ECG evidence of pre-excitation and presence of signs (including arrhythmia and/or aborted sudden cardiac death) or symptoms consistent with tachydysrhythmia. WPW syndrome is disqualifying for all flying classes unless ablated (see ablation waiver guide). WPW pattern only may be acceptable for continued flight duties if low risk.

Risk of WPW pattern is determined best by EP study but can also be inferred by absence of highrisk features on ECG monitoring. High risk findings in EP studies include the ability for fast conduction over the accessory pathway at very short coupling interval (referred to as a short refractory period), presence of multiple pathways, and/or the ability to conduct retrograde (thus allowing for AV re-entry tachycardias). Utilizing non-invasive modalities such as Holter monitoring or stress testing, if the WPW pattern resolves with increased heart rates (i.e., PR interval lengthens and delta wave disappears), it is commonly assumed that the pathway is "weak" and cannot conduct at shorter intervals which equates with fast heart rates. However, this is not fool-proof as this only reflects antegrade accessory pathway conduction and does not rule out the possibilities of retrograde conduction (of a manifest or concealed accessory pathway) or the presence of multiple pathways, which require an EP study to identify. Moreover, younger age such as the pediatric population has been shown to have increased risk of significant tachyarrhythmias when compared to older populations. Systematic review, in conjunction with the ACC/AHA/HRS guidelines, showed that the occurrence of arrhythmias in untreated asymptomatic individuals in the general population could be as high as 77% over five years; however always with highest risk at younger ages.

The most current guidelines give a class IIA recommendation for all patients with asymptomatic WPW pattern to undergo EP study to risk-stratify arrhythmic events and treatment with catheter ablation if the EP study identifies high risk; however, they also give a IIA recommendation for observation without further evaluation. Most importantly, the same guideline gives an IIA recommendation to treat with ablation in "asymptomatic patients if the presence of pre-excitation precludes specific employment (such as with pilots)." Given the low level of evidence supporting this employment recommendation, the USAF reviewed 60 years of aircrew data in over 200 cases of WPW Pattern which demonstrated a less than 1% annual risk of SVT and less than 0.03% risk of SCD; these risks were highest in the youngest and healthiest aircrew and lowest in aircrew over age 35. We therefore reserve EP study for those at high risk (any symptoms, arrhythmia, and/or persistent pre-excitation with exercise) or young age (most initial applicants).

Pilot candidates (FCI/IA) are higher risk given age and have a somewhat increased lifetime risk given their longer duration of possible service. Therefore, an EP study is recommended in ALL untrained pilot candidates and ablation is required if the EP study reveals any high-risk pathway. See ablation waiver guide for more details regarding waiver after ablation.

While all initial FCI/IA aircrew must undergo EP study, all other aircrew may demonstrate lower risk via loss of ventricular pre-excitation on ECG. The minimum acceptable diagnostic work up these airmen with WPW pattern is exercise stress testing and a Holter monitor looking for loss of pre-excitation with increased heart rate. Absence of these inferred "low-risk" findings will require an EP study for evaluation (with ablation if high risk pathway).

#### Electrophysiologic testing (EP) and Ablation

Recommendations by the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in 2015 suggest the usefulness of electrophysiologic (EP) studies of both symptomatic and asymptomatic persons with WPW pattern on EKG. The effectiveness and risks of treatment of high-risk accessory pathways with radiofrequency (RF) catheter ablation was reviewed in a systematic review in conjunction with the ACC/AHA/HRS guidelines. This review showed the complication rate of RF ablation to be between 0.9% and 1% of cases (these included ablation induced right bundle branch block, complete heart block, access site complications, and pneumothorax). In five years of follow-up, those that underwent RF ablation had a 7% incidence of arrhythmic events and those who did not undergo ablation had an incidence of 77%. Owing to the high success rate of RF ablation in highrisk accessory pathways and the low incidence of complications, this is currently the preferred treatment modality and in most guidelines considered first line treatment. ANY AIRCREW may CHOOSE to undergo EP study and ablation, even if low risk, and will be eligible for unrestricted waiver if successful. While most cases of WPW are sporadic, there is a familial tendency in about 3.4% of all cases. Studies have shown that this is from a mutation in the <u>PR</u>otein <u>K</u>inase, <u>A</u>MPactivated, <u>G</u>amma <u>2</u> non-catalytic subunit (PRKAG2) gene. In familial WPW, there is a higher risk of multiple accessory pathways and high-risk pathways. Routine genetic testing for WPW is not currently recommended nor does it change the waiver process.

AIMWTS review in Jul 2020 for the previous five years resulted in 135 members with a diagnosis of WPW. Breakdown of the cases revealed: 23 FC I/IA cases (4 disqualified), 53 FC II cases (1 disqualified), 36 FC III cases (4 disqualified), 2 ATC cases, 16 GBO cases, and 5 SWA cases.

ICD-9 codes for WPW		
426	Conduction disorders	
426.7	Anomalous atrioventricular excitation	

ICD-10 codes for WPW				
I45.89	Other specified conduction disorders			
I45.6	Pre-excitation syndrome			

## **IV. Suggested Readings**

1. Al-Khatib SM, Arshad A, Balk EM, et al. Risk Stratification for Arrhythmic Events in Patients With Asymptomatic Pre-Excitation: A Systematic Review for the 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation, 2016; 133(14): e575-e586.

2. 2019 ESC Guidelines for the Management of Patients With Supraventricular Tachycardia: The Task Force for the management of patients with supraventricular tachycardia of the European Society of Cardiology (ESC): Developed in collaboration with the Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J, 2020; 41: 655-720

3. Gray GW, Davenport ED, Nicol ED. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 5th ed. In press, pending publication 2020.

4. Strader JR, Jr, Gray GW, Kruyer WB. Clinical Aerospace Cardiovascular Medicine. Ch. 13 in: *Fundamentals of Aerospace Medicine*, 4th ed. Philadelphia: Lippincott Williams & Wilkins, 2008; 344-45.

5. Kruyer WB and Davenport ED. Cardiology. Ch. 2 in: *Rayman's Clinical Aviation Medicine*, 5th ed., Castle Connolly Graduate Medical Publishing, LTD, 2013; 75-79.

6. Guettler N, Bron D, Manen O, et al. Management of cardiac conduction abnormalities and arrhythmia in aircrew. Heart 2019;105:s38-49

7. Munger TM, Packer DL, Hammill SC, et al. A population study of the natural history of Wolff-Parkinson-White syndrome in Olmsted County, Minnesota, 1953-1989. Circulation, 1993; 87(3): 866-73.

8. Davenport ED, Rupp KAN, Palileo E, and Haynes J. Asymptomatic Wolff-Parkinson-White pattern ECG in USAF aviators. Aerosp Med Hum Perform, 2017; 88(1): 56–60

9. Fitzsimmons PJ, McWhirter PD, Peterson DW, and Kruyer WB. The natural history of Wolff-Parkinson-White syndrome in 228 military aviators: A long-term follow-up of 22 years. Am Heart J, 2001; 142(3): 530–36.

10. Obeyesekere MN, Leong-Sit P, Massel D, et al. Risk of Arrhythmia and Sudden Death in Patients with Asymptomatic Preexcitation: A Meta-Analysis. Circulation, 2012; 125: 2308-15.





# Acne

Revised: Sept 2022

Reviewed: Col Emily Wong (AF/SG Dermatology Consultant), Col Jon Ellis (Chief, ACS Ophthalmology), Dr. Max Lee (ACS Waiver Guide Coordinator), Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

## **Significant Changes:**

Updated references, waiver no longer required for isotretinoin after 2 week ground trial, electroretinogram no longer required for uncomplicated isotretinoin use.

# I. Waiver Consideration

Severe acne that is unresponsive to treatment and interfering with the satisfactory performance of duty or wear of the uniform or use of military equipment requires an evaluation for retention. Waiver is required for mild to moderate acne in flyers and operators if the condition is chronic or of a nature that requires frequent specialty medical care or interferes with the satisfactory performance of military duty if it is severe enough to cause recurrent grounding from flying duties. Treatment with approved topical agents does not require a waiver for any flying or special duty personnel. The local flight surgeon plays an important role in assessing for potential interference with use of aviation equipment and adverse effects of medication used to treat acne.

Systemic maintenance agents such as oral erythromycin, tetracycline, and trimethoprimsulfamethoxazole require a waiver for FC I/IA, FC II, FC III, ATC, GBO, and SWA personnel. If acne does not interfere with the use of life support equipment, treatment with doxycycline does <u>not</u> require a waiver for any flying or special duty personnel. These oral agents are compatible with flying once it is confirmed that side effects are absent or of minimal and acceptable aeromedical risk.

Use of isotretinoin no longer requires a waiver for all flying and special duty operations classes after a 2-week minimum DNIF period to assess for side-effects. Due to the drying effects of isotretinoin on the mucosal surfaces, the local flight surgeon will need to determine, on a case-by-case basis, the impact of the disease and medications on the operator's flying duties. Baseline electroretinography (ERG) for use of isotretinoin in pilots and operators is no longer required unless requested for clinical reasons by the treatment team. Complications related to isotretinoin including alteration in night vision, visual field changes, visual acuity, and other mucocutaneous complications will require waiver adjudication.

Aeromedical waivers are highly unlikely for acne treated with minocycline due to unacceptable risk of vestibular side-effects. Therapy with oral contraceptives may be considered and waiverable for women. Although spironolactone is sometimes used in conjunction with oral contraceptives for management of acne, due its diuretic effects and potential for hyperkalemia, waiver consideration is limited to non high-performance aircraft.

Table 1: Waiver potential for acne

Flying Class (FC)	Acne Treatment	Waiver Potential Waiver Authority ¹			
I/IA II/III ATC/SWA	Topical treatment – topical retinoids (tretinoin, adapalene, tazarotene), benzoyl peroxide, salicylic acid, azelaic acid, topical antibiotics (clindamycin, erythromycin, sulfacetamide-sulfur)	N/A			
	Oral contraceptive (female only)	N/A			
	Oral antibiotics – tetracycline, erythromycin, doxycycline, and trimethoprim-sulfamethoxazole ^{2,3}	Yes MAJCOM			
GBO	Topical treatment – topical retinoids (tretinoin, adapalene, tazarotene), benzoyl peroxide, salicylic acid, azelaic acid, topical antibiotics (clindamycin, erythromycin, sulfacetamide-sulfur)	N/A			
	Oral contraceptive (female only)	N/A			
	Oral antibiotics – tetracycline, erythromycin, doxycycline, and trimethoprim-sulfamethoxazole ^{2,3}	N/A			

1. Waiver authority for untrained applicants is AFRS/CMO.

2. Minocycline is "Non-Waiverable" under the Aircrew and GBO Med List.

3. No waiver is necessary for doxycycline if used for acne.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial/Renewal Waiver Request:

- 1. History of acne problem, age at onset, extent and location(s) of lesions, and a description of current and past therapy. Include all medications including dosage, and frequency, and side effects. In adult women, address menstrual regularity and presence or absence of hirsutism.
- 2. Comments addressing interference with use of flight or other equipment.
- 3. Dermatology consult if individual has recalcitrant moderate to severe inflammatory or severe/nodulocystic acne.
- 4. Medical evaluation board (MEB) reports and narrative, if required.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

Acne is a follicular disease with the principal abnormality being impaction and distention of the pilosebaceous unit with up to 85% incidence in the adolescent population. It typically appears at puberty and lessens in severity during the course of adolescence. Although initial manifestation of acne occurs during the second decade of life, the mean age at presentation to a physician is 24 years and is estimated that 33 percent of people ages 15 to 44 years-old are affected by acne. Adolescent acne has a male predominance, but post-adolescent disease predominately affects women. The social, psychological, and emotional impairment that can result from acne has been reported to be similar to epilepsy, asthma, diabetes, and arthritis.

Acne treatment goals are to relieve clinical symptoms and to prevent scarring. Dermatologists strongly encourage patients to obtain early treatment as the extent and severity of scarring are associated with acne severity and longevity prior to therapy.

The primary aeromedical events of concern are interference with the wear of protective aviation equipment, acne exacerbation due to rubbing, pressure and/or exposure to hot and humid environments, psychological factors, use of acne medications that are incompatible with flying duties, and extended grounding due to a difficult or prolonged treatment course. Lesions on the face may interfere with mask or respirator seal and helmet wear (chin straps). Lesions on the shoulder, chest, and back may cause discomfort and distraction when wearing restraint or parachute harnesses or with prolonged sitting. Repeated or prolonged rubbing or pressure against the skin can produce or exacerbate an eruption (mechanical acne) with striking inflammation.

Aeromedical events of concern regarding the use of isotretinoin are the known and common side effects of mucosal surface dryness, photosensitivity, and possible impact on visual acuity. The demato-photosensitizing effects of isotretinoin are moderate and not usually as significant as that seen with doxycycline (also used in flyers for malaria prophylaxis and acne). The impact on visual acuity, especially night vision, is not well understood as there are no studies that specifically evaluate this. The most common side effect of isotretinoin is skin dryness and mucosal membranes. The lips tend to be the most significantly affected surface, but the eyes and nares can also be affected. Any patient on isotretinoin must be evaluated every month by an iPledge REMSTM provider. Though rare, it is critical that the desiccating effect of isotretinoin, its potential for visual impairment, and wear of aircrew flight equipment must be carefully assessed during clinical follow-ups.

AIMWTS review from Nov 2015 to Feb 2022 revealed 119 Air Force flyers and operators with a diagnosis of acne. The breakdown of the number of waivers and number of total cases are tabulated below. Reassuringly, only 3 were disqualified primarily as the result of acne with 2 disqualifications related to the flyers' personal choice for continuing to take aeromedically unapproved medications for acne and 1 for isotrentinoin use which now has waiver potential.

Please use only these ICD-10 codes for acne		(# of waivers / total # of cases)						
for AIMWTS coding purposes		IFC I/IA	FC II	FC III	GBO	ATC	SWA	
L70.0	Acne vulgaris	5/6	27/28	2/8	63/65	3/5	6/6	
L70.8	Other acne							

#### **IV. Suggested Readings**

1. Webster GF. Acne vulgaris. BMJ. 2002 Aug 31;325(7362):475-9. PMID: 12202330; PMCID: PMC1123998. <u>https://www.bmj.com/content/325/7362/475.1.long</u>

2. Graber, E. Acne vulgaris: Overview of management. UpToDate. Topic update Oct 26, 2021. Accessed Mar 1 2022. <u>https://www.uptodate.com/contents/acne-vulgaris-overview-of-management</u>

3. Li C, Chen J, Wang W, Ai M, Zhang Q, Kuang L. Use of isotretinoin and risk of depression in patients with acne: a systematic review and meta-analysis. BMJ Open. 2019 Jan 21;9(1):e021549. doi: 10.1136/bmjopen-2018-021549. Erratum in: BMJ Open. 2019 Mar 15;9(3):e021549corr1. PMID: 30670500; PMCID: PMC6347928. https://bmjopen.bmj.com/lookup/pmidlookup?view=long&pmid=30670500

4. Mollan SP, Woodcock M, Siddiqi R, Huntbach J, Good P, Scott RA. Does use of isotretinoin rule out a career in flying? Br J Ophthalmol. 2006 Aug;90(8):957-9. doi: 10.1136/bjo.2006.092833. Epub 2006 May 24. PMID: 16723361; PMCID: PMC1857209. https://bmjopen.bmj.com/lookup/pmidlookup?view=long&pmid=30670500

#### Eczematous Dermatitis (Eczema) and Atopic Dermatitis (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator)

Significant Changes: Updated to reflect MSD changes. Waiver tolerance for untrained applicants expanded.

#### I. Waiver Consideration

Eczematous (Eczema), atopic dermatitis, or any other skin condition that is severe enough to require frequent absence from duty, interfere with the wearing of operational equipment, or uncontrolled despite adequate treatment with career field approved medications are disqualifying for all flying classes, ground-based operators, and special duty operators including for retention. Controlled eczema or atopic dermatitis with career field approved medications is not disqualifying for ATC or GBO duties. Eczema or atopic dermatitis requiring chronic topical corticosteroid therapy for symptomatic control is disqualifying for FC I/IA/II/III and special warfare duties. A history of eczema or atopic dermatitis after the twelfth birthday is also disqualifying for FC I/IA. Factors considered when accessing suitability for waiver include the severity of disease, evidence of active lesions, the risk associated with specific medication(s), the individual service member's tolerance of the medication(s) and adherence to therapy, and the presence of comorbid conditions (i.e., asthma, allergic rhinitis, and food allergies).

A policy memo released by SECAF in Jan 2017 allowed for select candidates medically classified as having mild forms of eczema to be processed for an accession waiver. Therefore, select FC I/IA and untrained applicants in all flying classes with active disease are eligible for waiver on a case-by-case basis if the disease is mild. Moderate to severe disease exceeds current waiver threshold for untrained personnel. Mild disease is defined aeromedically as disease that is controlled with the use of emollients or occasional low-to-moderate potency steroids, disease with no other significant disqualifying comorbidities, and/or disease that does not require more than annual dermatology visits. Moderate to severe disease is defined aeromedically as disease that is controlled with the use of chronic topical steroids or intermittent high potency steroids, disease that is controlled with use of systemic medications or phototherapy, disease that interferes with sleep or wearing of military equipment, disease with significant disqualifying comorbidities, and/or disease requiring more than annual dermatology evaluation. Additionally, FC I/IA applicants require pre- and post-bronchodilator spirometry testing prior to waiver submission to exclude the presence of comorbid pulmonary dysfunction. Abnormal pulmonary screening results should prompt full pulmonary function testing and further evaluation.

Members eligible for waiver will be considered once the individual demonstrates tolerability of the current treatment regimen, reduction of any distracting symptoms, and the ability to wear operational equipment. Initiation of treatment that is not on the approved career field medication list is disqualifying for all flying classes, ground base operators, and special duty operators. Systemic therapy with oral glucocorticoids, oral immunomodulators, or PUVA phototherapy for disease control exceeds historic waiver thresholds. UVB phototherapy is less toxic than PUVA phototherapy and can be considered on a case-by-case basis.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation	
I/IA	Active eczema or atopic dermatitis, mild ^{1,2}	Yes AETC	Yes	
	Active eczema or atopic dermatitis, moderate to severe ^{1,3}	No AETC	No	
	Verified history of eczema or atopic dermatitis after twelfth birthday ¹	Yes AETC	Yes	
II/III/SWA	Eczema, atopic dermatitis, or other skin condition when severe enough to require frequent absence from duty, interfere with the wearing of operational equipment, or uncontrolled despite adequate treatment with aeromedically approved medications ^{4,5}	No MAJCOM	No	
	Eczema or Atopic dermatitis treated with topical steroids (chronic usage), topical pimecrolimus, or topical tacrolimus	Yes MAJCOM	No	
	Eczema or atopic dermatitis treated with emollients or occasional topical steroids is not disqualifying	N/A	N/A	
GBO/ATC	Eczema, atopic dermatitis, or other skin disorder when severe enough to require frequent absence from duty, interfere with the wearing of operational equipment, or uncontrolled despite adequate treatment with career field approved medications ^{4,5}	No MAJCOM	No	
	Eczema or Atopic dermatitis treated with topical pimecrolimus or topical tacrolimus	Yes MAJCOM	No	
	Eczema or atopic dermatitis treated with emollients or topical steroids is not disqualifying	N/A	N/A	

 Table 1: Waiver potential for Eczema/Atopic dermatitis

1 FC I/IA applicants require pre- and post-bronchodilator spirometry testing prior to waiver submission.

- 2 Mild disease is defined aeromedically as disease that is controlled with the use of emollients or occasional low/medium potency steroids, disease with no other significant disqualifying comorbidities, and/or disease that does not require more than annual dermatology visits.
- 3 Moderate to severe disease is defined aeromedically as disease that is controlled with the use of chronic topical steroids or intermittent high potency steroids, disease controlled with use of systemic medications or phototherapy, disease that interferes with sleep or wearing of military equipment, disease with significant disqualifying comorbidities, and/or disease requiring more than annual dermatology evaluation.
- 4 Eczema or atopic dermatitis requiring treatment with any medication not included on the applicable career field approved medication list is disqualifying, and the waiver authority is AFMRA if waiver is being entertained.
- 5 Systemic therapy with oral glucocorticoids, oral immunomodulators, or PUVA phototherapy for disease control exceeds historic waiver thresholds. UVB phototherapy may be considered for waiver.

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1 Summary of presentation, course, and treatment.
- 2 Consultation reports form all treating providers or specialists, which should include:
  - a. Subjective symptoms and objective physical exam findings to include thorough skin exam.
  - b. Tolerability and doses of current treatment regimen.
    - i. For topical steroids use include the formulation, potency, total dose, treatment duration, site of application, and any evidence of skin thinning (telangiectasia, etc.)
  - c. Documentation excluding other atopic syndromes (i.e, asthma, allergic rhinitis, food allergies)
  - d. FC I/IA applicants required to have pre- and post-bronchodilator spirometry testing.
  - Any specific diagnostic tests performed, before and after treatment.
- 4 Current physical examination findings.
- 5 FL4 with RTD and ALC status, if applicable.
- 6 Any other pertinent information.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

### B. Renewal Waiver Request:

3

- 1 Updated AMS with interval history, including:
  - b. Current symptoms and development of any disease flares.
  - c. Current medications, doses, and adverse effects.
    - i. For topical steroids use include the formulation, potency, total dose, treatment duration, site of application, and any evidence of skin thinning (telangiectasia, etc.)

- d. Current physical examination findings to include thorough skin exam.
- 2 Any interval diagnostic tests performed.
- 3 Any other pertinent information.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

### **III. Aeromedical Concerns**

Eczematous (Eczema) or atopic dermatitis (AD) are relatively common conditions defined by chronic inflammation of the skin. It is primarily seen in prepubescence, but it can persist into or develop in adolescence or adulthood. Presentation can vary from very mild disease requiring no treatment or only topical emollients to severe disease requiring systemic immunotherapy therapy for symptomatic control. Common symptoms include dry and pruritic skin rashes affecting the skin flexures, hands, neck, or face (although any area of the body can be involved). If uncontrolled, discomfort from pruritus or pain can be significant and the resulting distraction may jeopardize flight safety or operational duties. Active disease might interfere with wear of operational or flight equipment. Additionally, the environmental condition and stressors attendant to aviation and operational duties or deployment to austere environments potentially results in disease flares.

Eczema and AD are associated with several aeromedically significant comorbidities including asthma, allergic rhinitis, and food allergies. A thorough evaluation should be documented to assess for these associated atopic diseases. A 2017 retrospective study involving 3966 children found those who developed AD in adolescence had a 30% cumulative incidence of developing asthma. Thus, FC I/IA applicants who have a history of eczema or atopic dermatitis after the twelfth birthday or current active eczema or atopic dermatitis should have full pre- and postbronchodilator spirometry test done prior to waiver submission. Abnormal results should prompt appropriate clinical evaluation.

The use of systemic immunotherapy such as oral glucocorticoids, cyclosporine, or PUVA have traditionally not been recommended for waiver given the unacceptable adverse effects and underlying disease severity. Psoralen plus ultraviolet A (PUVA) photochemotherapy carries significant short-term and long-term side effects. Short-term side effects include nausea, dizziness, headache, and photosensitivity. Long term side effects include pruritus, skin damage, and increased skin cancer risk. Broad-spectrum ultraviolet B (UVB) phototherapy is better tolerated without the adverse effect profile of PUVA. This therapy is deemed acceptable and its use has waiver potential. UVB therapy may require several treatments per week and potentially results in mobility restrictions if the treatment is necessary to maintain disease control. Topical corticosteroids are frequently used and are typically well tolerated. Prolonged use of topical steroids increases the risk of systemic adverse effects such as suppression of the hypothalamic-pituitary-adrenal axis, iatrogenic Cushing's syndrome, avascular necrosis, and glaucoma. Low or moderate potency steroids and intermittent use mitigates these risks.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 110 individuals with an AMS containing the diagnosis of Eczematous Dermatitis. Twelve individuals (7.3%)

were disqualified. A breakdown of the cases was follows: 27 FC I/IA cases (8 disqualified), 40 FC II cases (0 disqualified), 37 FC III cases (4 disqualified), 2 ATC/GBC cases (0 disqualified), 0 MOD cases, and 4 RPA Pilot cases (0 disqualified).

ICD-9 codes for Eczema/Atopic Dermatitis		
691.8	Atopic dermatitis and related conditions	
692.9 Contact dermatitis and other eczemas		

ICD-10 codes for Eczema/Atopic Dermatitis		
L20.9	Atopic dermatitis, unspecified (includes eczema)	
L30.9	Dermatitis, unspecified	

### **IV. Suggested Readings**

1. Lee JH, Son SW, and Cho SH. A Comprehensive Review of the Treatment of Atopic Eczema. Allergy Asthma Immunol Res, 2016; 8(3): 181-190.

2. Wong IT, Tsuyuki RT, et al. Guidelines for the management of atopic dermatitis (eczema) for pharmacists. Can Pharmacists J, 2017; 150(5): 285-297.

3. Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Derm, 2015; 71(6). https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis

4. Wan J, Mitra N, et al. Variations in risk of asthma and seasonal allergies between early and late onset pediatric atopic dermatitis: a cohort study. J Am Acad Derm, 2017; 77(4):643-640.

5. World Health Organization Classification of Topical Corticosteroids. https://emedicine.medscape.com/article/2172256-overview

### WAIVER GUIDE

Updated: Jan 2018 Supersedes Waiver Guide of Jul 2014 By: Lt Col Lance Nussbaum (RAM 19) and Dr Dan Van Syoc Reviewed by Lt Col Jeffrey Bidinger, AF/SG consultant for dermatology, and AFMSA staff

### CONDITION: Psoriasis & Psoriatic Arthritis (Jan 2018)

### I. Waiver Consideration.

For entry into the US Air Force, a current or past history of psoriasis is disqualifying (DoDI 6130.03); this would definitely impact those individuals applying for initial flying training as well. The diagnosis of psoriasis is disqualifying for flying class I/IA, II, III, and SWA duties (MSD P28). For ATC and GBO personnel, psoriasis is only disqualifying if not controlled by treatment, or controllable only with systemic medications or UV light therapy (MSD P26). Use of personal protective equipment is also going to be a big factor for all career fields for members with psoriasis. Psoriatic arthritis is not mentioned by name as disqualifying for aviation service, but "arthritis of any type of more than minimal degree, which interferes with the ability to follow a physically active lifestyle, or may reasonably be expected to preclude the satisfactory performance of duties" is disqualifying for all flying classes as well as for ATC, GBO, and SWA duties. Also, a medical evaluation board (MEB) is required if the psoriasis is extensive and not controlled or controllable only with potent cytotoxic/systemic agents (methotrexate, cyclosporine, oral retinoids, PUVA and immune modulating drugs, to include TNF-alpha inhibitors).

Flying	Condition/Treatment for	Treatment for	Waiver Potential
Class (FC)	Psoriasis	<b>Psoriatic Arthritis</b>	Waiver
			Authority
I/IA	History of psoriasis at any time	History of psoriatic	No
	whether or not under current	arthritis currently	AETC
	therapy of any kind	treated or not	
II/	Topical steroids, calcipotriene,	NSAIDS,	Yes
III/SWA*	topical retinoids	sulfasalazine	MAJCOM
	(tazarotene),UVB		
			Yes ^{\$}
	Etanercept, adalimumab,	Etanercept,	AFMRA
	infliximab, or tacrolimus	adalimumab, or	
	(topical)	infliximab, or	
		tacrolimus (topical)	
			No
		Oral retinoids,	AFMRA
	Pimecrolimus, oral retinoids,	methotrexate,	
	methotrexate, cyclosporine, and	cyclosporine, and	
	other immunomodulators	other	
	(except TNF-alpha inhibitors	immunomodulators	
	above), PUVA	(except TNF-alpha	
		inhibitors above)	37
ATC/GBO	Topical steroids, calcipotriene,	NSAIDS,	Yes
	topical retinoids (e.g. tazarotene), UVB	sulfasalazine	MAJCOM
	Etanercept, adalimumab,		Yes ^{\$}
	infliximab or tacrolimus	Etanercept,	AFMRA
	(topical)	adalimumab,	
		infliximab, or	
		tacrolimus (topical)	
	Pimecrolimus, oral retinoids,	Oral retinoids,	No
	methotrexate, cyclosporine, and	methotrexate,	AFMRA
	other immunomodulators (except	cyclosporine, and	
	TNF-alpha inhibitors above),	other	
	PUVA	immunomodulators	
		(except TNF-alpha	
		inhibitors above)	

 Table 1: Waiver Potential for psoriasis and psoriatic arthritis

* All initial training applicants to be treated as FC I/IA

\$ If on TNF-alpha inhibitor, waiver will be restricted (not worldwide qualified, TDY requires access to transport and refrigeration of etanercept/adalimumab). MEB is required. Observe for 3 to 6 months on therapy before consideration of waiver to allow for assessment of response, possible adverse effects. Forward to ACS for review.

AIMWTS review in Jan 2018 revealed a total of 382 cases with a psoriasis or psoriatic arthritis diagnosis. Of those, 61 were disqualified; however, only 39 of the disqualifications were related to

psoriasis or psoriatic arthritis disorders. The other 22 disqualifications were primarily due to other diagnoses besides psoriasis/psoriatic arthritis. There were 9 FC I/IA cases (6 disqualified), 167 FC II cases (5 disqualified), 5 RPA pilot cases (1 disqualified), 186 FC III cases (46 disqualified), 12 ATC/GBC cases (1 disqualified), and 3 MOD cases (2 disqualified).

### II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial and renewal waivers</u> must include:

A. History - to include extent of lesions, locations, symptoms, and a description of current therapy, all medications including dosage, and frequency, and comments addressing interference with use of aviation equipment or jeopardy to safe mission accomplishment. If arthritis, then in addition to joints involved should address any interference with flight controls and egress ability.

B. Physical - joints involved, surface area affected and description of lesions, body surface area involved (palm of hand = 1% BSA and can be used to estimate).

C. Copy of dermatology consultation.

D. All cases of psoriatic arthritis should be evaluated by a rheumatologist. These cases need to have results of radiographs for hands, feet, and any symptomatic joints.

E. Laboratory testing for initial waiver for psoriatic arthritis: complete blood count, sedimentation rate, C-reactive protein.

F. If topical vitamin  $D_3$  (calcipotriene) is used, verify with the aviator the amount of topical vitamin  $D_3$  cream use is less than 100 gm a week. Also baseline normal renal function should be confirmed prior to usage.

G. If on etanercept/adalimumab/infliximab, for initial waiver, results of IPPD or Quantiferon releasing assay required.

H. If on etanercept/adalimumab/infliximab, then MEB required.

## III. Overview.

<u>Psoriasis</u>: Psoriasis affects about two percent of the population in the United States, with approximately 150,000 new cases diagnosed per year, and is equally common in males and females. Approximately 80% of all psoriasis patients have mild to moderate disease with the remainder having moderate to severe disease.¹ Onset is a lifelong threat as it has been documented at birth and up to age 108, with peak incidence at 22.5 years. An early onset (before age 15) predicts more severe disease relative to the percentage of body surface involved and response to therapy.² While looked at as a simple dermatological disease, recent research has demonstrated a far more complex immune-mediated disease process. Psoriasis is associated with arthritis and inflammatory bowel disease. It is also an independent risk factor for diabetes, hypertension, coronary artery calcification, myocardial infarction, lymphoma, and depression.³⁻⁵ An important issue to consider is that the impact of psoriasis on quality of life of affected individuals is comparable to other disorders such as cancer, diabetes, heart disease, and depression.⁶

Psoriasis is a hyperproliferation and immune regulation disorder.⁷ Hyperproliferation is seen with increased numbers of epidermal cells, increased number of cells undergoing DNA synthesis, and an

increased turnover of epidermal cells.⁸ A T-cell immune response is noted with increased T-cells seen in the skin.⁹ TNF-alpha, gamma interferon, and various interleukins are overexpressed in psoriasis patients.¹⁰ Dendritic cells play a key role in this immune response as they are activated by environmental factors and subsequently produce interferon alpha and stimulate T-cell differentiation in the dermal layers.^{11, 12} Current psoriasis therapies attempt to address this complex interaction.

Morphologic appearance and distribution are keys to diagnosis, as well as the Auspitz phenomenon (after mechanical removal of a scale, small droplets of blood appear on the erythematous surface). Typical plaques are bilateral and symmetric, erythematous, dry, and scaling (silvery white scale) that favor extendor surfaces. Presentation may vary from a few localized psoriatic plaques to generalized skin involvement, to a life-threatening pustular psoriasis. The course of psoriasis is chronic and unpredictable. Plaques are the most common form of the disease and most (65%) have mild disease. While genetics appear to play a variable role in the development of psoriasis, the most significant triggers include environmental and behavioral factors such as cold weather, physical trauma, infections, stress, and drugs (lithium, beta-adrenergic blockers, antimalarial agents, angiotensin-converting enzyme inhibitors, and corticosteroid withdrawal).^{2, 7, 8, 9, 13} Given the increased deployment tempo to Africa, antimalarials are being prescribed to more and more military members. The 4-aminiquinolone compounds (chloroquine and hydroxychloroquine) are known to exacerbate existing psoriasis/psoriatic arthritis. In one review, 20 of 48 (42%) soldiers given cholorquine experienced an exacerbation of their psoriasis. Psoriasis is considered a contraindication for the use of chloroquine and hydroxychloroquine.¹⁴

Psoriasis distribution is usually symmetrical, and favors the elbows, knees, scalp, and sacrum. Palms, soles, nails and intertriginous (inverse psoriasis) areas can be involved. Guttate psoriasis is a form of psoriasis with typical lesions the size of water drops, 2 to 5 mm in diameter, that occur as an abrupt eruption following an acute infection, such as streptococcal pharyngitis, and usually in patients under 30. Chief complaints of psoriasis include: disfigurement, lowered self-esteem, being socially ostracized, pruritus and pain (especially palms, soles, and intertriginous areas), excessive scale, heat loss (with generalized lesions), and arthralgias.

Dermatologists may grade the severity of psoriasis on body surface area (BSA); less than three percent is mild, three to 10 moderate, and greater than 10 percent severe.¹⁵ The palm of the hand equals one percent of the skin. However, the severity of psoriasis is also measured by how psoriasis affects a person's quality of life. Psoriasis can have a serious impact even if it involves a small area, such as the palms of the hands or soles of the feet.

Treatment includes topical steroids, topical tar, topical vitamin D₃ (calcipotriene [Dovonex®]), topical retinoid (tazarotene [Tazorac®]), topical calcineurin inhibitors (pimecrolimus and tacrolimus), phototherapy, and systemic agents such as methotrexate, acitretin, or newer biologic immune response modifiers, such as adalimumab, etanercept and infliximab, for moderate to severe disease.¹⁶ Newer immunosuppressive agents such as ustekinumab (Stelara®), secukinumab (Cosentyx) or ixekizumab (Taltz) may also be considered, but are not approved for use in aircrew. Goal of therapy is to decrease body surface area, decrease erythema, scaling and thickness of plaques, improve quality of life and avoid adverse effects.¹⁷

Approximately 70 to 80% of all patients with psoriasis can be treated adequately with use of topical therapy. In cases of moderate-to-severe psoriasis (e.g. affecting large surface areas), the use of phototherapy, systemic drugs or both are more likely to be required. Management of each case needs to be individualized and may involve combinations of modalities.⁵

<u>Psoriatic Arthritis</u>: Psoriatic arthritis is one of the seronegative spondyloarthritis disorders, and as such, it is associated with a negative rheumatoid factor. It may precede (in children only), accompany, or more often, follow skin psoriasis. Estimates of the prevalence of psoriatic arthritis among individuals with psoriasis vary from 4 to 6 percent up to 30 percent; equal in female and male.¹⁸ Nail involvement occurs in more than 80% of patients with psoriatic arthritis, compared with 30% of patients with uncomplicated psoriasis.¹³ Approximately 20% of individuals with psoriatic arthritis develop destructive and potentially disabling disease.¹⁹

As in psoriasis, proinflammatory cytokines and activated T-cells are found in the affected tissues; namely synovium and joints. Joint symptoms include stiffness, inflammation and swelling. The most common areas involved include the distal interphalangeal joints and the spine.¹⁸ Pain is usually improved with physical activity. Over half of patients with psoriatic arthritis have radiographic abnormalities and nearly half of those recently diagnosed will have erosions within two years.²⁰ There are five recognized presentations of psoriatic arthritis:¹³

Туре	Percentage of all psoriatic arthritis	Features
Asymmetric oligo-arthritis (involving DIPs, PIPs and MCPs)	60 -70	Joints of fingers and toes ("sausage finger")
Symmetric polyarthritis	15	Clinically resembles rheumatoid arthritis, rheumatoid factor negative
Distal interphalangeal joint disease only	5	Mild, chronic, associated with nail disease
Destructive poly arthritis (arthritis mutilans)	5	Osteolysis of small bones of hands and feet; gross deformity; joint subluxation
Ankylosing spondylitis	5	With or without peripheral joint disease

**Table 2: Presentation of Psoriatic Arthritis** 

Treatment usually begins with nonsteroidal anti-inflammatory drugs (NSAIDs). Sulfasalazine, etanercept (Enbrel®), adalimumab (Humira®) and infliximab (Remicade®) are other waiverable medications used to treat psoriatic arthritis. Etanercept in one study resulted in 20% and 50% improvement in 59% and 37% of individuals, respectively.^{21, 22} Although etanercept may be administered at a dose of 25 mg twice a week, a dosage schedule of 50 mg once a week has shown similar efficacy and simplifies the regimen, particularly with the autoinjector dosage form. The drug is given in rotating fashion over the subcutaneous tissue of the thighs. Etanercept must be kept refrigerated between 36° to 46°F, for it degrades rapidly even at room temperature. Adalimumab also has demonstrated efficacy in the treatment of psoriatic arthritis and is FDA-approved for this indication. Typical dosing is 40 mg injected subcutaneously every other week. Handling of the

drug is similar to etanercept, but refrigeration requirements have recently changed (see www.humira.com).²³ Additional medications used for treatment such as methotrexate and cyclosporine are not waiverable.^{17, 21}

### **IV. Aeromedical Concerns.**

The main concerns are interference with wear of protective aviation equipment; distraction by pruritus or pain; triggering or exacerbation of the disease through repeated occupational trauma to the skin (Köebner's phenomenon); use of treatment medications that are incompatible with flying duties; unavailability of treatment in a deployed setting (ultraviolet light therapy); frequency of follow-up requiring excessive time lost from flying duties; and psychological factors. Although psoriasis usually spares the face and may not affect wear of a mask, scalp involvement is possible and may interfere with helmet use. Involvement of palms and soles may interfere with use of flight controls. Discomfort from pruritus or pain can be significant and the resulting distraction may jeopardize flight safety. These symptomas may also interfere with proper crew rest and lead to a subtle degradation of performance. Köebner's phenomenon may be caused by repeated rubbing or pressure including wear of a helmet or prolonged sitting in the cockpit.

While most topical treatments are well tolerated with few side effects, some may cause an irritant skin reaction. UVB phototherapy is well tolerated except for risk of burning and skin dryness. PUVA (oral photochemotherapy) short term side effects include nausea, dizziness, headache, pruritus, cutaneous and eye photosensitivity and long term side effect of increased risk of skin cancer. Joint involvement may interfere with use of flight controls, be a distraction due to discomfort, and limit egress ability. Some forms of therapy (e.g. ultraviolet light) may require several treatments per week, are not typically available in a deployed setting, and may require excessive time lost from flying duties. It is important to maintain awareness of the psychological aspect of this potentially disfiguring disease and its effect on the aviator's social situation.

Systemic treatments may have a range of significant side effects that are incompatible with flying duties in addition to the disqualifying nature of the severe forms of psoriasis. Methotrexate, because of serious toxicity involving multiple organs (e.g., lung, central nervous system), is not waiverable. Of the toxicities associated with anti-TNF therapy, those related to immunosuppression have been of greatest concern. The increased risk of developing demyelinating disease appears to be well within aeromedical standards. The same is true of lymphoma, and the latter would be unlikely to be of particular aeromedical concern. There is inconclusive evidence of possible increased risk for congestive heart failure in anticytokine therapy. Individuals on anti-TNF therapy are at greater risk of infectious complications, to include bacterial and granulomatous infections. Anti-TNF therapy should never be initiated in the setting of an infection, and before anti-TNF therapy is begun, a baseline HIV, hepatitis B and C profile and quantiferon gold TB test is required; for a positive quantiferon TB, antituberculous prophylaxis should be initiated.^{21, 23} Recommendations regarding duration of INH prophylaxis before beginning TNF-alpha inhibitors have been inconsistent. At the very least, consider withholding TNF-alpha inhibitors until an appropriate preventive regimen is established.²⁴

ICD-9 Codes for Psoriasis and Psoriatic arthritis		
696.0	Psoriatic arthropathy	
696.1	Psoriasis	
070.1	1 50110515	

ICD-10 Codes for Psoriasis and Psoriatic arthritis		
L40.59	Other psoriatic arthropathy	
L40.8	Other psoriasis	

### V. References.

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19. Gladman DD and Ritchlin C. Treatment of psoriatic arthritis. UpToDate. Sep 2016.

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22. Pickard JS. Infliximab (Remicade®) Memorandum for HQ AFMOA/SGPA, dated 19 Aug 09.

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# Abnormal Liver Enzymes and Gilbert Syndrome

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

## I. Waiver Consideration

Any type of chronic liver inflammation or chronic liver disease that reaches the threshold of clinical or operational significance is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Disqualifying conditions may include (but are not limited to) viral hepatitis, drug-induced or toxin-induced hepatitis, alcoholic hepatitis, autoimmune hepatitis, or non-alcoholic steatohepatitis (NASH). More specifically, any liver disease that meets any one of the following criteria is considered disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention:

- A. There is resultant impairment in liver synthetic function, or,
- B. There are resultant complications (e.g., portal hypertension, esophageal varices, bleeding dyscrasias, etc.), **or**,
- C. Requires specialty follow-up beyond six months.

In isolation, abnormal liver enzymes (e.g., elevations in aminotransferase levels, alkaline phosphatase, gamma-glutamyl transpeptidase (GGT), 5'-nucleotidase, or lactate dehydrogenase (LDH)) are not disqualifying. However, identification of abnormal liver tests necessitates further evaluation to determine a causative etiology, and the underlying diagnosis may be disqualifying. Asymptomatic Gilbert syndrome is not disqualifying, provided all clinically appropriate evaluation is complete and no other pathology is demonstrated.

Likewise, an isolated finding of asymptomatic hepatic steatosis on imaging is not disqualifying in the absence of hepatic inflammation or liver injury. To exclude ongoing inflammation or underlying injury, it is essential to demonstrate normal liver enzymes and synthetic function (i.e., normal AST, ALT, alkaline phosphatase, total and direct bilirubin, GGT, LDH, albumin, prothrombin time (PT), and INR). It is also essential that secondary causes of hepatic steatosis be appropriately excluded. For example, all patients with an incidental finding of hepatic steatosis on imaging warrant further testing for chronic viral hepatitis, screening for excessive alcohol consumption, screening for potential offending medications, supplements, or toxins, and other testing as the clinical scenario indicates (e.g., testing for iron overload, autoimmune hepatitis, etc.).

Cirrhosis that is associated with abnormal liver function studies or that requires specialist followup is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention, and it is generally not considered compatible with a waiver. Please refer to the Air Force Waiver Guide chapter *Hepatic Cirrhosis*. As above, other specific causes of liver disease may be disqualifying for certain career field duties and/or for retention. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide, including chapters *Chronic Viral Hepatitis* and *Hemochromatosis*. Sequelae of chronic liver disease may also be independently disqualifying. Please cross-reference the Medical Standards Directory for all potentially disqualifying conditions.

### **II. Information Required for Waiver Submission**

Not applicable. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for specific waiver submission requirements.

### **III. Aeromedical Concerns**

Liver enzymes that are commonly measured in the blood on laboratory testing include the aminotransferases (alanine aminotransferase (ALT) and aspartate aminotransferase (AST)), alkaline phosphatase, GGT, LDH, and 5'-nucleotidase. Abnormal liver enzymes are not disqualifying when considered in isolation. However, these enzymes are released into the blood stream when hepatocytes are injured or destroyed. The underlying disease states that result in elevations of liver enzymes may be associated with increased aeromedical or operational risk and thus be disqualifying for continued duty or for retention. Therefore, it is appropriate to consider abnormal liver studies as markers of acute or chronic medical conditions with potential serious aeromedical implications. It is essential that the etiology of aminotransferase elevations be elucidated in order to properly assess aeromedical and operational risk.

Common causes of elevated aminotransferase levels include the following: excessive alcohol consumption, chronic viral hepatitis, non-alcoholic fatty liver disease (NAFLD), steatohepatitis, hemochromatosis, toxins, drugs, ischemia, and celiac sprue. Other causes include Wilson disease, alpha-1 antitrypsin deficiency, and autoimmune hepatitis. Certain causes of liver injury resulting in elevations of liver enzymes are potentially reversible with removal of the offending agent, such as drug-induced liver injury, alcohol-related liver injury, and toxin-associated hepatitis. Other conditions are more chronic and often lead to progressive liver impairment, especially in the absence of optimal treatment. Such conditions as chronic viral hepatitis, hemochromatosis, Wilson disease, alpha-1 antitrypsin deficiency, autoimmune hepatitis, and celiac disease are all independently disqualifying and are associated with unique waiver considerations. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for additional information, including Air Force Waiver Guide chapters *Hepatic Cirrhosis*, Chronic *Viral Hepatitis*, and *Hemochromatosis*.

Symptoms or acute or chronic hepatitis may include fatigue, malaise, nausea, vomiting, diarrhea, and abdominal pain. Severe illness can lead to encephalopathy. Some individuals will progress to fulminant hepatic failure. At a minimum, these symptoms pose a risk of distraction from aviation and operational duties. Failure to appropriately diagnose the underlying etiology of abnormal liver studies and to perform risk stratification increases the chances of progression and complication of clinical and aeromedical or operational significance.

Gilbert syndrome is a benign condition characterized by isolated unconjugated (indirect) hyperbilirubinemia due to abnormal bilirubin glucuronidation. Typically, individuals are asymptomatic, although they may present with jaundice triggered by certain physiologic stressors such as dehydration, fasting, acute illness, menses, and physical exertion. A minority of patients may experience mild symptoms of vague abdominal discomfort, nausea, diarrhea, constipation, fatigue, or malaise. The hyperbilirubinemia of Gilbert syndrome is associated with increased risk of cholelithiasis. Asymptomatic Gilbert syndrome is not disqualifying, provided all clinically appropriate evaluation is complete and no other pathology is demonstrated. Individuals with symptoms require further evaluation to assess the impact of symptoms on duty performance.

Please use onl	Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
R74.0	Nonspecific elevation of levels of aminotransferase or lactic acid dehydrogenase [LDH]		
E80.7	Disorder of bilirubin metabolism, unspecified		

### **IV. Suggested Readings**

- Chalasani N, Younossi Z, Lavine JE, et al. The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance From the American Association for the Study of Liver Diseases. Hepatology 2018;67:328-357. Available at <u>http://aasldv2019stg.aasld.org/sites/default/files/2019-06/NAFLD%20Guidance%202018.pdf</u>. Accessed 12 January 2022.
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## **Celiac Disease**

Reviewed: Sep 2021

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: AIMWTS database review table.

## I. Waiver Consideration

Celiac disease is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Additionally, any malabsorption syndrome is disqualifying for all flying class and SWA duties. Malabsorption syndromes become disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention when they meet any one of the following criteria:

- A. Require a specialized diet that is not compatible with prolonged subsistence on meals-ready-to-eat (MREs), **or**,
- B. Symptoms persist despite medical treatment, or,
- C. Require frequent medical appointments, or,
- D. Result in ongoing specialist follow-up, or,
- E. Result in frequent missed duty time.

Symptoms associated with celiac disease may be independently disqualifying. For example, recurrent abdominal pain of sufficient severity to preclude satisfactory performance of duties, require frequent absences from duty, or necessitate frequent specialist follow-up is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Chronic diarrhea, regardless of cause, is disqualifying for all flying class and SWA duties. The use of any medication or supplement for symptom control that is not included on the applicable career field medication list is disqualifying for ongoing aviation or operational duty and would necessitate a waiver.

Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. There is no career field medication list for OSF or SWA personnel. However, as with the use of any medication or supplement in military members, the use of a prescription medication or supplement in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

In general, untrained personnel with a confirmed diagnosis of celiac disease are unlikely to be considered for an aeromedical waiver. Trained aircrew, GBO personnel, and special duty operators may be considered for a waiver after demonstrating adherence to a gluten-free diet and a period of asymptomatic stability.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority	Evaluation
FC I/IA	Any history of celiac disease	Unlikely	No
		AFRS/CMO	
FC II/III/ATC/	Celiac disease, adherent to a	Yes ¹	Yes ¹
GBO/OSF/SWA	gluten-free diet,	MAJCOM ³	
	asymptomatic without		
	complications or sequelae ²		

#### Table 1: Waiver potential for Celiac disease

1. Generally, untrained personnel are unlikely to receive an aeromedical waiver. An ACS review/evaluation is not required prior to disqualification.

- 2. Service member must be asymptomatic on a gluten-free diet and must demonstrate the ability to adhere to a gluten-free diet under the expected rigors of aviation and operational conditions.
- 3. Certification authority for untrained assets is AFRS/CMO, waiver authority for aeromedically unapproved medication use is AFMRA.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. List current medications with dosages.
  - c. Summarize diagnostic evaluation, including list of any/all procedures with dates.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of presentation and diagnostic evaluation, to date.
  - b. Assessment of adherence to and response to gluten-free diet. Include discussion of current degree of symptom control.
  - c. Physical examination, including thorough skin examination.
- 3. Laboratory studies required:
  - a. Current CBC and CMP.
- 4. Results of all testing performed in the course of diagnosis, evaluation, and management of celiac disease, including laboratory studies, imaging, endoscopy or colonoscopy reports, biopsy results (if performed), and any other ancillary studies.
  - a. Examples of additional studies that are often obtained in the evaluation of celiac disease include, but are not limited to, the following: esophagoduodenoscopy (EGD) with tissue biopsy, colonoscopy with tissue biopsy, total immunoglobulin A (IgA) level, anti-tissue transglutaminase (tTG) antibody, anti-endomysial antibody, and anti-gliadin antibody. These studies are not mandatory for waiver submission, all relevant test results should be forwarded with the waiver package.
- 5. Form FL4 with return to duty and ALC status, if member didn't meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include thorough skin examination.
  - b. Re-assessment of adherence to and response to gluten-free diet. Include discussion of current degree of symptom control.
  - c. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
- 2. All relevant interval consultation reports from the treating gastroenterologist, if applicable.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval endoscopy or colonoscopy reports, biopsy results (if performed), and any other ancillary tests. The following must be included:
  - a. Current CBC and CMP.
- 4. Form FL4 with return to duty and ALC status, if member didn't meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Celiac disease is an autoimmune condition that primarily causes gastrointestinal inflammation; however, extra-intestinal manifestations are not uncommon. Celiac disease may result in symptoms of abdominal discomfort or pain, bloating, and diarrhea. Additionally, it frequently leads to malabsorption that can precipitate weight loss and deficiencies of essential vitamins and nutrients, including vitamins A, D, E, K, B6, and B12, copper, zinc, thiamine, folic acid, ferritin, iron, magnesium, and selenium. The metabolic consequences of these deficiencies are manifold, with impacts on almost every organ system. Of particular aviation and operational concern are the risks of anemia, peripheral neuropathy, and osteoporosis. Anemia due to a combination of chronic inflammation and insufficient nutrients such as iron or vitamin B12 may be of insidious onset and result in subtle performance decrements, including reduced exertional capacity and impaired ability to tolerate hypoxia. Likewise, peripheral neuropathy may have a subtle onset and lead to loss of fine motor dexterity. Extra-intestinal symptoms of celiac disease include fatigue, headaches, neuropathy, neuropsychiatric disturbances, and rash (dermatitis herpetiformis). Rarely, occult gastrointestinal malignancies develop. Celiac disease may be associated with other autoimmune conditions such as type 1 diabetes mellitus or Hashimoto's thyroiditis. Although celiac disease is unlikely to result in sudden incapacitation, intestinal and extra-intestinal manifestations carry the potential to substantially interfere with the effective performance of aviation and operational duties.

Adherence to a gluten-free diet is the only validated method of eliminating inflammation and thereby controlling symptoms. Strict adherence to a gluten-free diet may be difficult or impossible under the rigors of an aviation or operational environment due to lack of access to gluten-free foods or lack of control over food sources. Symptom recurrence is usually due to poor dietary adherence or incidental exposure to gluten.

Review of the AIMWTS database from Sep 2019 through Sep 2022 revealed 34 cases with a diagnosis of celiac disease. The breakdown of the number of waivers and number of total cases are tabulated below. None of the four disqualifications were for reasons associated with the diagnosis of celiac disease.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		(# of waivers / total # of cases)					
		IFC I/IA	FC II	FC III	GBO	ATC	SWA
K90.0	Celiac Disease	0/1	13/13	12/13	2/3	2/3	1/1

### **IV. Suggested Readings**

- Bai JC, Ciacci C, et al. World Gastroenterology Organisation Global Guidelines: Celiac Disease. July 2016. Available at <u>https://www.worldgastroenterology.org/guidelines/celiac-disease/celiac-disease-english</u>. Accessed 6 September 2022.
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# **Chronic Viral Hepatitis**

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Capt Robert Wright (RAM 2023); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

## I. Waiver Consideration

Chronic hepatitis of any etiology is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties when there is either impairment in liver synthetic function or a need for specialty followup beyond six months. Chronic hepatitis that meets either of these criteria is also disqualifying for retention. Additionally, any viral hepatitis carrier state is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention, regardless of the presence or absence of liver dysfunction or the frequency of follow-up required. Generally, chronic viral hepatitis is not considered amenable for waiver in untrained assets. An aeromedical or operational waiver may be considered for trained assets after resolution of the acute phase of viral infection and following a period of demonstrated stability. A favorable waiver recommendation depends upon absence of any ongoing symptoms or sequelae of aeromedical concern, such as active hepatic inflammation or ongoing hepatocyte injury (characterized by transaminase elevations), functional hepatic impairment, or neuropsychiatric symptoms.

Cirrhosis secondary to chronic viral hepatitis that is associated with abnormal liver synthetic function, medical complications (e.g., portal hypertension, esophageal varices, bleeding dyscrasias, etc.), or that requires specialist follow-up is also disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Chronic viral hepatitis that has resulted in the development of liver cirrhosis is generally not considered compatible with a waiver.

Any medication used to treat chronic viral hepatitis that is not included on the career fieldspecific approved medication list is independently disqualifying. Waiver for such medications can be considered on a case-by-case basis for a waiver. However, it should be noted that individuals actively undergoing finite time-limited treatment courses for chronic viral hepatitis B or C (i.e.,pegylated interferon for the treatment of chronic hepatitis B or novel antiviral combination therapies for the treatment of chronic hepatitis C), are not amenable to any class of aeromedical or operational waiver during active treatment. Indefinite courses of daily oral nucleoside/nucleotide analogues (e.g., entecavir and tenofovir) used in the immunologic viral suppression of certain individuals with chronic hepatitis B have been waived on rare occasions.

Flying Class	Condition	Waiver Potential ACS Review of	
		Waiver Authority ¹	Evaluation
FC I/IA	Chronic Viral Hepatitis	No	No
	-	AFRS/CMO	
FC II/III/	Chronic Viral Hepatitis	Yes ²	Yes
ATC/GBO/	_	MAJCOM	
OSF/SWA			

Table 1: Waiver potential for Chronic Viral Hepatitis

1. Certification authority for untrained assets is AFRS/CMO.

2. Waiver may be considered after resolution of acute phase of viral infection and following a period of demonstrated stability without any persistent sequelae of aeromedical concern. Untrained applicants are generally considered not to have waiver potential.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of how the diagnosis was established, presenting features, and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of pertinent symptoms, including neuropsychiatric symptoms and fatigue, and comment on any impact to quality of life or occupational performance.
  - c. List all co-morbid conditions.
  - d. List all past treatments for hepatitis or its complications, including all medications, dosages, dates of administration, and any adverse effects.
  - e. List all current medications, dosages, dates of initiation, and any adverse effects.
- 2. Consultation reports from all treating specialists (e.g., gastroenterologist, hepatologist, infectious diseases specialist) and all subsequent consultation notes. These notes must include the following:
  - a. Description of any past treatment, with outcomes.
  - b. Recommendations for ongoing specialist follow-up, if any.
- 3. Laboratory studies required:
  - a. Current liver function tests, including both total and direct bilirubin
  - b. Current gamma-glutamyl transpeptidase (GGT)
  - c. Current lactate dehydrogenase (LDH)
  - d. All past liver function tests, with dates
  - e. Current prothrombin time and INR
  - f. Current CBC
  - g. Hepatitis B virus screening serologies:
    - i. Hepatitis B surface antigen
    - ii. Hepatitis B surface antibody

- iii. Hepatitis B core antibody
- h. If evidence of hepatitis B acute or chronic infection, the following is also required:
  - i. Hepatitis B e antigen
  - ii. Hepatitis B e antibody
  - iii. Hepatitis B core antibody (IgM)
  - iv. Total hepatitis B core antibody (IgM + IgG)
  - v. Quantitative hepatitis B viral DNA
- i. Hepatitis C antibody (screening)
- j. If history of hepatitis C viral infection, the following is also required:
  - i. Quantitative hepatitis C viral RNA (if treated for hepatitis C viral infection, include hepatitis C viral RNA level from 12 weeks post-treatment completion)
  - ii. Hepatitis C genotyping
- k. Hepatitis A antibody (IgG)
- 1. HIV 1 and 2 viral screening immunoassay
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of hepatitis, including any other laboratory studies, all imaging reports (e.g., liver ultrasound, CT, MRI, and/or elastography), biopsies/pathology results (if performed), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. <u>Renewal Waiver Request</u>:
  - 1. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
    - b. List all current medications, dosages, dates of initiation, and any adverse effects.
    - c. Describe any plans for ongoing surveillance/monitoring. Include any specialist clinical re-evaluations, laboratory studies, and/or imaging studies, and specify follow-up intervals.
  - 2. All relevant interval consultation reports from specialty providers (e.g., gastroenterologist, hepatologist, infectious diseases specialist).
  - 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, and any other ancillary tests.
  - 4. Form FL4 with return to duty and ALC status.
  - 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### **III. Aeromedical Concerns**

Aeromedical concerns related to viral hepatitis differ depending on whether the infection is acute or chronic in nature. Acute viral hepatitis causes a range of symptoms that may negatively impact aviation or operational duty performance. At best, mild symptoms may be distracting or result in mild impairment. At worst, the complications of acute viral hepatitis may be incapacitating. Symptoms include malaise, nausea, vomiting, diarrhea, and abdominal pain. When severe illness occurs, infected individuals may demonstrate encephalopathy and jaundice. Some individuals will progress to fulminant hepatic failure. In addition to symptom-directed supportive care, close monitoring is essential. As with any acute viral illness, a period of DNIF/DNIC/DNIA is advised until after complete resolution of symptoms. It is recommended that return to full operational status not be granted until after the complete resolution of both clinical and biochemical indicators of acute infection and hepatocyte injury (e.g., absence of symptoms and normalization of transaminase levels). Additionally, prior to return to full operational status, service members should undergo screening to exclude chronic viral carriage, which is observed following about 1-2% of acute hepatitis B infections and greater than 50% of acute hepatitis C infections.

Chronic hepatitis B or C viral infection is defined as a persistent carrier state beyond six months. Many individuals are asymptomatic. However, there is a high risk of progression to cirrhosis and hepatocellular carcinoma. About 25-40% of individuals with chronic hepatitis B and about 20-25% of individuals with chronic hepatitis C will eventually develop cirrhosis. These complications are not compatible with sustained aviation or operational duties. In order to optimize both the health of the infected service member and the possibility for a favorable waiver outcome, it is essential that individuals receive appropriate treatment, followed by surveillance for ongoing liver inflammation/hepatocyte destruction, as well as appropriate screening for progression or development of new complications. To optimize health outcomes and minimize occupational risk, individuals with chronic viral hepatitis should be appropriately immunized against pathogens that might precipitate further hepatic insult (e.g., hepatitis B or C, hepatitis A, influenza, and *S. pneumoniae*). Likewise, risk is mitigated by avoidance of other hepatotoxins (e.g., alcohol, excessive acetaminophen use). Risk is increased when other pathologic processes contribute to hepatic injury (e.g., hepatic steatosis, co-infection with HIV or another viral hepatitis).

With respect to chronic hepatitis B viral infection (HBV), in addition to the hepatic complications of the disease process, aeromedical concerns include extrahepatic sequelae and the adverse effects of treatment. Chronic HBV can be associated with immune-complex deposition. Depending on the organ systems affected, manifestations of immune-complex deposition include urticaria, arthritis, vasculitis, polyneuropathy, and glomerulonephritis. Any one of these syndromes may be incompatible with sustained flying or operational duties. The decision to treat chronic HBV depends upon multiple factors, including the presence or absence of cirrhosis, severity of alanine transaminase (ALT) elevation, quantitative viral load, and underlying patient-specific indications. Treatment for HBV requires careful management by a hepatologist or an experienced gastroenterologist. The goal of therapy is immunologic suppression, characterized by an undetectable quantitative HBV DNA titer and clearance of HBV surface antigen (HBsAg), as well as clearance of HBV e antigen (HBeAg) in those who were initially HBeAg positive.

HBV treatment regimens are complex and include weekly injections of subcutaneous pegylated interferon alfa-2a for 48 weeks or an indefinite course of a daily oral nucleoside/nucleotide analogue (e.g., entecavir, tenofovir alafenamide, tenofovir disoproxil fumarate, etc.). Side effects from any of these regimens pose serious aeromedical and operational risks, and active treatment may not be compatible with a waiver. Adverse effects while on pegylated interferon alfa-2a may include flulike illness, mood disturbance, cytopenias, infection, ischemic events, thyroid dysfunction, seizure, and hemorrhagic stroke. The use of oral nucleoside/nucleotide analogues can be associated with renal toxicity, lactic acidosis, pancreatitis, myopathy, headache, and fatigue, among other complications. These medications require close monitoring and follow-up with a specialist to assess for disease-related events and adverse effects of treatment, per guidelines established by the American Association for the Study of Liver Diseases (AASLD).

Like chronic HBV, chronic hepatitis C viral infection (HCV) is usually asymptomatic but can result in symptoms, sequelae, and extrahepatic manifestations that are not compatible with aviation or operational duties. Possible complications include, but are not limited to, vasculitis, kidney disease, diabetes, thyroid disease, and fatigue. Novel antiviral combination therapies such as glecaprevir-pibrentasvir, ledipasvir-sofosbuvir, and sofosbuvir-velpatasvir are associated with a favorable side effect profile and result in cure in more than 95% of patients. Similar to treatment for HBV, treatment for HCV requires close monitoring by an experienced specialist. However, the course of treatment with a novel antiviral regimen is shorter at 8-12 weeks. Individuals with diabetes or who are taking anticoagulant medications require closer monitoring due to hypoglycemia and bleeding risks. Waiver may be considered as early as 12 weeks following treatment completion for those individuals with an undetectable HCV RNA titer, normalization of liver function tests, and no other symptoms or complications related to the HCV infection or to antiviral therapy.

Cirrhosis and hepatic fibrosis are unfortunate consequences of chronic viral hepatitis that are not generally considered compatible with an aeromedical or operational waiver when there is evidence of abnormal synthetic liver function or serious complications. Serious sequelae include, but are not limited to, hepatic encephalopathy and variceal bleeding. Due to the associated complications that may arise suddenly and result in incapacitation with little or no warning, waivers are generally not entertained for chronic viral hepatitis that has resulted in the development of liver cirrhosis.

Review of the AIMWTS database from Jan 2019 through Jan 2022 revealed just 4 cases with a diagnosis of chronic viral hepatitis. A breakdown of the cases was as follows: 0 FC I/IA cases, 2 FC II cases (0 disqualified), 2 FC III cases (0 disqualified), 0 ATC cases, 0 GBO cases, and 0 SWA cases.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		
B18.1	Chronic Viral Hepatitis B	
B18.2	Chronic Viral Hepatitis C	
B18.8	Other Chronic Viral Hepatitis	

### **IV. Suggested Readings**

- 1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. Available at <u>http://www.hcvguidelines.org</u>. Accessed 12 January 2022.
- Ghany MG, Morgan TR, and the AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology 2020;71:686-721. Available at <u>https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep.31060</u>. Accessed 12 January 2022.
- Terrault NA, Lok ASF, McMahon BJ, et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. Hepatology 2018;67:1560-1599. Available at <u>https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep.29800</u>. Accessed 12 January 2022.
- 4. Wilkins T, Sams R, and Carpenter M. Hepatitis B: screening, prevention, diagnosis, and treatment. Am Fam Physician 2019;99:314-323. Available at <u>https://www.aafp.org/afp/2019/0301/p314.html</u>. Accessed 12 January 2022.





## **Crohn's Disease**

Reviewed: Oct 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Lt Col Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: Suggested readings (Section IV) updated.

## I. Waiver Consideration

Crohn's disease is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Generally, it is unlikely for untrained personnel to be considered eligible for aviation or operational duties. For trained personnel, factors that are considered when assessing suitability for waiver include, but are not limited to, the severity of the disease at time of diagnosis, whether there is evidence of clinical and endoscopic remission, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the individual service member's adherence to clinically indicated therapy, the individual's tolerance of treatment, the unique risks associated with the specific maintenance medication(s) utilized, and the cumulative risk of all associated complications and/or extra-intestinal disease manifestations.

Waiver may be considered once a service member is in disease remission on a stable, career field-approved medication regimen, without adverse effects. Individuals who are not adherent to an appropriate treatment regimen will not be considered waiver-eligible. Use of any medication not included on the career field-approved medication list is independently disqualifying and will be reviewed on a case-by-case basis.

There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of Crohn's disease in OSF and SWA personnel must be carefully evaluated for potential side-effects that might impact individual health or mission safety.

The presence of persistent endoscopic disease is associated with a higher risk of symptomatic recurrence, even when Crohn's disease is otherwise clinically quiescent. For this reason, individuals who achieve clinical remission but fail to demonstrate endoscopic remission are unlikely to be considered eligible for a waiver. For aeromedical and operational purposes, endoscopic remission is assessed either after completion of definitive treatment or while on stable maintenance therapy. For waiver consideration, endoscopic remission verification should include both visual (i.e., colonoscopic inspection) and histologic (i.e., tissue biopsy) demonstration of mucosal healing without evidence of active inflammation.

Any degree of small bowel involvement, including disease of the ileocolon, portends a higher risk of intestinal complications and generally proves more difficult to treat than Crohn's disease that is isolated to the colon. Computed tomography enterography (CTE) or magnetic resonance enterography (MRE) are often used during the initial phase of evaluation to assess for the presence of small bowel disease and to guide clinical decision-making. Prior to waiver

consideration, individuals with any history of small bowel involvement must demonstrate at least six months of asymptomatic stability and be without active intestinal complications (i.e., stricture, abscess, or fistula). Individuals with more than two prior surgeries for Crohn's disease is unlikely to be considered for waiver due to the high risk for future complications. Initial waivers for trained pilots with small bowel involvement and less than 12 months of demonstrated asymptomatic stability will be restricted to multi-place aircraft with another qualified pilot. Pilots who are granted an initial restricted waiver may be reconsidered for an unrestricted aeromedical waiver after 12 months of asymptomatic stability.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Crohn's disease of any degree	Unlikely AFRS/CMO	No
FC II/III/ATC/ GBO/OSF/SWA	Crohn's disease isolated to colon ^{2,3,4}	Yes ¹ MAJCOM ⁶	Yes ¹
	Crohn's disease with small bowel involvement (i.e., proximal GI, terminal ileum, or ileocolonic) ^{2,3,4,5}	Yes ¹ MAJCOM ⁶	Yes ¹

Table 1: Waiver potential for Crohn's disease

1. Generally, it is unlikely for untrained personnel to be considered eligible for aviation or operational duties.

2. For trained personnel, factors that are considered when assessing suitability for waiver include, but are not limited to, the severity of the disease at time of diagnosis, whether there is evidence of clinical and endoscopic remission, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the individual service member's adherence to clinically indicated therapy, the individual's tolerance of treatment, the unique risks associated with the specific maintenance medication(s) utilized, and the cumulative risk of all associated complications and/or extra-intestinal disease manifestations.

- 3. Clinical and endoscopic remission should be demonstrated prior to waiver consideration. For aeromedical and operational purposes, endoscopic remission is assessed either after completion of definitive treatment or while on stable maintenance therapy. For waiver consideration, endoscopic remission verification should include both visual (i.e., colonoscopic inspection) and histologic (i.e., tissue biopsy) demonstration of mucosal healing without evidence of active inflammation.
- 4. Use of any medication not included on the career field-specific approved medication list is independently disqualifying.
- 5. Individuals with small bowel involvement must be asymptomatic for six months, with no active intestinal complications (i.e., stricture, abscess, fistula), and with no more than two prior surgeries. Pilots with small bowel involvement will initially be considered for a restricted waiver to multi-place aircraft with another qualified pilot. An unrestricted waiver for pilots with small bowel involvement can be considered after 12 months of asymptomatic stability.
- 6. Certification authority for untrained assets is AFRS/CMO. Waiver authority for aeromedically unapproved medication use is AFMRA.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of ongoing symptoms (e.g., abdominal pain, diarrhea, stool frequency, hematochezia, melena, weight loss, frequency of exacerbations/pattern of recurrence, any known exacerbating factors, etc.).
  - c. Specify presence or absence of complications (e.g., bleeding, perforation, fistula, stricture, abscess, etc.).
  - d. Specify presence or absence of extra-intestinal manifestations (e.g., joint involvement, skin involvement, eye involvement, etc.).
  - e. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - f. List current medications with dosages.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course (including any history of surgery).
  - b. Discussion of current treatment, including dose, frequency, formulation, and all appropriate monitoring with schedule for follow-up (e.g., biologic agents require laboratory studies with a metabolic panel and CBC every 3-6 months and annual tuberculosis testing).
  - c. Documentation of the presence or absence of complications.
  - d. Documentation of the presence or absence of extra-intestinal manifestations.
  - e. Detailed plan of ongoing treatment and monitoring.
- 3. Laboratory studies required:
  - a. Current CBC.
  - b. Current CMP.
  - c. Current erythrocyte sedimentation rate (ESR).
  - d. Current C-reactive protein (CRP) level.
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of Crohn's disease (i.e., laboratory studies, imaging, ancillary studies).
  - a. Include procedural reports and pathology results from any and all diagnostic or surveillance colonoscopies/endoscopies that were performed.
  - b. Must include a repeat colonoscopy while clinically stable with visual and histologic demonstration of endoscopic remission.
  - c. Include radiology reports of any and all CTE and/or MRE studies performed.
- 5. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms, objective findings, or interval flares.
  - b. Specify presence or absence of complications (e.g., bleeding, perforation, fistula, stricture, abscess, etc.).
  - c. Specify presence or absence of extra-intestinal manifestations (e.g., joint involvement, skin involvement, eye involvement, etc.).
  - d. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
- 2. All relevant interval consultation reports from the treating gastroenterologist.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval colonoscopy/endoscopy reports and biopsy results, and any other ancillary tests. The following must be included:
  - a. Current CBC.
  - b. Current CMP.
  - c. Current erythrocyte sedimentation rate (ESR).
  - d. Current C-reactive protein (CRP) level.
- 4. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Crohn's disease is a chronic inflammatory disease that may affect any portion of the gastrointestinal (GI) tract. It generally follows a relapsing and remitting course. The "skip lesions" of Crohn's disease are one of multiple features that distinguishes it from ulcerative colitis (UC), which follows a contiguous pattern, usually beginning at the rectum. Crohn's disease may be isolated to the small bowel (i.e., proximal GI tract and/or terminal ileum), the large bowel, or may involve both the small and large bowel. Crohn's disease that is isolated to the small and large bowel is described as ileocolonic. Additionally, extra-intestinal manifestations of Crohn's disease are common. Systems that are often affected include the eyes (e.g., uveitis, iritis), skin (e.g., erythema nodosum, pyoderma gangrenosum), and musculoskeletal structures (e.g., arthritis, ankylosing spondylitis).

For clinical or investigational purposes, the severity of Crohn's disease and degree of disease activity/control at a given point in time may be assessed with a formulaic grading system. A commonly employed grading system is the Crohn's disease activity index (CDAI). This index combines subjective and objective information to generate a quantitative score. However, for aeromedical and operational purposes, these values are not routinely utilized.

The aeromedical and operational hazards associated with Crohn's disease stem from the unpredictability of the disease, its symptoms, and the risks associated with treatment regimen,

which may adversely affect duty performance, mission completion, and safety. Common symptoms of Crohn's disease include abdominal pain, bloating, diarrhea, hematochezia, weight loss, and fatigue. Adequate treatment that results in complete clinical and endoscopic remission with full suppression of active inflammation (e.g., negative serum inflammatory markers) can mitigate aeromedical and operational risk, provided that the potential consequences of maintenance therapy do not exceed acceptable waiver tolerances and there are no other complications of aeromedical or operational concern.

Several medications that are frequently used in the management of Crohn's disease are associated with a rate of severe adverse effects or with a need for clinical and laboratory monitoring that may not be compatible with sustained aviation or operational duty. Among these medications are systemic glucocorticoids, azathioprine, and 6-mercaptopurine. With the exception of time-limited utilization of some oral budesonide formulations, active treatment with systemic glucocorticoids is not amenable to aeromedical waiver. Additionally, the previous use of systemic glucocorticoids for more than three consecutive weeks in any 12 month period is independently disqualifying and requires demonstration of an intact hypothalamic-pituitaryadrenal (HPA) axis prior to waiver consideration. Please refer to the Aerospace Medicine Waiver Guide for Systemic Glucocorticoid (Steroid) Therapy. Waiver for azathioprine and 6mercaptopurine use may rarely be considered on a case-by-case basis for certain low-risk personnel (e.g., ATC and GBO duties). In other individuals, the risk of severe myelosuppression, pancreatitis, and hepatotoxicity must be examined closely for compatibility with continued aviation or operational duty. The likelihood of myelosuppression is greatest during the first year of treatment, and testing for thiopurine methyltransferase (TPMT) enzyme activity may assist with identifying individuals at highest risk of severe myelosuppression.

It should be noted that service members who elect to under-treat their Crohn's disease with the aim of avoiding non-approved medications will not be considered for an aviation or operational waiver. Though use of any medication not included on the career field-approved medication list is independently disqualifying, there are several effective medications that are approved for maintenance therapy of Crohn's disease in aircrew, ATC, and GBO personnel. These medications include mesalamine, sulfasalazine, infliximab, and adalimumab. Under-treatment of Crohn's disease leads to mild chronic active inflammation or frequent recurrent active inflammation and substantially increases the likelihood of both symptomatic acute flares and disease complications. At a minimum, symptoms such as fatigue, abdominal pain, and increased stool frequency would be expected to distract from the safe performance of aviation or operational duties. At worst, an acute flare of severe abdominal pain or diarrhea could be suddenly incapacitating. Furthermore, anemia due to a combination of chronic inflammation and/or occult blood loss may be of insidious onset and result in subtle performance decrements, including reduced exertional capacity and impaired ability to tolerate hypoxia.

In additional to the risk of chronic, low-grade symptoms and the increased likelihood of severe acute flares, individuals with under-treated or sub-optimally controlled Crohn's disease are more likely to develop intestinal complications as a result of chronic or recurrent inflammation. The risk of intestinal complication is also higher when small bowel involvement is present. These complications include perforations, fistulas, abscesses, and strictures. These intestinal complications, especially strictures, increase the risk of small bowel obstruction (SBO).

Recurrent abdominal surgery is another risk factor for SBO. Due to gas expansion at altitude, intraluminal gas and partial SBO may become acutely symptomatic, with sudden onset of severe and incapacitating abdominal pain and vomiting.

Historical estimates place the 10-year cumulative risk that those with small bowel involvement will requiring a major abdominal surgery between 40-55%. Newer data from the era of biologic therapy places this risk closer to 30%. Due to the high rate of acute complication with the potential for serious aviation or operational consequences, any history of small bowel involvement necessitates a waiver restriction for pilots (multi-place aircraft, with another qualified pilot). An unrestricted waiver for pilots with small bowel involvement can be considered after 12 months of asymptomatic stability. The risk of complication after repeated small bowel surgery are often considered to exceed waiver risk tolerances. Therefore, any service member with two or more small bowel surgeries for Crohn's disease will unlikely be considered eligible for aeromedical waivers.

For Crohn's disease, GI involvement may not be contiguous, and surgical resection is not considered curative. This lack of contiguous GI involvement contrasts with ulcerative colitis, which is characterized by an absence of skip lesions, and in which colectomy is often a definitive treatment. However, if a service member is treated with partial or total colectomy for Crohn's disease, a waiver may be considered, provided that the individual is asymptomatic without post-operative complication or persistent ostomy. Presence of a persistent ostomy is generally felt to be incompatible with continued aviation or operational duties.

In general, individuals pursuing a waiver for Crohn's disease are expected to demonstrate asymptomatic clinical stability, passing four or fewer bowel movements daily, without active complications, with normal inflammatory markers, and with no adverse effects of treatment that might significantly impact the performance of aviation or operational duties. Prior to waiver request, demonstration of clinical and endoscopic remission is required, regardless of whether remission is maintained spontaneously or through the use of career field-approved medications. Once an individual is asymptomatic (i.e., in clinical remission), endoscopic remission must be confirmed. Although repeat endoscopy to assess for mucosal healing is not always performed in clinical practice, the risk of disease flare-up or long-term complication is increased in individuals who do not achieve endoscopic remission, despite absence of symptoms.

Review of the AIMWTS database from Oct 2019 through Oct 2022 revealed 25 cases with a diagnosis of Crohn's disease. The breakdown of the number of waivers and number of total cases are tabulated below. The sole disqualification was not related to the member's diagnosis of Crohn's disease or a related complication.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		(# of waivers / total # of cases)					
		IFC I/IA	FC II	FC III	GBO	ATC	SWA
K50.9	Crohn's disease, unspecified	0/0	15/15	2/3	7/7	0/0	0/0

### **IV. Suggested Readings**

- Bernstein CN, Eliakim A, Fedail S, et al; Review Team. World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. J Clin Gastroenterol 2016;50:803-818. Available at <u>https://www.worldgastroenterology.org/UserFiles/file/guidelines/inflammatory-bowel-diseaseenglish-2015.pdf</u>. Accessed 18 October 2022.
- Farraye FA, Melmed GY, Lichtenstein GR, Kane SV. ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease. Am J Gastroenterol 2017;112:241-258. Erratum in: Am J Gastroenterol 2017;112:1208. Available at <u>https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Preventive_Care_in.15.aspx</u>. Accessed 18 October 2022.
- Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018;113:481-517. Erratum in: Am J Gastroenterol 2018;113:1101. Available at <u>https://journals.lww.com/ajg/Fulltext/2018/04000/ACG_Clinical_Guideline_Management_of_Crohn_s.10.asp</u> <u>x</u>. Accessed 18 October 2022.
- Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. J Crohns Colitis 2020;14:4-22. Available at <u>https://academic.oup.com/eccojcc/article/14/1/4/5620479?login=false</u>. Accessed 18 October 2022.





# **Diverticular Disease**

Revised: Aug 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

Any history of diverticulitis, symptomatic diverticulosis, or symptomatic Meckel's diverticulum is disqualifying for all flying class and SWA duties. Diverticulosis that is detected incidentally on imaging or colonoscopy obtained for another indication and that remains asymptomatic is not disqualifying. Diverticulosis and diverticulitis are not specifically disqualifying for GBO, ATC, or OSF personnel. Isolated diverticulosis and diverticulitis are not disqualifying for retention.

The symptoms of diverticular disease, its consequent complications, or its treatments may be disqualifying for continued aviation or operational duties or for retention. For example, gastrointestinal hemorrhage is disqualifying for all flying class, ATC, and SWA duties. Similarly, any history of partial colectomy is disqualifying for all flying class, ATC, and SWA duties. Post-colectomy hyper-defecation or the maintenance of an ostomy following colectomy is disqualifying for all flying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Recurrent abdominal pain of sufficient severity to preclude satisfactory performance of duties, require frequent absences from duty, or necessitate frequent specialist follow-up is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention.

Other possible complications of diverticular disease that may or may not be disqualifying for continued aviation or operational duties or for retention include, but are not limited to, intestinal strictures, peritoneal adhesions, fistula formation, intestinal perforation, and gastrointestinal bleeding. Please cross-reference the Medical Standards Directory and the appropriate Air Force Waiver Guide for all potentially disqualifying conditions and treatments.

A waiver for a history of symptomatic diverticular disease may be considered after completion of all clinically appropriate interventions and follow-up, as recommended by the treating specialist. Prior to waiver approval, individuals must demonstrate a period of asymptomatic stability, preferably without the need for aeromedically unapproved medications to control symptoms or prevent disease recurrence. To ensure that clinical management was appropriate and follow-up was sufficient, consultation with a gastroenterologist, general surgeon, or colorectal surgeon prior to waiver submission is required.

After resolution of an episode of acute diverticulitis, a colonoscopy to assess the degree of diverticulosis and to exclude colorectal cancer is generally medically recommended. As such, an individual requesting a waiver following an episode of acute diverticulitis will be required to provide a colonoscopy report performed after resolution of infection and inflammation. Please note that a colonoscopy is not required to establish the diagnosis of acute diverticulitis and can increase the risk of perforation if performed in the setting of active inflammation or infection. It

is advised that the follow-up colonoscopy be timed in accordance with specialist recommendations and established treatment guidelines.

Any recurrence of symptoms in an individual who was previously granted a waiver for diverticular disease invalidates the existing waiver, necessitates DNIF/DNIC/DNIA, and requires reconsideration of waiver prior to return to flight or operational status. Since the episodic recurrence may significantly alter the aeromedical or operational risk, all waivers for diverticular disease are invalidated by any symptom recrudescence, including previously granted indefinite waivers. Prior to waiver re-submission, all clinically recommended evaluations and interventions should be completed, and the individual should again demonstrate a period of asymptomatic stability.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Active or symptomatic, diverticulitis, diverticulosis, or Meckel's diverticulum ¹	No AFRS/CMO	No
	History of diverticulitis, symptomatic diverticulosis, or symptomatic Meckel's diverticulum, resolved without sequelae	Yes ² AFRS/CMO	No ⁴
FC II/III/SWA	Active or symptomatic, diverticulitis, diverticulosis, or Meckel's diverticulum ¹	No MAJCOM ³	No
	History of diverticulitis, symptomatic diverticulosis, or symptomatic Meckel's diverticulum, resolved without sequelae	Yes ² MAJCOM ³	No ⁴
ATC/GBO/OSF	History of diverticulitis, symptomatic diverticulosis, or symptomatic Meckel's diverticulum, resolved without sequelae	N/A ⁵	N/A

1. Active, persistent, or chronic symptoms of diverticular disease are not amenable to waiver.

2. A remote history of an isolated episode of diverticular disease may be compatible with an indefinite waiver.

3. Certification authority for untrained assets is AFRS/CMO.

4. ACS review may be requested at the discretion of the waiver authority.

5. While diverticulosis and diverticulitis are not specifically disqualifying for GBO, ATC, or OSF personnel, the symptoms of diverticular disease, its complications, or its treatments may be disqualifying. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide. See "Waiver Considerations," above.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of ongoing symptoms.
  - c. Specify presence or absence of complications (e.g., bleeding, perforation, fistula, abscess, etc.).
  - d. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - e. List current medications with dosages.
- 2. Consultation report from all treating specialists (e.g., gastroenterologist, general or colorectal surgeon), and all subsequent consultation notes.
- 3. Laboratory studies required:
  - a. Current CBC.
  - b. Current CMP.
- 4. Results of all testing performed during diagnosis, evaluation, and management of diverticular disease, including laboratory studies, imaging, and any other ancillary studies. Must include the following:
  - a. Colonoscopy report obtained after resolution of active infection and inflammation is required for all cases of acute diverticulitis, unless documentation from treating gastroenterologist or general surgeon supports that a colonoscopy is not clinically indicated, citing medical evidence.
  - b. Procedural reports and pathology results from all diagnostic or surveillance colonoscopies that were performed, as applicable.
  - c. Associated hospital records (e.g., admission history and physical, discharge summary), as applicable.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards for other associated conditions or complications.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Summarize any interval evaluation and/or treatment.
  - c. Document the presence or absence of new complications (e.g., bleeding, perforation, fistula, abscess, etc.).
  - d. List current medications with dosages.

- 2. All interval consultation reports from specialty providers (e.g., e.g., gastroenterologist, general or colorectal surgeon).
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval colonoscopy reports and biopsy results, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards for other associated conditions or complications.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

The symptoms and complications stemming from diverticular disease place a service member at significant risk of sudden incapacitation during the performance of aviation or operational duties. Symptoms of acute diverticulitis can be severe and disabling, if not life-threatening. The acute infection of diverticulitis may develop with very little prodrome and be rapidly progressive without prompt medical intervention. Initial symptoms may include severe abdominal pain, nausea, vomiting, constipation or diarrhea, and fever. Although mild diverticulitis can be safely treated in an outpatient setting, it requires very close medical monitoring to ensure that the infection is not worsening. Severe diverticulitis requires hospitalization and treatment with intravenous antibiotics to prevent complications such as sepsis, shock, abscess formation, colonic perforation, and even death.

Beyond diverticulitis, another serious, potentially life-threatening complication of diverticular disease that could swiftly lead to incapacitation in an aviation or operational environment is diverticular bleeding. The bleeding associated with diverticular disease tends to occur suddenly, and the amount of blood lost can be profound. Often, individuals are asymptomatic prior to the acute lower GI hemorrhage. With rapid and profuse blood loss, they may develop symptoms of hypovolemia and hemodynamic instability, including lightheadedness or dizziness, pre-syncope, syncope, and death. As with acute diverticulitis, acute diverticular bleeding necessitates immediate medical evaluation and intervention. Though many individuals will experience spontaneous cessation of hemorrhage, many require transfusion, and a single occurrence of diverticular bleeding increases future risk for re-bleeding.

Occasionally, individuals with diverticular disease develop chronic symptoms that might include distracting abdominal pain, constipation, or bloating. Persistent or recurrent inflammation increases the risk of complications, which include colonic strictures, fistulas, and perforations, as well as peritoneal adhesions. Due to the risks associated with both acute and chronic symptomatic diverticular disease, appropriate medical therapy is a priority. During periods of active or symptomatic diverticular disease, the aeromedical and operational risks exceed the acceptable threshold for continued duties, and DNIF/DNIC is necessary for all flying class and SWA personnel while undergoing appropriate medical and/or surgical evaluation and treatment. Given the risks described above, DNIF/DNIC/DNIA is also appropriate for GBO, ATC, and OSF personnel with active or symptomatic diverticular disease, although the condition is not specifically disqualifying for these career fields and does not require a waiver.

The symptoms, complications, and treatments associated with diverticular disease (e.g., recurrent abdominal pain, colectomy with or without colostomy, fistula formation, stricture, colonic perforation, gastrointestinal hemorrhage, etc.) may be independently disqualifying for continued aviation or operational duties or for retention. Please cross-reference the Medical Standards Directory and the appropriate Air Force Waiver Guide for all potentially disqualifying conditions and treatments.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 39 cases with a diagnosis of diverticulitis or diverticulosis. The breakdown of the number of waivers and number of total cases are tabulated below. The two FC II disqualifications were for reasons other than diverticular disease.

ICD-10	CD-10 Code		(# of waivers / total # of cases)				
		IFC I/IA	FC II	FC III	GBO		
K57.80	Diverticulitis of intestine, part unspecified, with perforation and abscess without bleeding						
K57.81	Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding						
K57.90	Diverticulosis of intestine, part unspecified, without perforation or abscess without bleeding	0	20/22	14/14	1/1		
K57.91	Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding						
K57.92	Diverticulitis of intestine, part unspecified, without perforation or abscess without bleeding						
K57.93	Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding						

## **IV. Suggested Readings**

- Francis NK, Sylla P, Abou-Khalil M, et al. EAES and SAGES 2018 consensus conference on acute diverticulitis management: evidence-based recommendations for clinical practice. Surg Endosc 2019;33:2726-2741. Available at <u>https://link.springer.com/content/pdf/10.1007/s00464-019-06882-z.pdf</u>. Accessed 16 August 2022.
- Hall J, Hardiman K, Lee S, et al., on behalf of the Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Treatment of Left-Sided Colonic Diverticulitis. Dis Colon Rectum 2020;63:728-747. Available at

https://journals.lww.com/dcrjournal/fulltext/2020/06000/the_american_society_of_colon_and_rectal_surgeons. 6.aspx. Accessed 16 August 2022.

- Murphy T, Hunt RH, Fried M, Krabshuis JH, and the WGO Practice Guidelines Committee. World Gastroenterology Organisation Practice Guidelines: Diverticular Disease. 2007. Available at <u>https://www.worldgastroenterology.org/UserFiles/file/guidelines/diverticular-disease-english-2007.pdf</u>. Accessed 16 August 2022.
- Stollman N, Smalley W, Hirano I, and AGA Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guideline on the Management of Acute Diverticulitis. Gastroenterology 2015;149:1944–1949. Available at <u>https://www.gastrojournal.org/article/S0016-5085(15)01432-8/pdf</u>. Accessed 16 August 2022.

**Eosinophilic Esophagitis and Other Eosinophilic Gastrointestinal Disorders (Feb 2021)** Authors/Reviewers: Maj Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

### I. Waiver Consideration

Eosinophilic esophagitis (EoE) and other eosinophilic gastrointestinal disorders (i.e., eosinophilic gastritis, eosinophilic enteritis, and eosinophilic colitis) are disqualifying for all flying class, GBO, ATC, and SWA duties. EoE and other eosinophilic gastrointestinal disorders are disqualifying for retention when they are complicated by any of the following: persistent symptoms; esophageal stricture; esophageal fibrostenosis; malabsorption that is refractory to treatment or results in malnutrition/weight loss; need for recurrent esophageal dilation or surgery; or frequent specialty follow-up more than annually.

Typically, an initial aeromedical waiver is considered once the member is in clinical and histologic remission. Because clinical symptoms do not directly correlate with histologic remission, and because evidence of histologic disease activity increases the risk of both future anatomic esophageal complications and recurrent clinical symptoms, maintenance pharmacologic therapy is required prior to waiver consideration in the absence of histologic remission. For waiver purposes, approved pharmacologic therapy includes acid-suppressing agents, antihistamines, topical corticosteroids administered via swallowed metered dose inhaler actuations, and montelukast. Please refer to the appropriate career field approved medication list. Other factors that are considered when assessing suitability for waiver include presence of anatomic complications (e.g., esophageal stricture, esophageal fibrostenosis, etc.), presence of comorbidities (e.g., food allergies, asthma, eczema, allergic rhinitis), and that treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines. Waiver for untrained assets in any flying or operational class may be considered on a case-by-case basis.

Flying Class	Condition	Waiver Potential ^{1,2}	ACS Review or
		Waiver Authority	Evaluation
FC I/IA	Eosinophilic esophagitis or	Yes	Yes
	any other eosinophilic	AFRS/CMO	
	gastrointestinal disorder		
FC II/III/SWA	Eosinophilic esophagitis or	Yes	Yes
	any other eosinophilic	MAJCOM	
	gastrointestinal disorder		
ATC/GBO	Eosinophilic esophagitis or	Yes	No ³
	any other eosinophilic	MAJCOM	
	gastrointestinal disorder		

Table 1: Waiver potential for EoE and other eosinophilic gastrointestinal disorders

1. Untrained assets may be eligible for waiver on a case-by-case basis. Certification authority for untrained assets is AFRS/CMO.

2. In the absence of histologic remission, maintenance pharmacologic therapy is required prior to waiver consideration.

3. ACS review may be requested at the discretion of the waiver authority.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 8. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of pertinent symptoms (e.g., dysphagia, food impaction, etc.).
  - c. Document all comorbidities (e.g., food allergies, asthma, eczema, etc.)
  - d. Medical history and all medications with dosages.
  - e. Summary of diagnostic evaluation, including list of any/all procedures with dates.
  - f. Specify current treatment regimen, if any. Include dosages, and comment on tolerance of treatment.
- 9. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of current treatment (e.g., dietary modifications, acid-suppressing agent, or topical corticosteroids) including dose, frequency, and formulation.
  - b. Documentation of the presence or absence of complications (e.g., esophageal stricture or fibrostenosis) and whether esophageal dilation was required.
  - c. Recommendations for disease surveillance.
- 10. If applicable, consultation report from an allergist (may be obtained to evaluate for food allergies).

- 11. Results of all testing performed in the course of diagnosis, evaluation, and management of EoE or other eosinophilic gastrointestinal disorder, including laboratory studies, imaging, and any other ancillary studies. The below-listed studies must be included:
  - a. All laboratory studies (e.g., CBC, CMP, and/or allergy testing (e.g., skin prick testing or serology)).
  - b. Radiology reports from all diagnostic or follow-up imaging studies, if applicable.
  - c. Procedural and biopsy reports from diagnostic and surveillance endoscopies.
- 12. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 13. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### B. <u>Renewal Waiver Request</u>:

- 7. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - c. Documentation of the presence or absence of complications (i.e., esophageal stricture or fibrostenosis) and whether esophageal dilation was required.
  - d. Plan for monitoring of recurrence.
- 8. All relevant interval consultation reports from specialty providers (e.g., gastroenterology, allergy).
- 9. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval endoscopy reports and biopsy results, and any other ancillary tests.
- 10. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 11. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### **III. Aeromedical Concerns**

Eosinophilic esophagitis (EoE) and other eosinophilic gastrointestinal disorders (i.e., eosinophilic gastritis, eosinophilic enteritis, and eosinophilic colitis) are characterized by chronic eosinophilic inflammation in the gastrointestinal tract leading to organ dysfunction and clinical symptoms. EoE is the most common disease among the eosinophilic gastrointestinal disorders. The pathogenesis of EoE remains incompletely understood, but it involves a complex interplay of genetic, immune, and environmental factors. Around 75% of individuals are atopic and demonstrate food allergen or aeroallergen sensitization. Other atopic disorders of aeromedical significance may be present (e.g., asthma, eczema, allergic rhinitis).

The diagnosis of EoE is based on the combination of clinical symptoms, histologic demonstration of elevated tissue eosinophils in biopsied mucosa (defined as 15 or more eosinophils per high-power field), and the exclusion of other disorders that could cause or

contribute to esophageal eosinophilia. Previously, to establish a diagnosis of EoE, an individual was required to demonstrate failure of improvement with proton-pump inhibitor (PPI) therapy. However, recent guidelines acknowledge that both PPI-responsive esophageal eosinophilia (PPI-REE) and "classic" EoE present with similar clinical, endoscopic, and histologic features. Thus, PPI-REE likely represents a subset of EoE. Gastroesophageal reflux-disease (GERD) is independently associated with esophageal eosinophilia. However, GERD frequently co-exists with EoE and PPI-REE.

The aeromedical and operational risk associated with any untreated eosinophilic gastrointestinal disorder stems from the potential that symptoms or complications may occur during the course of duties, resulting in a threat to flying or operational safety. Individuals with uncontrolled eosinophilic gastrointestinal disorders may experience dysphagia, food impaction, chest pain, emesis, anorexia, abdominal pain, or diarrhea. At the least, symptoms may be distracting and result in impaired duty performance. At the worst, complications such as food impaction may result in acute incapacitation. The long-term complications that may arise in the setting of undertreated disease include esophageal strictures, fibrostenosis, and malabsorption. The longer an eosinophilic gastrointestinal disorder such as EoE remains under-treated, the greater the likelihood for structural complications and the greater the risk for serious events such as dysphagia or food impaction. Under-treated individuals are at higher risk of needing an urgent or emergent endoscopy for indications such as food bolus removal or esophageal dilation. Depending on the local operational environment, these invasive procedures may not be readily available.

The main therapeutic options for EoE are dietary modification and pharmacotherapy with either a PPI, topical corticosteroid, or both. Dietary approaches include the empiric elimination of the six most common food allergens (cow's milk, egg, soy, wheat, peanut/tree nut, and fish/shellfish) or the elimination of specific foods based on the results of allergy testing. Interestingly, a greater percentage of individuals with EoE achieve induction and maintenance of clinical and histologic remission with an empiric six-food elimination diet compared to allergy testing-directed dietary elimination (75% versus 33% of individuals, respectively). However, adherence to a six-food elimination diet is difficult to maintain.

PPI therapy results in successful induction of histologic remission in about 40-50% of individuals. Although the dosing and duration of treatment are not well-defined by existing clinical trials, long-term treatment with the lowest effective dose is recommended for aeromedical purposes due to the high percentage of individuals who develop recurrent symptoms after PPI discontinuation. Long-term PPI therapy is typically well tolerated, and recent prospective studies failed to demonstrate an association with significant metabolic (e.g., decreased bone mineral density) or nutritional (e.g., hypomagnesemia, low vitamin B-12 levels) adverse effects. However, enteric complications such as *C. difficile* colitis are slightly higher in individuals on extended duration PPI therapy.

Finally, topical corticosteroids are effective in inducing and maintaining clinical and histologic remission in a subset of individuals with EoE. Long-term treatment with topical corticosteroids is well tolerated without significant aeromedical adverse effects. Studies examining the long-term

consequences of prolonged topical corticosteroid use in pediatric patients demonstrated an association with the development of adrenal insufficiency. However, the risk of adrenal insufficiency in adults is low. Thus, routine testing of the hypothalamus-pituitary-adrenal axis to assess for secondary adrenal insufficiency is not recommended for aeromedical purposes, unless otherwise clinically indicated.

Review of the AIMWTS database from Feb 2016 through Feb 2021 revealed 316 cases with a diagnosis of EoE or other eosinophilic gastrointestinal disorder. A breakdown of the cases was as follows: 9 FC I/IA cases (8 disqualified), 159 FC II cases (3 disqualified), 100 FC III cases (9 disqualified), 16 ATC cases (3 disqualified), 23 GBO cases (1 disqualified), and 9 SWA cases (1 disqualified). Of the 17 disqualified cases involving trained individuals, most were disqualified for reasons other than the EoE or other eosinophilic gastrointestinal disorder.

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes				
K20.0	Eosinophilic esophagitis			
K52.81	Eosinophilic gastritis or gastroenteritis			
K52.82	Eosinophilic colitis			

### **IV. Suggested Readings**

- Dellon ES, Gonsalves N, et al. ACG Clinical Guideline: Evidence Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esopagitis (EoE). Am J of Gastroenterol 2013;108:679-692. Available at <u>https://ncbi.nlm.nih.gov/pubmed/23567357</u>. Accessed 16 February 2021.
- Lucendo AJ, Molina-Infante J, et al. Guidelines on eosinophilic esophagitis: evidence-based statements and recommendations for diagnosis and management in children and adults. United European Gastroenterol J 2017;5:335-358. Available at <u>https://ncbi.nlm.nih.gov/pmc/articles/PMC5415218/</u>. Accessed 16 February 2021.
- Hirano I, Cha ES, et al. Clinical Practice Guidelines: AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esopahgitis. Gastroenterology 2020;158:1776-1786. Available at <u>https://www.gastrojournal.org/article/S0016-5085(20)30265-1/fulltext</u>. Accessed 16 February 2021.

### Esophagitis, Including Gastroesophageal Reflux Disease (GERD) (Feb 2021)

Authors/Reviewers: Dr. Christopher Keirns, Maj Laura Bridge, and Maj Luke Menner (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

**Significant Changes:** Waiver guide restructured; updated to reflect the most recent MSD; *Esophagitis* and *GERD* waiver guides combined.

### I. Waiver Consideration

Esophagitis of any etiology that requires treatment beyond the anti-reflux medications included in the appropriate career field approved medication list *or* is associated with anatomic or functional esophageal disease is disqualifying for all flying class, GBO, ATC, and SWA duties. Examples of disqualifying anatomic or functional complications include (but are not limited to) the following: esophageal diverticulum, varices, fistula, stricture, Barrett's esophagus, pronounced dilation, achalasia, or dysmotility. Any esophageal disease that is uncontrolled despite maximum medical or surgical therapy *or* that results in malnutrition or weight loss *or* that requires frequent specialty follow-up more than annually *or* that results in recurrent esophageal dilation or surgery is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention.

Anti-reflux medications that are approved for aircrew and GBOs are specified in the *Official Air Force Aerospace Medicine Approved Medications* lists. All duty classes are permitted to make occasional over-the-counter (OTC) use of approved histamine-2 receptor antagonists (H-2 blockers) and proton pump inhibitors (PPIs) for the relief of minor, self-limited heartburn symptoms. However, flight medicine evaluation is required for use of these medications beyond two doses per week or for any symptoms lasting more than 48 hours. Chronic utilization of career field approved anti-reflux medications for uncomplicated GERD does not require waiver if symptomatic control is confirmed and there is no other disqualifying esophageal disease or complication present.

Typically, aeromedical waivers for esophagitis are considered once clinical and histologic remission is confirmed. Other factors that are considered when assessing suitability for a waiver include the presence or absence of anatomic complications (e.g., esophageal stricture, Barrett's esophagus, etc.), whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, and whether non-approved medications are required to sustain remission.

Table 1: Waiver potential for Esophagitis, including Gastroesophageal Reflux Disease (GERD)

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Uncomplicated GERD controlled with approved medications	N/A	N/A
	GERD treated surgically; GERD requiring unapproved medication(s) for control; or complicated GERD	No AFRS/CMO	No
	Non-GERD esophagitis ¹	Yes AFRS/CMO	Yes
FC II/III/SWA ²	Uncomplicated GERD controlled by approved medications	N/A	N/A
	GERD treated surgically; Non-GERD esophagitis; or complicated GERD ^{1,3}	Yes MAJCOM	Yes
	GERD requiring unapproved medication(s) for control ⁴	Yes AFMRA	Yes
ATC/GBO ²	Uncomplicated GERD controlled by approved medications	N/A	N/A
	GERD treated surgically; Non-GERD esophagitis; or complicated GERD ¹	Yes MAJCOM	No ⁵
	GERD requiring unapproved medication(s) for control ⁴	Yes AFMRA	No ⁵

1. Waivers for esophagitis due to an etiology other than GERD are considered on a case-by-case basis. Please refer to the Aerospace Medicine Waiver Guide chapter on *Eosinophilic Esophagitis and Other Eosinophilic Gastrointestinal Disorders*, if appropriate.

2. Untrained assets may be eligible for waiver on a case-by-case basis. Certification authority for untrained assets is AFRS/CMO.

3. Unrestricted FC II waivers are unlikely for aviators treated with magnetic sphincter augmentation (LINX®). See the below section on "Aeromedical Concerns" for further discussion.

4. Waivers for the use of non-approved medications may be considered on a case-by-case basis.

5. ACS review may be requested at the discretion of the waiver authority.

### II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of pertinent symptoms (e.g., dysphagia, odynophagia, food impaction, emesis, weight loss, anorexia, hematemesis, melena, hematochezia, etc.).
  - c. Medical history and all medications with dosages.
  - d. Summary of diagnostic evaluation, including list of any/all procedures with dates.
  - e. Specify current treatment regimen, if any. Include dosages, and comment on tolerance of treatment.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of current treatment (e.g., dietary modifications, anti-reflux medication, etc.) including dose, frequency, and formulation.
  - b. Documentation of the presence or absence of complications (e.g., esophageal stricture, Barrett's esophagus, past history of esophageal dilation, etc.).
  - c. Recommendations for disease surveillance.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of esophagitis, including laboratory studies, imaging, and any other ancillary studies.
  - a. Include procedural reports and pathology results from any and all diagnostic or surveillance endoscopies that were performed.
  - b. Include results of *H. pylori* testing, if available.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
  - 1. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
    - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
    - c. Documentation of the presence or absence of complications (e.g., esophageal stricture, Barrett's esophagus, need for esophageal dilation, etc.).
    - d. Plan for monitoring of recurrence.
  - 2. All relevant interval consultation reports from the treating gastroenterologist, if applicable.

- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval endoscopy reports and biopsy results, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### **III. Aeromedical Concerns**

Esophagitis refers to inflammation of the esophageal mucosa that can result from the reflux of gastric contents, certain infectious organisms, corrosive agents, irradiation, or direct contact with swallowed pills. The two most common causes of esophagitis in the USAF population are GERD and eosinophilic esophagitis (EoE). Please refer to the Aerospace Medicine Waiver Guide chapter on *Eosinophilic Esophagitis and Other Eosinophilic Gastrointestinal Disorders* for additional information.

The aeromedical concerns related to esophagitis are manifold and range from mildly distracting symptoms to acute complications that might be severe or life-threatening in the aviation or operational environment. In many cases, the pain of acid reflux causes mild or moderate annoyance. However, it can also be severe enough to mimic an acute coronary syndrome, and it is a frequent cause of non-cardiac chest pain presenting in an emergency department setting. Likewise, the aspiration of refluxed gastric acid may result in choking or coughing symptoms ranging from mild to incapacitating. Other serious complications of esophagitis include food impaction, esophageal perforation, and massive gastrointestinal hemorrhage. Untreated or undertreated esophagitis can lead to the development of esophageal cancer, which is itself associated with pain, dysphagia, odynophagia, esophageal obstruction, and hemorrhage. Depending on the underlying etiology of the esophagitis, there may be additional aeromedical concerns.

The aviation environment can result in physiologic stresses that increase the intra-abdominal pressure and alter the pressure gradient between the abdomen and thorax, resulting in worsening of gastroesophageal reflux. Among the factors that are implicated in the exacerbation of reflux are increased gravitational forces and abdominal muscle contraction. Symptoms of chest pain, coughing, and choking are likely to be potentiated during flight in individuals with under-treated esophagitis. Most often, these symptoms will not result in sudden incapacitation. However, they are still of significant concern, particularly for pilots of high-performance single-seat aircraft that lack crew redundancy.

Chronic esophagitis can lead to anatomical changes such as stricturing, which elevate the risk of dysphagia and food impaction. Chronic esophagitis may also result in Barrett's esophagus, or metaplasia of the esophageal mucosa, which portends a low but increased risk of progression to esophageal adenocarcinoma and often requires frequent endoscopic surveillance. Rarely, esophageal perforation or ulceration may cause massive gastrointestinal hemorrhage which could lead to sudden incapacitation. In the event that definitive medical care cannot be quickly accessed, brisk gastrointestinal bleeding can be fatal.

There are multiple medications approved for use in aircrew and other operators that can effectively control esophagitis in order to eliminate symptoms and mitigate the risk of complications. Examples of approved medications that both control symptoms and prevent functional and anatomic complications include PPIs, H-2 blockers, and sucralfate. Although OTC antacids such as calcium carbonate (e.g., Tums®) or magnesium hydroxide (e.g., Mylanta®, Maalox®) are safe for use in the aeromedical environment, reliance on such medications to treat breakthrough symptoms may indicate ongoing esophageal inflammation that could progress if the underlying cause of the esophagitis is not addressed. It is recommended that any service member requiring frequent OTC antacids be evaluated in the flight medicine clinic and that more aggressive therapy and/or specialist consultation with a gastroenterologist be considered.

Gastroesophageal reflux that is refractory to treatment with PPIs may be intervened upon surgically. Usually, surgical candidates must demonstrate inadequate symptom control or endoscopic findings of persistent esophagitis despite maximal pharmacologic acid suppression. There is no current consensus regarding a best surgical intervention for all patients with treatment-refractory GERD. Factors that influence the choice of procedure include disturbance of esophageal motility, prior surgical history, esophageal length, and the experience of the operating surgeon. For a patient with normal esophageal length and motility, the historical procedure of choice is laparoscopic Nissen fundoplication. However, magnetic sphincter augmentation (LINX®) is an alternative FDA-approved intervention for refractory GERD that has been gaining in popularity since 2012. An implanted LINX® device works by augmenting the lower esophageal sphincter (LES) with a ring of magnets. The attraction of the magnets increases the LES closure pressure while permitting the passage of food with swallowing.

From an aeromedical perspective, there are concerns about the potential for LINX® device migration and resultant complications in high-performance aviation environments. Waivers may be considered on a case-by-case basis for non-high performance aviators after resolution of any post-procedural dysphagia or bloating. Again, there is insufficient evidence to strongly advocate for one surgical procedure over another for the treatment of refractory GERD. Therefore, it is reasonable to weigh an aviator's career field and flight environment in medical decision making under these circumstances.

Review of the AIMWTS database from Feb 2016 through Feb 2021 revealed 108 cases with a diagnosis of esophagitis (excluding eosinophilic esophagitis). A breakdown of the cases was as follows: 2 FC I/IA cases (2 disqualified), 52 FC II cases (1 disqualified), 38 FC III cases (7 disqualified), 5 ATC cases (1 disqualified), 3 GBO cases (0 disqualified), and 8 SWA cases (1 disqualified).

Please use *only* these ICD-10 code for AIMWTS coding purposes

K20.9	Esophagitis, unspecified
K21.0	Gastro-esophageal reflux disease with esophagitis

### **IV. Suggested Readings**

- Hunt R, Armstrong D, et al. World Gastroenterology Organization Global Guidelines GERD Global Perspective on Gastroesophageal Reflux Disease. J Clin Gastroenterol 2017;51:467-478. Available at <u>https://journals.lww.com/jcge/fulltext/2017/07000/World_Gastroenterology_Organisation_G</u> lobal.5.aspx. Accessed 18 February 2021.
- Muthusamy VR, Lightdale JR, et al. The role of endoscopy in the management of GERD. Gastrointest Endosc 2015;81:1305-1310. Available at https://www.giejournal.org/article/S0016-5107(15)00147-9/pdf. Accessed 18 February 2021.
- 3. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-328. Available at <a href="https://journals.lww.com/ajg/Fulltext/2013/03000/Guidelines_for_the_Diagnosis_and_Management_of.6.aspx">https://journals.lww.com/ajg/Fulltext/2013/03000/Guidelines_for_the_Diagnosis_and_Management_of.6.aspx</a>. Accessed 18 February 2021.
- 4. Shaheen NJ, Falk GW, Iyer PG and Gerson L. Diagnosis and management of Barrett's esophagitis. Am J Gastroenterol 2016;111:30-50. Available at <a href="https://journals.lww.com/ajg/fulltext/2016/01000/acg_clinical_guideline_diagnosis_and_ma_nagement.17.aspx">https://journals.lww.com/ajg/fulltext/2016/01000/acg_clinical_guideline_diagnosis_and_ma_nagement.17.aspx</a>. Accessed 18 February 2021.





## Hemochromatosis

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

## I. Waiver Consideration

Hemochromatosis is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. FC I/IA applicants are not thought to have waiver potential. Untrained FC III, ATC, GBO, OSF, and SWA applicants may be considered for waiver on a case-by-case basis, provided that there was never evidence of end-organ damage at any time during diagnostic evaluation or throughout course of treatment, and provided that they are stable on a maintenance phlebotomy regimen. Factors considered when assessing suitability for waiver for any individual with hemochromatosis include whether the treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the degree and stability of iron control, the frequency of therapeutic phlebotomy, and the presence of complications (e.g., cirrhosis, diabetes mellitus or other diseases of endocrine dysfunction, cardiac conduction abnormalities or arrhythmias, cardiomyopathy, refractory arthropathy, etc.). The sequelae of iron deposition in various tissues throughout the body may result in complications that are independently disqualifying for continued aviation, ground based, or operational support duties, and/or for retention. Cross-reference the Medical Standards Directory for all potentially disqualifying sequelae.

Periodic phlebotomy to maintain iron stores in an appropriate range and thereby reduce tissue deposition and long-term adverse health outcomes requires a 72-hour DNIF after each phlebotomy in all FC II, FC III, and OSF personnel. An 8-hour DNIF/DNIC is required after each phlebotomy for RPA pilots, ATC, and SWA personnel; and a 4-hour DNIF/DNIA is required after each phlebotomy for RPA sensor operators and MOD personnel.

Flying Class	Condition	Waiver Potential ¹	ACS Review or
		Waiver Authority	Evaluation
FC I/IA	Hemochromatosis	No	No
		AFRS/CMO	
FC II/III	Hemochromatosis, stable,	Yes	Yes
	without end-organ dysfunction ²	AFMRA ³	
ATC/GBO/OSF/	Hemochromatosis, stable,	Yes	No ⁴
SWA	without end-organ dysfunction ²	AFMRA ³	

Table 1: Waiver potential for Hemochromatosis

1. FC I/IA applicants are generally not considered eligible for a waiver. Waiver for other untrained individuals may be considered on a case-by-case basis with ACS review.

Maintenance phlebotomy requires DNIF, DNIC, or DNIA after each phlebotomy (i.e., 72-hr DNIF for FC II, FC III, and OSF personnel, 8-hr DNIF/DNIC for RPA pilot, ATC, and SWA personnel, and 4-hr DNIF/DNIA for RPA sensor operators and MOD personnel)

3. Certification authority for untrained assets is AFRS/CMO.

4. ACS review may be requested at the discretion of the waiver authority.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

**NOTE:** It is required that all original cardiac imaging and electrical tracings be submitted to ACS Cardiology for independent review. Electronic submission to the ECG Library is preferred. If electronic submission is not possible, electronic media can be sent via USPS or FedEx to the address below. Please include the service member's name, full social security number, date of mailing, and a POC at the submitting flight surgeon's office with all mailed materials. State in the AMS the date of submission.

Attn: Case Manager for [specify the appropriate MAJCOM] USAFSAM/FECI Facility 20840 2510 Fifth Street Wright-Patterson Air Force Base, OH 45433-7913

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of how the diagnosis was established, presenting features, and all pertinent physical findings (positive and negative).
  - b. Specify the presence or absence of symptoms at initial presentation and throughout evaluation/treatment course; include the original indication for genetic testing.

- c. Include a comprehensive review of symptoms and physical examination addressing the following systems: cardiac, gastrointestinal/abdominal, endocrine, neuropsychiatric, musculoskeletal.
- d. Summary of diagnostic evaluation, including list of any/all treatments with dates.
- e. Medical history and all medications with dosages.
- 2. Consultation reports from all treating specialists (e.g., gastroenterologist, hepatologist, geneticist if applicable, cardiologist if applicable) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course.
  - b. Detailed plan of ongoing treatment and monitoring. Include frequency of maintenance phlebotomy, if required.
  - c. Specify presence or absence of complications (e.g., hepatic fibrosis, cirrhosis, cardiac conduction abnormalities or arrhythmias, cardiomyopathy, diastolic dysfunction, heart failure, diabetes mellitus, hypothyroidism, other endocrine dysfunction).
  - d. If laboratory liver studies are abnormal (e.g., elevations of transaminase levels, alkaline phosphatase, gamma-glutamyl transpeptidase, or lactate dehydrogenase; abnormalities in markers of synthetic liver function such as albumin or prothrombin time) OR if ferritin is greater than 1000 ng/mL, a statement from a gastroenterologist or hepatologist defining criteria for liver biopsy is required.
- 3. Laboratory studies required:
  - a. Current BMP
  - b. Current liver function tests, including both total and direct bilirubin
  - c. Current gamma-glutamyl transpeptidase (GGT)
  - d. Current lactate dehydrogenase (LDH)
  - e. Current iron studies, including total serum iron, ferritin, serum transferrin, and transferrin saturation
  - f. Current prothrombin time (PT) and INR
  - g. Current CBC
  - h. Current TSH
  - i. All past BMP, liver function tests, GGT, LDH, iron studies, ferritin, PT, INR, CBC, and TSH results, with dates
  - j. Genetic test results, if obtained
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of hemochromatosis, including other laboratory studies, all imaging reports (e.g., liver ultrasound, CT, MRI, and/or elastography), biopsies/pathology results (if performed), and any other ancillary studies.
  - a. ECG, transthoracic echocardiogram, and 24-hour Holter monitor MUST be included for all FC II waiver requests (see note above).
- 5. Form FL4 with return to duty and ALC status.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
- 2. All relevant interval consultation reports from specialty providers (e.g., gastroenterologist, hepatologist). These notes must include the following:
  - a. Detailed plan of ongoing treatment and monitoring. Include frequency of maintenance phlebotomy, if required.
  - b. Specify presence or absence of complications (e.g., hepatic fibrosis, cirrhosis, cardiac conduction abnormalities or arrhythmias, cardiomyopathy, diastolic dysfunction, heart failure, diabetes mellitus, hypothyroidism, other endocrine dysfunction).
  - c. If laboratory liver studies are abnormal (e.g., elevations of transaminase levels, alkaline phosphatase, gamma-glutamyl transpeptidase, or lactate dehydrogenase; abnormalities in markers of synthetic liver function such as albumin or prothrombin time) OR if ferritin is greater than 1000 ng/mL, a statement from a gastroenterologist or hepatologist defining criteria for liver biopsy is required.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, and any other ancillary tests. The following must be included:
  - a. Current BMP
  - b. Current liver function tests, including both total and direct bilirubin
  - c. Current prothrombin time and INR
  - d. Current CBC
  - e. Current iron studies, including total serum iron, ferritin, serum transferrin, and transferrin saturation
- 4. Form FL4 with return to duty and ALC status.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

## **III. Aeromedical Concerns**

Hemochromatosis is a state of excess total body iron (i.e., iron overload). Typically, the term hemochromatosis is used to refer to hereditary hemochromatosis (HH) a genetic disorder characterized by a mutation in the HFE gene that results in an increase in the intestinal absorption of iron. Hereditary hemochromatosis is an autosomal recessive disorder with low penetrance. Many different mutations of the HFE gene are described in medical literature, but not all HFE genotypes lead to phenotypic iron overload. Two of the most common HFE mutations identified in individuals with phenotypic hemochromatosis are C282Y and H63D. Among those with HH, individuals with homozygous C282Y mutations account for more than 90% of those with clinically significant iron overload. There are other genotypes that portend a higher likelihood of clinical disease, including compound heterozygosity for the C282Y and H63D mutations.

HFE gene mutations and their phenotypic expression are of aeromedical and operational significance due to the risk of serious medical complications associated with iron overload. When total body iron is elevated, the excess iron is deposited in various tissues, including cardiac, liver, thyroid, pancreas, pituitary, and joints. Cardiac deposition can result in cardiomyopathy, conduction disturbances (e.g., sick sinus syndrome, heart block, and arrhythmias), diastolic dysfunction, and heart failure. The consequences of cardiac involvement with hemochromatosis include sudden incapacitation. Iron is toxic to the liver, causing inflammation and hepatocyte destruction. Ongoing inflammation can progress to fibrosis and cirrhosis, and chronic inflammation increases the risk of hepatocellular carcinoma. Abnormalities of synthetic liver function can result in coagulopathy, variceal bleeding, ascites, or hepatorenal syndrome. Iron deposition in the pancreas, pituitary gland, or thyroid gland can result in endocrine dysfunction and manifest as diabetes mellitus, hypopituitarism, hypogonadism, and hypothyroidism. A thorough evaluation for end-organ damage should be accomplished prior to waiver submission.

The primary treatment for hemochromatosis is periodic therapeutic phlebotomy to achieve and maintain a serum ferritin between 50-100  $\mu$ g/L. Studies demonstrate that keeping ferritin at this goal effectively prevents the development and progression of end-organ damage. The burden imposed on operational readiness by treatments such as regular phlebotomy will be taken into consideration at the time of waiver review. Among factors that will be considered include the accessibility/availability of necessary treatment and frequency of required treatment (and thereby, frequency of DNIF/DNIC/DNIA periods).

Review of the AIMWTS database from Jan 2019 through Jan 2022 revealed 21 cases with a diagnosis of hemochromatosis or iron overload. A breakdown of the cases was as follows: 0 FC I/IA cases, 10 FC II cases (0 disqualified), 6 FC III cases (0 disqualified), 2 ATC cases (0 disqualified), 1 GBO cases (0 disqualified), and 2 SWA cases (0 disqualified).

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes			
E83.11	Hemochromatosis		

### **IV. Suggested Readings**

- Bacon BR, Adams PC, Kowdley KV, et al. AASLD Practice Guideline: Diagnosis and Management of Hemochromatosis: 2011 Practice Guideline by the American Association for the Study of Liver Disease. Hepatology 2011;54:328-343. Available at <u>https://www.aasld.org/sites/default/files/2019-06/Hemochromatosis2011.pdf</u>. Accessed 12 January 2022.
- Kowdley KV, Brown KE, Ahn J, and Sundaram V. ACG Clinical Guideline: Hereditary hemochromatosis. Am J Gastroenterol 2019;114:1202-1218. Available at <a href="https://journals.lww.com/ajg/Fulltext/2019/08000/ACG_Clinical_Guideline_Hereditary_Hemochromatosis.11">https://journals.lww.com/ajg/Fulltext/2019/08000/ACG_Clinical_Guideline_Hereditary_Hemochromatosis.11</a>. <a href="https://aspx.aspx.aspx.aspx.aspx.aspx">aspx</a>. Accessed 12 January 2022.
- European Association for the Study of the Liver. EASL clinical practice guidelines for HFE hemochromatosis. J Hepatol 2010;53:3-22. Available at <u>https://easl.eu/wp-content/uploads/2018/10/Hemochromatosis-English-report.pdf</u>. Accessed 12 January 2022.





# Hepatic Cirrhosis

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

## I. Waiver Consideration

Cirrhosis that is associated with abnormal liver function, medical complication, or that requires specialist follow-up is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention, and it is generally not considered compatible with a waiver. Waivers may be considered for certain low-risk trained individuals on a case-by-case basis after a careful assessment of individualized aeromedical and operational risk. Waivers are not entertained for untrained personnel.

Specifically, any liver disease that meets any one of the following criteria is considered disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention:

- A. There is resultant impairment in liver synthetic function, or,
- B. There are resultant complications (including, but not limited to, portal or portopulmonary hypertension, esophageal varices, bleeding dyscrasias, venous thromboembolism, ascites, spontaneous bacterial peritonitis, encephalopathy, hepatorenal syndrome), **or**,
- C. Requires specialty follow-up beyond six months.

Certain disease processes that may ultimately lead to cirrhosis are independently disqualifying. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide, including chapters *Chronic Viral Hepatitis*, *Hemochromatosis*, and *Alcohol Use Disorder*. Sequelae of chronic liver disease may be independently disqualifying. Please cross-reference the Medical Standards Directory for all potentially disqualifying conditions.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority ¹	Evaluation
FC I/IA	Cirrhosis	No	No
		AFRS/CMO	
FC II/III/	Compensated cirrhosis,	Yes ²	Yes ³
ATC/GBO	without synthetic liver	AFMRA	
OSF/SWA	dysfunction or ongoing		
	inflammation/injury, without		
	history of complication		

### Table 1: Waiver potential for Hepatic Cirrhosis

1. Certification authority for untrained assets is AFRS/CMO.

2. No waiver potential for untrained assets. Rarely a waiver may be considered in certain low-risk trained individuals on a case-by-case basis. No indefinite waivers.

3. If waiver authority is interested in considering a waiver for a trained individual, then ACS review is strongly recommended prior to waiver approval.

### Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of how the finding of cirrhosis was established, presenting features, and all pertinent physical findings (positive and negative).
  - b. Specify the presence or absence of symptoms at initial presentation and throughout disease course.
  - c. Describe the diagnostic evaluation and specify the underlying disease process that caused the cirrhosis.
  - d. Specify the presence or absence of complications related to cirrhosis (e.g., portal or portopulmonary hypertension, esophageal varices, bleeding dyscrasias, venous thromboembolism, ascites, spontaneous bacterial peritonitis, encephalopathy, hepatorenal syndrome, etc.).
  - e. List all past and ongoing treatments for the underlying disease process or for its complications. Include the following: all procedures; all current and historic medications, dosages, dates of administration; any adverse effects or complications stemming from treatment.
  - f. Include a comprehensive review of symptoms and physical examination addressing the following systems: cardiovascular, gastrointestinal/abdominal, psychiatric (e.g., mood, fatigue, malaise, cognitive changes), hematologic, neurologic, and musculoskeletal.
  - g. Comment on any impact to quality of life or occupational performance.
  - h. List all co-morbid conditions.
  - i. Medical history and all medications with dosages.
  - j. All past and current supplement use.
  - k. Quantify lifetime and current alcohol use.
- 2. Consultation reports from all treating specialists (e.g., gastroenterologist or hepatologist) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course.
  - b. Detailed plan of ongoing treatment and monitoring.
  - c. Specify presence or absence of complications (see above examples).
  - d. If laboratory liver studies are abnormal (e.g., elevations of transaminase levels, alkaline phosphatase, gamma-glutamyl transpeptidase, or lactate dehydrogenase; abnormalities in markers of synthetic liver function such as albumin or prothrombin time), a statement from a gastroenterologist or hepatologist defining criteria for liver biopsy is required.
- 3. Laboratory studies required:
  - a. Current BMP
  - b. Current liver function tests, including both total and direct bilirubin
  - c. Current gamma-glutamyl transpeptidase (GGT)
  - d. Current lactate dehydrogenase (LDH)

- e. Current prothrombin time and INR
- f. Current CBC
- g. Iron studies, including total serum iron, ferritin, serum transferrin, and transferrin saturation
- h. Fasting lipid panel
- i. All past liver function tests, GGT, LDH, PT, INR, and CBC results, with dates
- j. Hepatitis A antibody (IgG)
- k. Hepatitis B surface antigen, surface antibody, and core antibody
- 1. Hepatitis C antibody
- m. Results of any other clinically indicated laboratory tests performed in the course of diagnosis, evaluation, and management of cirrhosis (e.g., alpha-1 antitrypsin level and genotype, ceruloplasmin, anit-nuclear antibodies, anti-mitochondrial antibodies, anti-smooth muscle antibodies, anti-liver/kidney/microsomal antibodies, immunoglobulins)
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of hepatitis, including all imaging reports (e.g., liver ultrasound, CT, MRI, and/or elastography), biopsies/pathology results (if performed), procedure reports (e.g., esophagoduodenoscopy for surveillance of varices), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
  - 1. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
    - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - 2. All relevant interval consultation reports from specialty providers (e.g., gastroenterologist or hepatologist). These notes must include the following:
    - a. Detailed plan of ongoing treatment and monitoring.
    - b. Specify presence or absence of complications (e.g., portal or portopulmonary hypertension, esophageal varices, bleeding dyscrasias, venous thromboembolism, ascites, spontaneous bacterial peritonitis, encephalopathy, hepatorenal syndrome).
    - c. If laboratory liver studies are abnormal (e.g., elevations of transaminase levels, alkaline phosphatase, gamma-glutamyl transpeptidase, or lactate dehydrogenase; abnormalities in markers of synthetic liver function such as albumin or prothrombin time), a statement from a gastroenterologist or hepatologist defining criteria for liver biopsy is required.
  - 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, and any other ancillary tests. The following must be included:
    - a. Current BMP
    - b. Current liver function tests, including both total and direct bilirubin
    - c. Current prothrombin time and INR
    - d. Current CBC

- 4. Form FL4 with return to duty and ALC status.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

### **III. Aeromedical Concerns**

Hepatic cirrhosis represents the end stage of a continuum of progressive liver injury and fibrosis. Over time, ongoing inflammation, tissue damage, and regeneration leads to nodularity, scarring, and organ dysfunction. As liver disease progresses, it becomes increasingly irreversible, and risks of multisystem complications increase. Aeromedical concerns of chronic liver disease and liver cirrhosis are manifold. Mild symptoms might include fatigue, malaise, and lethargy. Abnormalities of synthetic liver function can result in coagulopathy, low oncotic pressure, fluid shifts, edema, and ascites. A combination of factors in decompensated cirrhosis may lead to hepatic encephalopathy, variceal bleeding, portal hypertension, or hepatorenal syndrome. Other complications include anemia of chronic disease and metabolic bone disease.

The implications of cirrhosis in the aviation or operational environment are myriad. Some complications of cirrhosis, such as variceal bleeding, can occur suddenly with no or little prodrome, resulting in sudden incapacitation or death. Other complications, such as hepatic encephalopathy, may be of more insidious onset, resulting in subtle performance decrement, impaired judgement, delayed reaction time, and impaired executive functioning, with potentially catastrophic consequences in the aviation or operational environment. Impairment in G-tolerance would be expected due to fluid shifts caused by a variety of factors, including decreased oncotic pressure and increased pressure in the portal venous system. Anemia of chronic disease would lead to decreased tolerance of hypoxia.

Many different conditions that cause chronic liver injury or inflammation can lead to cirrhosis. Examples of disparate disease processes that converge on the common endpoint of cirrhosis include medication and toxin effects, autoimmune processes, infections, metabolic processes, and genetic diseases. Specific examples include chronic alcohol abuse, primary biliary cirrhosis, primary sclerosing cholangitis, autoimmune hepatitis, chronic viral hepatitis, hemochromatosis, Wilson's disease, alpha-1 antitrypsin deficiency, and non-alcoholic fatty liver disease (NAFLD). The underlying disease states that result in cirrhosis may be associated with additional symptoms or complications that convey increased aeromedical or operational risk. Therefore, it is essential that the etiology of the cirrhosis be elucidated in order to perform an appropriate risk assessment. Many of these underlying conditions are independently disqualifying for continued duties and are associated with unique waiver considerations. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for additional information, including Air Force Waiver Guide chapters *Chronic Viral Hepatitis* and *Hemochromatosis*.

Review of the AIMWTS database from Jan 2017 through Jan 2022 revealed no cases of chronic liver disease which had progressed to include a diagnosis of hepatic cirrhosis.

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes					
K70.3	Alcoholic cirrhosis				
K74.5	Biliary cirrhosis, unspecified				
K74.60	K74.60 Unspecified cirrhosis of liver				

### **IV. Suggested Readings**

1. Biggins SW, Angeli P, Garcia-Tsao G, et al. Diagnosis, Evaluation, and Management of Ascites, Spontaneous Bacterial Peritonitis and Hepatorenal Syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. Hepatology 2021;74:1014-1048. Available at https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep.31884. Accessed 12 January 2022.

 European Association for the Study of the Liver. EASL Clinical Practice Guidelines on non-invasive tests for evaluation of liver disease severity and prognosis - 2021 update. J Hepatol 2021; 75:659-689. Available at https://www.journal-of-hepatology.eu/article/S0168-8278(21)00398-6/fulltext. Accessed 12 January 2022.

 National Guideline Centre (UK). Cirrhosis in Over 16s: Assessment and Management. London: National Institute for Health and Care Excellence (NICE); 2016 Jul. Available at <u>https://www.nice.org.uk/guidance/ng50/resources/cirrhosis-in-over-16s-assessment-and-management-pdf-1837506577093</u>. Accessed 12 January 2022.

4. Smith A, Baumgartner K, Bositis C. Cirrhosis: diagnosis and management. Am Fam Physician 2019;100:759-770. Available at <a href="https://www.aafp.org/afp/2019/1215/afp20191215p759.pdf">https://www.aafp.org/afp/2019/1215/afp20191215p759.pdf</a>. Accessed 12 January 2022.





## Irritable Bowel Syndrome (IBS)

Revised: Aug 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

Irritable bowel syndrome (IBS) with symptoms that cannot be controlled by dietary modification alone is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties. IBS becomes disqualifying for retention if symptoms result in frequent medical appointments, need for ongoing specialty follow-up, or frequent missed duty time. Symptoms associated with IBS may be independently disqualifying. For example, recurrent abdominal pain of sufficient severity to preclude satisfactory performance of duties, require frequent absences from duty, or necessitate frequent specialist follow-up is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Chronic diarrhea, regardless of cause, is disqualifying for all flying class and SWA duties. The use of any medication or supplement for symptom control that is not included on the applicable career field medication list is disqualifying for ongoing aviation or operational duty and would also necessitate a waiver.

Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of IBS in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

When IBS symptoms are controlled and individuals remain asymptomatic with solely dietary modification, without use of medication, supplement, or other intervention, then the condition is not disqualifying, and no waiver is necessary. Waivers are generally not considered for untrained applicants with IBS that requires more than dietary modification for symptom control or who have ongoing active symptoms. The symptoms of IBS correlate closely with psychological stress. The rigors of training along with the stress of the aviation or operational environment would be expected to exacerbate flares of such duty-limiting or distracting symptoms as severe abdominal pain and diarrhea. Thus, although certain untrained individuals deemed to be low aeromedical risk may be considered for waiver on a case-by-case basis, untrained applicants with active IBS or IBS requiring medication management have limited waiver potential. For trained personnel, waivers may be considered on a case-by-case basis. Weighed factors for waiver consideration include, but are not limited to, historic severity of symptoms, degree of current symptom control at time of waiver submission, duration of stability, and the risks associated with any medication or intervention necessary to maintain symptom control and stability.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority	Evaluation
FC I/IA	IBS not controlled by dietary	No ²	No
	modification alone ¹	AFRS/CMO	
FC II/III/ATC/	IBS not controlled by dietary	Yes ^{2,3}	$No^5$
GBO/OSF/SWA	modification alone ¹	MAJCOM ⁴	

Table 1: Waiver potential for Irritable Bowel Syndrome (IBS)

1. Mild IBS that is controlled with dietary modification alone is not disqualifying and no waiver is required.

2. In general, waivers for untrained assets are unlikely. A waiver for untrained assets will only be considered in individuals deemed to be low aeromedical risk on a case-by-case basis. No indefinite waivers.

3. Waivers for the use of non-approved medications may be considered on a case-by-case basis.

4. Certification authority for untrained assets is AFRS/CMO. Waiver authority for aeromedically unapproved medication use is AFMRA.

5. ACS review may be requested at the discretion of the waiver authority. ACS review is recommended for untrained assets.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of pertinent symptoms (e.g., abdominal pain, bloating, diarrhea, constipation, stool frequency, frequency of exacerbations/pattern of recurrence, duration of exacerbations, exacerbating and alleviating factors, etc.).
  - c. Summarize all medications and interventions attempted to treat or alleviate symptoms (pharmacologic and non-pharmacologic), with doses (as applicable), dates and duration of intervention, and effectiveness.
  - d. List current medications with dosages.
  - e. Summarize diagnostic evaluation, including list of any/all procedures with dates.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of current treatment (e.g., dietary modifications, pharmacotherapy, etc.) including dose, frequency, and formulation.
  - b. Discussion of current degree of symptom control.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of IBS, including laboratory studies, imaging, endoscopy or colonoscopy reports and biopsy results (if applicable), and any other ancillary studies.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - c. Documentation of interval recurrences, changes in symptom pattern, or treatment.
- 2. All relevant interval consultation reports from the treating gastroenterologist, if applicable.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval endoscopy or colonoscopy reports and biopsy results, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Different criteria exist for diagnosing IBS. The most commonly followed diagnostic guidelines are the Rome criteria, but other criteria may also be utilized (e.g., Manning criteria). In general, IBS is associated with symptoms such as abdominal pain, intermittent diarrhea and/or constipation, and bloating. Other symptoms may include fecal urgency, a sense of incomplete evacuation, flatulence, mucus passage with defecation, and pain that is relieved with defecation. Severity of the symptoms vary between affected individuals. A single individual may experience significant fluctuation in symptoms, often experiencing exacerbations in correlation with periods of worsened emotional or psychologic stress. Many individuals with IBS learn to control their symptoms through stress-reduction techniques and dietary modification. Often, foods that are high in fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (FODMAPs) worsen symptoms of IBS. However, a diet of eliminating all high-FODMAP foods is severely restricting and generally not considered sustainable in an operational environment. A FODMAP elimination diet is considered a temporary measure to alleviate symptoms, followed by gradual re-introduction of foods to identify specific triggering foods that may be avoided in order to reduce the recurrence of IBS symptoms.

Those service members with IBS of sufficient severity that dietary modification alone does not control symptoms are disqualified for all flying class, GBO, ATC, OSF, and SWA duties. The predominant aeromedical and operational concerns are that symptoms of IBS are unpredictable, worsen with stress, and may become distracting or even incapacitating during the performance of aviation or operational duties with little or no warning. Symptoms such as bloating and abdominal pain can worsen with altitude changes due to expansion of intraluminal gas. Even with mild symptoms like fecal urgency and frequent defecation may present an inconvenience during extended aviation and operational missions. Furthermore, the stressors of the aviation, space, or other austere living conditions would be expected to exacerbate symptoms.

IBS is usually a chronic, frequently lifelong condition, with a course that may wax and wane over an individual's lifespan. Its chronicity and tendency to worsen with stress is of particular concern when considering an untrained applicant in whom relapses or exacerbations of symptoms may cause significant lost duty over the course of military service.

Many medications used in the treatment of IBS may carry an elevated risk of systemic side effects that could preclude safe performance of aviation or operational duties. In particular, medications with anticholinergic properties are of concern due to their potential to cause systemic complications that include cognitive slowing, mood changes, vision changes, and cardiovascular instability. The use of any medication or supplement in the treatment of IBS is disqualifying and requires a waiver, as it may indicate underlying disease severity. Non-approved medications may not be amenable to waiver, even if other factors related to disease control and stability are favorable. Of note, there is no career field medication list for OSF or SWA personnel. In OSF and SWA personnel, as will all other personnel requiring waiver for medication and/or supplement use in the treatment of IBS, the risks and benefits of each medication/supplement must be considered carefully in the unique clinical and operational context and must be carefully evaluated for potential side effects that might impact individual health or mission safety.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 85 cases with a diagnosis of irritable bowel syndrome. The breakdown of the number of waivers and number of total cases are tabulated below.

ICD-10	ICD-10 Code		(# of waivers / total # of cases)				
		IFC I/IA	FC II	FC III	ATC	GBO	SWA
K58.0	Irritable bowel syndrome w/ diarrhea						_ / _
K58.1	Irritable bowel syndrome w/ constipation	2/4	20/24	23/37	1/4	8/11	5/5
K58.2	Mixed irritable bowel syndrome						

### **IV. Suggested Readings**

- Ford AC, Moayyedi P, Chey WD, et al., for the ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Am J Gastroenterol 2018;113(Suppl 2):1-18. Available at <a href="https://journals.lww.com/ajg/fulltext/2018/06002/american_college_of_gastroenterology_monograph_on.l.aspx">https://journals.lww.com/ajg/fulltext/2018/06002/american_college_of_gastroenterology_monograph_on.l.aspx</a> . Accessed 17 August 2022.
- Quigley EM, Fried M, Gwee KA, et al. World Gastroenterology Organisation Global Guidelines Irritable Bowel Syndrome: A Global Perspective Update September 2015. J Clin Gastroenterol 2016;50:704-713. Available at <u>https://www.worldgastroenterology.org/UserFiles/file/guidelines/irritable-bowel-syndrome-english-2015.pdf</u>. Accessed 17 August 2022.
- Smalley W, Falck-Ytter C, Carrasco-Labra A, et al. AGA Clinical Practice Guidelines on the laboratory evaluation of functional diarrhea and diarrhea-predominant irritable bowel syndrome in adults (IBS-D). Gastroenterology 2019;157:851–854. Available at <u>https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2819%2941083-4</u>. Accessed 17 August 2022.
- Weinberg DS, Smalley W, Heidelbaugh JJ, and Sultan S. American Gastroenterological Association Institute Guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology 2014;147:1146– 1148. Available at <u>https://www.gastrojournal.org/article/S0016-5085(14)01089-0/pdf</u>. Accessed 17 August 2022.





## Pancreatitis

Revised: Aug 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

Any history of either acute or chronic pancreatitis, regardless of cause, is disqualifying for all flying class and SWA duties. A history of acute pancreatitis that is complicated by persistent pancreatic pseudocysts is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Chronic pancreatitis or recurrent episodes of acute pancreatitis is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Chronic pancreatitis or recurrent episodes of acute pancreatitis is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention if associated with any one of the following:

- A. steatorrhea, or,
- B. disturbance of glucose metabolism requiring insulin or hypoglycemic agents, or,
- C. abdominal pain resulting in repeated hospitalization or frequent absences from duty.

The symptoms or complications of pancreatitis may be independently disqualifying for continued aviation or operational duties or for retention. For example, recurrent abdominal pain of sufficient severity to preclude satisfactory performance of duties, require frequent absences from duty, or necessitate frequent specialist follow-up is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Individuals with chronic pancreatitis are at risk for a variety of complications that may be disqualifying, including sequelae of exocrine insufficiency such as osteoporosis and diabetes mellitus. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions.

Waivers are unlikely for personnel with active symptoms of chronic pancreatitis or evidence of ongoing inflammation. Following resolution of an isolated, uncomplicated case of acute pancreatitis, waiver may be considered for disqualified aviators and SWA personnel, including untrained individuals. Prior to requesting a waiver, it is expected that an individual will demonstrate a period of asymptomatic stability. The risk of recurrent pancreatitis or the development of future complications varies depending upon whether an underlying causative etiology is identified and corrected. The cause of pancreatitis and risk of recurrence will influence waiver eligibility. In general, in untrained applicants with a history of recurrent acute pancreatitis, a history of chronic pancreatitis, or a history of resolved pancreatitis with a persistent complication, a waiver is unlikely to be considered. However, for certain untrained applicants who are determined to be low aeromedical risk after careful review, a waiver may be considered on a case-by-case basis. Likewise, waivers are considered on a case-by-case basis for trained individuals with a history of recurrent acute pancreatitis, or a history of resolved pancreatitis, a history of resolved chronic pancreatitis, a history of resolved chronic pancreatitis with persistent complication.

Factors that may influence a waiver decision include, but are not limited to, the underlying cause of the pancreatitis, the likelihood of interventions to reduce future recurrences, need for aeromedically unapproved medications to reduce recurrence or treat sequelae of pancreatitis, and the particular nature and associated risks of any complications or chronic symptoms that may be present (e.g., exocrine insufficiency, malabsorption, pseudocysts, diarrhea, chronic pain, etc.). Idiopathic pancreatitis or pancreatitis due to a hereditary cause is unlikely to be waived. Any history of segmental surgical resection of the pancreas will not be considered favorably.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority	Evaluation
IFC I/IA	Single episode of acute and	Yes	No
	uncomplicated pancreatitis,	AFRS/CMO	
	resolved without sequelae		
	History of chronic	Unlikely	No
	pancreatitis, recurrent	AFRS/CMO	
	episodes of acute		
	pancreatitis, or single episode		
	of acute pancreatitis with		
	persistent complication		
FC II/III/SWA	Single episode of acute and	Yes	No ³
	uncomplicated pancreatitis,	MAJCOM ¹	
	resolved without sequelae		
	History of chronic	Yes ²	No ³
	pancreatitis, recurrent	MAJCOM ¹	
	episodes of acute		
	pancreatitis, or single episode		
	of acute pancreatitis with		
	persistent complication		
ATC/GBO/OSF	History of chronic	Yes ²	No ³
	pancreatitis, recurrent	MAJCOM ¹	
	episodes of acute		
	pancreatitis, or single episode		
	of acute pancreatitis with		
	persistent complication		

1. Certification authority for untrained assets is AFRS/CMO.

2. Aeromedical waivers may be considered in personnel determined to be low aeromedical risk on a case-by-case basis. No indefinite waivers. Aeromedical waivers for untrained assets and individuals with active chronic pancreatitis are unlikely.

3. ACS review may be requested on a case-by-case basis at the discretion of the waiver authority.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of ongoing symptoms.
  - c. Specify presence or absence of complications (e.g., pseudocyst, abscess, necrosis, splanchnic venous thrombosis, pseudoaneurysm, abdominal compartment syndrome, prediabetes, diabetes, exocrine pancreatic insufficiency, etc.).
  - d. Specify if an underlying cause of the pancreatitis was identified and describe how it was addressed.
  - e. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - f. List current medications with dosages.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Documentation of the presence or absence of complications (see A.1.c. above).
  - b. Documentation of the presence or absence of current symptoms.
  - c. Discussion of likelihood of recurrence.
- 3. Laboratory studies required:
  - a. Current CBC.
  - b. Current fasting BMP (must include fasting glucose).
  - c. Current liver function panel.
  - d. Current serum amylase and lipase levels.
  - e. Current trypsin level.
  - f. Current fasting lipid panel.
- 4. Results of all testing performed in the course of diagnosis, evaluation, and management of pancreatitis, including laboratory studies, imaging, and any other ancillary studies. Must include the following:
  - a. CT scan of the abdomen/pelvis obtained post-recovery (radiology report), which should comment upon the presence of ongoing inflammation, necrosis, pseudocyst formation, or calcifications.
  - b. If CT scan does not sufficiently evaluate the gallbladder, then an ultrasound to assess for gallbladder disease (e.g., gallstones, sludge) is required (radiology report).
  - c. All procedural reports, operative reports, and pathology results, as applicable.
  - d. Associated hospital records (e.g., admission history and physical, discharge summary), as applicable.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Summarize any interval evaluation and/or treatment.
  - c. Document the presence or absence of new complications (see A.1.c. above).
  - d. List current medications with dosages.
- 2. All interval consultation reports from the treating gastroenterologist, if applicable.
- 3. Laboratory studies required:
  - a. Current CBC.
  - b. Current fasting BMP (must include fasting glucose).
  - c. Current liver function panel.
  - d. Current serum amylase and lipase levels.
  - e. Current trypsin level.
  - f. Current fasting lipid panel.
- 4. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval procedure reports, and any other ancillary tests.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

The aeromedical concerns associated with pancreatitis differ slightly depending upon the underlying causative etiology, whether the pancreatitis is acute or chronic, and whether there are any associated complications or sequelae. The most common cause of acute pancreatitis in the United States is cholelithiasis, which accounts for approximately 40-70% of cases. Alcohol consumption accounts for 25-35% of total cases. Hypertriglyceridemia is a recognized but less common cause, accounting for between 1-14% of cases. In order to provoke pancreatitis, triglycerides must be significantly elevated (i.e., greater than 1000 mg/dL). Milder elevations of triglycerides in an individual with a history of acute pancreatitis should prompt an evaluation for another potential underlying etiology. Acute pancreatitis is also a known complication following endoscopic retrograde cholangiopancreatography (ERCP).

Less common causes of pancreatitis include predisposing genetic mutations (e.g., *CFTR* or *SPINK1* genes), medications, and abdominal trauma resulting in pancreatic injury. Rare causes of pancreatitis include biliary sludge, biliary microlithiasis, other forms of biliary obstruction, hypercalcemia, certain infections, toxins, vascular disease, and anatomic abnormalities of the pancreas. About 15-20% of acute pancreatitis is idiopathic, meaning that an underlying etiology is not identified after a thorough investigation that includes advanced diagnostic procedures such as magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound, ERCP, analysis of bile for microlithiasis, and sphincter of Oddi manometry.

Depending on the cause of acute pancreatitis, the condition can occur suddenly, without prodrome. The first symptoms of acute pancreatitis may include severe abdominal pain, vomiting, and dyspnea, which may rapidly result in incapacitation. Patients may develop hemodynamic instability, which is at least partly caused by a systemic inflammatory response. Severe acute pancreatitis can quickly progress to multi-organ failure and can become life-threatening if definitive medical care is delayed. Potentially fatal complications of severe acute pancreatitis include acute respiratory distress syndrome and abdominal compartment syndrome.

Chronic pancreatitis is characterized by persistent or frequently recurrent pancreatic inflammation, injury, and dysfunction. Active chronic pancreatitis is generally not felt to be compatible with sustained aviation or operational duties. Symptoms of chronic or recurrent abdominal pain and steatorrhea may be distracting or even incapacitating during the performance of aviation and operational duties. Complications of both acute and chronic pancreatitis include pseudocyst, abscess, necrosis, splanchnic venous thrombosis, pseudoaneurysm, abdominal compartment syndrome, prediabetes, diabetes, and exocrine pancreatic insufficiency. Complications are varied and present unique aeromedical and operational risks, which must be carefully considered in context.

Many of the underlying causes and resultant complications of pancreatitis are independently disqualifying. Please cross-reference the Medical Standards Directory and the pertinent Air Force Waiver Guide for all potentially disqualifying conditions.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 54 cases with a diagnosis of pancreatitis. The breakdown of the number of waivers and number of total cases are tabulated below. Three of the six disqualifications were for reasons associated with the diagnosis of pancreatitis.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		(# of waivers / total # of cases)					
		IFC I/IA	FC II	FC III	GBO	ATC	
K85.9	Acute pancreatitis, unspecified			0.1 /0.0	a (a	0.11	
K86.0	Alcohol-induced chronic pancreatitis	1/1	24/27	21/23	2/2	0/1	
K86.1	Other chronic pancreatitis						

### **IV. Suggested Readings**

- 1. Conwell DL, Lee LS, Yadav D, et al. American Pancreatic Association Practice Guidelines in Chronic Pancreatitis: Evidence-Based Report on Diagnostic Guidelines. Pancreas 2014;43:1143-1162. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5434978/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5434978/</a>. Accessed 30 August 2022.
- Crockett SD, Wani S, Gardner TB, et al. on behalf of American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guideline on Initial Management of Acute Pancreatitis. Gastroenterology 2018;154:1096–1101. Available at <a href="https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2818%2930076-3">https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2818%2930076-3</a>. Accessed 30 August 2022.
- Pancreatitis. NICE Guideline. National Institute for Health and Care Excellence. September 2018. Available at <a href="https://www.nice.org.uk/guidance/ng104/resources/pancreatitis-pdf-66141537952453">https://www.nice.org.uk/guidance/ng104/resources/pancreatitis-pdf-66141537952453</a>. Accessed 30 August 2022.





# Peptic Ulcer Disease (PUD)

Revised: Aug 2022

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

For the purposes of this waiver guide, peptic ulcer disease (PUD) refers to ulceration of the lining of the esophagus, stomach, or duodenum. This use of the term PUD is consistent with its usage in the Medical Standards Directory (MSD). Active PUD is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties. Additionally, any history of PUD meeting any one of the following criteria is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties:

- A. Previously or currently refractory to treatment, or,
- B. Associated with complication (including, but not limited to, hemorrhage, stricture, obstruction, or perforation), **or**,
- C. Previously or currently necessitating long-term use of acid suppression therapy (e.g., proton pump inhibitor) to prevent recurrence.

PUD is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention, if it meets any of the following criteria:

- A. Causes repeated incapacitation, or,
- B. Causes frequent absences for duty, or,
- C. Requires frequent specialist follow-up.

The symptoms of PUD or its consequent complications may also be disqualifying. For example, gastrointestinal hemorrhage is disqualifying for all flying class, ATC, and SWA duties. Recurrent abdominal pain of sufficient severity to preclude satisfactory performance of duties, require frequent absences from duty, or necessitate frequent specialist follow-up is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. Gastritis in the absence of ulceration may be disqualifying when chronic or severe, or when treatment necessitates use of medications not included in the applicable career field medication list. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment or prevention of PUD in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

After treatment for PUD is complete, endoscopic healing is demonstrated, and a period of asymptomatic control is established, then waiver consideration is generally favorable. Complicated PUD (e.g., associated with hemorrhage, stricture, obstruction, or perforation), severe disease, or recurrent disease is scrutinized more carefully prior to the granting of a waiver. PUD requiring use of aeromedically unapproved medications to maintain asymptomatic remission may not be amenable to waiver. Complicated PUD, severe or refractory disease, and individuals requiring treatment with aeromedically unapproved medications are considered for waiver on a case-by-case basis. If an acid suppression regimen is clinically indicated to reduce the risk of disease recurrence, waiver will not be considered favorably if the service member fails to demonstrate adequate adherence.

Flying Class	Condition ²	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Active or symptomatic PUD	No AFRS/CMO	No
	History of PUD, with or without complication, adequately treated and resolved, with demonstrated endoscopic healing, including PUD requiring long-term use of acid suppression therapy to prevent recurrence ⁵	Yes ³ AFRS/CMO	Yes
FC II/III/ATC/ GBO/OSF/SWA	Active or symptomatic PUD	No MAJCOM ⁴	No
	History of PUD, with or without complication, adequately treated and resolved, with demonstrated endoscopic healing, including PUD requiring long-term use of acid suppression therapy to prevent recurrence ⁵	Yes ³ MAJCOM ⁴	Yes

Table 1: Waiver potential for Peptic Ulcer Disease (PUD)¹

1. PUD refers to ulceration of the lining of the esophagus, stomach, or duodenum. It may be confirmed by laboratory testing, imaging, or endoscopy.

2. Please refer to the "Waiver Considerations" section for a list of disqualifying criteria.

3. Waivers for the use of non-approved medications may be considered on a case-by-case basis.

4. Certification authority for untrained assets is AFRS/CMO. Waiver authority for non-approved medication use is AFMRA.

5. If an acid suppression regimen is clinically indicated to reduce the risk of disease recurrence, waiver will not be considered favorably if the service member fails to demonstrate adequate adherence.

### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of pertinent symptoms (e.g., dysphagia, odynophagia, food impaction, emesis, weight loss, anorexia, hematemesis, melena, hematochezia, abdominal pain, etc.).
  - c. Specify presence or absence of exacerbating factors and whether they are controlled (e.g., NSAID use, tobacco use, alcohol consumption).
  - d. Specify presence or absence of complications (e.g., bleeding, stricture, obstruction, perforation, etc.).
  - e. Medical history and all medications with dosages.
  - f. Summary of diagnostic evaluation, including list of any/all procedures with dates.
  - g. Specify current treatment regimen, if any. Include dosages, and comment on tolerance of treatment.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of current treatment (e.g., dietary modifications, anti-reflux medication, etc.) including dose, frequency, and formulation.
  - b. Documentation of the presence or absence of complications (see above).
  - c. Recommendations for disease surveillance.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of PUD, including laboratory studies, imaging, and any other ancillary studies.
  - a. Include procedural reports and pathology results from any and all diagnostic or surveillance endoscopies that were performed.
  - b. Include results of *H. pylori* testing, if available (if positive, confirm eradication).
  - c. Current CBC.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - c. Documentation of the presence or absence of complications (e.g., bleeding, stricture, obstruction, perforation, etc.).

- d. Plan for monitoring of recurrence.
- 2. All relevant interval consultation reports from the treating gastroenterologist, if applicable.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval endoscopy reports and biopsy results, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

The specific aeromedical concerns and level of risk stemming from PUD vary depending on the causative etiology, severity of symptoms, and response of the disease to medical interventions such as acid suppression therapy. Sudden incapacitation can occur as a result of acute gastrointestinal hemorrhage in the setting of erosion into a blood vessel or due to gastrointestinal perforation. In some cases, blood loss may be chronic and anemia of aeromedical or operational significance anemia may develop insidiously, resulting in subacute symptoms of fatigue, lightheadedness, or decreased G-tolerance that can result in subtle performance decrements. Additionally, anemia impairs an aviator's ability to tolerate hypoxia in the event of an in-flight emergency. Other complications due to PUD may be independently disqualifying for aviation or operational duties or for retention. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions.

In some cases of PUD, medications that are not included in the career field approved medication list may be clinically indicated to control disease or prevent disease recurrence. The use of such medications is disqualifying for continued aviation or operational duties in the absence of a waiver, and the risks and benefits of each medication must be considered carefully in the unique clinical and operational context. Of note, there is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment or prevention of PUD in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 28 cases with a diagnosis of peptic ulcer disease. The breakdown of the number of waivers and number of total cases are tabulated below. The one sole disqualification was for an unrelated medical issue.

ICD-10 Code		(# of waivers / total # of cases)						
		IFC I/IA	FC II	FC III	ATC	GBO	SWA	
K27.0	Acute peptic ulcer, site unspecified, with hemorrhage							
K27.1	Acute peptic ulcer, site unspecified, with perforation							
K27.2	Acute peptic ulcer, site unspecified, with both hemorrhage and perforation							
K27.3	Acute peptic ulcer, site unspecified, without hemorrhage or perforation	-						
K27.4	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage	2/2	11/11	9/9	0/1	1/1	3/3	
K27.5	Chronic or unspecified peptic ulcer, site unspecified, with perforation							
K27.6	Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation							
K27.7	Chronic peptic ulcer, site unspecified, without hemorrhage or perforation							
K27.9	Peptic ulcer, site unspecified, unspecified as acute or chronic, without hemorrhage or perforation							
Z87.11	Personal history of peptic ulcer	1						

## **IV. Suggested Readings**

- Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of *Helicobacter pylori* infection. Am J Gastroenterol 2017;112:212-238. Available at <u>https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Treatment_of_Helicobacter.12.as</u> <u>px</u>. Accessed 17 August 2022.
- Gralnek IM, Dumonceau JM, Kuipers EJ, et al. Diagnosis and management of nonvariceal upper gastrointestinal hemorrhage: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2015;47:1-46. Available at
- <u>https://www.esge.com/assets/downloads/pdfs/guidelines/2015_s_0034_1393172.pdf</u>. Accessed 17 August 2022.
  Laine L, Jensen DM. Management of patients with ulcer bleeding. Am J Gastroenterol 2012;107:345–360. Available at <u>http://s3.gi.org/physicians/guidelines/UlcerBleeding.pdf</u>. Accessed 17 August 2022.
- Tarasconi A, Coccolini F, Biffl WL. Perforated and bleeding peptic ulcer: WSES guidelines. World J Emerg Surg 2020;15:3. doi: 10.1186/s13017-019-0283-9. Available at <u>https://www.wses.org.uk/wp-</u> content/uploads/2020/02/perforated-peptic-ulcers-GL.pdf. Accessed 17 August 2022.





# **Ulcerative Colitis**

Reviewed: Oct 2022

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Lt Col Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

# Significant Changes: Suggested readings (Section IV) updated.

# I. Waiver Consideration

Ulcerative Colitis (UC) of any severity or distribution is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. In other words, isolated proctitis, UC that is limited to the left side of the colon, as well as extensive or pancolonic disease are all equally disqualifying. It is unlikely for untrained personnel to be considered for waiver eligibility for aviation or operational duties. For trained personnel, factors considered when assessing suitability for waiver include, but are not limited to, the severity of the disease at time of diagnosis, whether there is evidence of clinical and endoscopic remission, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the individual service member's adherence to clinically indicated therapy, the individual's tolerance of treatment, the unique risks associated with the specific maintenance medication(s) utilized, and the cumulative risk of all associated complications and/or extra-intestinal disease manifestations.

Waiver may be considered once a service member is in disease remission on a stable, career field-approved medication regimen, without adverse effects. Individuals who are not adherent to an appropriate treatment regimen will not be considered waiver-eligible. Use of any medication not included on the career field-approved medication list is independently disqualifying and will be reviewed on a case-by-case basis.

There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of UC in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

The presence of persistent endoscopic disease is associated with a higher risk of symptomatic recurrence, even when UC is otherwise clinically quiescent. For this reason, individuals who achieve clinical remission but fail to demonstrate endoscopic remission are unlikely to be considered eligible for a waiver. For aeromedical and operational purposes, endoscopic remission is assessed either after completion of definitive treatment or while on stable maintenance therapy. For waiver consideration, endoscopic remission verification should include both visual (i.e., colonoscopic inspection) and histologic (i.e., tissue biopsy) demonstration of mucosal healing without evidence of active inflammation.

Finally, aeromedical and operational waivers for UC treated with curative surgery are considered on a case-by-case basis, with consideration given to post-operative complications and functional outcomes. Persistent ostomy is generally not considered compatible with aviation and operational duties.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Any history of ulcerative colitis, regardless of extent or severity	Unlikely AFRS/CMO	No
FC II/III/ATC/ GBO/OSF/SWA	Any history of ulcerative colitis, regardless of extent or severity (exception, UC treated surgically) ^{3,4,5}	Yes ² MAJCOM ⁷	Yes ²
	Ulcerative colitis treated with colectomy ⁶	Yes ² MAJCOM ⁷	Yes ²

#### Table 1: Waiver potential for Ulcerative Colitis¹

1. Ulcerative Colitis (UC) of any severity or distribution is equally disqualifying, including proctitis, UC that is limited to the left side of the colon, as well as extensive or pancolonic disease.

- 2. Generally, it is unlikely for untrained personnel to be considered for waiver eligibility for aviation or operational duties. An ACS review/evaluation is not required prior to permanent disqualification.
- 3. For trained personnel, factors that are considered when assessing suitability for waiver include, but are not limited to, the severity of the disease at time of diagnosis, whether there is evidence of clinical and endoscopic remission, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the individual service member's adherence to clinically indicated therapy, the individual's tolerance of treatment, the unique risks associated with the specific maintenance medication(s) utilized, and the cumulative risk of all associated complications and/or extra-intestinal disease manifestations.
- 4. Clinical and endoscopic remission should be demonstrated prior to waiver consideration. For aeromedical and operational purposes, endoscopic remission is assessed either after completion of definitive treatment or while on stable maintenance therapy. For waiver consideration, endoscopic remission verification should include both visual (i.e., colonoscopic inspection) and histologic (i.e., tissue biopsy) demonstration of mucosal healing without evidence of active inflammation.
- 5. Use of any medication not included on the career field-specific approved medication list is independently disqualifying and will be reviewed by on a case-by-case basis.
- 6. Waiver may be considered on a case-by-case basis after curative surgery. Factors considered include, but are not limited to, post-operative complications and functional outcomes. Presence of an ostomy is generally not felt to be compatible with sustained aviation or operational duties.
- 7. Certification authority for untrained assets is AFRS/CMO. Waiver authority for aeromedically unapproved medication use is AFMRA.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).

- b. Specify presence or absence of ongoing symptoms (e.g., abdominal pain, diarrhea, stool frequency, hematochezia, melena, weight loss, frequency of exacerbations/pattern of recurrence, any known exacerbating factors, etc.).
- c. Specify presence or absence of extra-intestinal manifestations (e.g., joint involvement, skin involvement, eye involvement, etc.).
- d. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
- e. List current medications with dosages.
- 2. Consultation report from the treating gastroenterologist and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course (including any history of surgery).
  - b. Discussion of current treatment, including dose, frequency, formulation, and all appropriate monitoring with schedule for follow-up (e.g., biologic agents require laboratory studies with a metabolic panel and CBC every 3-6 months and annual tuberculosis testing).
  - c. Documentation of the presence or absence of extra-intestinal manifestations.
  - d. Detailed plan of ongoing treatment and monitoring.
- 3. Laboratory studies required:
  - a. Current CBC.
  - b. Current CMP.
  - c. Current erythrocyte sedimentation rate (ESR).
  - d. Current C-reactive protein (CRP) level.
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of ulcerative colitis, including laboratory studies, imaging, and any other ancillary studies.
  - a. Include procedural reports and pathology results from any and all diagnostic or surveillance colonoscopies/endoscopies that were performed.
  - b. Must include a repeat colonoscopy while clinically stable with visual and histologic demonstration of endoscopic remission.
- 5. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms, objective findings, or interval flares.
  - b. Specify presence or absence of extra-intestinal manifestations (e.g., joint involvement, skin involvement, eye involvement, etc.).
  - c. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
- 2. All relevant interval consultation reports from the treating gastroenterologist.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval

colonoscopy/endoscopy reports and biopsy results, and any other ancillary tests. The following must be included:

- a. Current CBC.
- b. Current CMP.
- c. Current erythrocyte sedimentation rate (ESR).
- d. Current C-reactive protein (CRP) level.
- 4. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

Ulcerative colitis (UC) is a chronic inflammatory disease that affects the large intestine in a contiguous pattern, usually beginning at the rectum. It generally follows a relapsing and remitting course. The contiguous distribution of UC is one of multiple features that distinguishes it from Crohn's disease, which may affect any portion of the gastrointestinal (GI) tract. Depending upon the degree of colonic involvement, UC may be subdivided into proctitis, left-sided disease, or extensive disease. Additionally, extra-intestinal manifestations of UC are common. Systems that are often affected include the eyes (e.g., uveitis, iritis), skin (e.g., erythema nodosum, pyoderma gangrenosum), and musculoskeletal structures (e.g., arthritis, ankylosing spondylitis).

The aeromedical and operational hazards associated with UC stem from the unpredictability of the disease, its symptoms, and the risks associated with its treatments, which may adversely affect duty performance, mission completion, and safety. Common symptoms of UC include abdominal pain, bloating, diarrhea, hematochezia, weight loss, and fatigue. Adequate treatment that results in complete clinical and endoscopic remission with full suppression of active inflammation (e.g., negative serum inflammatory markers) can effectively mitigate aeromedical and operational risk, provided that the potential consequences of maintenance therapy do not exceed acceptable waiver tolerances and there are no other complications of aeromedical or operational concern.

Several medications that are frequently used in the management of UC are associated with a rate of severe adverse effects or with a need for clinical and laboratory monitoring that may not be compatible with sustained aviation or operational duty. Among these medications are systemic glucocorticoids, azathioprine, and 6-mercaptopurine. With the exception of time-limited utilization of some oral budesonide formulations, active treatment with systemic glucocorticoids is not amenable to any form of waiver. Additionally, the previous use of systemic glucocorticoids for more than three consecutive weeks in any 12-month period is independently disqualifying and requires demonstration of an intact hypothalamic-pituitary-adrenal (HPA) axis prior to waiver consideration. Please refer to the Aerospace Medicine Waiver Guide for *Systemic Glucocorticoid (Steroid) Therapy*. Waiver for azathioprine and 6-mercaptopurine use may rarely be considered on a case-by-case basis for certain low-risk personnel (e.g., ATC and GBO duties). In other individuals, the aeromedical risks of severe myelosuppresion, pancreatitis, and hepatotoxicity must be examined closely for compatibility with continued aviation or operational duty. The likelihood of myelosuppression is greatest during the first year of treatment, and

#### Ulcerative Colitis

testing for thiopurine methyltransferase (TPMT) enzyme activity may assist with identifying individuals at highest risk of severe myelosuppression.

It should be noted that service members who elect to under-treat their UC with the aim of avoiding non-approved medications will not be considered for an aviation or operational waiver. Though use of any medication not included on the career field-approved medication list is independently disqualifying, there are several effective medications that are approved for maintenance therapy of UC in aircrew, ATC, and GBO personnel. These medications include mesalamine, sulfasalazine, infliximab, and adalimumab. Under-treatment of UC leads to mild chronic active inflammation or frequent recurrent active inflammation and substantially increases the likelihood of both symptomatic acute flares and disease complications. At a minimum, symptoms such as fatigue, abdominal pain, and increased stool frequency would be expected to distract from the safe performance of aviation or operational duties. At worst, an acute flare of severe abdominal pain or diarrhea could be suddenly incapacitating. Furthermore, anemia due to a combination of chronic inflammation and/or occult blood loss may be of insidious onset and result in subtle performance decrements, including reduced exertional capacity and impaired ability to tolerate hypoxia.

In general, individuals pursuing a waiver are expected to demonstrate asymptomatic clinical stability, having four or fewer bowel movements daily, without active complications, with normal inflammatory markers, and without adverse effects of treatment that might significantly impact the performance of aviation or operational duties. Prior to requesting a waiver, demonstration of clinical and endoscopic remission is required, regardless of whether remission is maintained spontaneously or through the use of career field-approved medications. Once an individual is asymptomatic (i.e., in clinical remission), endoscopic remission must be confirmed. Although repeat endoscopy to assess for mucosal healing is not always performed in clinical practice, the risk of disease flare-up or long-term complication is increased in individuals who do not achieve endoscopic remission, despite absence of symptoms.

About 10 to 15% of individuals with UC require a partial or total colectomy. Often, these resections are curative, and maintenance therapy is no longer required. Provided that an individual is asymptomatic without surgical complication, ileostomy, or colostomy, an aeromedical waiver may be considered. Presence of a persistent ostomy is generally not felt to be compatible with continued aviation or operational duties.

Review of the AIMWTS database from Oct 2019 through Oct 2022 revealed 120 cases with a diagnosis of UC. The breakdown of the number of waivers and number of total cases are tabulated below. All of the 11 disqualifications were for reasons associated with the diagnosis of UC. Four of the 11 disqualifications were in untrained individuals. Three of the 7 remaining disqualifications were subsequently waived once disease control and demonstrated stability.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes			(# of wai	vers / to	/ total # of cases)			
		IFC I/IA	FC II	FC III	GBO	ATC	SWA	
K51.9	Ulcerative colitis, unspecified	0/3	62/66	25/27	12/12	3/5	7/7	

### **IV. Suggested Readings**

- Bernstein CN, Eliakim A, Fedail S, et al.; Review Team. World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. J Clin Gastroenterol 2016;50:803-818. Available at <u>https://www.worldgastroenterology.org/UserFiles/file/guidelines/inflammatory-bowel-diseaseenglish-2015.pdf</u>. Accessed 18 October 2022.
- Farraye FA, Melmed GY, Lichtenstein GR, Kane SV. ACG Clinical Guideline: Preventive Care in Inflammatory Bowel Disease. Am J Gastroenterol 2017;112:241-258. Erratum in: Am J Gastroenterol 2017;112:1208. Available at <u>https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Preventive_Care_in.15.aspx</u>. Accessed 18 October 2022.
- Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020;158:1450-1461. Available at <u>https://www.gastrojournal.org/article/S0016-5085(20)30018-4/pdf</u>. Accessed 18 October 2022.
- Ko CW, Singh S, Feuerstein JD, et al.; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis. Gastroenterology 2019;156:748-764. Available at <u>https://www.gastrojournal.org/action/showPdf?pii=S0016-5085(18)35407-6</u>. Accessed 18 October 2022.
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384-413. Available at <u>http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf</u>. Accessed 18 October 2022.

Anemia, Blood Loss, and Bone Marrow Donation (Nov 2020) Revised: November 2020 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, and Maj Laura Bridge (ACS Internal Medicine)

**Significant Changes:** Updated to reflect the most recent MSD; substantial information regarding aeromedical concerns related to bone marrow donation added.

#### I. Waiver Consideration

Hemoglobin measurements that are consistently below the expected lower limit of normal based on gender and race/ethnicity are disqualifying for all flying class and SWA duties. For aeromedical purposes, the lower limit of normal hemoglobin is defined as specified in Table 2. Regardless of hemoglobin or hematocrit measurements, anemia that meets any one of the following criteria is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, and for retention: results in symptoms; is unresponsive to appropriate therapy; requires hematology follow-up more than once annually. Anemia that was due to a nutritional deficiency and that resolves after correction of this deficiency is not disqualifying (e.g., folate, vitamin B12). Note that iron deficiency anemia requires a diagnostic evaluation to determine the cause of the iron deficiency, even if iron levels and anemia are corrected with iron supplementation.

It is of paramount importance that any individual with a hemoglobin that is persistently below the expected lower limit of normal undergo a thorough diagnostic evaluation to determine the underlying cause of the anemia. This diagnostic evaluation is necessary regardless of the presence or absence of symptoms. An appropriate diagnostic evaluation may identify correctable causes of anemia. It is also essential to exclude causative etiologies that may be independently disqualifying for military duties or retention.

The specific clinical evaluation for anemia is individualized based upon the patient presentation. Laboratory testing, ancillary testing, and specialist consultation is guided by a thorough history and physical. Typically, every diagnostic evaluation for anemia will include a complete blood count (CBC) with red blood cell (RBC) indices, a peripheral smear, and a reticulocyte count. Based on the results of the CBC, additional testing may include iron studies (total serum iron, total iron binding capacity, and ferritin), measurement of vitamin B12 and folate, hemoglobin electrophoresis, and potentially bone marrow biopsy.

Donation of blood products (500 mL or more) is temporarily disqualifying for all flying class, ATC, GBO, OSF, and SWA personnel. A waiver is not required, but a DNIF/DNIC/DNIA period is necessary after completion of blood product donation. The length of the DNIF/DNIC/DNIA period varies based upon career field. Aviators (FC I/IA, II, III, OSF) require a 72 hour DNIF; RPA pilots, ATC personnel, and SWA personnel require an 8 hour DNIF/DNIC; RPA sensor operators and MOD personnel require a 4 hour DNIF/DNIA.

Flying Class	Condition	Waiver Potential ³ Waiver Authority	ACS Review or Evaluation
FC I/IA	Hemoglobin less than aeromedically-defined lower limit of normal, without another underlying disqualifying condition	Yes ⁴ AETC	No ⁵
FC II/III/SWA	Hemoglobin less than aeromedically-defined lower limit of normal, without another underlying disqualifying condition	Yes ⁴ MAJCOM	No ⁵
ATC/GBO	Hemoglobin less than aeromedically-defined lower limit of normal, without another underlying disqualifying condition	N/A ⁶	N/A ⁶

Table 1: Waiver potential for low hemoglobin after exclusion of a disqualifying cause^{1,2}

1. Refer to Table 2 for lower limit of normal thresholds based on gender and race/ethnic norms.

2. All individuals must undergo an appropriate clinical evaluation in order to elucidate the causative etiology of the anemia. If this evaluation does not identify a diagnosis that is independently disqualifying IAW the most recent version of the MSD, then utilize this table to assess waiver potential. If a disqualifying condition is identified as the underlying cause of the low hemoglobin, refer to the relevant aeromedical standards to assess waiver potential.

- 3. In the absence of any pathophysiology with the potential to progress or worsen, an indefinite waiver is likely once historical stability of hemoglobin levels is demonstrated.
- 4. Must be asymptomatic with demonstrated historical stability and without need for hematology follow-up.
- 5. ACS review may be requested at the discretion of the waiver authority
- 6. If the anemia is disqualifying for retention IAW the most recent version of the MSD, then it is also disqualifying for all duties requiring enhanced medical standards (including ATC and GBO), and a waiver is required.

Table 2: Lower limit of normal (LLN) hemoglobin (g/dL), aeromedical standard adjusted for gender and race/ethnicity

Race/Ethnicity	Male LLN	Female LLN
Caucasian	13.7	12.2
Black/African American	12.9	11.5
Hispanic	13.7	11.8
Asian	13.0	11.8
Other	13.0	11.8

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 12. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Specify presence or absence of symptoms at initial presentation and throughout evaluation/treatment course.
  - c. Medical history and all medications with dosages.
  - d. Summary of diagnostic evaluation, including list of any/all treatments with dates.
  - e. Specify current treatment regimen, if any. Include dosages, and comment on tolerance of treatment.
- 13. Consultation report from any specialty provider and all subsequent consultation notes.
- 14. Results of all testing performed in the course of diagnosis, evaluation, and management of anemia, including laboratory studies, imaging, and any other ancillary tests. The below-listed studies must be included:
  - a. Current CBC with RBC indices
  - b. Peripheral smear
  - c. Reticulocyte count
- 15. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 16. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
  - 6. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination.
    - b. Complete list of current medications with dates of initiation, doses, and all adverse effects.
    - c. Documentation of medication adherence.
    - d. Report of any new subjective symptoms.
  - 7. All interval consultation reports from specialty providers.
  - 8. Results of all interval testing performed in the course of ongoing anemia evaluation and management, including laboratory studies, imaging, and any other ancillary tests.
  - 9. Current CBC with RBC indices
  - 10. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
  - **11.** If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

#### **III. Aeromedical Concerns**

Irrespective of the underlying cause, both anemia (defined by low hemoglobin level, as specified in Table 2) and loss of blood volume can lead to reduced tissue oxygenation and end-organ dysfunction. The resulting signs and symptoms include fatigue, generalized weakness, decreased stamina, lightheadedness, chest pain, and decreased Gz tolerance. In the setting of concomitant hypoxia, there is not only decreased oxygen carrying capacity in the blood, there is also decreased oxygen available for perfusion. As a result, tissue oxygenation is further compromised. During physical exertion, tissue demands for oxygen are increased. The deficiency of the blood's oxygen carrying capacity may cause a more profound relative impairment in tissue oxygenation. The added physiologic stressors of hypoxia and/or exertion may overwhelm the ability of the body to compensate for anemia, leading to more profound symptomatology and more severe end-organ damage.

When the onset of anemia is gradual, individuals may remain asymptomatic under normal physiologic conditions (i.e., in the absence of hypoxia, altitude-exposure, dehydration, physical exertion, etc.) until hemoglobin levels approach 5-6 g/dL. Anemia of more rapid onset typically results in the manifestation of symptoms at higher hemoglobin concentrations, especially when the loss of hemoglobin or RBC mass is accompanied by an acute loss of intravascular volume. Although individuals under normal physiologic conditions may tolerate an acute loss of up to 20% of intravascular volume without cardiovascular compromise, the multitude of potential physiologic stressors inherent in the aviation or operational environment merit a cautious approach to blood loss. To ensure that a service member will not develop signs or symptoms of anemia while performing essential duties, any acute blood loss of more than 500 mL necessitates a temporary DNIF/DNIC/DNIA period. For aeromedical purposes, blood loss of more than 500 mL includes donation of whole blood, plasma, or platelets. See the "Waiver Considerations" section for the duration of the DNIF/DNIC/DNIA period specific to particular career fields, or refer to the MSD. Provided the service member feels well at the conclusion of the DNIF/DNIC/DNIA period, re-evaluation in the flight medicine clinic is not necessary prior to resuming normal aviation or operational duties.

Bone marrow donation or donation of peripheral blood progenitor cells (PBPCs) is a more involved process than blood product donation. Both traditional bone marrow harvesting and peripheral collection of progenitor cells requires DNIF/DNIC/DNIA for all flying class, ATC, GBO, OSF, and SWA duties until all the following criteria are met:

- A. The surgical site is well-healed (if applicable), and,
- B. Any distracting pain is resolved, and,
- C. Hemoglobin is stable above 10 g/dL.

A waiver is not required following bone marrow or progenitor cell donation. However, a drop in hemoglobin of several grams (approximately 3 g/dL) is expected immediately following traditional bone marrow donation. It may take several months for the hemoglobin to recover to the pre-donation concentration. Oral iron supplementation is often prescribed to facilitate recovery. After an appropriate ground trial to demonstrate medication tolerance, the use of oral

iron is compatible with continued flying and operational duties. If parenteral iron replacement is necessary, it should occur during the DNIF/DNIC/DNIA period.

Peripheral collection of blood progenitor cells necessitates mobilization of progenitor cells through the administration of a granulocyte colony-stimulating factor (G-CSF). Usually, the G-CSF is begun several days prior to the planned collection. Use of G-CSF requires DNIF/DNIC/DNIA. Individuals who donate PBPCs are at lower risk of developing anemia compared to traditional bone marrow donation. However, service members must be evaluated for potential side effects of the G-CSF prior to return to aviation/operational duties. Aeromedical concerns include the potential for distracting musculoskeletal pain that could interfere with aircrew or operational duties. The majority of PBPC donors experience generalized musculoskeletal pain of mild or moderate intensity within 24 hours of G-CSF administration. This pain usually peaks around the fifth day and resolves within one week.

Review of the AIMWTS database from Nov 2017 through Nov 2020 revealed 171 cases with a diagnosis of anemia. A breakdown of the cases was as follows: 20 FC I/IA cases (3 disqualified), 39 FC II cases (1 disqualified), 82 FC III cases (4 disqualified), 10 ATC cases (1 disqualified), 13 GBO cases (1 disqualified), and 7 SWA cases (0 disqualified). Of the 10 disqualified cases, all were disqualified for reasons other than the diagnosis of anemia. Additionally, most cases would no longer be disqualifying IAW the most recent version of the MSD.

Please use onl	y these ICD-10 codes for AIMWTS coding purposes
D50.9	Iron Deficiency Anemia, unspecified
D50.8	Other deficiency anemias
D58.9	Hereditary hemolytic anemia, unspecified
D59.9	Acquired hemolytic anemia, unspecified
D61.89	Other specified aplastic anemias & other bone marrow failure syndromes
D64.9	Anemia, unspecified

#### **IV. Suggested Readings**

- 1. Anemia resource page of American Family Physician. American Academy of Family Physicians. Available at <a href="https://www.aafp.org/afp/topicModules/viewTopicModule.htm?topicModuleId=2">https://www.aafp.org/afp/topicModules/viewTopicModule.htm?topicModuleId=2</a>. Accessed 3 November 2020.
- Janz TG, Johnson RL, Rubenstein SD, et al. Anemia in the emergency department: evaluation and treatment. Emerg Med Pract 2013;15. Available at <u>https://scghed.com/wp-content/uploads/2017/07/Anaemia.pdf</u>. Accessed 3 November 2020.
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 Beutler E, Waalen J. The definition of anemia: what is the lower limit of normal of the blood hemoglobin concentration? Blood 2006;107:1747-1750. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895695/. Accessed 3 November 2020.





# **Congential and Acquired Asplenia**

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured. Updated to reflect the most recent MSD.

# I. Waiver Consideration

Asplenia for any reason, whether post-operative following a splenectomy or due to functional or congenital asplenia, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. Any congenital abnormality or disease of the spleen is also disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. Acquired or congenital asplenia or splenic dysfunction can be considered for waiver in both trained and untrained individuals, provided that there are no other medical concerns that would preclude safe performance of duties and that continued service in the career field dose not subject the service member to excessive health risk. Please note also that chronic, inoperable splenomegaly is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. The finding of isolated splenomegaly is beyond the scope of this Air Force Waiver Guide chapter. There are many indications for splenectomy; and various diseases may result in splenomegaly, splenic dysfunction, splenic infarction, and functional asplenia. These conditions may be independently disqualifying and include, but are not limited to, autoimmune cytopenias, infiltrative disorders (e.g., sarcoidosis, leukemia, lymphoma, or amyloidosis), sickle cell disease and other disorders of hemoglobin synthesis, splenic abscess formation, and splenic venous thromboembolism (VTE). Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions.

Requirement for an initial waiver for splenectomy/asplenia, followed by regular waiver renewal intervals, provides opportunities to review and update the asplenic individual's immunizations and to confirm access to an un-expired emergency antibiotic for use at the earliest symptom of systemic infection. Periodic waiver reviews also allow for re-education of both flight medicine clinic personnel and the asplenic service member regarding proper medical precautions in asplenia, which not only mitigate the health risk to the affected individual but also ensure optimal aeromedical and operational risk reduction.

Flying Class	Condition ¹	Waiver Potential ² Waiver Authority ³	ACS Review or Evaluation
FC I/IA	History of congenital or acquired asplenia / splenectomy for any cause	Yes AFRS/CMO	No ⁴
FC II/III/ATC/ GBO/OSF/SWA	History of congenital or acquired asplenia / splenectomy for any cause	Yes MAJCOM	No ⁴

Table 1: Waiver potential for Congenital and Acquired Asplenia

1. Various independently disqualifying diseases may result in splenomegaly, splenic dysfunction, splenic infarction, and functional asplenia. Cross-referencing of the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions may be necessary.

2. No indefinite waivers.

3. Certification authority for untrained assets is AFRS/CMO.

4. ACS review may be requested at the discretion of the waiver authority.

# II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of the underlying reason for splenectomy or cause of asplenia, including initial presentation, age at presentation, presence or absence of symptoms at presentation and throughout evaluation/treatment course, all medical and surgical interventions, and response to these interventions including any complications (e.g., venous thromboembolism (VTE)).
  - b. In cases of splenectomy, report age of splenectomy and describe post-operative course. Specify any report of deep vein thrombosis, mesenteric thrombosis, or proximal venous thrombosis.
  - c. Medical history and all medications with dosages. Must include an active prescription for an emergency antibiotic to be taken at first symptom of possible systemic infection.
  - d. Documentation that service member has access to emergency antibiotic, is educated regarding early signs and symptoms of severe systemic infection, and is aware of procedure to follow in that event (i.e., take antibiotic immediately **and** then present immediately to nearest emergency medical care).
- 2. Consultation reports from all treating specialists (e.g., hematologist, surgeon, infectious diseases specialist, and/or immunologist) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course.

- b. Copies of all operative reports.
- c. Detailed plan of ongoing treatment and monitoring, as applicable.
- 3. Laboratory studies required:
  - a. Current CBC
  - b. Current lipid panel
- 4. Vaccination record, which must include the following (provide dates of administration and vaccine lot number):
  - a. Completion of 13-valent pneumococcal conjugate vaccine (PCV13)
  - b. Current (within 5-7 years) 23-valent pneumococcal polysaccharide vaccine (PPSV23)
  - c. Completion of H. influenzae type b vaccine (Hib)
  - d. Completion of quadrivalent meningococcal conjugate ACWY vaccine series (MenACWY), and revaccination every 5 years
  - e. Completion of monovalent meningococcal serogroup B vaccine series (MenB-4C or MenB-FHbp), and revaccination every 2-3 years
  - f. Completion of annual seasonal influenza vaccine
- 5. Results of any other testing performed in the course of diagnosis, evaluation, and management of splenectomy/asplenia, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 6. Form FL4 with return to duty and ALC status.
- 7. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
  - 1. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
    - b. Specify any report of VTE (e.g., deep vein thrombosis, mesenteric thrombosis, or proximal venous thrombosis).
    - c. Specify any signs or symptoms of pulmonary hypertension.
    - a. Complete list of current medications with dates of initiation, dosages, and all adverse effects. Must include an active prescription for an emergency antibiotic to be taken at first symptom of possible systemic infection.
    - b. Documentation that service member has access to emergency antibiotic, was reeducated regarding early signs and symptoms of severe systemic infection, and is aware of procedure to follow in that event (i.e., take antibiotic immediately **and** then present immediately to nearest emergency medical care).
  - 2. Any relevant interval consultation reports from specialty providers (e.g., hematologist, surgeon, infectious diseases specialist, and/or immunologist).
  - 3. Laboratory studies required:
    - a. Current CBC
    - b. Current lipid panel
  - 4. Updated vaccination record, which must include the following (provide dates of administration and vaccine lot number):
    - a. Completion of 13-valent pneumococcal conjugate vaccine (PCV13)

- b. Current (within 5-7 years) 23-valent pneumococcal polysaccharide vaccine (PPSV23)
- c. Completion of H. influenzae type b vaccine (Hib)
- d. Completion of quadrivalent meningococcal conjugate ACWY vaccine series (MenACWY), and revaccination every 5 years
- e. Completion of monovalent meningococcal serogroup B vaccine series (MenB-4C or MenB-FHbp), and revaccination every 2-3 years
- f. Completion of annual seasonal influenza vaccine
- 5. Results of any other testing performed in the course of diagnosis, evaluation, and management of splenectomy/asplenia, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 6. Form FL4 with return to duty and ALC status.
- 7. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# **III. Aeromedical Concerns**

The spleen is the largest lymphoid organ in the body. Among its many functions, it filters circulating red blood cells, removing abnormal red cells from the circulation to prevent intravascular hemolysis. It also filters and removes freely circulating hemoglobin and iron, serves as a reservoir for platelets, and acts as a giant lymph node, producing antigen-specific IgM antibodies that are crucial to the body's early immune response to an infection.

There are many underlying causes for congenital and acquired absence of the spleen or impairment in splenic function (hyposplenism). Various diseases may result in splenomegaly, splenic dysfunction, splenic infarction, and functional asplenia. As above, these conditions may be independently disqualifying and include, but are not limited to, autoimmune cytopenias, infiltrative disorders (e.g., sarcoidosis, leukemia, lymphoma, or amyloidosis), sickle cell disease and other disorders of hemoglobin synthesis, splenic abscess formation, and splenic venous thromboembolism (VTE). All individuals with a history of splenectomy, asplenia, or hyposplenism are at risk for various serious health consequences, especially thrombotic and immunologic complications, which will be addressed below.

Asplenic and hyposplenic individuals are particularly susceptible to severe infection with encapsulated bacteria (e.g., *Streptococcus pneumonia*, *Haemophilus influenza*, *Neisseria meningitides*, *Capnocytophaga*, and *Bordetella*) and parasitic organisms (e.g., *Babesia*, *Plasmodium falciparum*). Their infections are more likely to progress rapidly, and they are more likely to die from these infections than individuals with an intact and properly functioning spleen. Severe symptoms of infection may be of such acuity and swift progression that they cause incapacitation within hours of onset, jeopardizing service member health and mission safety. In addition to standard malaria prophylaxis and mosquito/tick avoidance, appropriate vaccinations against S. pneumoniae (pneumococcus), H. influenzae type b, N. meningitidis (meningococcus), and seasonal influenza, including re-vaccination at recommended intervals, is essential to reducing infection risk, thereby optimizing aeromedical and operational risk. Other interventions to mitigate risk include education and periodic re-education of the asplenic or

hyposplenic individual on self-monitoring for signs and symptoms of early infection. It is critical that asplenic or hyposplenic individuals have access to an un-expired emergency antibiotic (typically amoxicillin-clavulanate), know to initiate emergency antibiotic therapy immediately at earliest onset of a possible systemic infection (e.g, fever, chills, rigors, vomiting, or diarrhea), and comprehend the importance of seeking immediate emergency medical care in this event. For individuals who cannot use beta-lactams due to allergy, extended-spectrum fluoroquinolone such as levofloxacin or moxifloxacin can be utilized. The local flight surgeon's office should ensure that all individuals prescribed emergency antibiotic therapy are keeping their medication on hand while performing operational duties.

The risk of vascular complications in the setting of asplenia or hyposplenia is more difficult to describe, not only because it is less well-defined but also because there are no clear recommendations for anti-platelet or anticoagulation prophylaxis in this population. The rate of thromboembolism varies depending on underlying disease state (e.g., sickle cell disease vs. post-traumatic splenectomy), and risk of recurrence is higher after an initial event. For those who undergo a surgical splenectomy, the incidence of VTE is greatest in the early postoperative period, but the absolute risk of VTE ranges from just 3 to 7 percent. Malignancy and myeloproliferative neoplasms and increased platelet counts postoperatively appear to be associated with greater risk. From an operational perspective, any venous or arterial thromboembolic event could result in sudden incapacitation or sudden death. Please cross-reference the Air Force Waiver Guide Chapter *Venous Thromboembolism*.

Splenectomy may also be associated with pulmonary hypertension. The overall incidence of pulmonary hypertension in individuals following splenectomy is unknown but is likely low. Although the evidence for a causal relationship between splenectomy and pulmonary hypertension is lacking, the flight surgeon should continue to be aware of the importance of age-appropriate routine screening and evaluation of symptoms that suggest a cardiovascular condition. Typical symptoms of pulmonary hypertension would include fatigue, weakness, exertional dyspnea, angina, and syncope. When present, symptoms of pulmonary hypertension are caused by impaired oxygen transport and reduced cardiac output. Unfortunately, individuals are unlikely to manifest symptoms until there is already extensive damage to the pulmonary vasculature. As such, pulmonary hypertension is generally not compatible with continued aviation duties. Therefore, aviators with a history of splenectomy must be monitored regularly for any signs or symptoms suggestive of early pulmonary hypertension and be referred for further evaluation if this condition is suspected.

Review of the AIMWTS database from Jan 2019 through Jan 2022 revealed 22 cases with a disqualifying diagnosis of asplenia and/or splenectomy. A breakdown of the cases was as follows: 5 FC I/IA cases (1 disqualified), 11 FC II cases (0 disqualified), 4 FC III cases (0 disqualified), 0 ATC cases, 2 GBO cases (0 disqualified), and 0 SWA cases.

Please use onl	Please use <i>only</i> these ICD-10 codes for AIMWTS coding purposes		
Z90.81	Acquired absence of spleen		
D73.0	Hyposplenism		
Q89.01	Asplenia (congenital)		

## **IV. Suggested Readings**

- Bridgen ML. Detection, education and management of the asplenic or hyposplenic patient. Am Fam Physician 2001;63;499-508. Available at <u>https://www.aafp.org/afp/2001/0201/afp20010201p499.pdf</u>. Accessed 14 January 2022.
- Centers for Disease Control and Prevention. Immunization Schedules. Table 2: Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2021. Available at <u>https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html#table-conditions</u>. Accessed 14 January 2022.
- Davies JM, Lewis MPN, Wimperis J, et al. Review of guidelines for the prevention and treatment of infection in patients with an absent or dysfunctional spleen: Prepared on behalf of the British Committee for Standards in Haematology by a Working Party of the Haemato-Oncology Task Force. Br J Haematol 2011;155:308-317. Available at <u>https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1365-2141.2011.08843.x</u>. Accessed 14 January 2022.





# Sickle Cell Disease/Trait and Heterozygous Sickling Disorders

Revised: February 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: None.

## I. Waiver Consideration

Homozygous sickle cell disease (Hb SS), a history of symptomatic sickle cell trait (Hb AS), or heterozygosity with another mutant beta globin allele such as sickle- $\beta$  thalassemia (Hb S- $\beta^{\circ}$ thal), sickle cell-hemoglobin C disease (Hb SC), and sickle- $\beta$ + thalassemia (Hb S- $\beta$ + thal) are disqualifying for all flying class, ATC, GBO, OSF, SWA duties as well as retention. All initial flying class physical examinations require documented sickle cell screening and if positive, further characterization with hemoglobin electrophoresis. Asymptomatic Hb AS confirmed on hemoglobin electrophoresis is not disqualifying for any flying class, ATC, GBO, OSF, SWA duties or retention. However, EITHER the absence of symptoms commonly associated with a sickling disorder OR presence of symptoms attributable to intravascular sickling MUST be annotated on the initial flight or special operations physical exam prior to certification by the proper authority. Hb SS, Hb SC, Hb S- $\beta^{\circ}$  thal, Hb S- $\beta$ + thal, and a history of symptomatic Hb AS are not thought to have aeromedical waiver potential in the manned aviation environment. Aeromedical waiver for ATC and GBO personnel with a history of symptomatic Hb AS may be considered on a case-by-case basis following an accession or retention determination.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority ¹	ACS Review or Evaluation
FC I/IA	Hb SS, Hb SC, Hb S- $\beta^{\circ}$ thal, Hb S- $\beta^{+}$ thal, and <u>symptomatic</u> Hb AS	No AFRS/CMO	No
	Asymptomatic Hb AS	N/A ²	N/A
FC II/III/OSF/SWA	Hb SS, Hb SC, Hb S- $\beta^{\circ}$ thal, Hb S- $\beta$ + thal, and <u>symptomatic</u> Hb AS	No MAJCOM	No
	Asymptomatic Hb AS	N/A ²	N/A
ATC/GBO	Hb SS, Hb SC, Hb S- $\beta^{\circ}$ thal, Hb S- $\beta^+$ thal, and <u>symptomatic</u> Hb AS	No ³ MAJCOM	No ⁴
	Asymptomatic Hb AS	N/A ²	N/A

Table 1: Waiver potential for Hb SS, Hb SC, Hb S-β° thal, Hb S-β+ thal, and symptomatic Hb AS

1. Certification authority for untrained assets is AFRS/CMO.

2. Asymptomatic sickle cell trait (Hb AS) is not disqualifying. However, either the absence of symptoms associated with a sickling disorder or presence of symptoms attributable to intravascular sickling MUST be annotated on the initial flight or special operations physical exam prior to certification by the proper authority. See below for additional information required for initial physical certification.

3. Aeromedical waiver for both trained and untrained ATC and GBO personnel with a history of <u>symptomatic</u> Hb AS may be considered on a case-by-case basis following an accession or retention determination.

4. ACS review may be requested at the discretion of the waiver authority when waiver consideration is being given to ATC or GBO personnel with a history of symptomatic Hb AS.

## **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations. The following evaluation is required for <u>ALL</u> service members with sickle cell trait (Hb AS) prior to initial certification of flying class and special operations physical exams via PEPP. <u>ONLY</u> those individuals found to have Hb SS, Hb SC, Hb S- $\beta^{\circ}$  thal, Hb S- $\beta^{+}$  thal, and <u>symptomatic</u> Hb AS require AMS submission.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete history of symptoms with report of any symptomatic vaso-occlusive episodes, episodes of abdominal pain, hematuria, or renal dysfunction, and any history of rhabdomyolysis, splenic infarct, and/or sudden death with prolonged physical activity (e.g., military boot camp, training for athletic competition)
  - b. Complete list of all therapies, current medications with dates of initiation, doses, and all adverse effects
- 2. Consultation reports from all treating providers or specialists during symptomatic episodes:
  - a. Consultation report from a hematologist should be included if the diagnosis is uncertain
- 3. Laboratory studies required:
  - a. CBC, BMP, urinalysis, and hemoglobin electrophoresis
  - b. All other laboratory and imaging studies ordered by consulting specialist(s), if performed
- 4. Current physical examination findings.
- 5. Any other pertinent information.
- 6. Form FL4 with return to duty and ALC status, if applicable.
- 7. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

#### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Subjective symptoms with specific comment on any interval symptomatic vasoocclusive episodes.
  - b. Complete list of all therapies, current medications with dates of initiation, doses, and all adverse effects
- 2. All clinical notes and consultation reports from treating providers or specialists during symptomatic episodes (if applicable)
- 3. Laboratory studies required:
  - a. Updated CBC, BMP, and urinalysis
  - b. All other laboratory and imaging studies ordered by treating providers or consulting specialist(s) related to the diagnosis of hemoglobinopathy, if performed
- 4. Current physical examination findings.

- 5. Any other pertinent information.
- 6. Form FL4 with return to duty and ALC status, if applicable.
- 7. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

#### **III. Aeromedical Concerns**

Homozygous sickle cell disease (Hb SS), sickle cell trait (Hb AS), and heterozygosity with another mutant beta globin such as sickle- $\beta$  thalassemia (Hb S- $\beta^{\circ}$  thal), sickle cell-hemoglobin C disease (Hb SC), and sickle- $\beta$ + thalassemia (Hb S- $\beta$ + thal) are conditions that present aeromedical safety concerns in aviation and austere environments. Hb AS is the only condition that is thought to possess aeromedical waiver potential. With rare exception, Hb AS is not associated with increased risk of intravascular sickling and is not predicted to pose significant aeromedical risk. However, it is still imperative for the flight surgeon to educate aircrew and special duty operators about this condition and specifically emphasize the importance of hydration before rigorous activities.

Until 1982, individuals with Hb AS were restricted from entering military flight training or performing aircrew duties, and they were barred from attendance at the US Air Force Academy due to the rare occurrences of intravascular sickling under conditions of physiologic stress. Specifically, case reports have demonstrated an association of increased rates of intravascular sickling in individuals with Hb AS when placed in settings of dehydration, hypoxia, and/or strenuous exercise. In 1985, the Secretary of Defense ordered that "all military occupational restrictions on sickle cell trait be removed." This decision was considered appropriate, because the majority of individuals with Hb AS remain asymptomatic. In contrast to Hb SS and other heterozygous sickling disorders, Hb AS is a relatively benign condition with a better clinical course and more favorable prognosis. The lower percentage of abnormal hemoglobin molecules in Hb AS relative to other hemoglobinopathies result in less association with anemia, a less pronounced decrease in red blood cell survival, and normal or near-normal life expectancy. In contrast, Hb SS and other heterozygous sickling disorders are associated with a worse prognosis and commonly results in more significant anemia, a more pronounced shortening of red blood cell survival, and reduced life expectancy compared to a healthy control population.

In general, current Air Force guidance allows individuals with Hb S to access. When the percentage of Hb S exceeds 45%, it is typically indicative of an underlying Hb SS and/or other heterozygous sickling disorder. These individuals may be barred from accession to the military because the risk of adverse clinical outcomes is thought to exceed the threshold for military service. The following table summarizes the patterns of electrophoresis in the most common hemoglobinopathies:

Condition	Hb A (%)	Hb S (%)	Hb C (%)	Hb F (%)	Hb A2 (%)
Normal (Hb AA)	95-98	0	0	<2	2-3
Sickle cell trait	50-60	35-45 ²	0	<2	<3.5
(Hb AS)					
Sickle- $\beta$ + thalassemia	5-30	65-90	0	2-10	>3.5
(Hb S- $\beta$ + thal)					
Sickle-β thalassemia	0	80-92	0	2-15	>3.5
(Hb S- $\beta^{\circ}$ thal)					
Sickle-hemoglobin C	0	45-50	45-50	1-5	<3.5
disease (Hb SC)					
Homozygous sickle cell	0	85-95	0	5-15	<3.5
disease (Hb SS)					

 Table 2: Adult hemoglobinopathy patterns¹

1. Numbers indicate the percent of total hemoglobin in an untransfused adult patient. Ranges are approximate and may vary depending upon the particular laboratory and assay.

2. Percent Hb S can be as significantly lower in patients with sickle cell trait and concomitant alpha thalassemia.

Review of the AIMWTS database from Jan 2019 through Feb 2022 revealed just 4 individuals (3 untrained & 1 trained) submitted for waiver with a disqualifying diagnosis of symptomatic sickle cell disease/trait. A breakdown of the cases was as follows: 3 FC I/IA cases (3 disqualified), 0 FC II cases, 1 FC III case (0 disqualified), 0 ATC cases, 0 GBO cases, and 0 SWA cases. The 3 untrained individuals who were disqualified from FC I/IA, III, and SWA duties did receive a GBO waiver. The one trained FC III individual who was returned to manned aviation following a symptomatic event had a variety of unique situational contributors that made a sickling recurrence in the aviation environment unlikely.

Please use only	Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		
D57.0	Sickle cell disease with crisis		
D57.1	Sickle cell disease without crisis		
D57.2	Sickle cell/Hb-C disease		
D57.3	Sickle cell trait		
D57.4	Sickle cell thalassemia		
D57.8	Other sickle cell disorders		

#### **IV. Suggested Readings**

- Centers for Disease Control (CDC) Sickle Cell "Toolkit" and Informational Pages. Available at <u>http://www.cdc.gov/ncbddd/sicklecell/toolkit.html</u> and <u>http://www.cdc.gov/ncbddd/sicklecell/traits.html</u>. Accessed 7 February 2022.
- 2. National Athletic Trainers' Association Consensus Statement on Sickle Cell Trait and the Athlete. Available at <a href="https://www.nata.org/sites/default/files/SickleCellTraitAndTheAthlete.pdf">https://www.nata.org/sites/default/files/SickleCellTraitAndTheAthlete.pdf</a>. Accessed 7 February 2022.

**Thalassemia and Other Disorders of Hemoglobin Synthesis (Nov 2020)** Revised: November 2020 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, and Maj Laura Bridge (ACS Internal Medicine)

Significant Changes: Updated to reflect the most recent MSD.

#### I. Waiver Consideration

Any disorder of hemoglobin synthesis is disqualifying for all flying class and SWA duties. Thalassemia syndromes are included under this broader category of hemoglobin synthesis disorders. However, silent thalassemia carrier states (minima), asymptomatic  $\alpha$ -thalassemia trait (minor), and asymptomatic  $\beta$ -thalassemia trait (minor) are *not* disqualifying *if* all other aeromedical standards are met.

Sickle cell disease, symptomatic sickle cell trait, heterozygous sickle cell trait combined with another variant hemoglobin (including any form of  $\beta$ -thalassemia), or any other red blood cell (RBC) sickling syndrome are disqualifying for all flying class, GBO, ATC, and SWA duties, as well as for retention. When a silent thalassemia carrier state, asymptomatic  $\alpha$ -thalassemia trait, or asymptomatic  $\beta$ -thalassemia trait co-exists with another variant hemoglobin, then this combination is disqualifying for all flying class and SWA duties. Sickle cell disease, symptomatic sickle trait, and other RBC sickling syndromes including heterozygous sickle cell trait with  $\beta$ -thalassemia are addressed in the Air Force Waiver Guide chapter *Sickle Cell Disease/Trait & Heterozygous Sickling Disorders*.

Anemia is independently disqualifying for all flying class and SWA duties when the hemoglobin concentration remains consistently below the aeromedical standard. Please refer to the Aerospace Medicine Waiver Guide chapter on *Anemia* for the aeromedical standards pertaining to the lower limit of hemoglobin concentration.

Depending on the type of thalassemia syndrome or hemoglobinopathy, individuals may develop splenomegaly. The finding of splenomegaly is disqualifying for all flying class, GBO, ATC, and SWA duties, as well as for retention. Severe or refractory hemoglobinopathies (including thalassemia syndromes) may be treated with splenectomy, which is disqualifying for all flying class, GBO, ATC, and SWA duties, as well as for retention. Please refer to the Aerospace Medicine Waiver Guide chapter on *Splenectomy* for more information.

Waiver may be considered on a case-by-case basis for individuals with a thalassemia syndrome other than silent carrier states, asymptomatic  $\alpha$ -thalassemia trait, and asymptomatic  $\beta$ -thalassemia trait. Waiver may also be considered on a case-by-case basis for individuals with other disorders of hemoglobin synthesis. In general, waivers are not recommended for individuals with disorders of hemoglobin synthesis that result in anemia of aeromedical significance or who are at risk for decompensation during periods of increased physiologic stress.

Flying Class	Condition ¹	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	α-thalassemia or β-thalassemia trait	N/A ²	N/A
	Hemoglobin H disease	No AETC	No
	β-thalassemia intermedia and β-thalassemia major	No AETC	No
FC II/III/SWA	α-thalassemia or β- thalassemia trait	N/A ²	N/A
	Hemoglobin H disease	No MAJCOM	No
	β-thalassemia intermedia β- thalassemia and major	No MAJCOM	No
ATC/GBO ³	N/A	N/A	N/A

Table 1: Waiver potential for thalassemia syndromes

1. Thousands of unique genetic mutations that result in abnormal hemoglobin synthesis have been described. Conditions other than silent thalassemia carrier states, asymptomatic  $\alpha$ -thalassemia trait, and asymptomatic  $\beta$ -thalassemia trait will be considered for waiver on a case-by-case basis. In general, waivers are not recommended for disorders of hemoglobin synthesis (including the thalassemia syndromes) that result in anemia of aeromedical significance or with the potential for decompensation during periods of increased physiologic stress.

2. Isolated, asymptomatic  $\alpha$ -thalassemia and  $\beta$ -thalassemia trait (minor) are not disqualifying if the severity of the resultant anemia meets the aeromedical standard for acceptable lower limit of hemoglobin concentration. Please refer to the Aerospace Medicine Waiver Guide chapter on *Anemia*.

3. Thalassemia is not specifically disqualifying for ATC and GBO duties. However, any associated anemia may be independently disqualifying if the individual is symptomatic, the anemia is unresponsive to appropriate therapies, or follow-up with a hematologist is required more frequently than annually.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative). The physical examination must comment on the following: skin, mucous membranes, heart, lungs, abdomen (including presence or absence of a palpable spleen), and extremities.

- b. Specify the presence or absence of symptoms at initial presentation and throughout evaluation/treatment course.
- c. Summary of diagnostic evaluation, including list of any/all treatments with dates.
- d. Medical history and all medications with dosages.
- e. Specify ethnicity, place of ancestral origin, and any family history of anemia, hemoglobinopathy, thalasemmia, or other blood disorders.
- 2. Consultation report from any specialty provider and all subsequent consultation notes.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of thalassemia/hemoglobinopathy, including laboratory studies, imaging, and any other ancillary tests. The below-listed studies must be included:
  - a. Current complete blood count (CBC) with red blood cell (RBC) indices
  - b. Peripheral smear
  - c. Iron studies (total serum iron, total iron binding capacity, and iron saturation)
  - d. Ferritin
  - e. Hemoglobin electrophoresis
  - f. Reticulocyte count
  - g. If the spleen is palpated on physical exam, an abdominal ultrasound is required (radiology report is sufficient)
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. <u>Renewal Waiver Request</u>:
  - 1 Updated AMS with interval history, including:
    - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
    - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - 2 All relevant interval consultation reports from specialty providers.
  - 3 Results of all interval testing performed in the course of ongoing thalassemia/hemoglobinopahty evaluation and management, including laboratory studies, imaging, and any other ancillary tests.
  - 4 Current CBC with RBC indices.
  - 5 Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
  - 6 If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

#### **III. Aeromedical Concerns**

Of the thousands of different hemoglobin abnormalities that are known, the most common hemoglobin disorders are the thalassemia syndromes and sickle cell disease. The term *thalassemia* refers to a spectrum of diseases that are associated with reduced or absent synthesis of either the  $\alpha$ -globin or  $\beta$ -globin chain of the hemoglobin molecule. More common thalassemia syndromes include asymptomatic carrier states (minima),  $\alpha$ -thalassemia trait (minor),  $\beta$ -thalassemia trait (minor),  $\beta$ -thalassemia intermedia, and  $\beta$ -thalassemia major. Other types of thalassemia are rarer, such as delta-beta-thalassemia ( $\delta\beta$ -thalassemia).

Due to mutations in one or more of the alleles encoding  $\alpha$ - and/or  $\beta$ -globin synthesis, the thalassemia syndromes are characterized by decreased hemoglobin production, resulting in a hypochromic microcytic anemia. Hundreds of genetic mutations have been described. The clinical phenotype varies widely based on the type of mutation and the number of normal alleles. Presentations range from clinically asymptomatic to severe hemolytic anemia with transfusion dependence. In the most severe cases, the condition may not be compatible with life, resulting in fetal demise or stillbirth.

α-Thalassemia	Genotype	Expected	Typical
Syndrome		Hemoglobin	Phenotype
		Concentration	
		(g/dL)	
Silent carrier state	αα/α-	Normal	Asymptomatic; may develop mild
(minima)			microcytosis or hypochromia
Trait (minor)	α-/α- OR αα/	> 10	Asymptomatic; mild microcytosis
			and hypochromia
Hemoglobin H	α-/	7-10	Splenomegaly, hemolytic anemia,
			transfusion dependence develops
			in 2nd or 3rd decade; hemolysis
			worsens under oxidative stress
Hydrops fetalis	/	Incompatible with	Death in utero or shortly after
		life	birth
β-Thalassemia	Genotype ¹	Expected	Typical
Syndrome		Hemoglobin	Phenotype
Synurome		0	J 1
Synurome		Concentration	
Synurome		0	
Silent carrier state	$\beta/\beta^+$	Concentration	Asymptomatic; may develop mild
		Concentration (g/dL)	
Silent carrier state	$eta/eta^+$ $eta/eta^0$	Concentration (g/dL)	Asymptomatic; may develop mild
Silent carrier state (minima)	β/β ⁰	Concentration (g/dL) > 10	Asymptomatic; may develop mild microcytosis or hypochromia
Silent carrier state (minima)		Concentration (g/dL) > 10	Asymptomatic; may develop mild microcytosis or hypochromia Asymptomatic; mild microcytosis
Silent carrier state (minima) Trait (minor)	β/β ⁰	Concentration           (g/dL)           > 10           > 10	Asymptomatic; may develop mild microcytosis or hypochromia Asymptomatic; mild microcytosis and hypochromia
Silent carrier state (minima) Trait (minor)	β/β ⁰	Concentration           (g/dL)           > 10           > 10	Asymptomatic; may develop mild microcytosis or hypochromia Asymptomatic; mild microcytosis and hypochromia Moderate hemolysis, pronounced

Table 2.	Genotypic and	nhenotynic	characteristics	of the most co	ommon thalassem	ia syndromes
Table 2.	Genotypic and	phenotypic	character istics	of the most co	minon thatassem	la synuromes

1.  $\beta^+$  mutant allele results in reduced  $\beta$ -globin chain synthesis.  $\beta^0$  mutant allele results in *no*  $\beta$ -globin chain synthesis.

Identification of individuals with a disorder of hemoglobin synthesis is important for optimal clinical management. The genotypic abnormality determines the severity of the phenotypic expression, and detailed genetic analysis assists affected individuals with decision-making in respect to childbearing. However, for aeromedical purposes, it is the phenotypic expression that is of primary importance. Genotypic analysis is helpful in aeromedical risk assessment insofar as it predicts the potential clinical manifestations that a service member may experience.

Manifestations of clinically symptomatic thalassemia syndromes and other hemoglobinopathies that are of aeromedical importance include anemia, hemolysis, splenomegaly, RBC sickling, and iron overload. End-organ dysfunction may result from such pathophysiologic mechanisms as decreased tissue oxygenation or excess iron deposition. Aeromedical risks are manifold. For example, symptoms of anemia include fatigue, generalized weakness, decreased stamina, lightheadedness, chest pain, and decreased Gz tolerance. The body's ability to compensate for anemia may be overwhelmed in the setting of hypoxia or the physiologic stress of the aviation or operational environments. Hemolysis may be exacerbated by these same physiologic stressors, and hemolytic crises may be triggered by such mild insults as an acute viral illness or dehydration. For these reasons, conditions associated with anything other than the mildest degree of abnormal hemoglobin synthesis are not thought to carry waiver potential. In particular, individuals requiring transfusion or who may be at risk for decompensation under conditions of physiologic stress are not considered to be eligible for a waiver.

Review of the AIMWTS database from Nov 2017 through Nov 2020 revealed 82 cases with a diagnosis of thalassemia. A breakdown of the cases was as follows: 21 FC I/IA cases (3 disqualified), 13 FC II cases (0 disqualified), 39 FC III cases (1 disqualified), 1 ATC cases (0 disqualified), and 5 GBO cases (1 disqualified), 3 SWA cases (0 disqualified). Most of these cases represented  $\alpha$ - and  $\beta$ -thalassemia trait (minima or minor) and many were granted an indefinite waiver. Of the 6 disqualified cases, all were disqualified for reasons other than the thalassemia. Additionally, most cases would no longer be disqualifying IAW the most recent version of the MSD.

Please use <i>only</i> these ICD-10 codes for AIMWTS coding purposes				
D56.9	Thalassemia, unspecified			
D58.2	Other hemoglobinopathies			

# **IV. Suggested Readings**

- Hemoglobinopathies: current practices for screening, confirmation and follow-up. Centers for Disease Control and Prevention and Association of Public Health Laboratories. December 2015. Available at <u>https://www.cdc.gov/ncbddd/sicklecell/documents/nbs_hemoglobinopathy-testing_122015.pdf</u>. Accessed 6 November 2020.
- Ryan K, Bain BJ, Worthington D, et al. Significant haemoglobinopathies: guidelines for screening and diagnosis. Br J Haematol 2010;149:35-49. Available at <u>https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1365-2141.2009.08054.x</u>. Accessed 6 November 2020.
- Taher A, Vichinsky E, Musallam K, et al. Guidelines for the Management of Non Transfusion Dependent Thalassaemia (NTDT). Weatherall D, editor. Nicosia (Cyprus): Thalassaemia International Federation; 2013. Available at <u>https://thalassaemia.org.cy/wp-content/uploads/2017/10/NTDT-final-combined-1.pdf</u>. Accessed 6 November 2020.





# Thrombocytopenia, Immune Thrombocytopenia (ITP), and Thrombotic Thrombocytopenic Purpura (TTP)

Revised: Aug 2022

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator); Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

**Significant Changes:** Waiver guide restructured, updated to reflect the most recent MSD and clinical nomenclature.

## I. Waiver Consideration

Any disorder of platelet function and/or thrombocytopenia with platelet counts < 100,000/mm³ are disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. These disorders of platelet function include, but are not limited to, immune thrombocytopenia (ITP, formerly known as "idiopathic thrombocytopenia") and immune thrombotic thrombocytopenic purpura (TTP, formerly known as "idiopathic thrombocytopenic purpura").

The use of any medication used to treat such disorders that is not included on the applicable career field medication list is also disqualifying for ongoing aviation or operational duty and would necessitate a waiver. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of thrombocytopenia in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

Waiver may be considered for trained personnel with a history of a single episode of resolved ITP or thrombocytosis after at least six months of demonstrated asymptomatic stability, off of any medication used to treat the thrombocytopenia, with sustained platelet counts above 100,000/mm³. For untrained FC II, FC III, ATC, GBO, OSF, and SWA applicants with a history of a single episode of resolved ITP or thrombocytosis who meet the aforementioned criteria, a waiver may also be considered. Additionally, a waiver may be considered for FC I/IA applicants with a history of thrombocytopenia or ITP occurring in childhood and resolving before the age of 18. However, a waiver is unlikely for FC I/IA applicants with any history of ITP, TTP, or thrombocytopenia with platelet counts below 100,000/mm³ occurring after age 18.

Both trained and untrained FC II, III, ATC, GBO, OSF, and SWA personnel may request a waiver for a history of recurrent ITP or for thrombocytosis with platelet counts maintained between 50,000-100,000/mm³. Again, it is expected that individuals will be asymptomatic, off of all medications used to treat thrombocytopenia, with stable platelet counts for at least 6 months prior to waiver submission. Waiver eligibility for these individuals will be assessed on a case-by-case basis. Waivers are unlikely when platelets are consistently below 50,000/mm³.

The aeromedical risks associated with even a single episode of TTP are significantly higher than the risks associate with ITP or thrombocytopenia of other etiologies. As such, two years of disease-free stability should be demonstrated before a waiver consideration for both trained and untrained FC II, III, ATC, GBO, OSF, and SWA personnel, and platelet counts must be maintained above 100,000/mm³. Generally, any individual with a history of recurrent TTP is unlikely to be granted a waiver.

Flying Class	Condition	Waiver Potential	ACS Review or	
IFC I/IA	Thrombocytopenia or ITP occurring in childhood and	Waiver Authority Yes AFRS/CMO	Evaluation No	
	resolving before age 18 years History of ITP or TTP occurring after age 18 years or any sustained platelet	Unlikely AFRS/CMO	No	
FC II/III/ATC/	count below 100,000/mm ³ on repeat testing History of a single episode of	Yes ¹	No	
GBO/OSF/SWA	ITP, resolved, with sustained platelets above 100,000/mm ³ , off all medication with stable platelets for at least 6 months	MAJCOM ²	INU	
	History of recurrent ITP, or ongoing ITP that is not resolved with platelets maintained between 50,000- 100,000/mm ³ , off all medication with stable platelets for at least 6 months	Yes ¹ MAJCOM ²	Yes ³	
	History of recurrent ITP, or ongoing ITP that is not resolved with platelets below $50,000/\text{mm}^3$	No MAJCOM ²	No	
	History of a single episode of TTP, resolved, with sustained platelets above 100,000/mm ³ , with 2 years of disease-free stability	Yes ¹ MAJCOM ²	No ³	
1 NT ' 1 (° '/ '	History of recurrent TTP	Unlikely MAJCOM ²	No	

 Table 1: Waiver potential for Thrombocytopenia, Immune Thrombocytopenia (ITP), and Thrombotic Thrombocytopenic Purpura (TTP)

1. No indefinite waivers.

2. Certification authority for untrained assets is AFRS/CMO.

3. ACS review is recommended for FC II, III, OSF, and SWA personnel. ACS review for other personnel may be requested at the discretion of the waiver authority.

# II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - c. List current medications with dosages.
- 2. Consultation report from the treating hematologist and all subsequent consultation notes.
- 3. Laboratory studies required:
  - a. Current CBC with differential.
  - b. All past CBC results with dates.
  - c. Peripheral blood smear.
  - d. Bone marrow aspiration (required if age greater than 60 years or if clinically indicated).
  - e. If treated with glucocorticoid therapy for more than three consecutive weeks in the previous 12 months, then demonstration of an intact hypothalamic-pituitaryadrenal (HPA) axis is required (refer to the *Systemic Glucocorticoid (Steroid) Waiver Guide*).
    - i. Serum morning cortisol level is required.
    - ii. If morning cortisol is < 18 mcg/dL, then an adrenocorticotropic hormone (ACTH) stimulation test is required.
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of thrombocytopenia, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Summarize any interval evaluation and/or treatment.
  - c. List current medications with dosages.
- 2. All interval consultation reports from the treating hematologist, if applicable. A new hematology consultation is required if there was any interval fluctuation in platelet counts since the previous waiver or if platelet counts are below 100,000/mm³.
- 3. Laboratory studies required:
  - a. Current CBC with differential

- b. All interval CBCs obtained at least every 3 months (not required after 6 or more years of sustained stable remission)
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of thrombocytopenia, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

In general, thrombocytopenia is defined as a platelet count below 150,000/mm³. Platelet counts in cases of mild thrombocytopenia range between 100,000-150,000/mm³. The risk of bleeding with trauma or surgery is typically not increased until platelets fall below 75,000/mm³. Spontaneous bleeding is unlikely at platelet counts above 30,000/mm³, whereas individuals with platelets between 5,000-10,000/mm³ are at risk for spontaneous, life-threatening hemorrhage.

True thrombocytopenia may be caused by under-production of platelets or by increased platelet destruction. The severity of the clinical sequelae associated with thrombocytopenia vary dramatically depending upon the underlying cause of the low platelet count. For example, transient, mild hypothermia may result in a relatively benign thrombocytopenia due to splenic sequestration. In this example, rewarming leads to a return of normal platelet count and function, the aeromedical and operational risk associated with the thrombocytopenia is minimal after the cause of the hypothermia is addressed.

Hypersplenism resulting in increased platelet destruction is of greater clinical, aeromedical, and operational concern. More than 200 separate disease processes are associated with the development of congestive splenomegaly and hypersplenism. Generally, platelet counts in the setting of hypersplenism are maintained above 50,000/mm³. While spontaneous bleeding is not common at these counts, there may be an increased risk of bleeding with mild trauma such as might be encountered in an aviation or operational environment. It is important to note that splenomegaly and splenectomy (which is not always curative of associated thrombocytosis or anemia) may both be disqualifying for continued duty performance or retention. Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions.

Immune thrombocytopenia (ITP) and immune thrombocytopenic purpura (TTP) are more serious and potentially life-threatening causes of low platelet counts, especially in an adult population. Patients with ITP often present relatively acutely with petechiae, purpura, gingival bleeding, or recurrent ecchymosis. They may provide a slightly longer history of easy bruising. The longterm prognosis is excellent for ITP that occurs during childhood (before age 18 years) and that resolves completely. Regardless of treatment necessary to achieve remission, these individuals often sustain remission without recurrence or long-term sequelae. In contrast, adult-onset ITP (occurring at age 18 years or later) tends to follow a more persistent and indolent course, frequently characterized by recurrent exacerbations of disease over a period of many years. The estimated lifetime risk of fatal hemorrhage for a person with ITP is approximately 5%, while the risk of a nonfatal major hemorrhage is 3% per year for patients younger than 40 years of age. No conclusive data exist regarding the ability of clinical or laboratory parameters at time of diagnosis to predict the risk of major bleeding.

TTP is one of the thrombotic microangiopathy (TMA) syndromes. Primary TMA syndromes also include Shiga toxin-mediated hemolytic uremic syndrome (ST-HUS), complement-mediated TMA, and drug-induced TMA, which may be immune or non-immune mediated. TTP is an acute, fulminant disorder characterized by thrombocytopenia, microangiopathic hemolytic anemia, fever, variable neurological symptoms, and other end-organ damage. Affected organ systems include the CNS, heart, pancreas, thyroid gland, adrenal glands, and intestinal mucosa. In TTP, lung and kidney function are typically spared, though microthrombi are observed in the kidneys upon autopsy. Other TMA syndromes tend to be characterized by significant kidney damage and renal failure. Even among those fortunate individuals who recover from acute TTP, many experience demonstrable cognitive impairments to new learning and memory formation that persist for years.

The onset of TTP may be sudden, and the disease course may quickly progress to become lifethreatening, even with definitive medical care. Plasma exchange is the only therapy with data indicating survival benefit. Without plasma exchange, the acute mortality is approximately 90%. Some individuals may require treatment with glucocorticoids or other more intensive immunosuppressive agents such as rituximab, cyclophosphamide, vincristine, or cyclosporine to obtain a remission. Relapse is common, occurring in 20% of individuals with idiopathic TTP within the first year. The risk of relapse is highest in those with the most severe deficiencies of the protease ADAMTS13.

Treatment for ITP and TTP is often not compatible with sustained aviation or operational duties. For example, active use of corticosteroids or intravenous immunoglobulin infusions are not amenable to waiver. Splenectomy is independently disqualifying and requires a waiver. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 23 cases with a diagnosis of a thrombocytopenic disorder. The breakdown of the number of waivers and number of total cases are tabulated below. The two FC I/IA disqualifications were for reasons associated with the diagnosis of thrombocytopenia.

Please use <i>only</i> this ICD-10 code for AIMWTS		(# of waivers / total # of cases)				
coding p	ourposes	IFC I/IA	FC II	FC III	GBO	SWA
D69.3	Immune thrombocytopenic purpura	- / -				
D69.6	Thrombocytopenia, unspecified	3/5	10/11	4/4	2/2	1/1
M31.1	Thrombotic microangiopathy					

#### **IV. Suggested Readings**

- Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv 2019;3:3829-3866. Erratum in: Blood Adv 2020;4:252. Available at <u>https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for</u>. Accessed 18 Aug 2022.
- Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. Blood Adv 2019;3:3780-3817. Available at <u>https://ashpublications.org/bloodadvances/article/3/22/3780/428877/Updated-international-consensus-report-on-the?searchresult=1</u>. Accessed 18 Aug 2022.
- Zheng XL, Vesely SK, Cataland SR, et al. Good practice statements (GPS) for the clinical care of patients with thrombotic thrombocytopenic purpura. J Thromb Haemost 2020;18:2503-2512. Available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/jth.15009. Accessed 18 Aug 2022.
- Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for the diagnosis of thrombotic thrombocytopenic purpura. J Thromb Haemost 2020;18:2486-2495. Erratum in: J Thromb Haemost 2021;19:1381. Available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/jth.15006. Accessed 18 Aug 2022.
- Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. J Thromb Haemost 2020 Oct;18:2496-2502. Available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/jth.15010. Accessed 18 Aug 2022.





# Thrombocytosis

Revised: Aug 2022

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator); Lt Col Paul Vu (AFRMA Medical Standards Policy Chief)

**Significant Changes:** Waiver guide restructured, updated to reflect the most recent MSD and clinical nomenclature.

# I. Waiver Consideration

Any persistent elevation of platelets above 400,000/mm³ is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. Any myeloproliferative disorder, including but not limited to essential thrombocytosis, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention, regardless of platelet count. Any disorder of platelet function that predisposes to bleeding or coagulopathy is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties as well as for retention. Disorders of platelet function are covered in the Waiver Guide chapter *Thrombocytopenia, Immune Thrombocytopenia (ITP), and Thrombotic Thrombocytopenic Purpura (TTP)*. Isolated thrombocytosis that is confirmed by appropriate diagnostic evaluation to be due to an acute, self-limited, and otherwise benign reactive process (e.g., surgery or infection) is not disqualifying, provided that platelet counts return to normal.

The use of any medication used to treat such disorders that is not included on the applicable career field medication list is also disqualifying for ongoing aviation or operational duty and would necessitate a waiver. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of thrombocytosis in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

When a reactive thrombocytosis is sustained or chronic due to splenectomy, a waiver may be considered for both trained and untrained personnel after at least six months of asymptomatic stability without need for aeromedically unapproved medication. IFC I/IA candidates with thrombocytosis due to any cause other than splenectomy are generally not considered eligible for a waiver. Other untrained flying class and operational duty personnel with sustained thrombocytosis of any cause other than splenectomy are also unlikely to be considered for waiver, although certain low-risk individuals with sustained reactive thrombocytosis may be considered for waiver on a case by case basis.

Most causes of primary or autonomous thrombocytosis will not be considered compatible with continued aviation or operational duties. Rarely, a trained individual without any high-risk features or indication for cytoreductive therapy may be deemed eligible for a waiver after a

scrupulous and personalized risk assessment. Factors taken into consideration include, but are not limited to, absence of symptoms, stable platelet counts below 1,000,000/mm³, no history of thrombosis or hemorrhage, no JAK2 mutation, no concomitant tobacco use, and no comorbid cardiovascular risk factors such as diabetes or hypertension. Use of low-dose aspirin (e.g., 81 mg/day) to prevent or control vasomotor symptoms of thrombocytosis may be acceptable for waiver depending upon overall individualized risk.

Individuals with essential thrombocytosis and a clinical indication for cytoreductive therapy are typically not considered eligible for a waiver. Polycythemia vera with associated thrombocytosis, primary myelofibrotic thrombocytosis, and other myelodysplastic disorders resulting in thrombocytosis are also not generally thought to be compatible with waiver.

Flying Class	Condition	Waiver Potential	ACS Review or	
		Waiver Authority	Evaluation	
IFC I/IA	Sustained reactive thrombocytosis due to splenectomy ¹	Yes ² AFRS/CMO	No	
	All other cases of sustained thrombocytosis	Unlikely AFRS/CMO	No	
FC II/III/ATC/ GBO/OSF/SWA	Sustained reactive thrombocytosis due to splenectomy ¹	Yes ² MAJCOM ³	No	
	Sustained reactive thrombocytosis due to cause other than splenectomy	Yes ^{2,4} MAJCOM ³	Yes	
	Essential thrombocytosis, not requiring cytoreductive therapy	Yes ^{2,4,5} MAJCOM ³	Yes	
	Essential thrombocytosis, requiring treatment with cytoreductive therapy	Unlikely MAJCOM ³	No	
	All other causes of thrombocytosis	Unlikely MAJCOM ³	No	

 Table 1: Waiver potential for Thrombocytosis

1. History of splenectomy is independently disqualifying. Please refer to the Aerospace Medicine Waiver Guide chapter on *Congenital and Acquired Asplenia*.

2. No indefinite waivers.

3. Certification authority for untrained assets is AFRS/CMO.

4. Untrained applicants are generally not considered eligible for waiver.

5. Waiver may be considered for certain low-risk personnel on a case-by-case basis. Generally, waiver eligibility will depend upon the individual being asymptomatic and demonstrating stable platelet counts below 1,000,000/mm³, without need for treatment, without history of thrombosis or hemorrhage, and without JAK2 mutation or other high-risk features (e.g., concomitant tobacco use or comorbid hypertension, diabetes). Use of low-dose aspirin (e.g., 81 mg/day) to prevent/control vasomotor symptoms of thrombocytosis may be acceptable for waiver depending upon overall individualized risk.

## **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative). Include a thorough examination of the skin, abdomen, and neurologic system.
  - b. Specify any history of thrombosis or bleeding episodes.
  - c. List cardiovascular risk factors.
  - d. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - e. List current medications with dosages.
- 2. Consultation report from the treating hematologist and all subsequent consultation notes.
- 3. Laboratory studies required:
  - a. Current CBC with differential.
  - b. All past CBC results with dates.
  - c. Peripheral blood smear.
  - d. Serum ferritin.
  - e. Erythrocyte sedimentation rate (ESR).
  - f. C-reactive protein (CRP) level.
  - g. Janus kinase 2 (JAK2) gene mutation test result.
  - h. Bone marrow aspiration result.
- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of thrombocytosis, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Summarize any interval evaluation and/or treatment.
  - c. List current medications with dosages.
- 2. All interval consultation reports from the treating hematologist.
- 3. Laboratory studies required:
  - a. Current CBC with differential
  - b. All interval CBCs obtained at least every 6 months (if history of essential thrombocytosis) or 12 months (for other causes of thrombocytosis), or more often if clinically indicated

- 4. Results of any other testing performed in the course of diagnosis, evaluation, and management of thrombocytosis, including other laboratory studies, all imaging reports, biopsies/pathology results (if performed), and any other ancillary studies.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# **III. Aeromedical Concerns**

In general, thrombocytosis (also referred to as thrombocythemia) is a platelet count above a laboratory-defined upper limit of normal. In most cases, this upper limit is between 350,000-450,000/mm³. The World Health Organization (WHO) defines thrombocytosis as any platelet count above 450,000/mm³. A small percentage of healthy individuals will meet this definition of thrombocytosis. However, the overwhelming majority of platelet counts above 450,000/mm³ are due to either a primary clonal (i.e., autonomous) disorder or a reactive process.

Primary clonal (or autonomous) thrombocytosis due to a myeloproliferative disorder (e.g., polycythemia vera, chronic myeloid leukemia, primary myelofibrosis, essential thrombocytosis), myelodysplastic disorders, or hereditary condition is associated with an increased risk of both thrombosis and hemorrhage. Autonomous thrombocytosis is also associated with vasomotor symptoms that include headache, lightheadedness, visual changes, chest pain, erythromelalgia, and acral dysesthesia. The particular likelihood of any of these complications varies depending on the underlying etiology of the thrombocytosis (e.g., essential thrombocytosis, myelodysplastic disorder, hereditary thrombocytosis, etc.). Some causes of autonomous thrombocytosis are also associated with other cell line dyscrasias, such as anemia. At a minimum, vasomotor symptoms would be distracting in an aviation or operational environment. A more severe complication such as erythromelalgia or intense chest pain could be debilitating enough to prevent safe performance of aviation or operational duties, while a catastrophic thrombotic or hemorrhagic event could occur without warning and be incapacitating or fatal.

Certain individuals with autonomous thrombocytosis may be candidates for low-dose aspirin therapy to reduce the risk of vasomotor symptoms. However, it is important to note that myelodysplastic disorders, especially essential thrombocytosis, are associated with the development of acquired von Willebrand disease. Use of aspirin in this setting does increase the risk of hemorrhage.

Clinically, cytoreductive agents are often used to lower platelet counts and complication rates in essential thrombocytosis and related disorders. Two of the most common cytoreductive agents are hydroxyurea and anagrelide. Due to their adverse effect profiles and the seriousness of the underlying conditions, neither the drugs nor the disease processes are considered compatible with continued aviation or operational duties. Even when platelets return to a normal range through cytoreduction, they are still qualitatively and functionally abnormal, and complications exceed acceptable risk thresholds.

Reactive thrombocytosis is most often a normal physiologic response to an underlying inflammatory condition. It may be transient, as occurs with an acute infection or surgery. It may also be sustained, as might occur following a splenectomy or in the setting of a chronic infectious process or autoimmune condition. Reactive thrombocytosis does not result in the vasomotor symptoms that are common with autonomous thrombocytosis. In general, reactive thrombocytosis is not associated with significant increase in risk of thrombotic or hemorrhagic complication beyond the risk due to the underlying disease state or inflammatory process. However, in extreme reactive thrombocytosis (platelet counts in excess of 1,000,000/mm³), the rates of thrombosis and hemorrhage are approximately 1% and 3%, respectively.

Sustained reactive thrombocytosis should prompt an evaluation for an undiagnosed or inadequately controlled infection, autoimmune process, malignancy, or other inflammatory disorders. Even if the thrombocytosis is stable and the patient is asymptomatic, the underlying condition may be disqualifying (e.g., splenectomy, chronic infection, autoimmune disease). Please cross-reference the Medical Standards Directory and Air Force Waiver Guide for all potentially disqualifying conditions and treatments.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 12 cases with diagnosis of a disorder that was associated with thrombocytosis. The breakdown of the number of waivers and number of total cases are tabulated below. Myeloproliferative and myelodysplastic disorders NOT presenting with thrombocytosis are not represented in the table.

Please use <i>only</i> this ICD-10 code for AIMWTS		(# of waivers / total # of cases)		
coding pu	coding purposes		FC II	FC III
D47.3	Essential thrombocythemia		3/4	2/2
D45	Polycythemia vera			
D47.1	Primary myelofibrosis		0/1	
C92.1	Chronic myeloid leukemia			
D46.9	D46.9 Myelodysplastic syndrome, unspecified			
D75.838	Reactive or Secondary thrombocytosis	1/1		3/3
D75.839	Thrombocytosis unspecified	0/1		

# **IV. Suggested Readings**

- Barbui T, Thiele J, Gisslinger H, et al. The 2016 WHO classification and diagnostic criteria for myeloproliferative neoplasms: document summary and in-depth discussion. Blood Cancer J 2018;8:15. Available at <u>https://www.nature.com/articles/s41408-018-0054-y.pdf</u>. Accessed 8 March 2022.
- Tefferi A and Barbui T. Polycythemia vera and essential thrombocythemia: 2021 update on diagnosis, riskstratification and management. Am J Hematol 2020;95:1599-1613. Available at <a href="https://onlinelibrary.wiley.com/doi/epdf/10.1002/ajh.26008">https://onlinelibrary.wiley.com/doi/epdf/10.1002/ajh.26008</a>. Accessed 8 March 2022.

## Venous Thromboembolism (VTE) (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator)

Significant Changes: Waiver requirements, anticoagulation agents considered, and aeromedical concerns section updated.

## I. Waiver Consideration

Venous thromboembolism (VTE) is a term used to describe an episode of pulmonary embolism or deep vein thrombosis. Any history of pulmonary embolism is disqualifying for all flying classes, ATC, GBO, and special warfare personnel. It is also disqualifying for retention. Additionally, any history of deep vein thrombosis is disqualifying for FC I/IA/II/III, ATC and special warfare personnel. A single episode of deep vein thrombosis is not disqualifying for GBO. Recurrent episodes of deep vein thrombosis is disqualifying for all flying classes, GBO duties, ATC duties, and special warfare duties, as well as for retention. The use of extended (previously referred to as indefinite) anticoagulation is independently disqualifying for all flying and special duty operators as well as for retention.

Aeromedical waivers for venous thromboembolism may be considered after completion of at least three months of anticoagulation. Documentation must be provided to indicate whether the episode of VTE was provoked or unprovoked. Provoked VTE is defined by the presence of an underlying major transient risk factor (i.e., surgery, leg injury, flight > 8 hr, estrogen therapy, pregnancy). Individuals submitting waiver for unprovoked VTE or recurrent VTE require a complete hypercoaglulable evaluation and age-appropriate cancer screening performed prior to waiver submission. After a single episode of either provoked or unprovoked VTE, anticoagulation must be continued for a minimum of three months. Individuals in whom extended anticoagulation is deemed reasonable by the treating provider will require waiver and retention determination. Aeromedical waivers for trained pilots with VTE who require extended anticoagulation will be restricted to FC IIC, non-high performance, non-ejection seat, dual-control aircraft.

Historically, warfarin (Coumadin®) has been the anticoagulant of choice for individuals requiring extended anticoagulation since monitoring and reversal agents are readily available. However, the monitoring for warfarin can be operationally burdensome given the need for frequent laboratory testing and dose adjustments. Direct oral anticoagulants (DOACs) such as apixaban (Eliquis®), rivaroxaban (Xarelto®), dabigatran (Pradaxa®), and edoxaban (Savaysa®) do not require monitoring or dose adjustments. These short-acting medications have similar safety and efficacy to warfarin with some agents having lower rates of spontaneous cranial and gastrointestinal hemorrhaging. Additionally, reversal agents are available for apixaban, rivaroxaban, and dabigatran. Individuals treated with DOACs can be considered for an aeromedical waiver on a case-by-case basis.

Flying Class (FC)	Condition ^{1,2,3}	Wavier Potential Waiver Authority	ACS Review or Evaluation
I/IA	Provoked VTE, single episode, no longer requiring anticoagulation	Yes AETC	Yes
	Recurrent or unprovoked VTE	No AETC	No
II/III ATC/SWA	Provoked VTE, single episode ⁴	Yes MAJCOM ⁵	Yes
	Recurrent VTE or unprovoked VTE ⁴	Yes MAJCOM ⁵	Yes
GBO	Deep vein thrombosis, single episode, no longer requiring anticoagulation	N/A	N/A
	Pulmonary embolism, single episode	Yes MAJCOM ⁵	Yes
	Recurrent VTE or unprovoked VTE	Yes MAJCOM ⁵	Yes

Table 1: Waiver potential for VTE including DVT and PE

1. Waivers for VTE may be considered after completion of at least three months of anticoagulation.

2. Individuals with provoked VTE do not require a hypercoagulable workup. Individuals with unprovoked or recurrent VTE require a hypercoagulable workup to include testing for Factor V Leiden and prothrombin gene mutations, protein C, S, and antithrombin activity/levels, and antiphospholipid antibody testing.

- 3. All individuals requiring the use of extended anticoagulation require aeromedical waiver. Utilization of DOACs can be considered for waiver on a case-by-case basis.
- 4. Pilots requiring extended anticoagulation will be considered for a restricted waiver only (non-high performance, non-ejection seat, and dual-control aircraft). Similarly, special warfare personnel on extended anticoagulation will require restriction from jump duties.
- 5. AFMRA is the waiver authority for unapproved medications or restricted waivers.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Consultation reports form all treating providers or specialists, which should include:
  - a. Documentation whether the VTE episode was provoked or unprovoked.
  - b. Hypercoagulable workup and age-appropriate cancer screening if VTE episode was unprovoked.
    - i. Should include testing for Factor V Leiden and prothrombin gene mutations, protein C, S, and antithrombin activity/levels, and antiphospholipid antibody testing
  - c. Current monitoring and treatment plan if individual requires extended anticoagulation.
  - d. Documentation of any associated complications such as post-thrombotic syndrome or chronic thromboembolic pulmonary hypertension (CTEPH).
- 3. Reports of any other pertinent laboratory studies or imaging studies obtained.
  - a. Current d-dimer.
  - b. Current CBC if on anticoagulation. If warfarin is the anticoagulant being utilized, INR values from the preceding three months should be provided.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated).
  - a. Individuals diagnosed with a pulmonary embolism require a full pulmonary function testing and repeat CT pulmonary angiogram (CTPA) after completion of three months of therapy and prior to waiver submission.
- 5. Current physical examination findings.
- 6. FL4 with RTD and ALC status, if applicable.
- 7. Any other pertinent information.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.
- B. <u>Renewal Waiver Request:</u>
  - 1 Updated AMS with interval history.
  - 2 Consultation reports from treating specialist if applicable including current monitoring and treatment plan if individual requires extended anticoagulation.
  - 3 Any interval imaging obtained pertaining to the episode of VTE and updated CBC if on anticoagulation.
  - 4 Current physical examination findings.
  - 5 Any other pertinent information.
  - 6 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# **III. Aeromedical Concerns**

Venous thromboembolism (VTE) presenting as a symptomatic deep vein thrombosis (DVT) or pulmonary embolism (PE) can potentially result in distracting or incapacitating symptoms. Acute DVT may cause symptoms such as swelling and distracting pain. Rarely, significant swelling may lead to neurovascular compromise of the affected limb. Post-thrombotic syndrome is a potential sequelae that can result in recurrent swelling and distracting symptoms. The development of subsegmental pulmonary embolisms may lead to dyspnea and chest pain. Submassive or massive pulmonary embolisms may lead to cardiovascular collapse. The most aeromedical concerning chronic sequelae from pulmonary embolisms is the development of chronic thromboembolic pulmonary hypertension (CTEPH), which would increase the risk of developing hypoxia at altitude, right-sided heart failure, and cardiac arrhythmias.

After completing treatment for an acute episode of VTE, an additional aeromedical concern is the development of a recurrent event. The highest risk of recurrence is within the first year, and individuals with unprovoked VTE are at a higher risk of recurrent events then an individual with a provoked VTE. VTE provoked by surgery is estimated to have a 3% risk of recurrence at 5 years. VTE provoked by a nonsurgical major transient risk factor (i.e., leg injury, flight of >8hrs, estrogen therapy, or pregnancy) has a 15% risk of recurrence at 5 years. Unprovoked VTE not involving a major transient risk factor has a 30% risk of recurrence at 5 years. Thus, individuals with unprovoked VTE should undergo a hypercoagulable workup and age appropriate cancer screening to evaluate for any underlying condition that predisposes to recurrent events. This data was derived from the CEHST guidelines for antithrombotic therapy for VTE disease.

Treatment options to reduce the risk of recurrent episodes of VTE have greatly expanded over the past decade. There are no current anticoagulants on any career-field approved medication lists. However, warfarin (Coumadin®) has been waivered on a case-by-case basis for many years and it historically was the preferred agent due to the ability to monitor adherence and the availability of a reversal agent. As noted above, laboratory monitoring and the need for dose adjustments can become operationally burdensome with warfarin utilization. Direct oral anticoagulants (DOACs) such as apixaban (Eliquis ®), rivaroxaban (Xarelto®), dabigatran (Pradaxa®), and edoxaban (Savaysa®) do not require monitoring or dose adjustments. These short-acting medications have similar safety and efficacy compared to warfarin with some agents having lower rates of spontaneous cranial and gastrointestinal hemorrhaging. Additionally, reversal agents are available for apixaban, rivaroxaban, and dabigatran. Individuals treated with DOACs have recently been considered for an aeromedical waiver on a case-by-case basis. The greatest aeromedical concern of current anticoagulation use is the aviation environment is the development of spontaneous cranial, spontaneous gastrointestinal, or traumatic hemorrhaging. The risk of developing spontaneous bleeding is low in young individuals without any significant comorbidities. There are several validated tools to estimate the risk of developing spontaneous bleeding such as the HAS-BLED tool. Although this specific model was designed looking at individuals with atrial fibrillation treated with anticoagulation to prevent embolic strokes, this tool can be used to assess if the risk of spontaneous bleeding with use of extended anticoagulation outweighs the risk of recurrent VTE. Traumatic hemorrhaging in an austere environment is a significant aeromedical risk. Some career fields such as special warfare airmen have duty requirements that may not be compatible with the use of extended anticoagulation.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 50 individuals with an AMS containing the diagnosis of VTE. Seven individuals (14%) were disqualified. A breakdown of the cases was follows: 5 FC I/IA cases (1 disqualified), 25 FC II cases (4 disqualified), 13 FC III cases (2 disqualified), 4 ATC/GBC cases (0 disqualified), 0 MOD cases, and 3 RPA Pilot cases (0 disqualified).

ICD-9 codes for Venous Thromboembolism (VTE)		
453.89	Deep venous thrombosis	
415.1	Pulmonary embolism	

ICD-10 codes for Venous Thromboembolism (VTE)		
I82.9	Deep venous thrombosis	
I26.9	Pulmonary embolism	

# **IV. Suggested Readings**

1. Kearon C, Akl EA, Ornalas, J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. CHEST: 2016; 149(2):315-352. https://www.ncbi.nlm.nih.gov/pubmed/26867832

2. Tristschler T, Kraaijpoel N, Le Gal G, et al. Venous Thromboembolism: Advances in Diagnosis and Treatment. JAMA. 2018; 320(15):1583-1594.

#### Ankylosing Spondylitis (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) Significant Changes: Content updated to reflect national guidelines.

## I. Waiver Consideration

Ankylosing spondylitis and other nonradiographic axial spondylopathies are disqualifying for all flying classes, ATC duties, GBO duties, special warfare duties, and for retention if symptoms require duty restrictions, frequent absences from duty, ongoing specialty care follow-up greater than once per year, or disease-modifying antirheumatic drugs (DMARDs)/biologic therapies. Additionally, the chronic use of non-selective, non-steroidal anti-inflammatory drugs (NSAIDs) requires waiver for all classes except for GBO duties. Factors considered when assessing suitability for aeromedical waiver include the severity of disease at diagnosis, evidence of stable disease, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the risk associated with specific medication(s), the individual service member's tolerance of the medication(s) and adherence to therapy, and the cumulative risk of all associated complications and/or extra-articular manifestations. Waiver can be considered once an individual is in disease remission on a stable, aeromedically-approved medication regimen, without adverse effects. Use of any medication not included on a career-field approved medication list is independently disqualifying and will be considered on a case-by-case basis.

Cervical spine involvement is relatively common in individuals with ankylosing spondylitis, predisposing individuals to atlantoaxial instability and/or atlantoaxial subluxation. Additionally, chronic inflammation of the axial skeletal system increases the risk of fracture and neurologic complications under forces generated during ejection. Thus, pilots eligible for waiver will be restricted to a FC IIB waiver, non-ejection seat aircraft. A restricted waiver might also be required for individuals assigned to rotary wing airframes due to the risk of disease progression under persistent vibration exposure in these airframes. Special warfare personnel may be restricted from jump status based on the severity of the underlying disease as well. These situations will be considered on a case-by-case basis.

Flying Class (FC)	Waiver Potential ¹	Waiver Authority	ACS Review or Evaluation
I/IA	No	AETC	No
II/III/Special Warfare	Yes ^{2,3,4}	MAJCOM ^{2,3,4}	Yes
ATC/GBO	Yes ^{3,4}	MAJCOM ^{3,4}	No

Table 1: Waiver potential for Ankylosing Spondylitis

6. Untrained personnel of any class are unlikely to receive an aeromedical waiver.

7. Waiver for pilots will be restricted to FC IIB. A FC IIC waiver, non-rotary wing aircraft, or restricted special warfare waiver precluding jump duties will be considered on a case-by-cases basis. AFMRA is the waiver authority for all restricted waivers and cases not meeting retention standards.

8. Use of any medication that is not included on the approved medication list is independently disqualifying, and the MAJCOM may disqualify the service member without AFMRA or ACS review. Waiver may be considered following an ACS review on a case-by-case basis in certain low-risk individuals treated with unapproved medications. The waiver authority for all non-approved medications is AFMRA.

9. Individuals controlled with TNF-alpha inhibitors require AF Form 469 document the need for access to transport and refrigeration (between 36 to 46 degrees Fahrenheit) for any TDY or deployment assignment.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1 Summary of presentation, course, and treatment.
- 2 Consultation reports form treating rheumatologist, which should include:
  - a. Subjective symptoms and objective physical exam findings
  - b. Current treatment plan, to include tolerance and current doses of maintenance medications and all appropriate monitoring labs for those medications (e.g., biologic agents require CBC/CMP every 3-6 months and annual TB testing).
  - c. Documentation excluding/including extra-articular manifestations (i.e., ocular, pulmonary, cardiac, psoriasis, inflammatory bowel disease, etc.)
- 3 All pertinent laboratory studies, including diagnostic and follow-up results.
  - a. Initial serologic testing including HLA-B27
  - b. Recent CBC, CMP, ESR, and CRP.
- 4 Radiology reports from all diagnostic or follow-up imaging studies.
  - a. Initial and updated plain films of the lumbar spine and sacroiliac joints (Ferguson view)

- b. Plain films of the cervical spine if indicated (i.e., neck or occipital pain)
- 5 Current physical examination findings with focus on musculoskeletal exam.
- 6 Echocardiogram if a murmur is auscultated.
- 7 Optometry or ophthalmology evaluation to exclude ocular involvement.
- 8 FL4 with RTD and ALC status, if applicable.
- 9 Any other pertinent information.
- 10 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### B. Renewal Waiver Request:

- 12. Updated AMS with interval history, including:
  - a. Current symptoms and development of any disease flares, complications, or extraarticular manifestations.
  - b. Current medications, doses, and adverse effects.
  - c. Current physical examination findings.
- 13. Consultation reports from treating rheumatologist.
- 14. Any interval imaging obtained pertaining to the ankylosing spondylitis diagnosis.
- 15. Updated CBC, CMP, ESR, and CRP.
- 16. Updated plain films of the lumbar spine and sacroiliac (Ferguson view).
- 17. Updated dilated ocular exam.
- 18. Any other pertinent information.
- 19. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### **III. Aeromedical Concerns**

Ankylosing spondylitis (AS) is a chronic inflammatory disorder resulting in articular and extraarticular symptoms. The most common presentation is the development of inflammatory low back pain (morning stiffness > 30 minutes, pain improved with movement and worse with rest, nocturnal pain, etc.) that may result in significant occupational and functional limitation in the aviation environment. Untreated AS may result in damage and deformities including lumbar spinal fusion, sacral erosions, and cervical spine involvement to include atlantoaxial instability and atlantoaxial subluxation. The progressive nature and involvement of the axial spine in AS increases the risk of traumatic fractures and neurologic compromise. Thus, pilots submitting a waiver will be restricted to a FC IIB waiver, non-ejection seat aircraft. Persistent exposure to vibrations especially in rotary wing airframes increases the risk of disease progression. Thus, a FC IIC waiver, restricted to non-rotary wing airframes, may be warranted depending on the severity of the underlying disease. Additionally, special warfare personnel with significant disease may be restricted from jump status on a case-by-case basis. Ankylosing spondylitis is associated with the development of extra-articular involvement including anterior uveitis, apical pulmonary fibrosis, and cardiac abnormalities (i.e. aortic insufficiency, conduction abnormalities, etc.) that carry further aeromedical risk. Nonradiographic axial spondylopathies present similarly to AS except typical radiographic changes such as sacroiliitis are absent. Nonradiographic axial spondylopathies are associated with other systemic autoimmune disease such as psoriasis and inflammatory bowel disease.

Non-steroidal anti-inflammatory drugs (NSAIDs) are the initial treatment of choice along with physical therapy. Non-selective NSAIDs such as indomethacin have been shown to decrease radiographic disease progression. Selective NSAIDs such as meloxicam and celecoxib are not as effective. Chronic use of non-selective NSAIDs requires a waiver for all flying classes except GBO personnel. There are multiple disease-modifying antirhuematic drugs and biologic agents used for the treatment of AS. The only career-field approved medications for treatment of AS are sulfasalazine, adalimumab, infliximab, and etanercept. Biologic agents such as adalimumab require access to transport and refrigeration (between 36 to 46 degrees Fahrenheit) for any TDY or deployment assignment.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 14 individuals with an AMS containing the diagnosis of AS. Two individuals (14.2%) were disqualified. A breakdown of the cases was follows: 0 FC I/IA cases, 11 FC II cases (1 disqualified), 2 FC III cases (1 disqualified), 0 ATC/GBC cases, 0 MOD cases, and 1 RPA Pilot cases (0 disqualified).

ICD-9 codes for Ankylosing Spondylitis		
720.0	Ankylosing spondylitis	

ICD-10 codes for Ankylosing Spondylitis	
M45.9	Ankylosing spondylitis, unspecified

# **IV. Suggested Readings**

1. Lee JS, Lee S, Bang SY, et al. Prevalence and risk factors of anterior atlantoaxial subluxation in ankylosing spondylitis. *Journal of Rheumatology*. 2012; 39(12):2321-2326.

2. Smith SD, Jurcisn JG, Bowden DR. CV-22 Human Vibration Evaluation. AFRL-RH-WP-TR-2208-0095. April 2008.

3. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondyloarthritis research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Care & research. *Arthritis and Rheumatology*. 2019 Aug 22. doi: 10.1002/art.41042. https://www.ncbi.nlm.nih.gov/pubmed/31436036

4. Ward MM, Reveille JD, Learch TJ, et al. Occupational physical activities and long-term functional and radiographic outcomes in patients with ankylosing spondylitis. *Arthritis and Rheumatology*. 2008; 59(6):822-832.

#### **Diabetes Mellitus (Dec 2019)**

Authors/Reviewers: Maj Laura Bridge, Dr. Christopher Keirns, and Capt Luke Menner (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator)

**Significant Changes:** Updated to reflect most recent guidelines on the management of diabetes and co-morbid diseases, including the current *Standards of Medical Care in Diabetes* from the American Diabetes Association

#### I. Waiver Consideration

Any type of diabetes mellitus is disqualifying for all flying duties, GBO duties, ATC duties and Special Warfare duties. It is also disqualifying for retention. Impaired fasting glucose, impaired glucose tolerance, or pre-diabetes mellitus are not considered disqualifying. However, treatment with metformin requires a waiver. Waiver requirements for diabetes mellitus or for the use of metformin generally follow the recommendations established in the most recent version of the "Standards of Medical Care in Diabetes," which is updated annually by the American Diabetes Association. Individuals who are not treated or monitored to recognized national or international standards of care will not be considered eligible for a waiver. Factors that are considered when assessing suitability for waiver include whether the treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the degree and stability of glucose control, the medication regimen and adherence to treatment, the cumulative risk of all co-morbid conditions, and whether other metabolic or cardiovascular risk factors are present. These factors are also considered in determining whether a restricted or unrestricted waiver is appropriate.

The use of insulin to control blood glucose is considered incompatible with military aviation and enhanced operational duties due to the high incidence and frequency of serious hypoglycemic adverse effects. Therefore, a waiver will not be considered for service members who require insulin treatment. Thus, any person with type 1 diabetes mellitus and anyone with latent autoimmune diabetes in adults (LADA) or type 2 diabetes mellitus treated with insulin will not be considered waiver-eligible.

All waivers for LADA and diabetes mellitus type 2 are considered on a case-by-case basis. Due to the high risk for complications of aeromedical significance, FC I/IA waivers are unlikely to be granted for applicants with any history of diabetes mellitus. Waivers may be considered in low-risk individuals who are treated with other anti-hyperglycemic agents or for untrained FC II, FC III, GBO, ATC, and SWA candidates.

In addition to insulin, many of the medications used to treat diabetes mellitus convey side effects that are incompatible with aviation or enhanced operational duties. The only medications officially approved for use in USAF aviators, ground-based operators, or other special duty operators are metformin and sitagliptin. These medications were approved after careful reviews demonstrated that with appropriate restrictions, the risk of adverse effects of aeromedical consequence were acceptable, including the risk of both symptomatic and subclinical hypoglycemia. To appropriately mitigate risk, waivers for pilots treated with metformin and/or sitagliptin are typically restricted to FC IIC, dual-control aircraft with another qualified pilot.

A waiver request may be considered once a service member demonstrates at least 30 days of stability on an appropriate medication regimen without adverse effects. Blood glucose must be adequately controlled according to accepted national and international guidelines (generally, HbA1c less than 7%). Please refer to the complete list of requirements for waiver consideration in section II, "Information Required for Waiver Submittal."

Flying Class (FC)	Condition	Waiver Potential Waiver Authority ¹	ACS Review or Evaluation
I/IA	Any history of diabetes mellitus type 1 or type 2, regardless of treatment (with the exception of uncomplicated gestational diabetes resolved after delivery)	No AETC	No
ΙΙ/ΙΙΙ	Diabetes mellitus type 2 controlled through therapeutic lifestyle with/without approved medication (i.e., metformin and/or sitagliptin) ²	Yes ² MAJCOM	Yes
	Diabetes mellitus type 1 or 2, treated with insulin or any other non-approved anti-hyperglycemic agent ³	No ³ MAJCOM/AFMRA ³	No ³
GBO/ATC/SWA	Diabetes mellitus type 2 controlled through therapeutic lifestyle with/without approved medication (i.e., metformin and/or sitagliptin)	Yes MAJCOM	No
	Diabetes mellitus type 1 or 2, treated with insulin or any other non-approved anti-hyperglycemic agent ³	No ³ MAJCOM/AFMRA ³	No ³

**Table 1: Waiver potential for Diabetes Mellitus** 

1 AFMRA is the waiver authority for all initial waivers in untrained FC II, III, ATC, GBO, and SWA applicants.

2 Waivers for pilots treated with metformin and/or sitagliptin are typically restricted to FC IIC, dual-control aircraft with another qualified pilot.

**3** Use of any medication that is not included on the approved medication list is disqualifying, and the MAJCOM may disqualify the service member without AFMRA or ACS review. Waiver may be considered following an ACS review on a case-by-case basis in certain low-risk individuals treated with alternative anti-hyperglycemic agents (e.g., GLP-1 receptor agonists, SGLT2 inhibitors). The waiver authority for all non-approved medications is AFMRA. Waiver will not be considered for insulin, and ACS review is not required.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. List all risk factors for metabolic syndrome and atherosclerotic cardiovascular disease (ASCVD)
    - i. Non-modifiable risk factors (age, gender, race/ethnicity, family history)
    - ii. Modifiable risk factors (tobacco use, current blood pressure, current lipid panel, personal history of treatment for hypertension or hyperlipidemia)
  - b. List all treatments trialed, their effectiveness, and any adverse effects
  - c. List current medications, doses, and adverse effects
    - i. At least 30-Days of medication regimen stability should be demonstrated
  - d. List all co-morbid conditions and describe degree of control
  - e. Document completion of a formal multi-disciplinary diabetes education program
- 2. Laboratory studies required:
  - a. Baseline blood glucose measurement and HbA1c level before starting treatment
  - b. Current fasting blood glucose measurement and HbA1c level
  - c. Baseline and current fasting comprehensive metabolic panel (CMP)
  - d. Current fasting lipid panel
  - e. Current quantitative spot urine albumin-to-creatinine measurement
  - f. If treatment includes metformin, include a current complete blood count (CBC) or vitamin B12 level
- 3. Current physical examination findings.
  - a. Include current blood pressure, weight, height
  - b. Report current diabetic foot exam (include visual inspection, vibration sensation assessed with a 128-Hz tuning fork, and either temperature or monofilament sensation)
- 4. Report of a dilated funduscopic examination obtained within the preceding 12 months.
- 5. Current ECG.
- 6. All pertinent clinical encounter notes related to the diagnosis and treatment of diabetes mellitus, including a recent note outlining degree of control/compliance and ongoing treatment plan.
- 7. FL4 with RTD and ALC status.
- 8. Any other pertinent information.
- 9. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# B. Renewal Waiver Request:

- 1 Updated AMS with interval history, including:
  - a Any changes in ASCVD risk factors
  - b. Current medications, doses, and adverse effects
- 2 Updated laboratory studies
  - a Current fasting blood glucose measurement and HbA1c level

- b Current fasting CMP
- c Current fasting lipid panel
- a. Current quantitative spot urine albumin-to-creatinine measurement
- b. If treatment includes metformin, include a current CBC or vitamin B12 level
- 3 Current physical examination findings.
  - a Include current blood pressure, weight, height
  - b. Report diabetic foot exam within the preceding 12 months (include visual inspection, vibration sensation assessed with a 128-Hz tuning fork, and either temperature or monofilament sensation)
- 4 Report of a dilated funduscopic examination obtained within the preceding 12-24 months.
- 5 All pertinent interval clinical encounter notes related to the diagnosis and treatment of diabetes mellitus, including a recent note outlining degree of control/compliance and ongoing treatment plan.
- 6 Any other pertinent information.
- 7 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# **III. Aeromedical Concerns**

Given that diabetes mellitus is a multi-systemic disease that also results in microvascular and macrovascular complications, the immediate and long-term aeromedical concerns are multiple. A primary concern is the risk for hypoglycemia in diabetics who require medication to control their blood glucose. Hypoglycemia is a frequent side effect of many anti-hyperglycemic agents, and risk varies with medication class. Symptoms of hypoglycemia include excess perspiration, tremulousness, nervousness or anxiety, dizziness and/or lightheadedness, central nervous system depression, confusion, difficulty speaking, and weakness. These symptoms are likely with moderate to severe hypoglycemia and are incompatible with flying duties. If hyperglycemia is prolonged, it can lead to polyuria, dehydration, nausea, fatigue, and changes in visual acuity. Subclinical hypoglycemia may result in subtle cognitive and performance decrements. The highest risk for serious consequences of hypoglycemia, including death, occurs in individuals with hypoglycemia unawareness. These individuals may not develop noticeable symptoms despite dangerously low blood glucose levels, and therefore they may not seek timely treatment. In addition to hypoglycemia, diabetes mellitus conveys an increased risk for atherosclerotic cardiovascular disease, including myocardial infarction and stroke. It is also associated with the development of microvascular and macrovascular disease, including retinopathy, nephropathy, and neuropathy, which carry further aeromedical risks.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 65 individuals with an AMS containing the diagnosis of DM. Thirteen individuals (20%) were disqualified. A breakdown of the cases was follows: 0 FC I/IA cases, 29 FC II cases (9 disqualified), 29 FC III cases (4 disqualified), 7 ATC/GBC cases (0 disqualified), 0 MOD cases, and 2 RPA Pilot cases (0 disqualified).

ICD-9 codes for Dia	abetes Mellitus
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250.00	Type 2 diabetes mellitus without mention of complication
250.90	Type 2 diabetes mellitus with unspecified complications
250.01	Type 1 diabetes mellitus without mention of complication
250.91	Type 1 diabetes mellitus with unspecified complications

ICD-10 codes for Diabetes Mellitus		
E11.9	Type 2 diabetes mellitus without complications	
E11.8	Type 2 diabetes mellitus with unspecified complications	
E10.9	Type 1 diabetes mellitus without complications	
E10.8	Type 1 diabetes mellitus with unspecified complications	

# **IV. Suggested Readings**

1. American Diabetes Association. *Standards of Medical Care in Diabetes – 2019*. Diabetes Care 2018; 42(Suppl. 1): S1-S194. Complete text available at https://care.diabetesjournals.org/content/42/Supplement_1. An abridged version of this article for primary care providers is available at https://clinical.diabetesjournals.org/content/37/1/11. A summary of annual revisions is available at https://care.diabetesjournals.org/content/42/Supplement_1/S4.

2. Grundy SM, Stone NJ, Bailey AL, et al. 2018

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/

ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Jointly published in Circulation 2019; 139(25):e1046-e1081 and J Am Coll Cardiol 2019; 73(24):e285-e350. Erratum in: Circulation 2019; 139(25):e1178-e1181 and J Am Coll Cardiol 2019; 73(24):3237-3241. Available at

https://www.ahajournals.org/doi/10.1161/CIR.00000000000624.

3. American College of Cardiology ASCVD Risk Estimator Plus. Available at https://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/.

## WAIVER GUIDE Updated: Jun 2017 Supersedes Waiver Guide of Jul 2013 By: Lt Col Ric Speakman (RAM 18) and Dr Dan Van Syoc Reviewed by Lt Col Michelle Sit, AF/SG consultant for rheumatology

# CONDITION: Gout (Jun 2017)

## I. Waiver Consideration.

Gout with frequent acute exacerbations in spite of therapy, or with severe bone, joint, or kidney disease is disqualifying for all Flying Classes, ATC, GBO, and SWA duties, as well as for retention. Any history of gout is disqualifying for flying classes, I, II, III, and SWA.

Standard	Gout Status	Waiver Potential
		Waiver Authority [†]
FC I/IA	History of Gout	No
		AETC
FC II/III	History of Gout	Yes
SWA		MAJCOM
	Treated with allopurinol,	Yes
	probenecid, or NSAIDs*	MAJCOM
	Colchicine	No
		MAJCOM
ATC, GBO	Treated with allopurinol,	Yes
	probenecid, or NSAIDs*	MAJCOM
	Colchicine	No
		MAJCOM

#### Table 1: Waiver potential for gout

* NSAIDs currently on approved career field specific medication list.

[†]Gout with frequent exacerbations in spite of therapy, or with severe bone, joint, or kidney damage requires an MEB and AFMRA retains waiver authority. For treatment modalities not on the approved medication list, AFMSA retains waiver authority.

Review of AIMWTS data in Feb 2017 revealed a total of 710 cases related to hyperuricemia and/or gout. There were 9 FC I/IA cases, 353 FC II cases, 300 FC III, 35 ATC/GBC cases, 7 MOD cases and 6 RPA pilot cases. Of the total, there were 83 disqualifications; 5 were FC I/IA, 33 were IFC II, 36 were FC III, 8 ATC/GBC, and 1 MOD; although gout should not be waived in FC I/IA applicants, there was a single FC I case was waived for gout. The remaining FCI/IA cases listed uric acid nephrolithiasis as a diagnosis without any history of joint involvement.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for the *initial waiver* for gout should include the following:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. Complete history to include description of acute gouty arthritis (duration, location, response to medical treatment), risk factors (aberrant diet, alcohol intake, elevated BMI) and associated conditions (HTN, kidney stones). Negatives for risk factors and associated conditions should be included.

C. Physical exam with special attention to joints and presence of tophi. Screening radiographs of the hands and feet as hands and feet hold wealth of information about joint health.

D. Labs: Results of joint aspiration; Serum BUN, creatinine, and uric acid. (Uric acid levels are frequently normal during attacks).

E. If prophylaxis begun, then current medication, dose, any side effects, and uric acid level (goal < 6.0 mg/dL). A 24-hour urine for uric acid is required to show that the individual is not a urate over producer if started on probenecid.

F. Consultation report from a rheumatologist or internist.

G. MEB results if completed.

The AMS for <u>waiver renewal</u> for gout should include the following:

A. Interim history to include any interval attacks to along with frequency, specific joint involvement, and treatment.

B. Physical exam with special attention to joints and presence of tophi. If abnormality of joints or tophi, then x-rays of involved area.

C. If on prophylactic treatment then annual uric acid level (goal <6.0 mg/dL) on medications and current medication, dose and side effects experienced.

D. Consultation report from a rheumatologist or internist.

## **III. Overview.**

Gout is a recurrent, often monoarticular, acute arthritis resulting from the deposition of urate crystals within joint spaces and in adjacent cartilage and tendons. Fundamental to the development of gout is a substantial increase in total body uric acid stores, as reflected in the metabolic disorder hyperuricemia. It is important to realize that all patients with gout have hyperuricemia (serum uric acid level exceeding 6.8 mg/dL), but the clear majority of hyperuricemic individuals never experience a clinical event resulting from urate crystal deposition.¹ Gout is a very common disease accounting for an estimated 7 million outpatient visits annually in the United States. Estimates of the prevalence of gout in the United States are estimated to exceed 8 million.¹ Both the incidence and prevalence of the gout appear to be increasing in both the United States and worldwide.²⁻⁷ The estimated prevalence of gout is 3.9% in the US.² The disease attacks men disproportionately, with 73% occurring in men. Gout is

predominantly an idiopathic or multifactorial disease of adult men, with a peak incidence in the fifth decade and it rarely occurs in men before adolescence or in women before menopause.^{1, 2}

Uric acid the end-product of purine metabolism in humans. Most mammals utilize uricase, an enzyme that oxidases uric acid to allantoin. Since humans do not have this ability, the accumulation uric acid is possible by either overproduction of purine metabolites or under-excretion of urate by the kidneys. Hyperuricemia most often (90%) results from insufficient renal excretion. There are genetic causes for both causes of hyperuricemia. Hyperuricemia is a prerequisite to developing gout, but only 20% of individuals with hyperuricemia will ever develop gout. Gout can be categorized into three classic stages: asymptomatic hyperuricemia, acute intermittent gout and chronic advanced gout. Gout can also result in renal disease involving glomerular, tubular, interstitial tissues and blood vessels, and uric acid nephrolithiasis.²

The initial episode of an acute gout attack usually follows decades of asymptomatic hyperuricemia. In men, it occurs nominally between the fourth and sixth decades while it is post menopause for women. As the increased concentration of urate exceeds 6.8 mg/dL the uric acid start to form insoluble monosodium urate (MSU) crystals in a lattice formation often in joints. During the acute attack, the lattice shatters and massive numbers of MSU crystals are released in to the joint space.² This acute gout is hallmarked by joint pain, swelling, warmth, and erythema. The pain reaches a crescendo within 12 hours. Joint involvement is usually monoarticular and most commonly involve the lower extremity. Gout is also self-limiting with resolution of symptoms in 5-8 days without treatment. The gouty symptoms can be thought of as an inflammatory reaction inside the joint from the MSU crystals.⁸

Untreated gout will progress to chronic polyarticular gout or advanced gout. This stage often occurs after a decade of pain free inter-critical periods have disappeared. Intense painful flairs now occur on top of baseline joint pain. Subcutaneous tophus is characteristic of advanced gout. These tophi may develop anywhere on the body.²

The diagnosis of gout is NOT dependent on hyperuricemia. As described above, hyperuricemia is not specific to gout. Interestingly, during an acute gouty flare, urate levels may drop as much as 2.0 mg/dL limiting the utility of this test in the diagnosis of gout. The "gold standard" of gout is demonstrating MSU crystals present in the acute joint. MSU crystals appear needle-shaped and negatively birefringent with polarized light. It should be noted that only 10% of patients have synovial fluid confirmation. Most commonly is a presumptive diagnosis based on the pattern of acute joint symptoms.²

The American College of Rheumatology published diagnostic criteria for gout in 2012. If MSU are found in synovial fluid or tophus is proven to contain urate crystals, then the gold standard has been met. Additionally, six or more of the following clinical, laboratory or radiologic findings should be obtained for a provisional diagnosis:¹

Asymmetric swelling with a joint on radiography Attack of monoarticular arthritis Culture of joint fluid negative for microorganisms during attack of joint inflammation Development of maximal inflammation within one day

## Hyperuricemia

Joint redness More than one attack of acute arthritis

Nephrolithiasis occurs in 10 to 25 percent of patients with primary gout. The likelihood of stones in each patient with gout increases with serum urate concentrations and with amounts of urinary uric acid excretion. It exceeds 50 percent with a serum urate level above 13 mg/dl or with urinary uric acid excretion rates more than 1100 mg every 24-hours.²

Treatment of gout focuses on the acute attack and preventing future attacks. In the acute setting, standard therapy consists of prompt treatment of the pain and disability with nonsteroidal antiinflammatory drugs (NSAIDs). NSAIDs given in full anti-inflammatory doses are effective in approximately 90% of patients, and the complete resolution of signs and symptoms usually occurs in a few days. Indomethacin has been the traditional NSAID choice by clinicians but is not currently waiverable. All NSAIDs are equally effective as indomethacin.¹ NSAIDS are cautioned with gastric intolerance or kidney injury. Colchicine is also used in the acute setting. This medicine was given FDA approval in 2009 but has been used for decades in the treatment of acute gouty flares. It is not currently a waiverable medicine and should be avoided with renal and hepatic insufficiency. Colchicine has some unpleasant gastrointestinal side effects. It is also contraindicated with clarithromycin. Finally, corticosteroids can be considered for patients that do not tolerate NSAIDS or colchicine. Corticosteroids may be delivered orally, intramuscularly or intra-articular with equal results.¹

Prevention is the next treatment modality to consider after the acute attack has subsided. Patient education should be stressed and dietary modifications considered. Weight loss reduces the risk of a gout attack. High-fructose corn syrup should be restricted along with purine-rich animal protein (organ meats, beef, lamb, pork and shellfish). Alcohol, especially beer should be limited.^{9, 10} Consumption of vegetables and low-fat dairy products should be encouraged.¹

If a patent has two more flares a year, 1 flare with chronic kidney disease (stage 2), tophi or a history of nephrolithiasis then pharmacologic urate lowering therapy (ULT) is recommended. As a rule, ULT should not be initiated during an acute gout attack, however once it has been initiated, it should be continued during an attack. First line ULTs are xanthine oxidase inhibitors: allopurinol (Zyloprim®) and febuxostat (Uloric®). Allopurinol is dosed to achieve the target serum urate level of less than 6 mg/dL.¹¹ Febuxostat is a similar medication that was approved for use in 2009, but it is considerably more expensive than allopurinol. Probenecid is considered a second line treatment because of numerous drug interactions. It works by increasing the urinary excretion of uric acid and may be used in combination with the first line ULTs. When used daily, colchicine has also been shown to reduce flares.

#### **IV. Aeromedical Concerns.**

Acute episodes of gout may cause significant physical incapacitation due to painful joints and cognitive impairment due to distraction of pain. In addition, the risk of nephrolithiasis increases modestly with the serum urate level and with the magnitude of daily urinary uric acid excretion.

Chronically, gout may cause significant physical incapacitation due to erosive joint deformities, urate nephropathy, and/or obstructive uropathy (e.g. nephrolithiasis).

NSAIDs can cause gastritis acutely; chronic use can result in peptic ulcer disease and both chronic and acute renal insufficiency. Colchicine may cause diarrhea in the typical prophylactic dose and it usually causes moderate to severe intestinal cramping and vomiting if given intravenous or in high dose orally to abort acute gout. All ULT drugs can precipitate an attack of acute gouty arthritis as serum uric acid levels are lowered. Up to 5% of patients are unable to tolerate allopurinol because of adverse events including headache and gastrointestinal irritation, and less commonly, but far more serious, is the occurrence of severe hypersensitivity reactions and bone marrow suppression.

The major questions to be answered prior to requesting a waiver include: Are the gouty attacks frequent and severe? Is the patient free of renal involvement? Is the serum uric acid kept at normal levels with medication and is the patient free of untoward side effects of the medication prescribed? All of these are important considerations for an airman with gout.¹²

ICD-9 codes for gout		
274	Gout	
274.0	Gouty arthropathy	
274.1	Gouty nephropathy	
274.82	Tophaceous gout	
274.9	Gout, unspecified	

ICD-10 codes for gout		
M10.00	Idiopathic gout, unspecified site	
M1A.9XX0	Chronic gout, unspecified without tophus (tophi)	
M10.30	Gouty due to renal impairment, unspecified site	
M1A.9XX1	Chronic gout, unspecified, with tophus (tophi)	
M10.9	Gout, unspecified	

## V. References.

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## Human Immunodeficiency Virus (HIV) Infection (May 2021)

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner (ACS Internal Medicine); Lt Col Kevin Heacock (ACS Neuropsychiatry); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver consideration section updated.

## I. Waiver Consideration

All flying classes, ATC, GBO, and SWA personnel diagnosed with human immunodeficiency virus (HIV) infection are disqualified from their specific operational duties and for retention. Trained personnel may be considered for waiver on a case-by-case basis. Waiver will generally be contingent on tolerability of medical therapy, demonstration of stability, and adherence to the guidelines established for HIV treatment. The member must have a current CD4 cell count above the threshold for opportunistic infection risk and must not have previously met the case definition for acquired immunodeficiency syndrome (AIDS). Appropriate viral suppression on a stable combination antiretroviral therapy (ART) regimen should be demonstrated with no symptomatic adverse drug effect or reaction. The goal for viral suppression will typically occur 8 to 24 weeks after ART initiation. Any current guideline recommended treatment combination will be considered for aeromedical waiver on a case-by-case basis.

Active duty Air Force members and Air Reserve Component (ARC) members on extended active duty will be referred to San Antonio Military Medical Center (SAMMC) for medical evaluation IAW AFI 44-178, Human Immunodeficiency Virus Program. ARC members not on extended active duty must obtain a medical evaluation from their civilian healthcare provider that meets the requirements of Attachment 8 in AFI 44-178.

Flying Class (FC)	Waiver Potential ¹	Waiver Authority	ACS Review or Evaluation
FC I/IA	No	AETC	No
FC II/III	Yes ^{2,3}	AFMRA	Yes ⁴
ATC/GBO/SWA	Yes ^{2,3}	AFMRA	Yes ⁴

#### Table 1: Waiver potential for HIV Infection

1. Waiver will be considered on a case-by-case basis for trained personnel only.

2. Waiver will not be considered if individual ever met criteria for AIDS (i.e, a CD4 cell count <200 cells/microL or a history of any AIDS-defining condition).

3. Must demonstrate appropriate viral suppression on a stable guideline recommended antiretroviral therapy regimen with CD4 cell counts >500 cells/microL. CD4 counts >300 cells/microL may be acceptable early in treatment course before maximal CD4 cell recovery has been achieved.

4. ACS review and evaluation will involve screening for potential cognitive and psychiatric disorders associated with HIV infection.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 14. Information to include in history:
  - a. Clearly delineate the disease presentation and course.
  - b. Complete list of current medications with dates of initiation and doses.
- 15. Consultation reports from all treating providers, which should include:
  - a. Subjective symptoms and objective physical exam findings.
  - b. Current treatment plan, to include tolerance of maintenance medications and all appropriate monitoring labs for those medications, as applicable.
  - c. If seen by Mental Health, please ensure consultation reports include a recent evaluation following the template in the Mental Health Waiver Guide Checklist (available on the Kx→Waiver Guide→Psychiatry section). This evaluation should be completed by a doctoral level mental health provider with preference for a Psychiatrist if the aviator is on psychotropic medication. Also include any completed psychological testing with RAW DATA and interpretation.
- 16. Laboratory studies required:
  - a. CD4 counts at diagnosis and on therapy.
  - b. Viral loads (viral RNA levels) at diagnosis and on therapy.
  - c. Complete metabolic panel and CBC at baseline and on therapy.
  - d. Lipid panel and fasting glucose on therapy.
  - e. All other laboratory studies ordered by consulting specialist(s)
- 17. Current physical examination findings which must include a thorough neurological review of systems and neurological exam.
- 18. FL4 with RTD and ALC status.
- 19. Any other pertinent information.
- 20. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# B. Renewal Waiver Request:

- 12. Updated AMS with interval history, including:
  - a. Documentation of member's compliance with required clinical follow-up and all required laboratory monitoring
  - b. Complete list of current medications with dates of initiation, doses, and all adverse effects.
  - c. Documentation of medication adherence.
  - d. Report of any new subjective symptoms.
- 13. All interval consultation reports from all treating providers.
- 14. Laboratory studies required:
  - a. All interval CD4 counts.
  - b. All interval viral loads (viral RNA levels).

- c. Updated complete metabolic panel and CBC at baseline and on therapy.
- d. Updated Lipid panel and fasting glucose or HbA1C on therapy.
- e. All other laboratory studies ordered by consulting specialist(s)
- 15. An updated objective physical exam which must include thorough neurological review of systems and neurological exam.
- 16. FL4 with RTD and ALC status.
- 17. Any other pertinent information.
- 18. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### **III. Aeromedical Concerns**

The primary aeromedical concern regarding individuals with HIV infection appropriately treated with standard of care antiretroviral medications and normal CD4 counts is neurocognitive impairment. Aviators and other special duty operators require a high degree of cognitive capability in an occupation with significant inherent risk. Clearly any condition that impairs cognitive capability is incompatible with aviation and other military duties. Importantly, measurable neurocognitive abnormalities, even if not severe enough to impair routine daily activities, can be of significance in the operational environment. HIV infection also carries increased risks of depression and suicide during the adjustment reaction phase of the infection. Additionally, the military member's emotional reaction to the diagnosis of HIV, the side effects of treatment regimens, and the need for close medical follow-up are all of potential aeromedical concern.

Acute HIV can be associated with an aseptic meningitis syndrome that may indicate early central nervous system infection or the propensity of HIV-related inflammation to disrupt the bloodbrain barrier. Mild, even asymptomatic, cognitive decrements have historically been described in all stages of infection, including among those treated with antiretroviral medications. Current clinical guidelines support the initiation of combination antiviral treatment as soon as HIV infection is diagnosed, regardless of clinical stage or CD4 T-cell level. As a result, a growing body of literature suggests that earlier treatment initiation reduces this T-cell activation and inflammation, reduces the probability of clinical progression, and limits the reservoir of HIV-infected tissue during long-term therapy. Importantly, rates of neurocognitive impairment have been shown to improve with antiretroviral therapy at all stages of disease. Contemporary research demonstrates a low prevalence of neurocognitive impairment in HIV-positive individuals, and may suggest a normal distribution of neurocognitive dysfunction apart from HIV serostatus.

Using current definitions, risk factors for HIV-associated neurocognitive dysfunction (HAND) have been shown to include older age, lower education, lower nadir CD4 count, and AIDS-defining illnesses. "Nowadays, the most severe manifestations of HAND do almost only affect either untreated or insufficiently treated subjects" (Eggers, et al 2017). Given that the HIV-prevalent population is aging, research among patient groups non-normative to USAF aircrew must be interpreted with some degree of caution. Compared with the national average, HIV-positive USAF personnel tend to be younger, better educated, are healthier at baseline, and score

higher on cognitive test assessments. Additionally, USAF personnel are diagnosed and initiate treatment earlier in the course of the disease (often within a year of seroconversion), resulting in both preservation of a high CD4 and rapid achievement of sustained viral suppression. Regardless, screening for potential cognitive and psychiatric disorders associated with HIV infection remains prudent prior to making any return to duty status determination. As all HIV cases require an in-person ACS evaluation, there is no need to do any neuropsychologic testing locally beyond what may have already been done for clinical purposes. The ACS Neuropsychiatry Branch will complete necessary testing during the in-person evaluation.

While most first-line agents for HIV management are relatively well-tolerated in comparison to older regimens, risk of toxicity and the occupational burden of intense of monitoring for medication side effects must be considered on a case-by-case basis. Fortunately, current first-line ART regimens do not include the non-nucleoside reverse transcriptase inhibitors that were historically associated with neuropsychiatric adverse effects. Acute idiosyncratic drug effects occur uncommonly with combination ART. Long-term toxicities of ART are also generally very slow to progress, can be monitored with routine testing modalities, and are not exacerbated by the aviation environment.

Flight surgeons should be aware that transient viremia, or "blips", during therapy can occur and do not necessarily represent treatment failure. The technical definition of a "blip" is a measurable viral load of <200 copies/mL that is followed by a return to a viral load below the limit of detection or quantification (e.g., <20 copies/mL). In clinical practice, repeating the viral load measurement at the next regularly scheduled lab draw is an option assuming there are no issues with adherence to prescribed therapies. However, the ACS recommends that repeat viral load measurements be repeated as soon as possible for all aviators and special duty operators. The goal is to ensure that a detectable viral load is not due to the development of medication resistance or loss of viral suppression that would increase the risk for developing long-term complications (e.g., HAND). There is no need to remove an individual from duty status while obtaining repeat testing for viral blips. However, if viral loads are found to be >200 copies/mL on initial or repeat testing, then grounding management actions are warranted pending repeat testing and follow-up with infectious disease. The ACS also recommends that individuals with persistent viral load measurements of 20 to 199 copies/mL on repeat testing follow-up with infectious disease as soon as possible, but temporary removal from duty status would not be required.

Review of AIMWTS data from Jan 2010 through May 2020 revealed a total of 32 waiver packages involving the use of HIV infection. Of that total, 1 was FC I/IA (1 disqualified), 9 were FC II (8 disqualified), 13 were FC III (12 disqualified), 8 were ATC/GBC (7 disqualified), and 1 was SWA (1 disqualified). The first USAF aeromedical waiver for HIV infection was granted in Dec 2019 following ACS review and evaluation.

Please use only these ICD-10 codes for AIMWTS coding purposes	
B20	Human Immunodeficiency Virus Infection

#### **IV. Suggested Readings**

1. Center for Disease Control and Prevention HIV Informational Website. Available at <u>https://www.cdc.gov/hiv/default.html</u>. Accessed 4 May 2021.

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4. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Available at <a href="https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines">https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines.</a> Accessed 4 May 2021

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16. Chan P, Hellmuth J, Spudich S, Valcour V. Cogntive impairment and persistent CNS injury in treated HIV. Curr HIV/AIDS Rep. 2016 Aug; 13(4): 209-217

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# Hypercholesterolemia and Hyperlipidemia

Revised: Jan 2022

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

**Significant Changes:** Waiver guide updated to ensure consistency with published career field medication lists.

# I. Waiver Consideration

Hypercholesterolemia and hyperlipidemia that is successfully treated with monotherapy using one of the aeromedically-approved lipid-lowering statin or bile acid-binding resin agents, is not disqualifying for any flying class, ATC, GBO, OSF, or SWA duties. The use of more than one lipid-lowering medication or the use of any aeromedically-unapproved aircrew medication is independently disqualifying for flying class I/IA, II, III, and ATC personnel. Certain aeromedically-approved non-statin and non-bile acid-binding resin lipid-lowering medications (i.e., ezetimibe, fenofibrate, and gemfibrozil) are also independently disqualifying for flying class I/IA, II, III, and ATC personnel and require waiver. Please note that ezetimibe, fenofibrate, and gemfibrozil are not disqualifying for GBO duties when utilized as monotherapy or in combination with a non-statin derivative medication. Use of any aeromedically-unapproved medication is also independently disqualifying for GBO personnel. For OSF and SWA personnel, lipid-lowering therapies are not disqualifying as no official approved medication list exists. However, the use of any new medication provided to these individuals must be carefully evaluated for potential side effects and impact on mission. It is strongly recommended that the MSD and the appropriate career field medication lists be cross-referenced for any and all treatments for hypercholesterolemia and hyperlipidemia.

Factors that are considered when assessing suitability for waiver of hypercholesterolemia and hyperlipidemia include whether the treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the risks associated with the specific medication(s), the individual service member's tolerance of the medication(s), adherence to therapy, and the cumulative risk of all co-morbid conditions (e.g., diabetes mellitus, heart disease, etc.). Waiver requirements also follow the recommendations established in the "2018 AHA/ACC Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology / American Heart Association Task Force on Clinical Practice Guidelines." FC I/IA individuals who meet criteria for cholesterol treatment but are not on an appropriate treatment regimen will not be considered waiver-eligible.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority ¹	ACS Review or Evaluation
I/IA	Hypercholesterolemia and Hyperlipidemia treated with medication other than a single aeromedically-approved statin or resin binding agent ^{2,3}	Yes AFRS/CMO	No
	Repeat fasting LDL > 190 mg/dL, with or without risk factors; or > 160 mg/dL with at least 2 cardiac risk factors	Yes ⁴ AFRS/CMO	No
II/III/ATC/GBO	Hypercholesterolemia and Hyperlipidemia treated with medication other than a single aeromedically-approved statin or resin binding agent ^{2,3,5}	Yes MAJCOM ⁶	No
OSF/SWA	Not Disqualifying ⁷	N/A	N/A

Table 1: Waiver potential for Hypercholesterolemia and Hyperlipidemia

1. Certification authority for untrained assets is AFRS/CMO.

2. Use of any medication that is not included on the applicable career field approved medication list is independently disqualifying.

- 3. Use of ezetimibe, fenofibrate, and gemfibrozil is independently disqualifying for all flying class and ATC duties. These medications are not disqualifying for GBO duties when utilized as monotherapy or in combination with a non-statin derivative medication.
- 4. In general, FC I/IA applicants who meet criteria for cholesterol treatment but are not on an appropriate treatment regimen will NOT be considered waiver-eligible.
- 5. FC II personnel being treated with gemfibrozil or fenofibrate in combination with statin therapy will typically be limited to non-high performance aviation duties.
- 6. Waivers for the use of non-approved career field medications will be considered on a case-by-case basis, and the waiver authority is AFMRA.
- 7. For OSF and SWA personnel, no official approved medication list exists. All new medications provided to OSF and SWA personnel should be carefully evaluated for potential side effects and impact on mission.

# **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. List all risk factors for atherosclerotic cardiovascular disease
    - i. Non-modifiable risk factors (age, gender, race/ethnicity, family history)
    - ii. Modifiable risk factors (tobacco use, current blood pressure, personal history of diabetes, personal history of treatment for hypertension)
  - b. List all treatments trialed, their effectiveness, and any adverse effects
  - c. List current medications, doses, and adverse effects

- d. List all co-morbid conditions and describe degree of control
- 2. Laboratory studies required:
  - a. Baseline fasting lipid panel before starting treatment
  - b. Baseline fasting comprehensive metabolic panel (CMP)
- 3. Current physical examination findings.
- 4. Any other pertinent information.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Any changes in atherosclerotic cardiovascular disease risk factors
  - b. Current medications, doses, and adverse effects
  - c. Updated fasting lipid panel
  - d. Updated fasting CMP
- 2. Current physical examination findings.
- 3. Any other pertinent information.
- 4. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# **III. Aeromedical Concerns**

While hypercholesterolemia is typically asymptomatic, it is a common and treatable risk factor in the development of atherosclerotic cardiovascular disease (ASCVD). The manifestations of ASCVD, which include coronary heart disease (myocardial infarction, angina, heart failure, and sudden cardiac death), cerebrovascular accident (stroke and transient ischemic attack), aortic atherosclerotic disease and aneurysm, and peripheral artery disease, can be potentially catastrophic, resulting in sudden incapacitation in the aviation environment. Additionally, these diseases are individually disqualifying for continued aviation duties and may not be eligible for waiver, depending upon crew position, disease severity, required therapies, and a variety of other factors. Furthermore, very high triglyceride levels may result in acute pancreatitis, which can be suddenly incapacitating (additional information available in the *Pancreatitis* Air Force Waiver Guide). Due to the risks associated with these outcomes, it is of critical importance to intervene early to reduce the possibility of an event that could result in devastating consequences for both the health of the affected service member and the success of the aviation mission.

Review of the AIMWTS database from Jan 2019 through Jan 2022 revealed 37 cases with a disqualifying diagnosis of hypercholesterolemia and/or hyperlipidemia. A breakdown of the cases was as follows: 1 FC I/IA cases (0 disqualified), 22 FC II cases (1 disqualified), 12 FC III cases (1 disqualified), 0 ATC cases, 2 GBO cases (0 disqualified), and 0 SWA cases. Review of the cases revealed that disqualifications resulted from other active co-morbid conditions.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		
E78.0	Pure hypercholesterolemia	
E78.1	Pure hyperglyceridemia	
E78.2	Mixed hyperlipidemia	

# **IV. Suggested Readings**

- Grundy SM, Stone NJ, Bailey AL, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiolgy 2019;73:e285-350. Available at http://www.onlinejacc.org/guidelines/cholesterol. Accessed 18 January 2022.
- 2. American College of Cardiology ASCVD Risk Estimator Plus. Available at <u>https://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/</u>. Accessed 18 January 2022.

## Hyperthyroidism (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured. Waiver potential updated. Table 1 updated.

## I. Waiver Consideration

All flying classes, ATC, and special warfare personnel diagnosed with subclinical hyperthyroidism or overt hyperthyroidism independent of the etiology, need for chronic maintenance therapy, and/or treatment with definitive therapy such as radioactive iodine ablation or thyroidectomy require aeromedical waiver. Hyperthyroidism that does not respond to treatment or that requires ongoing specialty care more often than annually is also disqualifying for all classes (including GBO) and for retention. The underlying disease process driving the hyperthyroid state requires appropriate medical attention, and should be clearly identified in the waiver package. Hyperthyroidism may be waivered on case-by-case basis following ACS review.

An initial aeromedical waiver can be considered once the underlying etiology has been addressed, and the individual demonstrates a clinical and biochemical euthyroid state. All personnel, including GBO, requiring current use of thionamide drugs (propylthiouracil or methimazole) are considered disqualified and will not generally be entertained for waiver. If definitive treatment with radioactive iodine ablation or thyroidectomy is completed, individuals warrant monitoring for the development of hypothyroidism. The need for thyroid replacement medication is potentially disqualifying. Please refer to the *Hypothyroidism* waiver guide.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes ¹	AETC	Yes
FC II/III	Yes ¹	MAJCOM	Yes
GBO/ATC/SWA	Yes ¹	MAJCOM	Yes

1. Wavier consideration is based on the underlying etiology of the hyperthyroidism and demonstration of a clinical and biochemical euthyroid state. The current use of thionamide drugs to maintain a euthyroid state will not generally be entertained for waiver.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. Describe episodes, including symptoms, duration, and frequency of events
    - i. Pertinent negative symptoms (eye, heart, psychiatric) must be reported as well as any current symptoms.
  - b. List all treatments and their effectiveness
  - c. Document the specific etiology (i.e., Grave's disease, TMNG, etc.)
- 2. Consultation reports from all treating providers or specialists, which should include:
  - a. Subjective symptoms and objective physical exam findings
  - b. Documentation of the presence or absence of orbitopathy.
- 3. Results of all pertinent laboratory studies, including diagnostic and follow-up results. This most include at least two recent consecutive sets of serum TSH, total T3, and free T4 values in the normal range (drawn 4-6 weeks apart), and thyroid antibody results (if obtained). A post-treatment CBC and CMP must also be provided if thionamide drugs (propylthiouracil or methimazole) treatment occurred.
- 4. Radiology reports from all diagnostic or follow-up imaging studies. (e.g., thyroid ultrasound, RAIU scan, etc.)
- 5. Ophthalmology consultant note if any symptoms or signs of optic neuropathy or orbitopathy were present.
- 6. Current physical examination findings.
- 7. Any other pertinent information.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.
- B. <u>Renewal Waiver Request:</u>
  - 1 Updated AMS with interval history, including:
    - a. Documentation of clinical and biochemical euthyroid state including updated TSH, free T4, and total T3.
    - b. Plan for monitoring of recurrence.
  - 2 Updated consultation reports from treating specialist.
  - 3 Current physical examination findings.
  - 4 Any other pertinent information.
  - 5 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# **III. Aeromedical Concerns**

Subclinical and overt hyperthyroidism can be associated with a variety of clinical manifestations that are of aeromedical concern. The focus of these aeromedical concerns center upon the effects

on the cardiopulmonary system, potential changes in neurological and behavioral status, and on treatment side effects. Cardiac manifestations (tachycardia, dysrhythmias) may cause sudden incapacitation. Neurocognitive effects such as impaired attention and memory, and psychiatric symptoms, such as subtle irritability, restlessness, emotional lability and anxiety, may result in subtle incapacitation. Patients with thyroid orbitopathy may have difficulty with eye movements. Additionally, corneal damage or optic neuropathy can occur. Other symptoms of untreated hyperthyroidism of operational importance include heat intolerance, fatigue, weakness, and tremor. All of these could be safety hazards as well as detract from duty performance. Posttreatment, the major aeromedical concerns are recurrence of hyperthyroidism (mainly after discontinuation of thionamide therapy) and the insidious onset of hypothyroidism, which can lead to apathy, slowed mentation, hypersomnolence, and performance degradation.

The use of thionamides for the treatment of hyperthyroidism is challenging operationally, since they are typically utilized for 6-18 months before discontinuation. Recurrence of hyperthyroidism after discontinuation of thionamides is high. Although long-term treatment with thionamides in select individuals to maintain a euthyroid state is a treatment strategy in some national guidelines, thionamides are not a definitive therapy for hyperthyroidism and require persistent monitoring (every 3-6 months) of thyroid levels with frequent dose adjustment to ensure a biochemical euthyroid state, which may not be possible in an operational setting. Since thionamides are not a definitive treatment, there is an aeromedical concern of breakthrough thyrotoxicosis while on treatment. Thus, the preferred aeromedical management is to pursue definitive treatment with either radioiodine ablation therapy or thyroidectomy. Additionally, thionamides may cause side effects incompatible with aviation duties to include vertigo, drowsiness, liver dysfunction as well as agranulocytosis. There is no specific laboratory monitoring for development of agranulocytosis or hepatotoxicy while on therapy except for baseline CBC and liver function panel. Thionamides are not on the approved aircrew medication list, and waiver for hyperthyroidism temporarily controlled with these medications is unlikely. There are no specific aeromedical concerns with radioiodine ablation treatment or thyroidectomy as long as long-term thyroid hormone supplementation is maintained, and there were no acute complications from the respective treatment.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 16 individuals with an AMS containing the diagnosis of Hyperthyroidism. One individual (6%) was disqualified. A breakdown of the cases was follows: 0 FC I/IA cases, 3 FC II cases (0 disqualified), 11 FC III cases (1 disqualified), 2 ATC/GBC cases (0 disqualified), 0 MOD cases, and 0 RPA Pilot cases.

ICD-9 codes for hyperthyroidism			
242.9	Thyrotoxicosis with or without goiter		
ICD-10 codes for hyperthyroidism			
E05.00	Thyrotoxicosis (hyperthyroidism)		

#### **IV. Suggested Readings**

1. De Leo S, Lee SY and Braverman LE. Hyperthyroidism. Lancet, 2016; 288(10047): 906-918.

2. Kahaly GJ, Bartalena L, Hegedus L, et al. 2018 European Thyroid Association Guideline for the management of Graves' Hyperthyroidisms. European Thyroid Journal. 2018; 7:167-186. https://www.karger.com/article/fulltext/490384

3. Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. Thyroid, 2016; 26(10): 1343-1421. <u>https://www.ncbi.nlm.nih.gov/pubmed/27521067</u>

## Hypogonadism (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) Significant Changes: Content updated to reflect national guidelines.

## I. Waiver Consideration

Hypogonadism is not specifically identified as a disqualifying diagnosis for aviation or special operator duties. However, the need for chronic (greater than 6 months) exogenous hormone therapy is disqualifying for all flying classes, GBO, ATC, and special warfare duties as well as for retention. Waiver requirements for hypogonadism treated with testosterone replacement generally follow the recommendations established in national guidelines. Factors that are considered when assessing suitability for waiver include whether an appropriate and thorough evaluation was completed and whether the treatment and monitoring are appropriate in the context of established national guidelines. The use of any medication not included on a career-field approved medication list is independently disqualifying and will be considered on a case-by-case basis.

An initial aeromedical waiver may be considered once an individual demonstrates tolerability of the testosterone replacement, has resolution of all initial presenting symptoms, and has completed appropriate laboratory monitoring. A diagnosis of hypogonadism is established by obtaining two separate <u>morning</u> testosterone levels that are less than 300 ng/dL in symptomatic individuals. Inappropriately normal or low levels of FSH/LH warrant further evaluation for secondary causes of hypogonadism. Secondary causes of hypogonadism should be excluded as many of these diseases are independently disqualifying and carry additional aeromedical risk. Individuals who do not meet diagnostic criteria for hypogonadism on testosterone replacement are unlikely to receive a waiver.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes ^{1,2}	AETC	Yes
II/III	Yes ^{1,2}	MAJCOM ³	No ⁴
GBO/ATC/Special Warfare	Yes ^{1,2}	MAJCOM ³	No ⁴

Table 1: Waiver potential for Hypogonadism

1 Control of manifested symptoms is required before waiver submission.

2 If the member has inappropriately normal or low FSH/LH in the setting of low testosterone, secondary causes of hypogonadism must be excluded as many of these diseases are independently disqualifying.

3 Use of any medication that is not included on the approved medication list is disqualifying, and the MAJCOM may disqualify the service member without AFMRA or ACS review. The waiver authority for all non-approved medications is AFMRA.

4 ACS review may be requested at the discretion of the waiver authority if there are clinical concerns.

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Consultation reports form all treating providers or specialists, which should include:
  - a. Documentation of presenting symptoms and signs consistent with hypogonadism.
  - b. Current treatment plan, to include formulation and current dose of testosterone replacement, tolerance to prescribed therapies, and all appropriate laboratory monitoring (total testosterone, CBC, and PSA if > 40 years old)
- 3. All pertinent laboratory studies, including diagnostic and follow-up results.
  - a. Two or more pre-treatment, morning testosterone levels which should be less than 300 ng/dl.
  - b. Free testosterone, SHBG, and estrogen levels if indicated or obtained by treating provider.
  - c. FSH/LH levels and if low or inappropriately normal a secondary evaluation should be performed to include prolactin, TSH, ferritin, and iron saturation.
- 4. Radiology reports from all diagnostic or follow-up imaging studies.
  - a. MRI of the pituitary is indicated in men with total testosterone levels of <150 ng/dL or when neurologic symptoms are present.
- 5. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 6. Current physical examination findings.

- 7. FL4 with RTD and ALC status.
- 8. Any other pertinent information.
- 9. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.
- B. Renewal Waiver Request:
  - 1 Updated AMS with interval history, including:
    - a. Current symptoms and signs associated with hypogonadism.
    - b. Current medications, formulation, doses, and development of any adverse effects.
    - c. Current physical examination findings.
  - 2 Consultation reports from treating specialist if applicable including current monitoring and treatment plan.
  - 3 All interval monitoring labs including updated CBC and testosterone levels.
  - 4 Any other pertinent information.
  - 5 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

### **III. Aeromedical Concerns**

Hypogonadism is a relatively common condition defined by a deficiency of testosterone hormone and/or a deficiency of the normal number of spermatozoa due to pathology at one or more levels of the hypothalamic-pituitary-testicular axis. Suggestive symptoms and signs of hypogonadism include reduced libido, decreased spontaneous erections, erectile dysfunction, infertility, loss of axillary and pubic hair, and hot flashes. Nonspecific symptoms and signs associated with hypogonadism include decreased energy, decreased motivation, depressed mood, sleep disturbances, decreased muscle mass and strength, and weigh gain. Studies have shown that up to one third of men diagnosed with hypogonadism do not meet diagnostic criteria for hypogonadism. Thus, it is important that individuals suspected of having hypogonadism be adequately evaluated prior to initiation of testosterone replacement. The diagnosis of hypogonadism is made in symptomatic individuals with two total testosterone measurements less than 300 ng/dL that were obtained on separate occasions in the early morning. Once a diagnosis of hypogonadism is established, LH and FSH should be obtained to determine whether the cause of hypogonadism is primary versus secondary. If the LH/FSH is low or inappropriately normal, further evaluation for secondary causes should be initiated since many of these diseases are independently disqualifying and carry additional aeromedical risk.

The adverse effects of exogenous testosterone therapy replacement include increased risk of potentiating an undiagnosed prostate cancer, worsening lower urinary tract symptoms, exacerbating untreated sleep apnea, and developing secondary polycythemia. The use of exogenous testosterone therapy has not been demonstrated to increase the risk of developing a cardiovascular event in individuals with hypogonadism. In fact, low testosterone levels are associated with increased incidence of major adverse cardiovascular risk factors. Multiple testosterone formulations are available. The use of implantable testosterone pellets are not approved for use in USAF personnel, but transdermal and injectable preparations are often

considered for waiver. Transdermal patches, gels, and foams might cause skin irritation at the site of application. Intramuscular injectable formulations potentially increase risk of supraphysiologic testosterone levels. Additionally, injectable formulations pose mobility and readiness challenges in the deployed setting.

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 158 individuals with an AMS containing the diagnosis of Hypogonadism. Seventeen individuals (10.8%) were disqualified. A breakdown of the cases was follows: 3 FC I/IA cases (2 disqualified), 71 FC II cases (3 disqualified), 57 FC III cases (9 disqualified), 19 ATC/GBC cases (2 disqualified), 5 MOD cases (0 disqualified), and 3 RPA Pilot cases (1 disqualified).

ICD-9 codes for Hypogonadism		
257.2 Other testicular hypofunction		

ICD-10 codes for Hypogonadism	
E29.1	Testicular hypofunction

## **IV. Suggested Readings**

1. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism.* 2018; 103(5):1715-1744.

https://academic.oup.com/jcem/article/103/5/1715/4939465

2. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. The Journal of Urology. 2018; 200(2):423-432. https://www.auajournals.org/doi/10.1016/j.juro.2018.03.115

3. Park HJ, Ahn ST, and Moon DG. Evolution of Guidelines for Testosterone Replacement Therapy. Journal of Clinical Medicine. 2019; 8(3):410. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6462962/</u>





# Hypothyroidism

Reviewed: Nov 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Lt Col Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

## Significant Changes: Suggested readings (Section IV) updated.

## I. Waiver Consideration

Hypothyroidism is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention when there is objective evidence of the hypothyroidism (e.g., laboratory confirmation) and when either of the following criteria are met: severe symptoms are present and do not resolve with treatment, or specialist follow-up is required more frequently than annually. Additionally, hypothyroidism is disqualifying for all flying class, ATC, and SWA duties if appropriate treatment necessitates maintenance medication, thyroid ablation, or surgery. In other words, any history of thyroidectomy (whether sub-total or total), thyroid ablation, or the use of medication to maintain stable thyroid hormone levels is disqualifying for all flying class, ATC, and SWA duties.

In isolation, the use of thyroid hormone replacement with an approved medication (e.g., levothyroxine and liothyronine) is not disqualifying for GBO duties and does not require a waiver. However, a period of DNIC/DNIA is required at the initiation of treatment to ensure safe tolerance of the medication without idiosyncratic reactions. Likewise, GBO personnel with symptoms of hyper- or hypothyroidism are required to be placed on DNIC/DNIA status until symptoms resolve. Please refer to the Official Air Force Aerospace Medicine Approved Medications list for the GBO career field for further information.

Medications to maintain appropriate thyroid hormone levels are not independently disqualifying for OSF or SWA personnel as a career field medication list for OSF or SWA personnel does not exist. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of hypothyroidism in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

It is important to note that hypothyroidism may be caused by a variety of mechanisms, and that the underlying etiology may be independently disqualifying for continued aviation or operational duties or for military retention. Likewise, complications or side effects of treatment may be disqualifying. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions.

Individuals requiring a waiver for hypothyroidism may submit a request once they are asymptomatic and clinically stable (i.e., no signs or symptoms to suggest hyper- or hypothyroidism). If a service member is treated with an approved formulation of thyroid hormone replacement and is tolerating the medication well without adverse effects, with appropriate planned surveillance and follow-up for dose titration, it is not necessary to wait for

the achievement of a biochemically euthyroid state prior to submitting a waiver request. In other words, provided that the individual is asymptomatic and is being followed appropriately, a waiver request may be submitted before normalization of the thyroid stimulating hormone (TSH) levels. However, a period of DNIF/DNIC/DNIA may be necessary in the event that an individual treated with exogenous thyroid hormone develops new symptoms of over- or under-replacement (i.e., hyper- or hypothyroidism). Return to operational status may be granted locally after re-establishment of a clinically euthyroid state (i.e., resolution of symptoms).

Waiver renewal requires verification that the service member continues to remain clinically euthyroid (i.e., asymptomatic). Demonstration of a biochemically euthyroid state with a recent normal TSH is desirable at the time of waiver renewal requests. In the absence of other clinical changes, it is not necessary to request an early waiver renewal if a service member who was previously maintained on a stable dose of thyroid hormone replacement requires a dose titration for the purpose of maintaining a biochemically euthyroid state. As above, it is up to the local flight surgeon to temporarily place a service member on DNIF/DNIC/DNIA status if the individual is symptomatic or there are overt clinical signs that thyroid hormone is over- or under-replaced. Return to duty status may be granted when symptoms resolve.

Generally, exogenous thyroid hormone preparations that are not included on the applicable career field approved medication list are not considered favorably for waiver. Again, while there is no career field medication list for OSF or SWA personnel, diligence in assessing for potential risks to individual health and mission safety is required with the use of any medication or supplement (see above).

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA	Hypothyroidism, with severe symptoms not resolved with treatment or requiring specialist follow-up more often than annually	Yes AFRS/CMO ²	No ³
	Hypothyroidism, requiring treatment with maintenance medication, thyroid ablation, or surgery ⁴	Yes AFRS/CMO ²	No ³
FC II/III/ ATC/SWA	Hypothyroidism, with severe symptoms not resolved with treatment or requiring specialist follow-up more often than annually	Yes MAJCOM ²	No ³
	Hypothyroidism, requiring treatment with maintenance medication, thyroid ablation, or surgery ⁴	Yes MAJCOM ²	No ³
GBO/OSF	Hypothyroidism, with severe symptoms not resolved with treatment or requiring specialist follow-up more often than annually ⁴	Yes MAJCOM ²	No ³

## Table 1: Waiver potential for Hypothyroidism¹

1. Subclinical hypothyroidism (i.e., normal serum free thyroxine (T4) concentration in the presence of an elevated TSH concentration) without a clinical need for maintenance medication is not disqualifying.

2. Certification authority for untrained assets is AFRS/CMO. Waiver authority for aeromedically unapproved medication use is AFMRA.

3. ACS review may be requested at the discretion of the waiver authority.

4. Use of any medication not included on the career field-specific approved medication list is independently disqualifying and will be reviewed by on a case-by-case basis.

## II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

## A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative). Include findings of complete examination of the head and neck, especially thyroid gland and lymph nodes.
  - b. Specify presence or absence of ongoing symptoms.
  - c. Specify if an underlying cause of the hypothyroidism was identified.

- d. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
- e. List current medications with dosages.
- 2. Documentation from the treating medical providers and all applicable consultation notes. These notes must include the following:
  - a. Documentation of the presence or absence of ongoing symptoms.
  - b. Assessment of medication tolerance and statement regarding adherence.
  - c. Plan for ongoing clinical, laboratory, and (if applicable) radiographic monitoring. Must include timeline for repeating TSH measurements to assess stability and after medication dose adjustments.
- 3. Laboratory studies required:
  - a. Current TSH and free thyroxine (free T4).
  - b. All past thyroid function test results (e.g., TSH, free T4, etc.), with dates.
- 4. Results of all testing performed in the course of diagnosis, evaluation, and management of hypothyroidism, including laboratory studies, imaging, and any other ancillary studies.
  - a. Examples of additional studies that are often obtained in the evaluation of hypothyroidism include, but are not limited to, the following: thyroid imaging (e.g., thyroid ultrasound, radioactive iodine uptake and scan); fine needle aspiration; thyroid peroxidase (TPO) antibodies; triiodothyronine (T3). These studies are not required for waiver submission, but all relevant test results should be forwarded with the waiver package.
- 5. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Updated head and neck examination, especially thyroid gland and lymph nodes.
  - a. Summarize any interval evaluation and/or treatment.
  - b. List current medications with dosages.
  - c. Plan for ongoing clinical, laboratory, and (if applicable) radiographic monitoring. Must include timeline for repeating TSH measurements to assess stability and after medication dose adjustments.
- 2. All interval documentation from the treating medical providers.
- 3. Laboratory studies required:
  - a. Current TSH and free T4.
  - b. All interval thyroid function test results (e.g., TSH, free T4, etc.), with dates.
- 4. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval procedure reports, and any other ancillary tests.
- 5. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Hypothyroidism is a relatively common condition defined by a deficiency of thyroid hormone. Subclinical hypothyroidism is also quite common and is characterized by a high thyroid stimulating hormone (TSH) with normal thyroid hormone level (free thyroxine (T4)). The clinical presentation of hypothyroidism is highly variable and depends upon the severity of thyroid hormone deficiency and the speed at which the deficiency develops. Common symptoms include fatigue, cold intolerance, weight gain, constipation, dry skin, myalgia, loss of libido in both men and women, menstrual irregularities in women, and erectile dysfunction in men. Mental slowness, depression, apathy, headache, arthralgias, myalgias, dyspnea on exertion, hair thinning/hair loss, and hoarseness can also occur. Symptoms of hypothyroidism are less prominent clinically and better tolerated when there is a gradual loss of thyroid function (as in most cases of primary autoimmune hypothyroidism) compared to the rapid onset of hypothyroidism that occurs following surgical thyroidectomy or radioactive iodine ablation.

When hypothyroidism is suspected, an appropriate laboratory evaluation begins with measurement of TSH and free T4 levels. An elevated TSH indicates the presence of primary hypothyroidism, while a low free T4 confirms a biochemical hypothyroid state. In the case of subclinical hypothyroidism, TSH is elevated above the reference range, but the free T4 is normal. Secondary (central) hypothyroidism is diagnosed when the serum free T4 concentration is abnormally low and the serum TSH concentration is not appropriately elevated. Central hypothyroidism results from inadequate TSH secretion, which can be caused by either acquired or congenital disorders of the hypothalamus or pituitary gland.

The major aeromedical concern associated with hypothyroidism is the insidious nature of the disease, which may delay a diagnosis until symptoms become significant enough to pose a potential threat to flying/operational safety. For this reason, close monitoring of patients with any history of overt hypothyroidism or subclinical hypothyroidism is essential. Importantly, improvement in the clinical symptoms of hypothyroidism can occur relatively quickly after the initiation of thyroid replacement therapy, although complete biochemical recovery may take as long as several months. Generally, TSH does not reach steady-state for at least six weeks following initiation or dose adjustment of exogenous thyroid hormone. However, an aeromedical waiver request can be initiated once a <u>clinically</u> euthyroid state is documented by the treating physician (i.e., the individual is asymptomatic). Asymptomatic subclinical hypothyroidism is not disqualifying, but repeat TSH and free T4 should be obtained at least annually.

Review of the AIMWTS database from Nov 2019 through Nov 2022 revealed 571 cases with a diagnosis of hypothyroidism. The breakdown of the number of waivers and number of total cases are tabulated below. Of the 20 DQs, only 2 were specific to hypothyroidism and/or associated therapies. One involved an untrained applicant treated with non-aircrew approved medication and the other involved use of thyroid replacement medication without clinical indication.

Please use <i>only</i> this ICD-10 code for		(# of waivers / total # of cases)					
AIMWTS coding purposes		IFC I/IA	FC II	FC III	GBO	ATC	SWA
E03.9 Hypothyroidism, unspecified		28/29	253/259	209/216	28/29	21/24	12/14

## **IV. Suggested Readings**

- Jonklaas J, Bianco AC, Bauer AJ, et al. Guidelines for the treatment of hypothyroidism: Prepared by the American Thyroid Association Task Force on Thyroid Hormone Replacement. Thyroid 2014;24:1670-1751. Available at <u>https://www.liebertpub.com/doi/pdf/10.1089/thy.2014.0028</u>. Accessed 14 November 2022.
- Jonklaas J, Bianco AC, Cappola AR, et al. Evidence-Based Use of Levothyroxine/Liothyronine Combinations in Treating Hypothyroidism: A Consensus Document. Thyroid 2021;31:156-182. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8035928/pdf/thy.2020.0720.pdf. Accessed 14 November 2022.
- Lefevre ML, on behalf of the U.S. Preventive Services Task Force. Screening for thyroid dysfunction: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2015;162:641-650. Available at <u>https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/thyroiddysfunction-screening</u>. Accessed 14 November 2022.

WAIVER GUIDE Updated: Oct 2017 Supersedes Waiver Guide of: Aug 2013 By: Lt Col Robert Woolley (RAM 18) and Dr Dan Van Syoc Reviewed by Lt Col John Baron, AF/SG consultant for nephrology

### CONDITION: Kidney Disease, Chronic (Oct 2017)

#### I. Waiver Consideration.

All forms of chronic kidney diseases are disqualifying for aviation duty in the Air Force. The only medications considered for waiver are those on the approved medication list at the time of the waiver submission. After thorough evaluation, the Medical Standards Directory (MSD) and waiver guide should be consulted for conditions such as anemia, diabetes, coronary artery disease, hypertension, electrolyte disturbances and other renal diseases. These conditions may be disqualifying independently or require initial review in lieu of a medical evaluation board (IRILO) through AFPC/DP2NP prior to waiver application. CKD is not specifically disqualifying for ATC and GBO duties; for these personnel, a waiver would only be indicated if they were being treated with an unapproved medication or their condition was sufficiently advanced that their overall health or treatment requirements could impact safety or duty performance, or they required specialty care more frequently than annually.

Flying Class (FC)	Condition	Waiver Potential	ACS
		Waiver Authority!	<b>Review/Evaluation</b>
I/IA	Stages 1-5	No	No
		AETC	
II*@	Stages 1-3a	Yes	If requested by
		MAJCOM	MAJCOM
	Stage 3b & 4	Maybe	Yes
		MAJCOM	
	Stage 5	No	Only if requested by
		MAJCOM	MAJCOM
III*@	Stages 1-3a	Yes	No
SWA		MAJCOM	
	Stage 3b & 4	Maybe	Yes, if waiver being
		MAJCOM	considered
	Stage 5	No	Only if requested by
		MAJCOM	MAJCOM
ATC/GBO	Stages 1-3a	Yes (if required)	No
		MAJCOM	
	Stage 3b & 4	Maybe	Yes, if waiver being
		MAJCOM	considered
	Stage 5	No	Only if requested by
* > 1		MAJCOM	waiver authority

 Table 1: Waiver potential for Chronic Kidney Disease (CKD)

* No waivers for untrained assets

(a) No indefinite waivers

If CKD requires ongoing specialist care more frequently than annually (and there is a requirement for MEB/I-RILO), then waiver authority as AFMRA.

AIMWTS review in Mar 2017 revealed 27 cases submitted for the diagnosis of chronic kidney disease. There were 0 FCI/IA cases, 8 FC II cases, 3 FC II RPA cases, 13 FC III cases, 1 GBC case, and 1 MOD case. Five of the cases were disqualified; 4 were FC III and 1 was an RPA pilot. Two of the disqualified cases were so dispositioned due to their kidney disease and the other three for a combination of medical conditions.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for initial waiver for CKD should include the following:

A. Complete history of the problem to include all consultants seen.

B. Physical exam results.

C. Labs – Random urine albumin and urine creatinine, random protein and urine creatinine, or 24 hour protein and 24 hour creatinine . Complete urinalysis with microscopic analysis (if heme, nitrate, or leucocyte esterase positive). Serum chemistries to include BMP, calcium, phosphorus, albumin, magnesium and total protein. Calculation of eGFR using MDRD, CKD-epi or calculation of 24hr creatinine clearance based on a 24 hour urine collection (if available). CBC and fasting lipids. Renal biopsy results with complete pathology report (if clinical evaluation of the patient led to a kidney biopsy).

D. Renal ultrasound (mandatory), any other imaging results (if accomplished).

E. Nephrologist or internist consultation report.

F. Current treatment to include all medications and dates started.

G. Results of MEB (if required) or copy of FL4 from DP2NP.

H. Detail of all other medical problems, if applicable.

The AMS for waiver renewal for CKD should include the following:

A. Updated history since last waiver.

B. Physical exam results.

C. Labs – Urinalysis (ACR if protein positive on dipstick), BMP with albumin and total protein, CBC and lipids at a minimum. Include all other urine studies labs and additional imaging and biopsy results (if applicable) since last waiver.

D. Most recent nephrologist or internist consultation report.

E. Current renal treatment to include all medications and dates started.

#### **III. Overview.**

Chronic kidney disease (CKD) is a worldwide public health problem which claims more lives in the US annually than breast or prostate cancer.^{1, 2} The etiology of CKD differs significantly between industrialized and non-industrialized nations, with lifestyle related conditions such as diabetes, hypertension, obesity and cardiovascular disease playing a much greater role in the development of CKD within the US and other "first-world" countries, whereas infectious disease, IgA nephropathy and disorders affecting the urinary outflow tract are much more likely to be the cause in developing nations.³ For nearly three decades, the incidence and prevalence of CKD has increased in the US, owing to multiple factors including an ageing population, increasing rates of lifestyle related diseases and improved detection through the development and increased clinical use of equations which estimate renal clearance rates.¹ After peaking in 2006, the overall prevalence of CKD in the US has remained fairly stable at around 14%, owing to slight decreases in both incidence and mortality since that time. Renal disease associated with

proteinuria, hematuria or congenital anomalies are addressed in other sections of the waiver guide which should be referred to as indicated.

CKD is defined as a moderate reduction in either creatinine clearance or estimated glomerular filtration rate (eGFR) that is persistent for more than 3 months, or the presence of other structural or functional abnormalities such as blood or protein in the urine, persisting for 3 months or more.⁴ The most commonly used method for estimating the glomerular filtration rate (GFR) at present is the Modification of Diet in Renal Disease (MDRD) or Levey equation which typically uses the variables of age, gender, serum creatinine level and race (black vs. non-black) to calculate a result.⁴⁻⁶ Because body size is correlated with both creatinine levels and clearance rate, the MDRD equation is normalized to a "standard" body surface area of 1.73 m², allowing comparison between individuals of differing body types.

Recently, there are newer equations which have proven to be more accurate when compared with MDRD, especially among those with lesser degrees of renal impairment. Most prominently is the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation which uses the same variables as the MDRD equation but is less commonly reported on laboratory results.⁷ CKD-EPI is also normalized to a body surface area of 1.73 m². More accurate still is the CKD-EPI equation that includes the additional variable of a serum cystatin C which is less affected by lean muscle mass than is creatinine.⁸

Proteinuria has previously been diagnosed using timed collections for quantification. Several studies have demonstrated the validity of using spot ratios in place of these timed collections for diagnostic purposes, however use of such ratios must be taken in context and may be misleading.⁹ Typically a urine protein to creatinine ratio of more than 30 mg/g and protein/creatinine ration greater than 150 is considered evidence of renal disease, however, there are benign disorders which may elicit such a result.⁶ Strenuous exercise will almost always be associated with both proteinuria and hematuria and a condition called orthostatic proteinuria (OP) is relatively common among the young but becomes fairly rare in adulthood.¹⁰ OP may be easily diagnosed after an appropriate period of rest by performing a timed collection during which the subject remains in the supine or recumbent position (usually 4 to 8 hours). If proteinuria is absent and there are no other indications of disease such as edema or hypoalbuminemia, one may consider this to be OP. Such cases should be followed with a routine urinalysis each year as OP typically resolves by the 3rd decade of life.

An eGFR of less than  $60\text{mL/min}/1.73 \text{ m}^2$  of body surface area or an albumin to creatinine ratio  $(ACR) \ge 30 \text{ mg/g}$  are considered indicative of underlying renal disease.⁶ Often referred to as Stage I to Stage V, one need not necessarily progress from one to the next. Mildly reduced clearance in and of itself is not diagnosed as CKD, thus Stage I and II are only diagnosed when there is another indication of structural or functional damage such as the presence of proteinuria. Stage III through V are determined solely based on moderate or greater deficiencies in clearance and may or may not be accompanied by other abnormalities.^{3, 7} The progression of renal disease is non-linear and mild disease may persist for decades before declining precipitously.¹¹ Most individuals with CKD will not progress to End Stage Renal Disease (ESRD) which requires dialysis therapy or transplant.¹ More commonly, those with CKD will succumb to other

cardiovascular diseases of which the renal disease may be both an etiologic factor and/or an indication of underlying vascular disease from another cause.^{2, 12, 13}

Moderate to severe CKD is associated with accumulation of waste products, electrolyte imbalances, anemia, osteodystrophy and potentially problems with volume regulation.^{3, 14} These conditions may not become symptomatic until much later in the course of the disease, however, early identification and treatment may effectively reduce or prevent their occurrence. Strategies may also be employed which have the potential for slowing decline in renal function, these include control of hypertension and blood sugar, appropriate weight loss and other novel approaches. Currently, routine screening for renal disease at periodic health examinations is not considered to be of benefit at the population level, however, screening for those in higher risk groups is likely warranted.^{7, 15, 16} High-risk groups include those with conditions previously mentioned such as hypertension, diabetes or cardiovascular disease, as well as those with recurrent urinary tract infections, kidney stones, known anatomic abnormalities or a family history of renal disease.

In general, patients diagnosed with CKD should have renal imaging studies performed as part of their initial evaluation.¹⁷ Typically, renal ultrasonography is readily available and can provide an appropriate amount of information in determining the overall anatomy as well as giving clues to the nature and duration of disease. Further studies may be warranted based on the clinical picture but are often not necessary. If studies involving administration of intravenous contrast material are recommended, it is advisable to consult with a nephrologist before proceeding as both iodine and gadolinium based media have been associated with adverse outcomes in the renally impaired.

Staging of CKD has become a valuable tool in identifying both level of kidney function and establishment of clinical practice guidelines which address the evaluation and treatment of common comorbidities which can occur as renal function declines. Although not universally adopted, many organizations have divided stage III into IIIa and IIIb as it is during this stage that higher risks and several comorbidities may become apparent.¹⁸ Most patients with Stage IIIa CKD without other functional or structural abnormalities can be successfully managed by their primary care physician utilizing published clinical practice guidelines. As mentioned earlier, progression of renal disease is non-linear and function may decline rapidly during the later stages. For this reason, specialty referral is indicated when eGFR drops below the CKD IIIa range or when other indications of renal damage exist.

Management of CKD is well described in the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines and is not discussed in this waiver guide.¹⁴

Stage	Description	GFR (mL/min/1.73 m ² )
Ι	Kidney Damage with normal or $\uparrow$ GFR	<u>&gt;90</u>
II	Kidney Damage with mild $\downarrow$ GFR	60 - 89
IIIa	Moderate ↓ GFR	45 - 59

Table 2: Stages of Chronic Kidney Disease³

IIIb	Moderate ↓ GFR	30 - 44
IV	Severe ↓ GFR	15 - 29
V	Kidney Failure	<15 (or dialysis)

Most patients with CKD will die with, not of the renal insufficiency, the majority will succumb to cardiovascular insult and only a very few will progress to end-stage renal disease (ESRD)². Nonetheless, preparation and prevention are essential to reducing future morbidity and mortality. The KDOQI guidelines can be invaluable in assisting the primary care provider with risk management.

Occasionally patients will present with advanced renal disease that is stage IIIb or worse. In those cases specialty referral is indicated, but it is important that care be taken to avoid otherwise normal clinical interventions that may inadvertently preclude future therapy. Blood transfusion should be avoided unless required as a lifesaving measure. Every unit of nonautologous blood has the potential of inducing antibody formation, thereby decreasing the potential of a high quality match for a kidney transplant. Second, is preservation of venous access, should a patient require hemodialysis, damage to superficial and central vessels from venipuncture and other procedures may complicate vascular access creation. The best practice is to limit venipuncture to the dominant extremity, using only the most distal accessible vessels.

## **IV. Aeromedical Concerns.**

CKD - in its early stages – is associated with a low risk of sudden incapacitation and is generally not associated with sensory or functional impairments in the aviator. The sporadic, non-linear progression of CKD is of far greater concern in this population. Advanced disease is often associated with anemia, perturbations of volume status and electrolyte imbalances, each of which can lead to physiologic incapacitation under the stresses encountered during flight. Additionally, the frequent medical care associated with moderate to severe CKD can come in direct conflict with the mobility requirements of aircrew and special duty operators. Our current inability to predict progression due to the non-linear nature of declining function makes it unwise to train new aviators with even mild degrees of CKD and make waivers inadvisable for that group. Trained aviators and those without responsibility for the primary control of the aircraft, may safely continue their roles until the requirements for medical follow-up, essential medications or comorbid conditions preclude continued service. Maximal therapy aimed at risk modification should be preeminent and should not be postponed or overlooked for the sake of maintaining flying status.

ICD-9 codes for Chronic Kidney Disease		
585.1-5	Chronic Kidney Disease stages I-V	
585.6	End Stage Renal Disease	
585.9	Chronic Kidney Disease, unspecified	

#### ICD-10 codes for Chronic Kidney Disease

N18.1-5	Chronic Kidney Disease, stages I-V	
N18.6	End Stage Renal Disease	
N18.9	Chronic Kidney Disease, unspecified	
I18.1	Hypertensive Chronic Kidney Disease, Stage V or ESRD	
I18.9	Hypertensive Chronic Kidney Disease (all other stages)	

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#### WAIVER GUIDE Updated: Mar 2015 Supersedes Waiver Guide of Jan 2011 By: Capt Vanessa Pearson (RAM 16) and Dr Dan Van Syoc Reviewed by: Lt Col Nicholas Conger, AF/SG consultant in Infectious Diseases

## CONDITION: Lyme Disease (Mar 2015)

### I. Waiver Considerations.

Patients should be DNIF while symptomatic and under treatment. Once all symptoms of the disease have resolved, the aviator can be returned to status without a waiver (true for all aviation classes). Lyme disease is not mentioned by name as disqualifying for any aviation class, but the residual symptoms mentioned in Section III may require a waiver. In these cases, waiver for flying classes I/IA, II, and III, as well as for ATC, GBO and SWA personnel may be considered, depending on the success of the therapy. An ACS review of cardiologic or neurologic complications is recommended.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS review/evaluation
I/IA	Stage II and III	Yes*	Yes
	Lyme disease with	AETC	
	complications or		
	-		
	residual symptoms		
II/III	Stage II and III	Yes*	Yes
	Lyme disease with	MAJCOM	
	complications or		
	residual symptoms		
	• •		
ATC, GBO, and	Stage II and III	Yes*	Yes
SWA	Lyme disease with	MAJCOM	
	complications or		
	residual symptoms		

#### Table 1: Waiver potential for Lyme disease

*FC I/IA candidates and all other initial training candidates need to be totally disease and complication free for at least 12 months prior to waiver consideration. Waiver authority in such cases is AETC.

Review of the AIMWTS data base through Nov 14 revealed a total of 8 cases submitted for waiver consideration with the diagnosis of Lyme disease. There was 1 FC I case, 4 FC II cases, 2 FC III cases, and 1 MOD case. All were granted waivers except for the MOD case which resulted in a disqualification for persistent neurological symptoms.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary for cardiology involvement should include:

A. Complete history and physical exam – to include description of symptoms before and after the acute episode, medications, and activity level.

B. Copies of reports and tracings/images of any cardiac tests (e.g. electrocardiogram, echocardiogram, treadmill, Holter monitor, cardiac cath, cardiac CT or MRI) performed locally for clinical assessment (i.e., serial ECGs for uncomplicated 2nd degree AV blocks; serial Holters/echos depending on the level of cardiac involvement to begin with; etc.). If reports not attached in AIMWTS, send to the ACS. (Notes 1 and 2)

C. Any procedure-related reports (e.g. pacers, EP studies, etc.), as applicable.

D. Results of serologic studies.

<u>Note 1</u>: Call ACS to get correct mailing address for all required videotapes and CDs. For expediting the case, recommend sending via FedEx. Include patient's name, SSN and POC at base.

Note 2: State in AMS when studies were sent to ACS.

The aeromedical summary for neurological involvement should include:

A. Complete history and physical exam – to include description of symptoms before and after the acute episode, medications, and activity level.

B. Neurology consultation report.

C. Neuropsych testing, as appropriate.

D. Results of serologic studies.

The aeromedical summary for arthritic involvement should include:

A. Complete history and physical exam – to include description of symptoms before and after the acute episode, medications, and activity level.

B. Rheumatology consultation report.

C. Results of serologic studies.

#### **III. Overview.**

Lyme disease is the most common tick-borne disease in the United States (U.S.).^{1,2} In North America, it is caused exclusively by the spirochete *Borrelia burgdorferi* whereas in Europe it is caused by *B. afzelii*, *B. garinii*, *B. burgdorferi*, and occasionally by other species of borrelia.² It occurs worldwide and has been reported on every continent except Antartica.¹ Lyme disease surveillance in the U.S. began in 1982 at the Centers for Disease Control (CDC) and became a nationally reportable disease in 1991. In the U.S., the number of reported cases has been steadily increasing from over 11,700 cases/year in 1995 to almost 30,000 cases/year in 2009. Since 2009, the number of cases decreased to less than 25,000 in 2010, 2011, and 2012, but there was

an increase again in 2013 to more than 27,000 (these numbers only reflect the number of confirmed cases not the number of probable cases).³ In 2013, the highest number of confirmed Lyme cases were in Pennsylvania (4,981), Massachusetts (3,816), New York (3,512), New Jersey (2,785), and Connecticut (2,111).⁴ In the Northeastern and North-central U.S., the black-legged tick (or deer tick, *Ixodes scapularis*) transmits Lyme disease and in the Pacific coastal U.S., the disease is spread by the western black-legged tick (*Ixodes pacificus*). A cluster of cases identified in 1975 had their epidemiological epicenter in Lyme, Connecticut, for which the disease was named.⁵ Documentation of this disease dates back to 1883 in Breslau, Germany by a physician named Alfred Buchwald. He described an expanding, ring like lesion now known as erythema migrans (EM), the most common symptom associated with early Lyme disease, and speculated that the rash came from the bite of an *Ixodes* tick.⁶

Three distinct foci occur in the United States: the Northeast (Maine to Maryland), the North Central (Wisconsin and Minnesota) and the West (northern California and Oregon). In Europe, most cases occur in the Scandinavian countries and in central Europe (Germany, Austria, and Switzerland), although cases have been reported in the United Kingdom (South Downs and New Forest areas).⁷ Other prevalent worldwide locations include Russia, China and Japan.⁸

The ticks have larval, nymphal and adult stages, each stage requiring a blood meal. In the Northeast and North Central U.S., an efficient cycle of infection of *B. burgdorferi* between nymphal ticks and white footed mice yields a high frequency of infection during the spring and summer months in humans. An abundance of deer, the adult ticks' preferred host, fulfill a similar role in the Northeast. *I. scapularis*, also known as *I. dammini*, serves as the tick vector.⁸ The principle vector in the Northwestern U.S. is *I. pacificus*. The frequency of human infection is relatively low in the Northwest, as *I. pacificus* tends to feed on lizards, which are not susceptible to the infection, and only occasionally feed on the dusky-footed woodrat while in the larval stage. In Europe and Asia the principal vectors include *I. ricinus* and *I. persulcatus*, respectively, which also serve as vectors of tick-borne encephalitis virus.⁹

Even though the likelihood of infection is twice as high in adult ticks than in the nymphal stage, most cases of transmission of early Lyme disease occur in the spring and summer months when the nymph is seeking a blood meal. Adult ticks are much larger and easier to identify and remove prior to transmission of infection. Animal studies confirm that approximately 36 - 72 hours are required for transmission of the infection to the animal host once the tick has attached itself to the host. During this time spirochetes in the midgut of the tick multiply and migrate to the tick's salivary glands, in preparation for transmission to the animal host.^{5, 10} Only ticks that are partially engorged with blood are associated with the development of EM at the site of the bite.¹⁰

Active Lyme disease occurs in three broad stages. The clinical symptoms of each stage may overlap. Individuals may also present in a later stage without presenting with symptoms of an earlier stage.^{9,11} In addition, there is a post-Lyme disease syndrome the practitioner should be aware of the includes nonspecific symptoms such as headache, fatigue, and joint pain that may linger for months.¹¹ The most common clinical manifestation of the first phase is EM.² EM occurs between 3 and 30 days, although it most commonly develops between 7 and 14 days. In

the U.S., EM (single or multiple) is found in about 90% of patients with objective evidence of infection with *B. burgdorferi*.¹² This lesion is usually greater than or equal to 5 cm in diameter, often with a central clearing, bull's-eye or target like appearance. Approximately 45 percent of patients with EM have spirochetemia which is not related to the size or duration of the presenting skin lesion.⁵ Hematogenous dissemination from the primary infection site may yield secondary lesions.

Lyme disease has a myriad of dermatologic, neurologic, cardiac, and musculoskeletal manifestations. The most common symptoms during the primary stage often resemble those of a viral infection, including myalgias, arthralgias, fatigue, headache, neck pain and possible fever. Rarely, respiratory, gastrointestinal or ocular complaints such as conjunctivitis, iritis, and keratitis may be reported.^{2, 5, 13} EM spontaneously resolves in approximately four weeks without treatment.⁸ Given these vague initial symptoms, this represents a challenge in early detection and initial treatment.

The second stage is manifested by dissemination of the disease within days up to 10 months following the initial tick bite.^{9,11} It is associated with hematogenous spread of the spirochete to extracutaneous sites. Treatment at this stage helps to prevent later problems associated with Lyme disease.¹¹ Sixty percent of untreated patients with EM will progress to mono or oligoarticular arthritis, usually involving the knee. Ten percent will manifest with neurologic complications, the most common of which is facial-nerve palsy. Neurologic involvement may occur within weeks. Acute neuroborreliosis may develop in up to 15 percent of untreated patients in the U.S. Potential manifestations include lymphocytic meningitis with episodic headache and mild neck stiffness, subtle encephalitis with difficulty with mentation, cranial neuropathy (particularly unilateral or bilateral facial palsy), motor or sensory radiculoneuritis, mononeuritis multiplex, cerebellar ataxia or myelitis.⁹ In children blindness may result secondary to increased intracranial pressure on the optic nerve.⁹ Acute neurologic abnormalities spontaneously improve or resolve over a period of weeks or months, even in untreated patients. Cardiac involvement may occur several weeks after the initial onset. Approximately five percent of untreated patients experience cardiac involvement, to include atrioventricular block, acute myopericarditis, mild left ventricular dysfunction and rarely cardiomegaly or fatal pancarditis.⁹, 11

The third stage includes late disease which may occur months to years following the initial tick bite.^{9, 11} In some individuals, symptoms at this stage may be the first symptoms of the disease.¹¹ Individuals experiencing joint involvement may sustain several brief attacks of arthritis with the potential for persistent joint inflammation. In up to 10 percent of cases, the arthritis may persist for months or years despite 30 days of intravenous (IV) or 60 days of treatment with oral antibiotics.⁵ Large joints, especially the knee are susceptible, presenting with joint swelling and pain which is thought to be mediated by the immune response by the spirochete in the joint.¹³ Up to five percent of untreated patients may experience chronic neuroborreliosis. This may occur after long periods of latent infection. In the U.S. and Europe, a chronic axonal polyneuropathy may develop manifesting as spinal radicular pain or distal paresthesia. In Europe, chronic encephalomyelitis may occur. It is most often characterized by spastic paraparesis, cranial neuropathy or cognitive impairment with marked intrathecal production of

antibodies against the spirochete. In the U.S., Lyme encephalopathy, a mild, late neurologic syndrome with subtle cognitive disturbances, has been reported.⁸

Diagnosis in the U.S. is usually based on the recognition of the characteristic clinical findings, a history of exposure in an area where the disease is endemic and except in patients with erythema migrans, an antibody response to *B. burgdorferi* by enzyme-linked immunosorbent assay (ELISA) and Western blotting. IgM antibody titers during the first month of infection are unreliable. IgG antibody responses are prevalent in most patients infected for one month. Even with antibiotic treatment, IgM and IgG titers may persist for many years.⁸

Treatment recommendations during the first stage of Lyme disease include: doxycycline 100 mg twice daily for adults; amoxicillin 500 mg three times daily for adults; or cefuroxime axetil 500 mg twice daily for adults. The duration of therapy has traditionally been three weeks, although some studies suggest that a 10 to 14 day duration of therapy may be as effective.¹⁴ Doxycycline is not recommended for children under 8 years of age or for pregnant or lactating women. Individuals with chronic musculoskeletal pain, neurocognitive symptoms or both that persist after antibiotic treatment for well-documented Lyme disease may have considerable impairment in their health-related quality of life. However further treatment with an extended (90 day) course of antibiotics in a controlled clinical trial in individuals without evidence of persistent infection by *B. burgdorferi* received no added benefit over those who received placebo. A substantial increase in the risk of morbidity and even death in patients secondary to extended antimicrobial therapy was noted in this study.¹⁵

Second (early disseminated) and third (late) stages of Lyme disease may be treated with intravenous (IV) ceftriaxone, a third generation cephalosporin. Recommended dosages include 2 g once daily in adults. Similarly, cefotaxime 2 g every eight hours is also recommended in adults. Additionally, penicillin G divided into doses given every four hours in patients with normal renal function may be effectively used. Eighteen to 24 million units per day in adults is the recommended dosage. Recommended duration of IV therapy is two to four weeks. Four weeks is the current standard in many communities, although there is no evidence to support greater efficacy of four versus two weeks. There is also no evidence that treating for more than four weeks is beneficial. However, a 28-day course is preferred if the patient suffers from facial nerve palsy that has not resolved within 14 days.¹⁴

Prevention may be accomplished through avoidance of tick-infested areas, wear of protective clothing, the use of repellents and acaricides, tick checks and modifications of landscapes in or near residential areas.⁸ In December 1998, GlaxoSmith- Kline gained U.S. Food and Drug Administration approval for a *B. burgdorferi* outer surface protein A (OspA)-based Lyme disease vaccine, LYMErix.¹⁶ The efficacy was 49 percent after two injections and 76 percent after three injections.⁸ The vaccine, however, was voluntarily withdrawn from the market because of poor sales.¹⁶ Antimicrobial treatment within 72 hours of a tick bite with a single 200 mg dose of doxycycline has been suggested as effective prophylaxis against the development of Lyme disease. Although a study reported an efficacy of 87 percent, it was limited by the number of participants in whom Lyme disease developed, resulting in a wide 95 percent confidence interval. This study is in direct contrast to other studies demonstrating no clear protection

attributable to antimicrobial prophylaxis administered after a tick bite.¹⁰ Regardless, it may be prudent in aircrew to consider doxycycline prophylaxis within 72 hours of a tick bite from an endemic area to preclude progression of possible Lyme disease, since doxycycline is an approved aircrew medication after ground testing.

## **IV. Aeromedical Concerns.**

The symptoms during primary Lyme disease, including arthralgias, fatigue, headache, neck pain and possible fever are obviously not optimal in the flying environment. As with all infectious diseases, if recognized and treated early with full resolution of symptoms, return to flight status is appropriate. However, if untreated, then aeromedical concerns of this disease are its debilitating effects in regards to the neurologic, cardiovascular, and arthritides that may result. Neurocognitive impairment, cardiac arrhythmias and arthritic pain are all manifestations that could impact the safety of the individual and mission.

ICD-9 code for	· Lyme disease
088.81	Lyme disease

ICD-10 code for Lyme disease			
	A69.20	Lyme disease, unspecified	

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# Malaria and Antimalarial Medications

Revised: February 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Suggested readings updated.

## I. Waiver Consideration

Any aircrew or special duty operator who contracts malaria requires DNIF, DNIC, or DNIA until successfully treated and fully recovered. With respect to malarial prophylaxis, there are several antimalarial medications which are approved for aeromedical and operational use without need for a waiver. These medications can be found in the "Official Air Force Aerospace Medicine Approved Medications" and "Official Air Force Ground Based Operator (GBO) Approved Medications" lists. The approved medications currently are chloroquine (Aralen®), doxycycline (Vibramycin®), primaquine (PQ), and atovaquone/proguanil (Malarone®). Ground testing requirements to exclude idiosyncratic reactions for all of these medications are identical, but the prescribing parameters differ between medications. Mefloquine (Larium®) IS NOT APPROVED for aeromedical and operational use. If mefloquine is mistakenly administered, a DNIF/DNIC/DNIA period of four weeks is required to observe for the development of neuropsychological side effects.

There are a variety of factors that will influence decision-making regarding malarial prophylaxis. Choice of an appropriate antimalarial depends on the distribution of *Plasmodium* spp. in the area(s) that will be traveled through, local drug resistance patterns, and length of anticipated exposure. Timing will also influence antimalarial choice. Some of the approved prophylaxis agents require initiation up to a week before travel, and the length of terminal prophylaxis after return from the endemic area also varies. For travel or deployment with short notice, one of the medications that does not require preloading would be preferred. Other factors that will influence aeromedical decision-making include the availability of established medical infrastructure at the destination and individual tolerability, side effects, or contraindications of the particular medications. Currently, there is no unified policy regarding malaria prophylaxis in USAF personnel. Different MAJCOMs or theater commanders may implement specific policies with consideration for the unique nature of their mission.

## II. Information Required for Waiver Submission

Not Applicable. Please cross-reference the appropriate career field medication list.

## **III. Aeromedical Concerns**

The prescribing of antimalarial medications by Flight Medicine providers for use in USAF aircrew and special duty operators is common due to the frequency of deployments to malaria endemic areas. To prevent malaria and to maintain the health and operational readiness of aircrew and special duty operators, a proper understanding of this disease and the use of

antimalarial chemoprophylaxis is essential. Malaria comprises at least five protozoan species transmitted by female *Anopheles* mosquitoes that bite primarily in the dark hours from dusk to dawn. *Plasmodium falciparum* may be rapidly fatal in nonimmune visitors to endemic areas; the other species (most commonly *P. vivax*, *P. ovale*) much less commonly cause severe disease, but infected individuals may relapse many weeks to months after exposure due to latent infection harbored in the liver. Both primary and relapsing malaria represent infection of erythrocytes—with multiple attendant complications—resulting at least in an uncomfortable, febrile syndrome that is incompatible with the aviation or operational environment.

Prevention is the first and best line of defense against malaria, including personal protective measures combined with strategies to avoid mosquito bites. Appropriate antimalarial chemoprophylaxis taken correctly should prevent clinical malaria disease during travel, but malaria infection can occur if the above protective measures fail and/or doses of chemoprophylaxis are missed. Malaria that is acquired while taking chemoprophylaxis may be atypical in presentation, delayed in onset, and more difficult to diagnose and differentiate from other illnesses. Relapsing forms of malaria (non-*falciparum* species) are prevented and cleared of their latent hepatic forms only by primaquine, its use variably termed "terminal prophylaxis," "presumptive anti-relapse therapy," or "radical cure."

Among the available chemoprophylactic agents, mefloquine (Larium®) is NOT APPROVED FOR USE due to potential neuropsychiatric side effects. Given its long half-life, members taking mefloquine by mistake must remain DNIF/DNIC/DNIA for four weeks and observed for adverse effects. Mefloquine is medically contraindicated for anyone with significant psychiatric history or cardiac conduction abnormality. <u>Chemoprophylaxis approved for use by aircrew or special duty operators includes chloroquine (Aralen®), doxycycline (Vibramycin®), atovaquone/proguanil (Malarone®), and primaquine (PQ).</u>

Chloroquine has a long half-life, making it appropriate for weekly dosing. Ground trial is required due to potential side effects such as nausea, abdominal discomfort, palpitations, agranulocytosis (or multiple cytopenias), headache, lightheadedness, ataxia, vertigo, tinnitus, sensorineural hearing loss, diarrhea, pruritus, fatigue, and visual symptoms (accommodation disturbance, blurred vision, scotoma, color vision changes, and visual field defects). Chloroquine may suppress the cell-mediated immune response, contributing to complications such as reactivation of the herpes viruses (e.g. zoster). Personnel experiencing significant neurological side effects must remain DNIF/DNIC/DNIA for four weeks while observed for side effect resolution. Members taking chloroquine for longer than several months should be examined periodically for visual adverse effects, including acuity and color discrimination. Although FDA indicated for malaria chemoprophylaxis, hydroxychloroquine currently is not approved for use in aircrew or special duty operators for the purpose of malaria prevention. Its use for this indication would require a waiver. Hydroxychloroquine has an adverse effect profile that is similar to chloroquine; both may prolong the QTc interval. In areas with chloroquine-sensitive P. falciparum, both chloroquine and hydroxychloroquine in adults is administered once weekly beginning one to two weeks prior to exposure, during exposure, and for four weeks following exposure.

<u>Doxycycline</u> is a daily chemoprophylaxis agent with a half-life so short that it needs to be taken reliably every 24 hours (regardless of number of time zones crossed). Ground trial is required to detect idiosyncratic reactions and demonstrate tolerability. Common adverse effects include gastrointestinal upset (ameliorated by taking with food), headache, tinnitus, photosensitivity, and vulvovaginal candidiasis. Pill esophagitis is a rare complication which can be avoided by taking with plenty of fluids and avoiding recumbence immediately after a dose. Doxycycline in adults is administered once daily beginning one to two days prior to exposure, during exposure, and for four weeks following exposure.

<u>Atovaquone/proguanil</u> (Malarone®) is a daily chemoprophylaxis agent that has a low rate of discontinuation due to side effects. Single-dose ground trial is required. Adverse effects may include nausea, abdominal discomfort, and headache; but photosensitivity and neuropsychiatric manifestations are not characteristic. Atovaquone/proguanil represents a more expensive malaria prophylaxis option, but it may be required preferentially for some regions (e.g., USAFRICOM AOR). Atovaquone/proguanil in adults is administered once daily beginning one to two days prior to exposure, during exposure, and for one week following exposure.

<u>Primaquine</u> (PQ) generally is reserved for terminal prophylaxis after travel to areas in which there is significant risk for exposure to non-*falciparum* malaria (relapsing species). PQ use per policy (e.g., for Force Health Protection purposes) must be in accordance with FDA indications, i.e. 15 mg daily for two weeks. However, the clinical (non-policy) off-label dosing of 30 mg daily for two weeks is more commonly used and widely accepted among travel medicine practitioners. PQ has also been used (similarly off-label) as a 30 mg daily primary chemoprophylaxis agent in areas without reported *P. falciparum*. Specifically, for short duration travel to areas with principally *P. vivax*, PQ is administered once daily beginning one to two days prior to exposure, during exposure, and for one week following exposure. G6PD activity must be assessed prior to any PQ use, and PQ is not recommended for pregnant or breastfeeding women due to the unknown G6PD status of the infant. Single-dose ground trial is required prior to aircrew or operational use. Adverse effects may include abdominal discomfort, nausea, rash, headache, pruritus, interference with accommodation, cytopenias (even in G6PD-normal individuals), and methemoglobinemia.

## **IV. Suggested Readings**

Resources available to the flight medicine providers caring for individuals travel to or deploy to at-risk locations:

Centers for Disease Control and Prevention
https://www.cdc.gov/malaria/about/distribution.html (geographic distribution)
https://www.cdc.gov/malaria/travelers/country_table/a.html (drug resistance by country)
Yellow Book: Health Information for International Travel (CDC publication)
https://wwwnc.cdc.gov/travel
Travax, US DoD website for operational travel medicine (CAC required)
https://www.travax.com/account/login/dod
Armed Forces Pest Management Board
https://www.acq.osd.mil/eie/afpmb/
Malaria Field Guide (US Army Public Health Command publication)
https://phc.amedd.army.mil/PHC%20Resource%20Library/ento-malaria-field-guide-tg336.pdf
World Health Organization. Guidelines for the treatment of malaria. Updated 13 July 2021.
https://www.who.int/teams/global-malaria-programme/guidelines-for-malaria

### WAIVER GUIDE Updated: Apr 2016 Supersedes Waiver Guide of Jan 2013 By: Maj Andrew Timboe (RAM 17) and Dr Dan Van Syoc Reviewed by: Col Matthew Carroll, AF/SG consultant for Rheumatology

## CONDITION: Osteoarthritis (Apr 2016)

## I. Waiver Consideration.

Arthritis of any type of more than minimal degree, which interferes with the ability to follow a physically active lifestyle, or may reasonably be expected to preclude the satisfactory performance of flying duties is disqualifying for all classes of flying. If the pain can be controlled with acetaminophen or an aeromedically approved nonsteroidal, the aviator can remain on these medications and be considered for a waiver. A waiver request that includes the use of an NSAID should include, at a minimum, a CBC and a comprehensive metabolic profile to monitor for adverse effects of the treatment, and done so in conjunction with manufacturer's recommendations.

Aviators with significant pain or limitations will need to be grounded until these issues are satisfactorily addressed. If pain and/or limitations persist despite maximal medical therapy, then disqualification from flying duties may need to be considered. If joint replacement is deemed appropriate, then the information in the Retained Orthopedic Hardware and Joint Replacement waiver guide should be followed, for guidance. OA of the spine that requires medical therapy and close observation is not waiverable for ejection seat aircraft. ATC and GBO personnel are covered under retention standards; internal derangement of the knee complicated by arthritis and severe osteoarthritis are listed as disqualifying for retention standards. Any joint pain that interferes with the ability to successfully complete the mission is disqualifying.

Flying Class	Condition/Treatment	Waiver Potential	
		Waiver Authority†	
I/IA	Stable OA on no meds+	Maybe	
		AETC	
	Symptoms controlled with	No	
	meds	AETC	
	Symptoms not controlled	No	
	with meds	AETC	
II/III	Stable OA on no meds+	Yes	
SWA		MAJCOM	
	Symptoms controlled with	Yes	
	meds#+	MAJCOM	
	Symptoms not controlled	Maybe	
	with meds*+	MAJCOM	
ATC/GBO	Stable OA on no meds+	Yes	
		MAJCOM	
	Symptoms controlled with	Yes	
	meds#+	MAJCOM	
	Symptoms not controlled	Maybe	
*0	with meds*+	MAJCOM	

 Table 1: Waiver potential for Osteoarthritis

*Symptomatic patients who go on to joint replacement may be eligible for a waiver – see Retained Hardware and Joint Replacement Waiver Guide.

#Medications used to control OA must be on the approved medication list; see note at end of Aeromedical Concerns for appropriate f/u if on chronic NSAIDs.

+No indefinite waivers; waiver should be renewed approximately every three years if stable.

†If member does not meet retention standards, then the waiver authority is AFMRA.

Review of AIMWTS data in Mar 2016 revealed 213 cases with the diagnosis of osteoarthritis. Breakdown of the cases revealed: 2 FC I/IA cases (both disqualified); 103 FC II cases (14 disqualified); 96 FC III cases (29 disqualified); 9 ATC/GBC cases (2 disqualified); and 3 MOD cases (none disqualified). Of the 47 disqualified cases, 17 cases were disqualified due to severe joint disease and 30 cases for multiple medical problems which included varying degrees of joint disease.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for *initial waiver* for osteoarthritis should include the following:

A. History of symptoms, history of trauma and activities, limitations secondary to disease, summary of all treatments to date, present level of activity, medications (including over the counter medications), and functional limitations. Document gastrointestinal and/or renal symptoms and signs related to medications taken, if present.

B. Physical - addressing range of motion, tenderness, edema/effusion, deformity, associated muscle strength/atrophy and neurologic signs (if symptoms/ present). Document skin/nail findings, if abnormal.

C. Labs: ESR as clinically indicated. RF is not needed unless there are clinical indications to do so. CBC and metabolic profile if on NSAIDs for three or months continually; at three months and then periodically if WNL. Synovial fluid analysis, if clinically indicated.

D. Orthopedic or rheumatology consultation report (general internal medicine will suffice if orthopedics and rheumatology not available). Physical therapy evaluation for range of motion, muscle strength, activity level, and limitations.

E. Operative reports, if applicable.

F. Results of X-rays; X-rays should always be ordered based on clinical findings with results interpreted in the context of the patient's symptoms and the American College of Rheumatology (ACR) classification criteria. MRI and X-Rays have significant discord with clinical findings. In general, MRI detects more asymptomatic degenerative changes and X-Rays can miss some degenerative symptomatic findings. Additionally, sometimes OA progresses radiographically with little clinical change. When available, radiographic studies can be helpful, but they are not a reliable diagnostic or monitoring tool. ACR classification criteria allow you to diagnose knee OA without radiographs.

G. Medical evaluation board (MEB) results (if applicable).

The AMS for *waiver renewal* for osteoarthritis should include the following:

A. Interim history and physical – focus on any changes since most recent waiver, present level of activity, medications, and limitations.

B. Applicable consult(s).

C. X-rays and lab results, if applicable.

D. RILO (if applicable)

## III. Overview.

Osteoarthritis (OA) is the most common joint disease worldwide, affecting an estimated 27 million Americans alone.^{1, 2} It is a chronic disease of joint cartilage and bone and generally a disease of older individuals. Disease onset begins after age 40, with an estimated prevalence of 70% to 90% in people over the age of 75. Men and women are initially equally affected; after age 50, incidence is greater in women. Often symptoms appear earlier and can be more severe in women; moderate to severe radiographic OA is more prevalent in women than men for the hands, feet and knees (equal for hips). And, symptomatic OA prevalence is greater in women for hands, feet, knees and hips.³⁻⁶ There is no known cure for the disease and current therapeutic strategies are directed at pain reduction and improvement of joint function.^{7, 8} OA is a leading cause of disability in the workplace, particularly in people over the age of 55.^{1, 9}

Osteoarthritis can be idiopathic (localized or generalized) or secondary to trauma (congenital, metabolic, endocrine, neuropathic or other medical causes).¹ The exact etiology of the pathology is

unknown, but involves the complex interplay of biomechanics, genetics and biochemicals.^{10, 11} OA is characterized clinically by joint pain, swelling and functional limitations/stiffness and most commonly affects the knees, hips, hands and spine. Radiographically, it is characterized by osteophytes, bony sclerosis and joint space narrowing, and histopathologically, there are alterations in cartilage and subchondral bone integrity.¹⁰ Modifiable risk factors for OA are weight, highimpact repetitive activities, and osteoporosis. Increased weight is the most significant independent predictor of both incidence and progression of OA in weight-bearing joints. Studies have demonstrated that weight reduction can reduce the development and progression of OA of the knee.¹¹ Maintaining an appropriate body weight may be the most important factor in preventing OA from occurring in weight-bearing joints.¹¹⁻¹³ In order to label osteoarthritis as "idiopathic," causes need to be considered and ruled out. These include but are not limited to: rheumatoid arthritis, lupus/other autoimmune arthritides, Wilson's disease, hemochromatosis, Paget's disease, septic arthritis, gout, and diabetic arthropathy. OA is classically associated with the absence of rheumatoid factors and with normal levels of acute phase reactants. However, rheumatoid factors may be present, usually in low titer, consistent with a person's advancing age. In addition, the erythrocyte sedimentation rate (ESR) and serum C-reactive protein concentration may be somewhat elevated, this is usually secondary to an associated disease. New markers which may be prognostic for progression of disease risk are on the horizon.¹⁴

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a validated instrument for the assessment of pain, stiffness, and physical function in patients with OA of the knee or hip. It assesses patients using 24 parameters and is particularly useful to monitor the course of the disease or to determine the effectiveness of therapeutic modalities.¹⁵ It tends to be used in the research arena, but is a very useful tool for evaluating the status of OA patients. The American College of Rheumatology has clinical classifications for hand, hip and knee OA, as well.¹⁶

For our population of aviators, the major joints of concern with OA are the neck, spine, hands knees, and hips. Arthritis in the neck, spine and hands can be especially problematic in fighter/ ejection seat aircraft as well as for helicopter aircrew and for boom operators. Risk factors for OA of the knee include obesity, knee injury, previous knee surgery, and occupational bending and lifting.¹³ For OA of the hip, the risk factors include older age, high bone mass, genetic predisposition, increased BMI, participation in weight-bearing sports, and occupations that require prolonged standing, lifting, or moving of heavy objects.¹⁷

The diagnosis of OA is mainly clinical. The main symptoms/signs that suggest the diagnosis are pain, stiffness, reduced movement, swelling, crepitus, age greater than 40, and the absence of systemic features such as fever.¹¹ Joint involvement is usually symmetric and morning joint stiffness that resolves within 30 minutes or occurs with mild-to-moderate activity is also common. With disease progression, more prolonged joint stiffness and joint enlargement becomes evident. Crepitus in the joint is a late manifestation of disease. Radiographic findings consistent with OA include presence of joint space narrowing, osteophyte formation, pseudocyst in subchondral bone, and increased density of subchondral bone. The absence of radiographic changes does not exclude the diagnosis of OA.⁸

Treatment modalities include nonpharmacologic, pharmacologic and surgery.¹⁸ Surgical intervention will not be covered in this waiver guide. The pharmacologic modalities can be analgesics, anti-inflammatory agents, intra-articular agents and the use of glucosamine with

chondroitin. With most OA patients, acetaminophen is the drug of choice; it can be used safely in doses up to 3g/day in patients not using other liver-metabolized medications or alcohol.¹⁹ Occasionally, the pain may be severe, and in those cases, the use of opioid analgesics such as codeine can be used, but should be avoided for long-term use. Non-steroidal anti-inflammatory agents (NSAIDs), such as ibuprofen, are commonly used. There is no convincing evidence that any of the available NSAIDs is more effective than any other for OA of the hip or knee.¹⁹ In comparing acetaminophen with NSAIDs, there is evidence that NSAIDs are superior to acetaminophen in terms of pain reduction and improvements in patient and physician global assessments and functional status. The relative superiority of NSAIDs over acetaminophen is most marked in those with moderate to severe levels of pain. The benefits of NSAIDs over acetaminophen are relatively modest, and therefore, additional factors are still important to consider in the decision to use these drugs.²⁰

There has been considerable discussion over the past several years concerning the use of natural substances, glucosamine and chondroitin, for the treatment of OA. It has been touted to relieve symptoms and stop the disease progression, however data in the past failed to prove convincingly that it works, how it works, or whether it is even safe to take long-term.²⁰ Recent analysis showed the combination of glucosamine and chondroitin was non-inferior to celecoxib after 6 months of use and there were few risks from its use.²¹ This natural combination therapy may be appropriate for a patient desiring to avoid acetaminophen or NSAIDs, but is not recommend for initial treatment.

Intra-articular corticosteroids can be very useful in OA patients who have pain despite appropriate dosing of an NSAID. Repeated injections over a period of up to two years appear to be safe and can be very effective.¹⁹ In addition, hyaluronic acid injections have been used with some degree of success in certain sub-populations. Randomized trials have shown success in OA of the ankles, shoulders, and hips. Multiple injections are required with approximately five injections necessary for adequate treatment; one injection weekly for five weeks. The exact mechanism of action is unknown, but there may be a combination of an anti-inflammatory effect, a local lubricant effect, and an analgesic effect by direct buffering of synovial nerve endings.¹⁸ With any intra-articular injection, the aviator needs to be placed in a DNIF status until the treatments are completed and the disease symptoms have improved.

The major nonpharmacologic entities include weight loss, rest, physical therapy, and exercise. Obesity and weight reduction are important, as noted above. Resting of the affected joint often alleviates pain, but prolonged rest may lead to muscle atrophy and decreased joint mobility.¹⁸ Physical therapy can improve flexibility and strengthen muscles supporting affected joints, and this often improves functional outcome and pain scores. In addition, there has been much discussion concerning orthoses, particularly for patients with OA of the knee. Research has suggested that neutral or laterally wedged shoe orthoses may be beneficial in the management of medial knee OA when used with walking shoes.²² Lastly, most recent studies support an appropriate exercise program as an integral part of the management of OA. Exercise goals are to reduce pain and functional impairment, protect involved and at-risk joints, and to prevent disability related to a more inactive lifestyle.^{23, 24} Use of heat and cold packs, as well as, topical capsaicin may be incorporated into the therapeutic regimen. Overall, pain and functional status of OA (especially of the hip and knee) seems to deteriorate slowly, and there is limited evidence of OA worsening after 3 years of follow-up; so, ultimately, any type of exercise program that is done regularly and monitored by health professionals is essential to improving activities of daily living and function.^{18, 25}

#### **IV. Aeromedical Concerns.**

The major concerns with aviators with OA are: distracting pain and joint limitations that may interfere with normal flight duties and with emergency egress activities. The chronic use of medications is of concern since it indicates ongoing pain; and the particular agents used to mitigate pain may result in other adverse aeromedical sequelae such as peptic ulcer disease, gastrointestinal bleeding, hepatic insufficiency, renal insufficiency or nephrolithiasis, altered mentation, sedation, etc. Acetaminophen and NSAIDs use can be waived on a regular basis, but use of opioid analgesics is not approved for aviation duties. If the aviator is using chronic NSAIDs, there must be regular follow-up with a CBC and BUN/Cr, and if using acetaminophen, to follow LFT level, and based on manufacturer recommendations.²⁶

ICD-9 codes for	CD-9 codes for osteoarthritis		
715	Osteoarthritis and allied disorders		
715.9	Degenerative Joint Disease		
716.59	Polyarthritis		
716.9	Unspecified arthropathy, Arthritis		

ICD-10 codes for osteoarthritis		
M15.8	Other polyosteoarthritis	
M19.90	Unspecified osteoarthritis, unspecified site	
M13.0	Polyarthritis, unspecified	
M12.9	Arthropathy, unspecified	

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# **Osteoporosis and Osteopenia**

Revised: Aug 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured, suggested readings updated.

## I. Waiver Consideration

Any history of osteopenia or osteoporosis is disqualifying for all flying class and SWA duties. Uncomplicated, asymptomatic osteopenia or osteoporosis is not disqualifying for GBO, ATC, or OSF duties. However, osteopenia or osteoporosis that requires specialist follow-up more frequently than annually or that results in sequelae (e.g., pain, weakness, deformity) that interfere with the wear of required occupational/deployment equipment is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention.

An individual with a secondary cause of bone mineral density loss may be disqualified due to the primary condition. The use of any medication not included on the applicable career field medication list is disqualifying for ongoing aviation or operational duty and would necessitate a waiver. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions and treatments. Although a career field medication list for OSF or SWA personnel does not exist, the use of a prescription medication or supplement for the treatment of low bone density in OSF and SWA personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

Osteopenia and osteoporosis are diagnosed based on low bone mineral density, measured by dual energy X-ray absorptiometry (DEXA or DXA), and assessed as the number of standard deviations (SD) from a population mean. The number of SDs from the mean bone density at a given site of measurement is expressed as either a Z-score or T-score. The Z-score, rather than the T-score, should be used to assess bone loss in premenopausal women and men younger than 50 years of age. The Z-score compares an individual's bone mineral density with an age-matched reference population. Any Z-score worse than -2.0 SD below the mean represents abnormally low bone density and necessitates further evaluation. *Low bone density that does not meet the diagnostic definition of osteopenia or osteoporosis is not disqualifying in the absence of other disqualifying factors*.

The reference mean used to calculate the T-score is based upon the bone density of a young premenopausal, healthy, female population. The International Society for Clinical Densitometry (ISCD) recommends using the World Health Organization (WHO) diagnostic criteria for osteoporosis in post-menopausal women and men aged 50 years or older. By WHO criteria, T-scores between -1.0 and -2.5 are categorized as osteopenia; while T-scores of -2.5 or worse are categorized as osteoporosis. A T-score below 0 but not as low as -1.0 may represent low bone density relative to the healthy mean, but it does not fit the diagnostic definition of osteopenia based on WHO criteria and ISCD recommendations. Low bone density that does not meet the definition of osteopenia or osteoporosis is not disqualifying in the absence of other disqualifying

factors. Any history of a fragility fracture is diagnostic of osteoporosis, regardless of the T-score. Any history of a fragility fracture is diagnostic of osteoporosis, regardless of the Z-score or T-score.

In the absence of any indication for pharmacologic therapy, individuals who are disqualified due to osteopenia and are otherwise asymptomatic may submit for a waiver after completion of all necessary endocrinologic and metabolic evaluation to exclude secondary causes of bone mineral loss. All other service members with complications related to osteoporosis/osteopenia may submit a waiver once an appropriate endocrinologic and metabolic evaluation is complete and the individual is stable and tolerating clinically-appropriate therapy without adverse effects. It is expected that individuals requesting a waiver will be recovered from any fractures or other complications without residual pain or sequelae that could interfere with aviation or operational duties, including the wearing of aviation or deployment equipment. The use of an aeromedically unapproved medications for the treatment of osteopenia or osteoporosis will not be considered favorably for waiver. Generally, aviators with any history of fragility fracture will only be considered for a restricted waiver, limited to non-high performance and non-ejection seat aircraft. Due to the risk of future fracture, certain high-velocity or high-impact activities are contraindicated in the setting of severe osteoporosis, osteopenia with a high estimated risk of fracture (e.g., based on the Fracture Risk Assessment Tool (FRAX®)), or a history of previous fragility fracture. In these cases, a waiver restriction prohibiting certain duties may be considered (e.g., no parachute or jump duty).

Flying Class	Condition ¹	Waiver Potential Waiver Authority ²	ACS Review or Evaluation
FC I/IA	Any history of osteopenia or osteoporosis	Yes AFRS/CMO	No ³
FC II/III/ SWA	Any history of osteopenia or osteoporosis	Yes MAJCOM	No ³
ATC/GBO/OSF	Osteopenia or osteoporosis that requires specialist follow-up more frequently than annually or with sequelae that interfere with the wear of required deployment/survival equipment	Yes MAJCOM	No ³

 Table 1: Waiver potential for Osteoporosis and Osteopenia

1. The underlying etiology of secondary osteoporosis may be independently disqualifying. The use of any aeromedically unapproved medication is independently disqualifying. Please cross-reference the Medical Standards Directory, Air Force Waiver Guide, and appropriate career field medication list for all potentially disqualifying conditions.

2. Certification authority for untrained assets is AFRS/CMO. Certification authority for non-approved medication use is AFMRA.

3. ACS review may be requested at the discretion of the waiver authority.

# **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Summary of diagnostic evaluation and treatment history, including list of any/all procedures with dates.
  - c. Specify presence or absence of any secondary cause of bone density loss.
  - d. List current medications with dosages.
- 2. Consultation report from the treating endocrinologist and all subsequent consultation notes, if applicable.
- 3. Laboratory studies required:
  - a. Current CMP.
  - b. Current phosphorus.
  - c. Current 25-OH vitamin D level.
  - d. 24-hour urine calcium.
  - e. Intact parathyroid hormone level and serum calcium (drawn simultaneously).
  - f. Thyroid stimulating hormone (TSH) level.
- 4. Imaging studies required (radiology report is sufficient):
  - a. Initial dual energy X-ray absorptiometry (DEXA or DXA) study and all subsequent follow-up studies
  - b. X-rays of any fragility fractures
- 5. Results of all testing performed during diagnosis, evaluation, and management of osteopenia or osteoporosis, including laboratory studies, imaging, and any other ancillary studies.
- 6. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Summarize any interval evaluation and/or treatment.
  - c. List current medications with dosages.
- 2. All interval consultation reports from the treating endocrinologist, if applicable.
- 3. Laboratory studies required:
  - a. Current CMP.
  - b. Current phosphorus.
  - c. Current 25-OH vitamin D level.

- d. Intact parathyroid hormone level and serum calcium (drawn simultaneously).
- e. Thyroid stimulating hormone (TSH) level.
- 4. Imaging studies required (radiology report is sufficient):
  - a. All interval dual energy X-ray absorptiometry (DEXA or DXA) studies.
  - b. X-rays of any interval fragility fractures.
- 5. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval procedure reports, and any other ancillary tests.
- 6. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

Osteoporosis and osteopenia are characterized by loss of bone mass and disruption of the bone microarchitecture. Both factors result in diminished bone strength, predisposing the affected individual to fractures. The major aeromedical and operational concerns associated with osteopenia and osteoporosis involve the risk to the health and welfare of the individual service member and the potential detrimental impact on mission completion and safety.

Individuals with osteopenia or osteoporosis are at heightened risk for fragility fractures, which are defined as fractures resulting from low or minimal force. Examples of mechanisms that might lead to fragility fractures include falling from a standing height or jumping from several feet of elevation, such as would be expected during emergency aircraft egress. Some activities performed regularly in the course of routine duties in certain career fields involve mechanical forces that could result in fracture in the setting of weakened bones from osteopenia or osteoporosis (e.g., axial-loading, high-G maneuvers, rapid accelerations and decelerations, heavy lifting, jumping, twisting, bending, etc.). In other career fields, such forces would only be encountered during emergency procedures such as rapid egress or aircraft ejection. Whether in the performance of routine duties or during emergency procedures, an acute fragility fracture would pose a risk to the individual service member's health and jeopardize the welfare of other members of the aircrew or operational unit and may place the mission at risk.

Common locations of fragility fractures include the spine, hips, wrists, upper arms, ribs, and pelvis. Depending on the location and severity of the fracture, immediate consequences could range from distracting pain to immobility and incapacitation (e.g., vertebral or femoral neck fracture). Long term consequences include chronic pain, deformity (e.g., kyphosis), musculoskeletal weakness, and loss of physical function (e.g., joint range of motion).

The individualized likelihood of a major osteoporotic fracture or hip fracture over a period of ten years can be calculated using the Fracture Risk Assessment Tool (FRAX®). This calculation is a validated clinical decision making tool for assessing treatment options using antiresorptive agents to reduce fracture risk. The FRAX® calculator takes into consideration an individual's ethnicity, gender, age, height, weight, smoking history, previous fracture history, family history of fracture, and risk factors for secondary osteoporosis.

In general, pharmacotherapy is recommended for anyone with a 10-year risk of major osteoporotic fracture of 20% or greater or a 10-year risk of hip fracture of 3% or greater. These individuals are at high risk for fragility fracture, even if their T-scores are not within the range of osteoporosis. Thus, these individuals have the highest risk for complications that would interfere with safe performance of aviation and operational duties.

By definition, individuals with low bone density who do not have a history of fragility fracture and low 10-year FRAX® score out of range for antiresorptive medication are at low risk for fracture over the time course of a limited-duration waiver. While their aeromedical and operational risk remain elevated above their non osteopenic/osteoperotic peers, the risk is anticipated to be low.

Bisphosphonate therapy is first-line treatment for fracture risk reduction in individuals with osteopenia or osteoporosis. Among the bisphosphonate class, alendronate is approved for use in aircrew and GBO personnel. It is effective at reducing the incidence of fragility fractures among those with diminished bone density and abnormal bone microarchitecture, and it is well-tolerated when administered properly. It is important that alendronate be taken on an empty stomach, with water only, without other food or beverage, one hour prior to the consumption of any further medication, food, or beverage. The oral bisphosphonates are all associated with a risk of pill esophagitis. For this reason, they should be taken with a full glass of water (8 ounces), and an upright posture should be maintained for at least one hour after medication ingestion. The risk of esophagitis can be minimized by consuming a meal or snack one hour after tablet ingestion.

In high-performance aircraft, bisphosphonate therapy has a theoretical concern for regurgitation of gastric contents that could result from the combined factors of G-suit abdominal compression, negative  $G_z$  forces, and recumbent positioning. In order to minimize this risk, it is recommended that high-performance aviators dose alendronate on a day when no flying is planned. Such dosing may be possible because alendronate is only administered once weekly. If conflict with the flying schedule is unavoidable, the aviator should medicate at least 60 minutes prior to flying and should eat a snack just before the mission to assist with neutralizing any active drug remaining in the stomach.

Review of the AIMWTS database from Aug 2019 through Aug 2022 revealed 29 cases with a diagnosis of osteoporosis or osteopenia. The breakdown of the number of waivers and number of total cases are tabulated below. Four FC II cases received operational restrictions from high-performance and/or ejection seat aircraft.

ICD-10 Codes		(# of waivers / total # of cases)			
		IFC I/IA	FC II	FC III	GBO
M80.8 M81.8	Other osteoporosis with current pathological fracture, unspecified site Other osteoporosis without current	1/1	20/20	7/7	1/1
101.0	pathologic fracture	1/1	20/20	,,,,	1/1
M85.9	Disorder of bone density and structure, unspecified				

# **IV. Suggested Readings**

- 1. 2019 ISCD Official Positions: Adult. International Society for Clinical Densitometry. Available at <a href="https://iscd.org/wp-content/uploads/2021/09/2019-Official-Positions-Adult-1.pdf">https://iscd.org/wp-content/uploads/2021/09/2019-Official-Positions-Adult-1.pdf</a>. Accessed 16 Aug 2022.
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WAIVER GUIDE Updated: Sep 2015 Supersedes Waiver Guide of Nov 2011 By: Lt Col An Duong (RAM 16) and Dr. Dan Van Syoc Reviewed by Lt Col Eric Barnes, AF/SG consultant for Nephrology

# CONDITION: Proteinuria & IgA Nephropathy (Sep 2015)

## I. Waiver Considerations.

Benign forms of proteinuria are routinely waived for all flying classes if it is deemed to be benign after specialty consultation. IgA nephropathy is disqualifying for FC I/IA, II, III, and SWA duties if the proteinuria exceeds 200 mg/24 hours. Chronic nephritis with renal function impairment and nephrosis worse than mild are disqualifying for all flying and special operational duties and require an MEB prior to waiver submission. Certain ACE inhibitors and ARBs are approved for aircrew use, as are a number of statins, though the role of the latter in IgA nephropathy is unclear. Corticosteroid therapy is not waiverable. If significant hematuria is also present, please consult with the waiver guide for hematuria for assistance.

Flying Class (FC)	Condition	Waiver Potential	
		Waiver Authority	
I/IA	Proteinuria without evidence of		
Untrained II/III/SWA	renal disease or hypertension	AETC	
	Proteinuria without evidence of	Mavhe	
	renal disease, but with	AETC	
	hypertension*+		
	Proteinuria with evidence of		
	renal disease with or without	No	
	hypertension	AETC	
	IGA Nephropathy with		
	proteinuria		
II/III	Proteinuria without evidence of	Yes	
SWA	renal disease or hypertension	MAJCOM	
	Proteinuria without evidence of	Yes	
	renal disease, but with hypertension *+#	MAJCOM	
	Proteinuria with evidence of		
	renal disease with or without	Yes	
	hypertension *+#	MAJCOM	
	IGA Nephropathy with		
	proteinuria +		
ATC/GBO	Chronic nephritis with renal function impairment	Maybe, after MEB MAJCOM	
	Nephrosis worse than mild	Maybe, after MEB MAJCOM	

Table 1: Waiver potential for proteinuria and IgA Nephropathy

* Hypertension controlled on low dose HCTZ, chlorothiazide, triamterene, lisinopril, ramipril, benazepril, telmisartan or losartan may be considered for waiver.

+ No indefinite waivers.

# FC IIA waiver can also be considered with HCTZ combined with lisinopril, ramipril, benazepril, telmisartan or losartan; atenolol alone or in combination; nifedipine (coat-core or GITS) alone or in combination; or amlodipine alone or in combination.

J Waiver for FC I/IA and untrained FC II and FC III may be considered if sustained HTN control well documented, on low standard dosage, no evidence of end organ damage and no side effects.

AIMWTS review in Sep 2015 for the diagnoses of proteinuria and IgA nephropathy revealed a total of 95 cases, with 19 of those resulting in a disqualification disposition. Breakdown of the cases revealed: 14 FC I/IA cases (6 disqualified), 43 FC II cases (5 disqualified), 28 FC III cases (6 disqualified), 7 ATC/GBC cases (1 disqualified), and 3 MOD cases (1 disqualified).

#### II. Information for Waiver Submission.

The aeromedical summary should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary for <u>initial waiver</u> for proteinuria and/or IgA nephropathy should include the following:

A. Complete history of the problem to include all consultants seen.

B. Physical exam results.

C. Labs – all urinalysis tests to include microscopic results, BUN/Cr, 24 hour urine, renal biopsy results if done.

D. Nephrologist consultation report if completed.

E. Current treatment to include all medications and dates started.

F. Results of MEB if aviator has IgA nephropathy, or nephropathies, or nephritis.

G. Detail of all other medical problems, if applicable.

The aeromedical summary for <u>waiver renewal</u> for proteinuria and/or IgA nephropathy should include the following:

A. Updated history since last waiver

B. Physical exam results.

C. Labs - all urinalysis tests, other labs and additional renal biopsies since last waiver.

D. Nephrologist consult report if new one accomplished.

E. Current treatment to include all medications and dates started.

# III. Overview.

Proteinuria is an early and sensitive marker for renal damage in many types of chronic kidney disease.¹ It characterizes most forms of glomerular injury, but is not necessarily diagnostic for renal injury. Urinalysis is a common test in the clinic and is performed for many reasons. Urinalysis is often part of a screening exam such as school physicals, preplacement exams and flight physicals. Annual screening for proteinuria is no longer felt to be cost-effective in the general population for those less than 60 years of age, but the National Kidney Foundation recommends regular surveillance for those at risk of kidney disease. Risk factors for kidney disease include family history of kidney disease, diabetes, hypertension, ethnic minority, obesity, and metabolic syndrome.^{2, 3} For patients at risk, it is important to detect disease early in its course as current therapy can significantly slow progression of proteinuric chronic kidney disease.

Urinary protein excretion in the normal adult should be less than 150 mg/day. If the excretion exceeds this level beyond a single measurement, the patient needs to be evaluated for possible glomerular disease. Transient proteinuria can occur in up to 7% of women and 4% of men and is often associated with fever or exercise. Such benign proteinuria nearly always resolves on follow-up; thus, isolated proteinuria is normally not evaluated unless confirmed on repeat analysis. The gold standard for quantification of proteinuria is a 24 hour urine collection. It is important to note that 24 hour collections are inconvenient for most patients and can be inaccurate due to over or under collecting of urine. For patients with albuminuria on urinalysis, a urine albumin/creatinine

(UACR) (normal  $\leq$  30 mg/L) or urine protein/creatinine (UPCR) (normal  $\leq$ 0.150) should be obtained for further evaluation.²

Common causes of proteinuria in an adult population include isolated proteinuria, orthostatic proteinuria, conditions causing nephritis, and as a result of systemic illness. Isolated proteinuria can result from problems such as febrile illness, other physiologic stress or vigorous exercise or from abnormal production in conditions including myeloma and monoclonal gammopathies, or from toxins such as cadmium.

Orthostatic proteinuria is not an uncommon condition in adolescents and young adults but it is rare after age 30. This condition is characterized by an increase in protein excretion in the upright position, but a normal excretion (< 50 mg/8 hours) when supine. This postural response contrasts with most patients with glomerular disease who will normally demonstrate a modest reduction in protein excretion while supine, but commonly not to normal levels. Glomerular disease may initially present with mild manifestations therefore people with orthostatic proteinuria should have a follow-up evaluation after one year to evaluate for persistence or progression.⁴

Patients with signs or symptoms suggestive of glomerular disease, such as persistent proteinuria or hematuria and/or impaired renal function, should be considered for a renal biopsy in order to obtain a diagnosis. The risks associated with a biopsy, such as bleeding, are minimal with experienced clinicians. The most frequent adult primary glomerular disorders are IgA nephropathy followed by focal and segmental glomerulosclerosis (FSGS) and then membranous nephropathy.⁵

IgA nephropathy was first described by Berger and Hinglais in 1968. It is now the most prevalent primary chronic glomerular disease worldwide and is defined as an immune-complex-mediated disease characterized by the presence of glomerular IgA deposits accompanied by a variety of histopathologic lesions.⁶

IgA nephropathy presents with episodic hematuria and often follows an upper respiratory infection – so called "synpharyngitic hematuria". It has macroscopic and microscopic forms; the latter is the more common form seen in adults. Between episodes of macroscopic hematuria, the urinalysis is often normal. The presence or absence of increasing proteinuria at the time of clinical diagnosis often determines whether patients with asymptomatic hematuria are biopsied.^{7,8} The disease was initially considered a benign form of hematuria, but it is now clear that up to 50% of patients may progress to end-stage renal disease.^{6,9} The remaining patients may enter a sustained clinical remission or have persistent low grade hematuria or proteinuria. The prognosis is variable and the outcome difficult to predict with accuracy in individual patients. It can present at any age, but is more common in the second and third decades. There is a male to female ratio ranging from 2:1 to 6:1 in Europe and the US. Ethnically, Caucasians and Asians are much more prone to this disease than are African Americans.⁶

IgA nephropathy may present in one of three ways. About 40-50 percent of patients present with one or more episodes of gross hematuria usually following an upper respiratory infection. Another 30-40 percent have microscopic hematuria and mild proteinuria incidentally detected on a routine examination. Less than 10 percent of patients present with nephrotic syndrome, or with acute rapidly progressive glomerulonephritis characterized by hematuria, edema, hypertension and renal insufficiency. A definitive diagnosis can only be made by renal biopsy and immunohistologic

examination. In patients who have isolated hematuria, a renal biopsy is usually performed only if there are signs suggestive of severe disease or progressive protein excretion above 0.5 to 1 gram/day, an elevated plasma creatinine, or hypertension. A skin biopsy looking for IgA deposition in the dermal capillaries has not proven to be predictive in IgA nephropathy.¹⁰

While there is no recognized cure for this disease, there are treatment options that slow disease progression, and up to 23% of patients will show a complete remission. A very important part of the evaluation of patients with IgA nephropathy is to predict their risk for progression to renal failure.¹¹ Risk factors for progressive renal failure include: elevated serum creatinine above 2.5 mg/dL at the time of diagnosis, hypertension, and persistent proteinuria above 0.5 to 1 g/day. The relationship between increasing proteinuria and a worse prognosis is probably a reflection of proteinuria as a marker for the severity of glomerular disease. The rate of progression is low among patients excreting less than 500 mg/day and fastest among those excreting more than 3.0 to 3.5 g/day of protein.

There are two separate approaches to the treatment of IgA nephropathy. General interventions to slow progression of renal disease that are not specific to IgA nephropathy include blood pressure control, angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) in patients with proteinuria. Reduction in proteinuria is the hallmark of effective treatment in preserving renal function in other types of nondiabetic proteinuric renal diseases.^{6, 12} Corticosteroids can be used in advanced cases of IgA nephropathy. Statin therapy for lipid-lowering is recommended in the majority of chronic kidney disease patients to lower cardiovascular risk and possibly reduce disease progression. Fish oil has been studied but its role in treating IgA nephropathy is not well defined.⁹ Some studies indicate that it may be useful for reducing renal inflammation and glomerulosclerosis.

The treatment of choice for individuals who progress to end-stage renal disease is preemptive renal transplantation – that is, transplantation before they require hemodialysis. Many of these patients are younger and otherwise healthy. Transplantation provides a reasonable quality of life and a lifespan longer than that of the hemodialysis patient. Kidney disease recurrence does occur in transplanted kidneys, however transplant centers are accustomed to monitoring patients at risk. Nearly one-third of transplant recipients will develop a clinically apparent recurrence of the disease in the transplanted kidney.¹³ The rate of recurrence is equal between cadaveric and living donors.⁷

#### **IV. Aeromedical Concerns**

Regarding proteinuria, flyers will be disqualified when diagnosed with "Proteinuria under normal activity (at least 48 hours post strenuous exercise) greater than 200 mg in 24 hours , or protein to creatinine ratio greater than 0.2 (by random urine sample), or other findings indicative of urinary tract disease unless consultation determines the condition to be benign. ." In other words, if the protein loss can be explained by a relatively benign process or is stable (protein cannot be > 500mg/24 hours), the aeromedical concerns would be negligible and waiver is favorably considered. For IgA nephropathy, the aeromedical concerns would be related to the renal function, any symptoms, and the medications being used. For most flyers, a return to flying (waiver) would be in order once the disease is in remission and requires no medication. In those with a more chronic or indolent form, the disease is usually one that is slowly progressive. Typically such

patients are treated with ACE inhibitors to preserve renal function, and a waiver will likely be granted if the patient is otherwise stable.¹⁴

ICD-9 Codes for Proteinuria		
791.0	Proteinuria	
583.81	Nephropathy, not specified	
583.9 IgA nephropathy		

ICD-10 Codes for Proteinuria		
R80.9	Proteinuria, unspecified	
N08	Glomerular disorders in diseases classified elsewhere	
N02.8	IgA nephropathy	

#### V. References.

1. Levey AS. Nondiabetic Kidney Disease. N Engl J Med, 2002: 347(19), 1505-11.

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WAIVER GUIDE Updated: Sep 2015 Supersedes Waiver Guide of Nov 2011 By: Lt Col Kevin D. Hettinger (RAM XVI) and Dr. Dan Van Syoc Waiver Guide reviewed by Col Matthew Carroll, AF/SG consultant for Rheumatology

# CONDITION: Raynaud's Phenomenom (Sep 2015)

#### **III. Waiver Considerations.**

Raynaud's or vasospastic disease is disqualifying for Flying Classes I/IA, II, III and SWA duties. Waiver potential for primary Raynaud's is outlined in the table below. For ATC and GBO personnel and Operational Support Flyers, retention standards state that Raynaud's phenomenon, if frequent, severe, associated with systemic disease or would limit worldwide assignability is disqualifying. Waiver potential for secondary Raynaud's is based on the causal systemic illness or disease process and will be handled on a case by case basis.

Flying Class	Condition/Treatment Waiver Potential	
(FC)		Waiver Authority**
I/IA	Primary Raynaud's of at least two years duration, infrequent, requiring no medications	Maybe AETC
	Primary Raynaud's requiring medication	No AETC
II/III/SWA	Primary Raynaud's, requiring no medications Primary Raynaud's requiring	Yes† MAJCOM Yes†*
	medications	IIA - AFMSA (e.g. calcium channel antagonist) II – MAJCOM (e.g. ACEi or ARB)
ATC/GBO/OSF	Primary Raynaud's, requiring no medications	N/A
	Primary Raynaud's requiring medications	Yes MAJCOM

#### Table 1: Waiver potential for primary Raynaud's

† Initial waiver duration for primary RP will generally be 2 years. If stability is noted at time of waver renewal, then a 3-year waiver duration is generally appropriate.

* Specifically, coat-core and GITS [Adalat CC[®] and Procardia XL[®], respectively] and amlodipine [Norvasc[®]]) are the only calcium channel antagonists approved in aviators; they are restricted to non-high performance aviators (FC IIA). ** If member does not meet retention standards, waiver authority becomes AFMRA.

A review of AIMWTS in Sep 2015 revealed 35 cases with a diagnosis of Raynaud's. All of the aeromedical summaries were reviewed. Twenty-four cases had primary Raynaud's, 2 cases had secondary Raynaud's, 1 case had Raynaud's secondary to chemotherapy, and 8 cases did not contain enough information to determine if they were secondary versus primary. Thirty of the waiver requests were approved and were either asymptomatic or had very infrequent exacerbations. Five of the 35 cases were disqualified due to uncontrolled RP and other disqualifying diagnoses. Breakdown was as follows: 3 FC I/IA cases (1 disqualified), 15 FC II cases (2 disqualified), 14 FC III cases (2 disqualified), 2 ATC/GBC cases and 1 MOD case.

# II. Information Required for Waiver Submission.

The aeromedical summary should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary for <u>initial waiver</u> for RP should include the following:

A. A detailed RP history with attention to inciting factors, frequency, severity and duration of attacks; treatments tried and responses; smoking history; family history of RP and connective tissue diseases. The history should identify factors increasing suspicion for secondary RP as listed above. Pertinent positives as well as negatives should be included. The following three questions should be addressed:

- 1. Are the patient's fingers unusually sensitive to cold?
- 2. Do the patient's fingers change color when they are exposed to cold temperatures?
- 3. Do they turn white, blue, or both?

B. Thorough physical exam looking for evidence of peripheral vascular disease, peripheral nerve entrapment syndromes, and evidence of diseases associated with secondary RP. A NC should be performed.

C. Laboratory studies should include: complete blood count, ESR and ANA.

D. If physical exam or laboratory findings are suggestive of a secondary cause of RP,

Rheumatology consultation must be obtained. Additional laboratory studies should include: basic metabolic panel and liver function tests, urinalysis, erythrocyte sedimentation rate, rheumatoid factor, c-reactive protein, complement (C3 and C4), and tests for disease-specific autoantibodies (such as anticentromere antibodies, SCL70 scleroderma and anti-topoisomerase I. Additional waiver criteria for secondary Raynaud's is based on the causal systemic illness or disease process. E. MEB results if required for cases that are frequent, severe, associated with systemic disease or would limit worldwide assignability.

The aeromedical summary for <u>waiver renewal</u> for RP should include the following:

A. History – frequency and severity of attacks; treatment and response; identify factors increasing suspicion for secondary RP.

B. Physical – looking for evidence of peripheral vascular disease, peripheral nerve entrapment syndromes, and evidence of diseases associated with secondary RP. A NC should be performed. C. Laboratories – not required unless evidence exists for auto-immune related secondary cause of RP.

D. Rheumatology consult – if evidence exists for auto-immune related secondary cause of RP.

#### **III. Overview.**

Raynaud's phenomenon (RP), first described by Maurice Raynaud in 1862, is an exaggerated vascular response to cold temperatures or emotional stress. Raynaud's phenomenon (RP) is an exaggerated vascular response of the digital arterial circulation triggered by cold ambient temperature and emotional stress. The diagnosis of RP is based on a history of excessive cold sensitivity and recurrent events of sharply demarcated pallor and/or cyanosis of the skin of the digits. During cold exposure (particularly during shifting temperatures and winter months), Raynaud's attacks increase in frequency and intensity.¹

Typically, RP presents as episodic attacks that have two distinct phases, an ischemic phase followed by a hyperemic phase. The ischemic phase is noted by well demarcated pallor of the fingers or toes progressing to cyanosis, typically starting in one or several digits spreading symmetrically to all digits. On re-warming, the attack generally ends with rapid reperfusion resulting in erythema (reactive hyperemia). In addition to the vasospastic color changes, other symptoms due to ischemia include pain, paresthesias, numbness, clumsiness of the hand/foot, and potentially ulceration of the skin.²

Patients with RP are classified as primary (formerly known as Raynaud's disease) or secondary (formerly known as Raynaud's syndrome). Differentiation between primary RP and secondary RP does not reflect a diagnosis in the strict sense, but rather a description of the current findings in an ongoing screening process. Primary RP describes those RP patients without an underlying disease identified or suspected. Secondary RP describes those RP patients who have a definitively established underlying disease. A third category, suspected secondary RP, is mentioned in the literature and describes those patients with findings suggestive of an underlying disease, such as abnormal nailfold capillaroscopy (NC) or abnormal rheumatologic laboratory testing, but that disease cannot be firmly established at the time of exam.³ Some underlying diseases associated with secondary RP include scleroderma, mixed connective tissue disease, systemic lupus erythematosus, vasculitis, hematologic abnormalities including cryoglobulinemia, and neurologic disorders including carpal tunnel syndrome. Certain medications (β-adrenergic receptor antagonists, ergot, and amphetamines), trauma, and vibration are also noted secondary RP triggers.²

The prevalence of RP estimated through population surveys has ranged between 5-20 percent for women and 4-14 percent for men with significant variation noted between populations studied. Additionally, colder climates have a higher RP burden.⁴ A systematic literature review of primary RP found the overall prevalence for primary RP varied from 1.6% to 7.2% in six cross-sectional studies in the general population

(women: 2.1–15.8% and men: 0.8–6.5%), including only studies with clear definition of RP or clear exclusion criteria for secondary RP.⁵ A meta-analysis of 10 studies with 640 patients diagnosed with primary RP found that 13% eventually developed a connective tissue disorder (secondary RP).²

The diagnosis of the RP is based on the history since there are no simple office tests for cold or emotion induced vasospasm and provocative testing is not recommended.² Criteria for the diagnosis of primary RP include vasospastic attacks precipitated by cold or emotional stress, symmetric attacks involving both hands, absence of tissue necrosis or gangrene, no history or physical findings suggestive of a secondary cause, normal NC, normal ESR, and negative

antinuclear antibody test.⁴ The likelihood of secondary RP is increased with presence of any of the following features: age of onset > 40 years, male gender, painful severe events with ulceration, asymmetric attacks, RP associated with signs or symptoms of another disease, abnormal labs suggestive of an autoimmune disorder of vascular disease, RP affecting areas proximal to the digits (hand, foot), or abnormal NC with enlarged or distorted capillary loops.²

A growing body of literature supports the use of NC in the primary care setting in the workup of RP.^{6,7} The use of NC provides the clinician a tool to be used in conjunction with the history and physical exam in discriminating between primary and secondary RP. One study suggests that in patients with RP and negative serologic tests, the presence of giant capillaries (p=0.001), avascular fields (p=0.02), or irregular architecture (p=0.0001) in NC is predictive for the development of a connective tissue disease, mainly scleroderma, CREST, or mixed connective tissue disease.⁷

The technique for NC involves placing a drop of immersion oil on the base of the fingernails of fourth and fifth digits and examining with a handheld ophthalmoscope set at 40+ diopters. The ophthalmoscope is advanced in and out (not touching the oil) until the capillaries are in focus. The normal vascular pattern seen in primary RP and normal vascular control patients consists of a longitudinal linear array of delicate "hairpin" capillary loops while the pattern seen in secondary RP often includes enlarged capillary loops, architectural derangements, and areas of decreased vascularity.⁸

The laboratory evaluation for patients suspected of secondary RP varies based on source cited but generally includes: complete blood count, basic metabolic panel and liver function tests, urinalysis, erythrocyte sedimentation rate, rheumatoid factor, C-reactive protein, complement (C3 and C4), antinuclear antibody, and tests for disease-specific autoantibodies (such as anticentromere antibodies and SCL70 scleroderma antibodies).^{2, 9} A rheumatology consultation is also appropriate for suspected secondary RP.

Management of RP is best accomplished by avoidance of cold temperatures and maintenance of total body warmth including the hands and feet. If emotional stress is a contributor, therapies aimed at stress reduction may be of benefit. Avoiding known RP triggers like sympathomimetic drugs, clonidine, and ergotamine is crucial as is avoiding smoking.⁴ Pharmacologic management is reserved for poorly controlled/severe RP. Calcium channel blockers are first line therapy with 30 mg of sustained release nifedipine or 5 mg of amlodipine daily recommended. Other classes of medications found beneficial include alpha adrenergic receptor antagonists, topical nitroglycerin, angiotensin converting enzyme inhibitors (ACEi), angiotensin receptor antagonists (ARB), phosphodiesterase inhibitors and selective serotonin reuptake inhibitors. Surgical management focuses on thorascopic sympathectomy and less commonly digital sympathectomy. In each instance recurrence/complication rates were high (82% with the thorascopic sympathectomy and 37% with the digital sympathectomy).¹⁰

#### **IV. Aeromedical Concerns.**

The major aeromedical concerns associated with a RP episode during flight include sudden subtle incapacitation, distraction and a reduced ability to manipulate cockpit switches. Secondary RP associated with an established underlying connective tissue disease is not compatible with flying. Unavoidable exposure to cold conditions may increase the frequency of episodes and interfere with

the performance of flying duties. This may be a significant factor in determining if the member should be maintained in the aviator status.

Calcium channel antagonists (specifically coat-core and GITS [Adalat CC® and Procardia XL®, respectively] and amlodipine [Norvasc®]) are approved in aviators; they are restricted to non-high performance aviators.

ICD-9 Code for Raynaud's phenomenon		
443.0	Raynaud's syndrome/disease	
443.9 Peripheral vascular disease, unspecified		

ICD-10 Code for Raynaud's phenomenon		
I73.00	Raynaud's syndrome without gangrene	
I73.9	Peripheral vascular disease, unspecified	

#### V. References.

1. Boin F and Wigley F. Clinical Features and Treatment of Scleroderma. Ch. 84 in *Kelly's Textbook of Rheumatology*, 9th ed. Ed. by Firestein, GS. Saunders, 2013.

2. Wigley FM. Clinical manifestations and diagnosis of Raynaud phenomenon. UpToDate, 25 Mar 15.

3. Hirschl M, Hirschl K, Lenz M, et al. Transition From Primary Raynaud's Phenomenon to Secondary Raynaud's Phenomenon Identified by Diagnosis of an Associated Disease. Arthritis & Rheumatism, 2006; 54(6): 1974-81.

4. Wigley FM. Raynaud's Phenomenon. N Engl J Med, 2002; 347: 1001-08.

5. Garner R, Kumari R, Lanyon P, et al. Prevalence, risk factors and associations of primary Raynaud's phenomenon: systematic review and meta-analysis of observational studies. BMJ Open 2015;5:e006389. doi:10.1136/bmjopen-2014-006389.

6. Cutolo M, Pizzorni C, and Sulli A. Capillaroscopy. Best Prac Res Clin Rheumatol, 2005; 19(3): 437-52.

7. Meli M, Gitzelmann G, Koppensteiner R, Armann-Vesti B.R. Predictive Value of Nailfold Capillaroscopy in Patients with Raynaud's Phenomenon. Clin Rheumatol, 2006; 25: 153-158.

8. Chatterjee S. Systemic Scleroderma. In Section 13 (Rheumatology and Immunology) in *Cleveland Clinic: Current Clinical Medicine*, 2nd ed., 2010.

9. Olin JW. Other Peripheral Arterial Diseases. Ch. 80 in *Cecil Textbook of Medicine*, 24th ed. Ed. by Goldman L. and Schafer A. Saunders, 2012.

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#### Rheumatoid Arthritis (Dec 2019)

Authors/Reviewers: Capt Luke Menner, Dr. Christopher Keirns, and Maj Laura Bridge (ACS Internal Medicine); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator)

Significant Changes: Content updated to reflect national guidelines.

#### I. Waiver Consideration

Rheumatoid arthritis is disqualifying for all flying duties, GBO duties, ATC duties, and special warfare duties. It is also disqualifying for retention. Aeromedical waiver is usually not recommended for untrained personnel. Factors considered when assessing suitability for aeromedical waiver include the severity of disease at diagnosis, evidence of clinical remission, whether treatment and monitoring are appropriate in the context of nationally or internationally recognized guidelines, the risk associated with specific medication(s), the individual service member's tolerance of the medication(s) and adherence to therapy, and the cumulative risk of all associated complications and/or extra-articular manifestations. Waiver can be considered once an individual is in disease remission on a stable, aeromedically-approved medication regimen, without adverse effects. Use of any medication not included on a career-field approved medication list is independently disqualifying and will be considered on a case-by-case basis.

Cervical spine involvement is common in individuals with rheumatoid arthritis, predisposing individuals to atlantoaxial instability and/or atlantoaxial subluxation. Thus, pilots eligible for waiver will be restricted to a FC IIB waiver, non-ejection seat aircraft. Additionally, special warfare personnel with cervical spine involvement demonstrated on imaging will be restricted from jump status. The most common imaging modality used to assess for cervical instability is plain film radiographs of the cervical spine in the following positions anteroposterior, lateral, open-mouth, flexion, and extension.

Flying Class (FC)	Waiver Potential ¹	Waiver Authority	ACS Review or Evaluation
I/IA	No	AETC	No
II/III/Special Warfare	Yes ^{2,3,4}	MAJCOM ^{2,3,4}	Yes
ATC/GBO	Yes ^{3,4}	MAJCOM ^{3,4}	No

 Table 1: Waiver potential for Rheumatoid Arthritis

1 Untrained personnel of any class are unlikely to receive an aeromedical waiver.

- 2 Waiver for pilots will be restricted to FC IIB. Special warfare personnel with documented cervical involvement will be restricted from jump duties. AFMRA is the waiver authority for all restricted waivers.
- 3 Use of any medication that is not included on the approved medication list is independently disqualifying, and the MAJCOM may disqualify the service member without AFMRA or ACS review. Waiver may be considered following an ACS review on a case-by-case basis in certain low-risk individuals treated with unapproved medications. The waiver authority for all non-approved medications is AFMRA.
- 4 Individuals controlled with TNF-alpha inhibitors require AF Form 469 document the need for access to transport and refrigeration (between 36 to 46 degrees Fahrenheit) for any TDY or deployment assignment.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Consultation reports form treating rheumatologist, which should include:
  - a. Subjective symptoms and objective physical exam findings
  - b. Current treatment plan, to include tolerance and current doses of maintenance medications and all appropriate monitoring labs for those medications (e.g., biologic agents require CBC/CMP every 3-6 months and annual TB testing).
  - c. Documentation excluding/including extra-articular manifestations (i.e., ocular, pulmonary, cardiac, etc.)
- 3. All pertinent laboratory studies, including diagnostic and follow-up results.
  - a. Initial serologic testing (e.g., RF, anti-CCP, and any other serologic testing)
  - b. Updated CBC, CMP, ESR, and CRP.
- 4. Radiology reports from all diagnostic or follow-up imaging studies.
  - a. Initial and updated plain films of the hands, feet, and cervical spine in anteroposterior, lateral, open-mouth, flexion, and extension views.
- 5. Current physical examination findings with focus on musculoskeletal exam.
- 6. Dilated ocular exam if treated with hydroxychloroquine.
- 7. FL4 with RTD and ALC status.
- 8. Any other pertinent information.

- 9. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.
- B. Renewal Waiver Request:
  - 1 Updated AMS with interval history, including:
    - a. Current symptoms and development of any disease flares, complications, or extraarticular manifestations.
    - b. Current medications, doses, and adverse effects.
    - c. Current physical examination findings.
  - 2 Consultation reports from treating rheumatologist.
  - 3 Any interval imaging obtained pertaining to the rheumatoid arthritis diagnosis.
  - 4 Updated CBC, CMP, ESR, and CRP.
  - 5 Updated plain films of the hands, feet, and cervical spine in flexion and extension views.
  - 6 Updated dilated ocular exam if treated with hydroxychloroquine.
  - 7 Any other pertinent information.
  - 8 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### **III. Aeromedical Concerns**

Rheumatoid arthritis (RA) is systemic inflammatory disease resulting in articular and extra-articular symptoms of aeromedical concern. The most common presentation is the development of symmetric, poly-articular synovitis of the small joints. Joint involvement with symptoms of prolonged morning stiffness, swelling, erythema, and pain potentially results in subtle performance decrement of aviation and operational duties. Untreated RA may result in damage and deformities of the joints that are irreversible. Cervical joint involvement such as atlantoaxial instability, atlantoaxial subluxation, or cranial settling, potentially results in severe neurologic sequelae or death in the event of trauma, especially if there is hyperextension or hyperflexion of the cervical spine. The most common imaging modality used to assess for cervical instability is plain film radiographs of the cervical spine in the following positions: anteroposterior, lateral, open-mouth, flexion, and extension. MRI of the cervical spine is indicated if plain film demonstrates abnormalities or individuals have radicular or myelopathic symptoms. Studies have shown a high rate of cervical involvement in individuals with rheumatoid arthritis, ranging between 43% and 86%. Individuals without any cervical involvement at the time of diagnosis have an estimated 4% to 10% annual risk of developing cervical instability. The most common symptoms of cervical involvement include neck and occipital pain. Pilots submitting a waiver for a diagnosis of rheumatoid arthritis will receive a restricted FC IIB waiver to non-ejection seat aircraft. Additionally, special warfare personnel with cervical spine involvement identified on imaging will be restricted from jump status. Rheumatoid arthritis is associated with the development of extraarticular involvement including potential ocular, pulmonary, cardiovascular, renal, neurologic, and hematologic manifestations that carry further aeromedical risk.

Many of the medications used to treat rheumatoid arthritis convey side effects incompatible with aviation or enhanced operational duties. There are multiple disease-modifying antirheumatic drugs (DMARDs) available. The first-line treatment for rheumatoid arthritis is methotrexate. Although clinically used as a first-line agent, the use of methotrexate might result in toxicity of multiple organ systems of aeromedical concern that are incompatible with flying duties. The pulmonary system is

the most concerning organ system involved in which toxicity can occur rapidly during any point of treatment, resulting in an acute pneumonitis and respiratory distress. The use of methotrexate exceeds historical waiver thresholds. The only career-field approved medications for treatment of RA are sulfasalazine, hydroxychloroquine, adalimumab, infliximab, and etanercept. Individuals treated with hydroxychloroquine require annual dilated eye exam to assess for retinal toxicity for aeromedical purposes. Biologic agents require access to transport and refrigeration (between 36 to 46 degrees Fahrenheit) for any TDY or deployment assignment.

Individuals who have received exogenous steroids for greater than a three-week duration within the last year to induce disease remission will require aeromedical assessment of the hypothalamicpituitary-adrenal axis prior to waiver consideration (Please see the Systemic Glucocorticoid (Steroid) Treatment waiver guide).

Review of the AIMWTS database from Jan 2015 through Nov 2019 revealed 18 individuals with an AMS containing the diagnosis of RA. Four individuals (22.2%) were disqualified. A breakdown of the cases was follows: 1 FC I/IA cases (1 disqualified), 9 FC II cases (2 disqualified), 0 FC III cases, 3 ATC/GBC cases (2 disqualified), 0 MOD cases, and 0 RPA Pilot cases.

ICD-9 codes for Rheumatoid Arthritis		
714.0	Rheumatoid arthritis	

ICD-10 codes for Rheumatoid Arthritis	
M06.9	Rheumatoid arthritis, unspecified

# IV. Suggested Readings

1. Gillick JL, Wainwright J, and Das K. Rheumatoid Arthritis and the Cervical Spine: A Review of the Role of Surgery. *International Journal of Rheumatology*. Epub 2015; doi: 10.1155/2015/252456. <u>https://www.ncbi.nlm.nih.gov/pubmed/26351458</u>

2. Singh JA, SAAG KG, Bridges SL, and et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis and Rheumatology*. 2016; 68(1):1-25. https://www.ncbi.nlm.nih.gov/pubmed/26545940

#### PrEP, HIV Pre-Exposure Prophylaxis (May 2020)

Authors/Reviewers: Dr. Christopher Keirns, Maj Laura Bridge, and Capt Luke Menner (ACS Internal Medicine); Lt Col Jason Okulicz (Infectious Disease SG Consultant); Dr. Dan Van Syoc (ACS Waiver Guide Coordinator); and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: Addition of Descovy® as an acceptable HIV PrEP regimen in USAF aircrew and special duty personnel.

# I. Waiver Consideration

All flying classes, ATC, GBO, and SWA personnel utilizing Truvada® (tenofovir disoproxil fumarate-emtricitabine [TDF/FTC]) or Descovy® (tenofovir alafenamide-emtricitabine [TAF/FTC]) for PrEP to reduce the risk of HIV infection require aeromedical waiver. Personnel prescribed TDF/FTC or TAF/FTC may be considered for waiver on a case-by-case basis. Waiver will generally be contingent on tolerability of the medication and adherence to the guidelines established by the CDC for HIV PrEP. Clinical follow-up visits are required at least every three months and must include a sexually transmitted infection (STI) symptom assessment, documentation of medication adherence, and behavioral risk reduction counseling to include education and reinforcement of safe sex practices. Additionally, updated HIV testing every three months, bacterial STI testing every three to six months, and serum creatinine (renal function) measurement every six months are required. Discontinuation of HIV PrEP with appropriate counseling about stopping/restarting PrEP is required should the member be TDY/deployed to a location that cannot support continued strict compliance with the CDC guidelines (i.e., any TDY/deployment greater than 90 days). Interval discontinuation of PrEP for the purpose of TDY/deployment followed by resumption upon return to home station does not require new waiver evaluation in the absence of any other clinical changes.

Flying Class (FC)	Waiver Potential ^{1,2}	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes	AETC	No
FC II/III	Yes	MAJCOM	No
ATC/GBO/SWA	Yes	MAJCOM	No

5. Waiver for both trained and untrained personnel will be considered on a case-by-case basis.

6. All required interval quarterly lab work that is obtained following waiver approval will need to be inputted into the "Interim Results" AIMWTS section every 6 months.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete, the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations. Member must be on the medication for 30 days, have had a 30 day follow up (telephone consult acceptable), before waiver request can be submitted. All required interval quarterly lab work that is obtained following waiver approval will need to be inputted into the "Interim Results" AIMWTS section every 6 months.

# A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Clearly delineate the underlying clinical indications for use of HIV PrEP therapy
  - b. Complete list of current medications with dates of initiation, doses, and all adverse effects
- 2. Consultation reports from all treating providers, which should include:
  - a. At least one clinician visit documenting HIV-negative status
  - b. Assessment for medication side effects
  - c. Discussion of medication tolerance and adherence after beginning PrEP (e.g., one month after initiation)
- 3. Laboratory studies required:
  - a. Recent 4th generation HIV antigen/antibody test
  - b. Baseline serum creatinine
  - c. All other laboratory studies ordered by consulting specialist(s)
- 4. Current physical examination findings.
- 5. Any other pertinent information.
- 6. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.
- B. <u>Renewal Waiver Request:</u>
  - 1 Updated AMS with interval history, including:
    - a. Clearly document member's compliance with required quarterly clinical follow-up and all required laboratory monitoring
    - b. Complete list of current medications with dates of initiation, doses, and all adverse effects
  - 2 All interval consultation reports from all treating providers, including all quarterly clinical follow-up notes. Each quarterly clinical follow-up should include the following:
    - a. Description of member's compliance with required clinical and laboratory monitoring
    - b. STI symptom assessment
    - c. Documentation of medication adherence
    - d. Behavioral risk reduction counseling to include education and reinforcement of safe sex practices
  - 3 Laboratory studies required:
    - a. All interval measurements of renal function
    - b. All interval HIV test results
    - c. All interval bacterial STI testing results
  - 4 Current physical examination findings.
  - 5 Any other pertinent information.
  - 6 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### **III. Aeromedical Concerns**

Truvada® (tenofovir disoproxil fumarate-emtricitabine [TDF/FTC]) and Descovy® (tenofovir alafenamide-emtricitabine [TAF/FTC]) have both been approved by the FDA for HIV pre-exposure prophylaxis (PrEP) in high-risk individuals to mitigate the risk of HIV-transmission. Individuals considered at high-risk of new HIV infection include those with HIV-positive sexual partners; injection drug users who share injection equipment or were in treatment for injection drug use within the preceding six months; and both heterosexual and homosexual individuals engaging in high-risk sexual behaviors as described in CDC practice guidelines for PrEP. TDF, TAF and FTC are nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) that inhibit HIV replication and can prevent seroconversion in HIV-negative individuals who are exposed to the virus. The efficacy of TDF/FTC and TAF/FTC at reducing the risk of HIV-seroconversion has been demonstrated in multiple studies of high-risk HIV-negative individuals.

TDF/FTC is a well-tolerated medication, and the rate of aeromedically-relevant adverse effects is considered acceptable provided consistent adherence to proper clinical and laboratory monitoring. TAF/FTC is also well-tolerated and is likely the preferred agent for individuals with bone or renal contraindications to TDF/FTC. The most commonly reported adverse effects include gastrointestinal symptoms such as nausea, vomiting, and diarrhea in about 5 to 10% of patients and neurologic symptoms such as headache (2 to 6%), insomnia (0-8%), and fatigue (2 to 9%). The majority of these symptoms appear to resolve within a month of taking the medications ("start-up syndrome"). There are no reported neurocognitive or neuropsychiatric side effects from TDF/FTC or TAF/FTC use. The CDC recommends regular laboratory monitoring to assess for HIVseroconversion, acquirement of other sexually transmitted infections (STIs), and the development of kidney toxicity while on FTC/TDF. Specifically, the CDC recommends HIV testing every three months, bacterial STI testing every three to six months, and serum creatinine (renal function) measurement every six months. Additionally, the CDC recommends clinical follow-up visits with the prescribing provider at least every three months. Each clinical follow-up encounter should include an STI symptom assessment, documentation of medication adherence, and behavioral risk reduction counseling to include education and reinforcement of safe sex practices. The clinical follow-up and laboratory monitoring required while taking these medications may impose operational and mobility limitations when the frequent monitoring and behavioral counseling are not available. Discontinuation of PrEP by the treatment team for the purpose of extended TDY/deployment (i.e., greater than 90 days) will likely be required.

Review of AIMWTS data from Aug 2018 to Apr 2020 revealed a total of 69 waiver packages (62 Individuals) involving the use of HIV PreP. Of that total, 7 were FC I/IA (1 disqualified), 30 were FC II (0 disqualified), 26 were FC III (2 disqualified), 6 were ATC/GBC (0 disqualified), and 0 were MOD. Review of the cases revealed that these disqualifications resulted from other active co-morbid conditions. None of the disqualifications after Aug 2018 were a result of HIV PrEP. AIMWTS review prior to Aug 2018 revealed nine aeromedical waiver packages submitted for use of TDF/FTC for HIV PrEP. All cases resulted in disqualification. These cases varied broadly by career field, with three GBC, two FC II, and four FC III waiver requests. The first USAF aeromedical waiver for TDF/FTC use in a FC III aviator was granted in Aug 2018.

Common ICD-9 codes used for HIV PrEP			
V01.89	Exposure to STD		
V07.9	Other specified prophylactic measure		
V69.2	High risk sexual behavior		

Common ICD-10 codes used for HIV PrEP			
Z20.6	Contact with and (suspected) exposure to HIV		
Z41.8	Other specified prophylactic measure		
Z72.51,	High risk sexual behavior, .51 heterosexual,		
Z72.52, Z72.53	.52 homosexual, .53 bisexual		

# **IV. Suggested Readings**

1. CDC website: https://www.cdc.gov/hiv/risk/prep/index.html

2. Centers for Disease Control and Prevention. Prexposure prophylaxis for the prevention of HIV infection in the United States. Available at <u>https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf</u>

3. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines (2015). Morbidity and Mortality Recommendations and Reports. 2015;64(RR3):1-137.





# Systemic Glucocorticoid (Steroid) Therapy

Revised: Aug 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Capt Cody Hedrick and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Flying class consideration for chronic therapy

# I. Waiver Consideration

Active treatment with systemic glucocorticoids (GCs) are disqualifying for all flying class, ATC, GBO, OSF, and SWA duties. Flying class I, II, III, and ATC personnel who are actively being treated with systemic GCs are ineligible for waiver due to the risk of developing aeromedically and operationally significant adverse physiologic effects/complications. Treatment with chronic systemic GCs is also disqualifying for GBO duties as these therapies are not specifically listed on the applicable career field medication list; however, these members may be considered for waiver if the underlying condition is controlled and the individual is stable on therapy, without idiosyncratic reactions. Although no approved medication list exists for OSF and SWA personnel, the active treatment with systemic GCs is felt to have the potential to adversely impact mission accomplishment in these members. Therefore, OSF and SWA personnel should also be placed in DNIF/DNIC status while actively being treated with systemic GCs. Lastly, the diagnosis of adrenal insufficiency (Addison's disease) is also disqualifying for all flying class, ATC, GBO, OSF, and SWA duties. A waiver for primary adrenal insufficiency is unlikely due to the elevated risk of adrenal crisis.

History of systemic GCs use is not disqualifying for any flying class, ATC, GBO, OSF, or SWA duties provided that the hypothalamic-pituitary-adrenal (HPA) axis is intact and the underlying condition for which systemic GCs were prescribed is resolved and/or is not disqualifying. As chronic suppression of the HPA axis with systemic GC use can result in adrenal insufficiency and increase the risk of acute adrenal crisis, documentation of an intact HPA axis should be accomplished prior to returning any military member to flying or special operational duty if systemic GC use was greater than three consecutive weeks within the last twelve months. If an aeromedical waiver is required for the underlying condition, submission of the waiver package should occur after completion of systemic GC treatment and resolution or stabilization of the condition. In this instance, the aeromedical waiver package should include a recent measurement of the member's basal serum cortisol and if indicated results of an adrenocorticotropic hormone (ACTH) stimulation test (Table 1).

The initial test to determine an intact HPA axis should be a fasting morning serum basal cortisol. If serum basal cortisol levels are 18 mcg/dL, the risk of relative adrenal insufficiency or development of adrenal crisis is aeromedically acceptable. No further testing would be clinically or aeromedically indicated. If the serum basal cortisol level is < 18 mcg/dL, an ACTH stimulation test is used to further assess the HPA axis due to increased risk of underlying adrenal insufficiency. Recombinant ACTH (Cosyntropin®) 250 mcg is injected IV or IM after a baseline cortisol level is drawn. Stimulated cortisol levels are then drawn at 30 and 60 minutes. A stimulated cortisol level 18 mcg/dL is considered normal. ACTH stimulation testing can

be performed at any point after GC discontinuation, but it is typically performed one month after discontinuing therapy. If abnormal, stimulation testing can be repeated at monthly intervals until cortisol levels normalize.

Flying	<b>Duration of Systemic</b>	Required Testing
Class ^{1,2,3}	Glucocorticoid (GC) Therapy	
All	$\leq$ 3 weeks of systemic GC therapy, or	N/A
	completion of systemic GC therapy	
	more than 12 months ago	
All	> 3 weeks of systemic GC therapy	Serum morning basal cortisol level
	during the preceding 12 months	1 mcg/dL: no further testing needed
		<18 mcg/dL: ACTH stim test required
All	> 3 weeks of systemic GC therapy	Cortisol level post-ACTH stimulation:
	during the preceding 12 months and	1 mcg/dL: no further testing needed
	morning cortisol level is <18mcg/dL	<18 mcg/dL: Repeat monthly until
		HPA axis normalizes

 Table 1: Workup Required <u>AFTER</u> Systemic Glucocorticoid Therapy Discontinuation

1. Aeromedical waiver is NOT required if systemic glucocorticoid treatments have been discontinued, the HPA axis is intact, and there is no underlying disqualifying condition.

2. Generally, only GBO personnel requiring chronic systemic glucocorticoid use will be considered favorably for aeromedical waiver once idiosyncratic reactions have been ruled out and the underlying condition is controlled.

3. Underlying conditions that are disqualifying per the MSD require waiver submission even if no longer being treated with systemic glucocorticoids. Consult the applicable waiver guide if the underlying condition requires waiver.

# **II. Information Required for Waiver Submission**

Not Applicable. Please cross-reference the Medical Standards Directory and the appropriate career field medication list. Refer to the Air Force Waiver Guide for condition-specific waiver submission requirements (if applicable).

# **III. Aeromedical Concerns**

HPA axis suppression after the completion of systemic GC therapy is a significant aeromedical concern. Individuals with any use of systemic GC therapy are at risk for adrenal insufficiency due to HPA axis suppression; however, this is less likely to occur with a short course of therapy (i.e., less than three weeks duration). The greatest risk of HPA axis suppression occurs when supraphysiologic doses of GCs are administered, duration of therapy is greater than three weeks, split and nighttime doses are administered, or with Cushingoid features. Tapering GC therapy slowly is required to restore the HPA axis while minimizing the risk of precipitating adrenal insufficiency or crisis. Adrenal insufficiency presents insidiously with symptoms of fatigue, weight loss, postural dizziness, anorexia, and vague abdominal discomfort. Adrenal crisis presents acutely with symptoms of severe weakness, abdominal pain, nausea, electrolyte derangements, syncope, confusion, and potentially shock leading to progressive circulatory collapse and death. High emotional or physiologic stress, such as encountered in the aviation and special operation environments, increases the risk of precipitating symptoms of relative adrenal

insufficiency and also acute adrenal crisis. Risk is highest when there is association with surgical procedures, infection, or abrupt systemic GC withdrawal. Even without these additional risk factors for developing adrenal crisis, all aircrew and special duty operators should undergo testing of the HPA axis after discontinuation of systemic GCs when the course of treatment exceeds three weeks duration within the preceding twelve months. An aeromedical waiver is not required in individuals demonstrating intact HPA function; however, the underlying condition that required prolonged systemic GC use may be disqualifying. Refer to the appropriate waiver guides if there are underlying conditions the necessitated GC use.

#### **IV. Suggested Readings**

- Bornstein SR, Allolio B, Arlt W, Barthel A, Don-Wauchope A, Hammer GD, Husebye ES, Merke DP, Murad MH, Stratakis CA, Torpy DJ. Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016 Feb;101(2):364-89. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4880116/. Accessed 16 August 2022.
- Broersen LH, Pereira AM, Jørgensen JO, Dekkers OM. Adrenal Insufficiency in Corticosteroids Use: Systematic Review and Meta-Analysis. J Clin Endocrinol Metab. 2015 Jun;100(6):2171-80. Available at https://academic.oup.com/jcem/article/100/6/2171/2829580. Accessed 16 August 2022.
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# Urticaria, Angioedema, and Anaphylaxis

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Significant Changes: AIMWTS waiver table and suggested readings updated.

# I. Waiver Consideration

Chronic urticaria or angioedema (i.e., urticaria and angioedema that is present most days of the week for a period of six weeks or more) is disqualifying for all flying class and SWA duties. Any history of solar urticaria is specifically disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention. If chronic urticaria, including cold urticaria, or angioedema is severe and refractory to treatment, it also becomes disqualifying for GBO, ATC, and OSF duties, as well as for retention. Isolated episodes of self-limited (i.e., acute) urticaria or angioedema that resolves without complication is not disqualifying. However, aviators must remain DNIF and other personnel must remain DNIC/DNIA until all symptoms completely remit.

A single episode of *severe allergic reaction* to any common foods, spices, or food additives, or a single episode of *severe allergic reaction* to insect venom inoculation (e.g., a sting or a bite) is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties. It is not disqualifying for retention, but any requirement to carry an epinephrine auto-injector does require a deployment waiver. Any history of food-induced *anaphylaxis* is disqualifying for all flying class and SWA duties. Any history of recurrent *anaphylaxis*, with or without an identifiable trigger, is disqualifying for all flying class, GBO, ATC, OSF, and SWA duties, as well as for retention.

Due to the unpredictability of angioedema or anaphylaxis and the high risk to individual safety (and thereby mission and team/crew safety) in the event of a severe recurrent episode, waivers for chronic urticaria, angioedema, or anaphylaxis are carefully considered on a case-by-case basis. It is expected that all cases will undergo an ACS review. A variety of factors that are weighed when assessing waiver suitability, including, but not limited to, the historical severity of symptoms, the treatments required to resolve or control symptoms, and the frequency of episodes.

To be eligible for waiver, the service member must undergo a thorough allergy evaluation to identify any potential inciting triggers. If aeromedical and operational risk can be effectively mitigated through avoidance or elimination of a causative factor, then waiver will often be considered favorably. Idiopathic urticaria, angioedema, or anaphylaxis may be amenable to waiver if the individual is able to demonstrate a period of asymptomatic remission with use of a prophylactic medication regimen that is approved for use in the applicable career field (e.g., with daily use of a prophylactic dose of an approved second-generation, non-sedating antihistamine). There is no career field medication list for OSF or SWA personnel. As with the use of any medication or supplement in military members, the use of a prescription medication or supplement for the treatment of urticaria, angioedema, or anaphylaxis in OSF and SWA

personnel must be carefully evaluated for potential side effects that might impact individual health or mission safety.

The use of any medication not included on the career field-approved medication list is independently disqualifying. The use of the biologic agent omalizumab (Xolair®) may be considered for waiver on a case-by-case basis, particularly in lower risk career fields. However, other immunosuppressive agents (e.g., cyclosporin, systemic glucocorticoids, etc.) used to treat refractory disease are unlikely to receive an aeromedical waiver. A clinical requirement to carry an epinephrine auto-injector may not be compatible with unrestricted flying duties and could result in a IIC restriction for pilots (multi-place aircraft with another qualified pilot), particularly in cases involving unknown or unavoidable provocative stimuli.

The use of allergen immunotherapy (AIT) is disqualifying for all flying class and SWA duties. A four-hour period of DNIF/DNIC/DNIA is necessary for all aviators, including ATC and SWA personnel, after each AIT injection. An aeromedical or operational waiver can be considered for use of AIT to treat environmental and aeroallergens after the service member demonstrates tolerability of treatment during an appropriate lead-in phase. In the past, it was necessary to achieve maintenance dosing for AIT targeted against environmental and aeroallergens. However, service members may now be considered for an earlier waiver if clinically stable with appropriate follow-up, provided the dosing regimen is deemed compatible with the continued operational tempo.

It is critical to note that aeromedical and operational risk associated with the use of AIT to address symptoms of chronic rhinosinusitus, conjunctivitis, or urticaria is not equivocal to the use of desensitization AIT when there is a history of anaphylaxis to insect venom. Whereas AIT for environmental and aeroallergen treatment may often safely be discontinued or interrupted without adverse health consequences to the individual if necessitated by operational needs, the same is not true for desensitization therapy to insect venom. Therefore, interruption of venom desensitization is not endorsed for operational needs, and waivers for this indication will be scrutinized more carefully.

Flying Class	Condition	Waiver Potential ¹ Waiver Authority	ACS Review or Evaluation
FC I/IA	Chronic urticaria or angioedema	Yes AFRS/CMO ²	Yes
	Urticaria or angioedema that is chronic, severe, and not controlled with approved medications	Unlikely AFRS/CMO ²	No
	History of anaphylaxis	Yes AFRS/CMO ²	Yes
FC II/III/SWA	Chronic urticaria or angioedema	Yes MAJCOM ²	Yes
	Urticaria or angioedema that is chronic, severe, and not controlled with approved medications	Unlikely MAJCOM ²	No ³
	History of anaphylaxis	Yes MAJCOM ²	Yes
ATC/GBO/OSF	Urticaria or angioedema that is chronic, severe, and not controlled with approved medications	Unlikely MAJCOM ²	No ³
	History of anaphylaxis	Yes MAJCOM ²	No ³

Table 1: Waiver potential for Urticaria, Angioedema, and Anaphylaxis

1. No indefinite waivers.

2. Certification authority for untrained assets is AFRS/CMO. Waiver authority for aeromedically unapproved medication use is AFMRA.

3. ACS review may be requested at the discretion of the waiver authority.

# II. Information Required for Waiver Submission

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

# A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative). Include symptoms associated with episodes, duration of episodes, and frequency of recurrences.
  - b. Summary of diagnostic evaluation, including list of any/all procedures with dates.
  - c. List exacerbating/triggering factors (if known).
  - d. Summary of all treatments and their effectiveness.
  - e. Document all comorbidities (e.g., food allergies, asthma, eczema, etc.).
  - f. List current medications with dosages.

- 2. Consultation report from the treating allergist and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and treatment course.
  - b. Date of last recurrence.
  - c. Current treatment or prophylaxis recommendations.
  - d. If on allergy immunotherapy, an outline of the anticipated course of ongoing treatment must be included.
- 3. Results of any other testing performed in the course of diagnosis, evaluation, and management of urticaria, angioedema, or anaphylaxis, including laboratory studies, imaging, and any other ancillary studies.
- 4. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination.
  - b. Specify any interval recurrences.
  - c. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
- 2. All interval consultation reports from the treating allergist. If on allergy immunotherapy, an outline of the anticipated course of ongoing treatment must be included.
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, interval colonoscopy/endoscopy reports and biopsy results, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# **III. Aeromedical Concerns**

The primary aeromedical and operational concerns for aviators and other service members with a history of chronic or recurrent urticaria, angioedema, or anaphylaxis relate to the risk that a subsequent event could result in sudden incapacitation or symptoms of sufficient severity to adversely affect performance, mission, or safety. In most cases, the risk of sudden incapacitation and death is presumed to be highest for those individuals with a history of anaphylaxis. When untreated, anaphylaxis can result in airway compromise and/or cardiovascular collapse in less than five minutes. The severity of a recurrence cannot be reliably predicted based on the extent/severity of symptoms during previous episodes. Likewise, the course of an episode may be unpredictable, and previous patterns of symptom progression do not necessarily foretell how future episodes will evolve. Symptoms may return after an initial improvement or may persist for hours or days, requiring further medical intervention to prevent systemic collapse.

Angioedema is a common component of anaphylaxis and may co-occur with urticaria; however, angioedema may occur independently. The risks and approaches to management differ with the

underlying etiology. While an avoidable/allergic trigger can be identified in some cases, the cause of chronic angioedema or urticaria is often idiopathic. Recurrences can be unpredictable. In some cases, symptoms are provoked by physical or emotional stressors, such as those encountered in aviation and operational environments. Edema of the tissues of the tongue, palate, and pharynx may lead to respiratory compromise and sudden incapacitation. In the absence of anaphylaxis (i.e., a history of multisystem involvement), the risk of sudden incapacitation is considered less. When swelling is limited to the face and cheeks, there remains a potential for progression without medical intervention. Even mild symptoms pose a risk for distraction and performance decrement, particularly during critical phases of flight. Facial swelling could interfere with the wearing of the aviator mask or other life support equipment, and periorbital swelling could obstruct the field of vision.

Chronic urticaria without angioedema is usually considered non-life threatening, but extensive involvement can result in distraction and performance decrement, particularly during critical phases of flight. If left untreated, symptoms can progress, and the possibility for the development of angioedema exists. Like angioedema, urticarial symptoms can be provoked by stress in some individuals. Of aeromedical and operational significance, many of the medications used to treat or control chronic urticaria are sedating. Fortunately, there are two second-generation antihistamines that are approved for use in USAF aircrew (fexofenadine and loratadine), which are often effective at maintaining remission when used daily. A third antihistamine, cetirizine, is approved for use in GBO personnel. However, none of these medications are approved for the treatment or prophylaxis of urticaria and/or angioedema, and use for this indication requires a waiver. The use of montelukast for the treatment and prophylaxis of urticaria is approved for all aircrew and GBO personnel, with an appropriate waiver for the underlying condition.

When an allergen is identified as a triggering factor causing recurrent urticaria, angioedema, or anaphylaxis reactions, an individual may be a candidate for immunotherapy to reduce the risk of future recurrence. AIT is associated with an ongoing risk for systemic reaction including anaphylaxis. Due to the greater likelihood of such reactions during the build-up phase, waivers are generally not considered until an individual demonstrates stability. In the past, service members were required to achieve maintenance dosing prior to waiver request submission. An earlier waiver request may be considered on a case-by-case basis, dependent on a variety of factors. Individualized assessments of risk will depend upon the severity of symptoms or previous reactions prior to the initiation of AIT, symptoms since initiation of AIT, and tolerance of treatment without adverse reactions. The clinical impact of operationally-necessitated interruptions in AIT will also be weighed. AIT desensitization in the setting of a previous anaphylactic reaction to insect venom is considered to be higher risk than AIT for refractory allergic rhinitis, conjunctivitis, sinusitis, or urticaria. Thus, interruptions in AIT for insect venom desensitization will not be considered favorably for waiver. However, the severity of the underlying condition prior to initiation of AIT will be taken into consideration in all cases.

Occasionally, non-approved biologic agents such as omalizumab (Xolair®) may be used for recurrent urticaria that does not respond to less potent agents. Recourse to these agents is indicative of the severity of the underlying condition, which might not be waiverable. The biologic agents themselves are also associated with significant aeromedical and operational risks, including delayed anaphylaxis. Therefore, biologic agents may be considered on a case-by-case

basis in select subset of individuals who are otherwise determined to be low-risk for serious health effects in a low-risk operational setting.

Review of the AIMWTS database from Nov 2019 through Nov 2022 revealed 305 cases with a diagnosis of urticaria, angioedema, or anaphylaxis. The breakdown of the number of waivers and number of total cases are tabulated below. Of the 21 DQs, 8 were specific to urticaria, angioedema, anaphylaxis, and/or associated therapies.

Please use <i>only</i> this ICD-10 code for AIMWTS coding purposes		(# of waivers / total # of cases)					
		IFC I/IA	FC II	FC III	GBO	ATC	SWA
L50.9	Urticaria, unspecified	7/7	54/57	36/40	5/6	4/4	3/4
T78.2	Anaphylaxis, unspecified	9/12	34/35	44/47	25/26	4/4	11/11
T78.3	Angioneurotic edema	1/1	34/35	10/11	2/3	0/0	1/2

# **IV. Suggested Readings**

- Kolkhir P, Pogorelov D, Darlenski R, et al.; WAO Junior Members Group. Management of chronic spontaneous urticaria: a worldwide perspective. World Allergy Organ J 2018;11:14. Available at <u>https://waojournal.biomedcentral.com/track/pdf/10.1186/s40413-018-0193-4.pdf</u>. Accessed 22 November 2022.
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#### WAIVER GUIDE Updated: Jun 2017 Supersedes Waiver Guide of May 2013 By: Lt Col. Paul R. Newbold (RAM 18) and Dr. Dan Van Syoc Reviewed by Col Timothy Phillips, AF/SG consultant for urology

#### CONDITION: Bladder Cancer (Jun 2017)

#### I. Waiver Considerations.

History of bladder cancer is disqualifying for all flying classes, as well as for ATC, GBO, and SWA duties. It is also disqualifying for retention, so an MEB is necessary prior to waiver consideration.

Flying Class	Condition	Waiver Potential	ACS review/evaluation
(FC)		Waiver Authority	
I/IA	Stages 0 and I	Yes#†	Yes%
		AETC	
II/III	Stages 0, I, II and	Yes+*†	Yes%
	possibly early III	AFMRA	
ATC, GBO	Stages 0, I, II and	Yes+*†	No
SWA	possibly early III	AFMRA	

#### Table 1: Waiver potential of bladder cancer.

# For FC I/IA candidates, waiver may be considered after 5 years of remission, asymptomatic.

+ For trained personnel, waiver may be considered six months after treatment completed, in remission and asymptomatic.

* For untrained personnel, waiver may be considered after 5 years of remission.

[†] No indefinite waivers.

% ACS review needed only if waiver authority considering a waiver

Review of AIMWTS database in Jun 2017 revealed 30 waiver submissions for the diagnosis of bladder cancer. There were 4 disqualifications. Breakdown of the cases is as follows: 0 FC I/IA cases, 17 FC II cases (1 disqualified), 2 RPA cases, 10 FC III cases (3 disqualified), and 1 MOD case. The one disqualified FC II case was for high grade disease; two of the FC III disqualified cases were for another medical reason, and the last disqualified case was for a FC III applicant with ongoing therapy and for high myopia.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations. Waiver can be considered once the aviator is asymptomatic from both the disease and therapy.

The AMS for initial waiver for bladder cancer should include:

A. History – symptoms, pathology, stage, treatment, including date of last treatment, surveillance plan and activity level.

B. List and fully discuss all clinical diagnoses and diagnoses requiring a waiver.

C. Reports from all imaging studies.

D. All cystoscopy/surgical reports along with pathology-confirmed histological diagnosis.

E. Current urinalysis.

F. Urology/oncology consults to include the quarterly tumor surveillance follow-up in accordance with National Comprehensive Cancer Network (NCCN) guidelines.

G. Tumor board report, military or civilian, if applicable.

H. Medical evaluation board results.

I. Confirmation the aviator does not require continued therapy (other than routine follow-up) and that he or she is free of physical limitations.

The AMS for waiver renewal for bladder cancer should include the following:

A. History – brief summary of stage, treatment, frequency of surveillance and results, any symptoms, activity level; all must be consistent with NCCN guidelines.

B. Physical – pertinent to present case.

C. Urology/oncology consult.

D. Labs – all urinalysis and cystoscopy results since last waiver.

#### **III. Overview.**

Bladder cancer is the fourth most common cause of cancer in males and affects men three times more frequently than women. Its incidence also increases with age, with 90% of cases occurring in individuals over age 55.¹ In the U.S., approximately 77,000 new cases and 16,000 deaths occur each year due to bladder cancer.² In addition, there are an estimated 500,000 individuals in the US with a history of bladder cancer making its prevalence greater than that of lung cancer.³ Cigarette smoking is a well-known risk factor, increasing the risk 2-4 fold, and is associated with 50-66% of all bladder cancers in men.^{1,4} Unlike lung cancer, the risk for bladder cancer remains elevated for many years after the smoking cessation, probably accounting for the rising incidence of disease noted in the past few decades.¹ Bladder cancer is much less common in African Americans than in Caucasians, who have the highest rate in the US population.

It has been estimated that occupational exposures may account for up to 20% of all bladder cancer cases. Exposures to toxins in the textile dye and rubber tire industries are risk factors. Historically, these industries used  $\beta$ -naphthylamine, 4-aminobiphenyl and benzidine, all of which were highly associated with bladder cancer. These chemicals have been banned, but the long latency between exposure and disease development makes it difficult to ascertain a definitive relationship for a whole host of other compounds which are still used in these industries.⁶ Chronic infection can also be a risk factor for bladder cancer. This is seen more commonly in under-developed countries and thought to be largely related to infection with schistosomiasis.⁷

As with most cancers, prognosis is largely determined by stage and grade; other factors include location of the lesion, number of lesions, and maximum diameter of the largest tumor.⁸ The

American Joint Committee on Cancer staging system (also known as TNM) is the most widely used system for staging⁹ (see Table 2), while the World Health Organization and International Society of Urologic Pathologists published a recommended revised consensus classification system in 2004 (see Table 3).¹⁰ The upper urinary tract should be imaged during initial work up as 5% of bladder cancers can have an associated upper tract lesion.¹¹

Urothelial carcinoma, also known as transitional cell carcinoma, is the most common pathologic subtype of bladder cancer and is seen in over 90% of all tumors. Squamous cell tumors account for about 5% of all cases and adenocarcinomas are about 1% of the total. The presenting symptom in the majority of cases is hematuria, which can be either continuous or intermittent. Therefore, the American Urologic Association (AUA) recommended in 2001 that all patients with hematuria, particularly those without evidence of infections, stones or other common causes, undergo cystoscopy and upper tract imaging. The physical exam is unremarkable in most bladder cancer patients, particularly those with non-muscle invasive disease, (which accounts for 70% to 75% of patients).¹ As our aviation population is relatively young, most of the cases will be early in the lifecycle and more likely to be non-muscle invasive in nature.

Stage	Clinical Tumor Stage		
TX	Tumor cannot be assessed		
Т0	No evidence of primary tumor		
Та	Non-invasive papillary carcinoma		
Tis	Carcinoma in situ: "flat tumor"		
T1	Tumor invades subepithelial connective tissue		
T2	Tumor invades muscularis propria		
pT2a	Tumor invades superficial muscularis propria (inner half)		
pT2b	Invades deep muscularis propria (outer half)		
T3	Tumor invades perivesical tissue/fat		
pT3a	Invades perivesical tissue/fat microscopically		
pT3b	Invades perivesical tissue/fat macroscopically (extravesical mass)		
T4	Tumor invades any of the following: prostatic stroma, seminal		
	vesicles, uterus, vagina, pelvic wall, abdominal wall		
T4a	Tumor invades prostatic stroma, uterus, vagina		
T4b	Tumor invades pelvic wall, abdominal wall		
	Regional Lymph Nodes (N)		
NX	Regional lymph nodes cannot be assessed		
N0	No regional lymph node metastasis		
N1	Single regional lymph node metastasis in the true pelvis (hypogastric,		
	obturator, external iliac, or presacral lymph node)		
N2	Multiple regional lymph node metastasis in the true pelvis		
	(hypogastric, obturator, external iliac, or presacral lymph node		
	metastasis)		
N3	Lymph node metastasis to the common iliac lymph nodes		
	Distant Metastasis (M)		
M0	No distant metastasis		
M1	Distant metastasis		

Table 2: American Joint Committee on Cancer Bladder Staging System⁹

# Table 3 – AJCC Stage Grouping for Bladder Cancer⁹

Stage	Primary Tumor	Regional Lymph Distant			
	(pT)	Nodes (N)	Metastasis (M)		
0a	Та	NO	M0		
0is	Tis	NO	M0		
Ι	T1	NO	M0		
II	T2a	NO	M0		
	T2b	NO	M0		
III	T3a	NO	M0		
	T3b	NO	M0		
	T4a	NO	M0		
IV	T4b	NO	M0		
	Any T	N1-3	M0		
	Any T	Any N	M1		

## Table 4: WHO Grading Classification of Non-muscle Invasive Urothelial Neoplasia¹⁰

Hyperplasia (flat and papillary)
Reactive atypia
Atypia of unknown significance
Urothelial dysplasia
Urothelial carcinoma in situ
Urothelial papilloma
Papillary urothelial neoplasm of low malignant potential
Nonmuscle invasive low-grade papillary urothelial carcinoma
Nonmuscle invasive high-grade papillary urothelial carcinoma

Treatment is largely dependent upon the grade and stage. Therapy can range from transurethral resection of a bladder tumor (TURBT) to radical cystectomy and resection of affected structures. Often, intravesical therapy is used as an adjunct to tumor resection and/or as a prophylactic measure to prevent recurrence.

For non-muscle invasive tumors (defined as stages Ta, Tis, and T1), the initial treatment is a complete TURBT and an examination under anesthesia (EUA) to rule out a palpable mass which would suggest muscle invasive disease. For T1 tumors, up to 30% of cases will be understaged by TURBT, so repeat TURBT is recommended to decrease likelihood of actual understaging. The majority of these non-muscle invasive tumor cases will recur and up to 25% will progress, so rigorous surveillance and follow-up is mandatory. Fluorescence endoscopy after intravesicular instillation of a porphyrin such as hexaminolevulinate may be more effective than white light endoscopic resection for the detection of multifocal tumors, improving the outcomes of TURBT.¹² Intravesical therapy is generally used in the adjuvant setting to prevent further recurrence. Bacillus Calmette-Guérin (BCG) and mitomycin C are widely used as intravesical immunotherapy and chemotherapy agents but others can be used as well. A key point with these agents is that patients often have no side effects for several cycles, and then up to 90% may develop cystitis and up to than 25% will develop fever, malaise, and hematuria.^{1,4} These symptoms generally resolve quickly after completion of therapy, which is usually administered once/week for 6 weeks.

For invasive tumors (T2 and above) and for some high grade T1 tumors, radical cystectomy is the recommended therapy, with consideration of neoadjuvant chemotherapy and radiotherapy, depending on stage of disease at presentation and the patient's overall health status. Bladder preservation or sparing treatment using primary chemotherapy and external beam radiotherapy is an option in selected patients with T2 and T3a urothelial carcinomas, but is associated with higher rates of recurrence and disease specific mortality. Often this approach is reserved for patients who are medically unfit for major surgery or for those seeking an alternative treatment course.⁵

Because of a fairly high risk of recurrence for all grades and stages, there will be a lifetime need for disease surveillance. The National Comprehensive Cancer Network provides guidance for surveillance stratified by surgical approach to the primary tumor. Patients treated with

cystectomy get laboratory evaluations every three to six months for the first two years. These tests include urine cytology, liver and renal function tests, and serum electrolytes. Patients treated with cystectomy also get a chest x-ray and abdominal and pelvic CT exams every six to twelve months for the first two years and then as clinically indicated.⁵ Patients treated with bladder preservation (TURBT or partial cystectomy) get the same evaluations as patients treated with cystectomy as well as serial cystoscopies with cytological evaluation every three to six months for the first two years, with intervals based on physician discretion.¹³ In general, all patients with non-invasive disease can expect a recurrence rate of 50%, but this rate is higher in those with high-grade disease.³ After two years without recurrence, the recommendation is for indefinite annual exams.⁵ Several urothelial malignancy markers have recently been approved by the FDA, but there is currently insufficient evidence for their routine use in detection of new disease or surveillance.^{11, 14} One issue with the utilization of markers is the finding of a positive marker with normal cystoscopy. These findings have been termed "anticipatory" positives with some studies suggesting that they detect cancer prior to cystoscopic visualization. Studies are ongoing to determine the incremental benefit of markers and the cost-effectiveness of their use.¹⁵

#### **IV. Aeromedical Concerns.**

The aeromedical concerns are based more on the treatment and possible therapy complications than on the disease itself. If the aviator is off all treatment medications and is disease-free (considered to be in remission) and asymptomatic, he or she can be considered for a waiver. Due to a relatively high risk for recurrence, the flyer needs frequent follow up with their urologist. There is low likelihood that recurrence of non-invasive disease would cause sudden incapacitation.

ICD-9 codes for Bladder Cancer		
188	Malignant neoplasm of bladder	
233.7	Carcinoma in situ of bladder	

ICD-10 codes for Bladder Cancer		
C67.9	Malignant neoplasm of bladder, unspecified, C67.x (.08	
	specific site of bladder)	
D09.0	Carcinoma in situ of bladder	

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# **Breast Cancer**

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Significant Changes: Waiver guide restructured.

# I. Waiver Consideration

Any history of a malignant neoplasm, including breast cancer, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Treatment of any malignancy or the sequelae of either the malignancy or its treatment may be independently disqualifying. For example, persistent breast pain that prevents the wearing of military equipment is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Adjuvant endocrine therapy to reduce the risk of late recurrence, a new primary breast cancer, and to improve overall survival is also disqualifying for all flying class, ATC, GBO, and SWA duties. Tamoxifen and raloxifene are approved for use with a waiver. Other adjuvant endocrine therapies and immunotherapies are not formally approved for use, but waivers may be considered on a case-by-case basis (e.g., aromatase inhibitors). The presence of complications or adverse effects stemming from endocrine therapy (e.g., muscle pain that is distracting or interferes with duty performance, osteoporosis, etc.) make a waiver less likely. It is recommended that the MSD and the appropriate career field medication list be cross-referenced for any and all treatments, complications, or residual symptoms.

Typically, an aeromedical or operational waiver for breast cancer is considered after completion of all planned treatment (including any reconstructive surgeries) and the establishment of disease-free asymptomatic clinical stability. It is expected that the service member will be in remission and be following a routine schedule of post-treatment surveillance, in accordance with established professional guidelines (e.g., National Comprehensive Cancer Network Guidelines). Any adverse outcomes of the primary malignancy or its treatment should be addressed before requesting a waiver, with clear establishment of clinical, biochemical, and radiographic stability, as applicable. A period of at least six months of stable post-treatment surveillance is required prior to consideration of a waiver for most trained assets; whereas five years of surveillance is required prior to consideration of a waiver for most untrained individuals. Case-by-case consideration may be given to an earlier waiver in select low-risk cases.

Flying Class	Condition	Waiver Potential ¹ Waiver Authority ²	ACS Review or Evaluation
FC I/IA	Breast cancer, stages 0-IIB ³	Yes AFRS/CMO	Yes
	Breast cancer, stage IIIA-IV	No AFRS/CMO	No
FC II/III	Breast cancer, stages 0-IIB ^{3,4}	Yes	Yes
	Breast cancer, stages IIIA-IIIC ^{3,5}	Yes	Yes
	Breast cancer, stage IV	No AFMRA	No
ATC/GBO/ OSF/SWA	Breast cancer, stages 0-IIB ^{3,4}	Yes AFMRA	No ⁶
	Breast cancer, stages IIIA-IIIC ^{3,5}	Yes AFMRA	No ⁶
	Breast cancer, stage IV	No AFMRA	No

 Table 1: Waiver potential for Breast Cancer

1. No indefinite waivers

2. Certification authority for untrained assets is AFRS/CMO.

3. Waiver for untrained assets may be considered after <u>five years</u> of stable, asymptomatic, disease-free surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

- 4. Waiver for trained assets may be considered after <u>six months</u> of stable, asymptomatic, disease-free surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.
- 5. Waiver for trained assets may be considered after <u>two years</u> of stable, asymptomatic, disease-free surveillance following completion of definitive treatment.
- 6. ACS review may be requested at the discretion of the waiver authority.

# **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

## A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Fully describe the course of treatment, including dates of each intervention and any side effects, adverse outcomes, or complications.
  - c. Specify presence or absence of any residual symptoms or sequelae following completion of treatment.
  - d. List any current medications, dosages, dates of dose adjustments, and any medication adverse effects.

- e. Specify current surveillance regimen, including schedule of specialist clinical reevaluation, laboratory testing, and any applicable imaging. Explain any discrepancies in surveillance plan from established post-treatment guidelines.
- 2. Consultation report from all treating specialists, as applicable (e.g., medical oncologist, radiation oncologist, surgeon) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and staging.
  - b. Summarization of complete treatment course, including any modifications to initial planned treatments with explanation.
  - c. Recent post-treatment follow-up note addressing clinical stability and commenting on presence or absence of residual disease, symptoms, or sequelae of the breast cancer or its treatment.
  - d. Detailed plan of ongoing surveillance for recurrence, including interval of followup and specific monitoring tests planned.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of breast cancer, including laboratory studies, imaging, pathology results, and any other ancillary studies. The below-listed studies must be included:
  - a. Current CBC with differential
  - b. Current comprehensive metabolic panel (CMP)
  - c. Pathology report from all biopsy and surgical samples, including results of hormone receptor and HER2/neu receptor testing
  - d. Results of all diagnostic, staging, and surveillance imaging studies, as applicable in accordance with established guidelines (e.g., screening and/or diagnostic mammogram, breast ultrasound, axillary ultrasound, breast MRI, bone scan, PET-CT, abdominal and pelvic CT or MRI, etc.)
  - e. If treatment included anthracycline chemotherapy, then a post-treatment echocardiogram or multigated acquisition scan (MUGA) is required to assess left ventricular function
- 4. All operative and procedure reports, including reports from any and all reconstructive surgeries.
- 5. Current physical examination findings, including:
  - a. Bilateral clinical breast examination of any conserved breast tissue
  - b. Examination of chest wall/surgical site
  - c. Examination of lymph nodes
  - d. Examination of bilateral upper extremities with particular attention to range of motion and presence or absence of lymphedema
- 6. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 7. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Any new subjective symptoms or objective findings and a current examination of any conserved breast tissue, the chest wall, lymph nodes, and bilateral upper extremities with particular attention to range of motion and presence or absence of lymphedema.

- b. Complete list of current medications with dates of initiation, dosages, dates of dose adjustments, and all adverse effects.
- c. Summary of interval surveillance evaluations and studies.
- d. Updated plan of ongoing surveillance for recurrence.
- 2. Current physical examination findings, including:
  - a. Bilateral clinical breast examination of any conserved breast tissue
  - b. Examination of chest wall/surgical site
  - c. Examination of lymph nodes
  - d. Examination of bilateral upper extremities with particular attention to range of motion and presence or absence of lymphedema
- 3. All relevant interval consultation reports from specialty providers (e.g., medical oncologist, radiation oncologist, surgeon).
- 4. Results of all interval testing performed in the course of ongoing management and surveillance, including all laboratory studies, imaging, and other ancillary tests.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# **III. Aeromedical Concerns**

In locales with well-established breast cancer screening programs, the majority of breast cancers are diagnosed before the development of any signs or symptoms of clinical, aeromedical, or operational significance. Among women who undergo diagnostic evaluation due to concerning symptoms, the most common presenting feature is a breast mass or lump. Axillary adenopathy or changes in the skin of the breast are signs of more locally advanced disease. Other signs and symptoms include nipple changes (e.g., new inversion, spontaneous discharge) and breast pain. Even when these symptoms are present, the impact on aviation or operational duties is generally negligible, although pain and discomfort may interfere with the wearing of equipment, and anxiety or worry about symptoms could potentially distract from duty performance.

The majority of newly diagnosed breast cancers are either confined to the breast or the spread is limited to less than three regional lymph nodes (i.e., stage I or II). Distant metastases are present at first diagnosis in only 6% of women. Unfortunately, the risk of later metastasis in women who are initially diagnosed with early-stage disease is relatively high at 30%. When breast cancer metastasizes, it most commonly spreads to the liver, brain, bone, and lungs. In these cases, the aeromedical and operational risk depends on metastatic burden and the particular organ systems involved. Metastatic spread to any organ system may result in complications with aeromedical and operational impact such as respiratory impairment or bone fracture. However, metastasis to the brain is of special concern due to the difficulty of screening to detect early involvement. As a result, the first indication of brain metastases may be the development of symptoms, some of which convey serious risk in an aviation or operational environment (e.g., cognitive changes, hemorrhage, or seizure).

Treatment for breast cancer includes surgery (e.g., lumpectomy/breast-conserving surgery or radical mastectomy, with or without axillary lymph node dissection), chemotherapy, external beam radiation, endocrine therapy, and biologic therapy. Each intervention is associated with unique adverse effects and complications. For example, mastectomy and lymph node resection may result in significant loss of chest wall muscle, lymphedema of the upper extremities, or damage to the long thoracic and/or thoracodorsal nerves. Consequences of both surgery and radiation include chronic pain, weakness, or restriction in the range of motion of the ipsilateral upper extremity. Chemotherapy may result in long-term complications such as cardiac toxicity or peripheral neuropathy. The risk of adverse cardiac outcomes is greatest with the use of anthracycline agents, and a post-treatment assessment of left ventricular function with either an echocardiogram or multigated acquisition scan (MUGA) is required prior to waiver consideration.

After completion of definitive treatment for the original primary tumor, many women will be placed on a prolonged course of endocrine therapy to reduce the risk of late recurrence and the development of a second primary breast cancer. These medications include tamoxifen and the aromatase inhibitors. Adverse effects are common on endocrine therapy, particularly the aromatase inhibitors. These adverse effects and are often of significant aeromedical concern, including pronounced musculoskeletal pain and stiffness, bone loss, fatigue, brain fog, and hot flashes. As such, careful and individualized consideration must be given to the cumulative risks of the underlying cancer and all treatments before any waiver decision is rendered.

Selection of treatment is guided by risk stratification that considers a variety of factors including extent of disease (e.g., stage), hormone receptor and HER2/neu receptor status, gene expression profile, and patient characteristics such as age, menopausal status, and smoking history. Additional considerations when choosing a course of therapy include the potential complications associated with different treatments and patient preference. There are several prognostic tools that assist clinicians and patients in shared decision making around an individualized treatment plan. The nuances of these tools and treatment decisions is beyond the scope of this waiver guide, but validated prognostication tools may be utilized during the course of a waiver review to further define individualized aeromedical or operational risk.

In summary, aeromedical and operational waiver consideration for service members with a history of breast cancer is highly individualized and includes assessments of the personalized risk from the cancer itself, particularly with concern to the likelihood of late recurrence and/or metastasis, as well as risks associated with treatment. The ongoing use of endocrine therapy for chemoprophylaxis carries additional risk, and waivers for these medications are considered on a case-by-case basis.

Review of AIMWTS data from Dec 2018 through Dec 2021 revealed a total of 31 waiver packages involving breast cancer. Of that total, 0 was FC I/IA, 10 were FC II (0 disqualified), 18 were FC III (0 disqualified), 3 were ATC/GBO (0 disqualified), and 0 were SWA. All but two of these 31 waiver packages involved breast cancers that were either confined to the breast or had limited spread to regional lymph nodes (i.e., stage I or II disease).

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
C50.9	Malignant neoplasm of breast of unspecified site	
Z85.3	Personal history of malignant neoplasm of breast	
D24.9	Benign neoplasm of unspecified breast	

# **IV. Suggested Readings**

- Henry NL, Somerfield MR, Abramson VG, et al. Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer: Update of the ASCO Endorsement of the Cancer Care Ontario Guideline. J Clin Oncol 2019;37:1965-1977. Available at https://ascopubs.org/doi/10.1200/JCO.19.00948. Accessed 14 December 2021.
- 2. Korde LA, Somerfield MR, Carey LA, et al. Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline. J Clin Oncol 2021;39:1485-1505. Available at https://ascopubs.org/doi/pdf/10.1200/JCO.20.03399. Accessed 14 December 2021.
- 3. National Comprehensive Cancer Network. Breast Cancer (Version 8.2021). 13 September 2021. Available at <a href="https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf">https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf</a>. Accessed 14 December 2021. (Note: A free account must be created to access this guideline).
- 4. National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis. (Version 1.2021). 6 May 2021. Available at <u>https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf</u>. Accessed 14 December 2021. (Note: A free account must be created to access this guideline).
- Visvanthan K, Fabian CJ, Bantug E, et al. Use of Endocrine Therapy for Breast Cancer Risk Reduction: ASCO Clinical Practice Guideline Update. J Clin Oncol 2019;37:3152-3165. Available at <u>https://ascopubs.org/doi/10.1200/JCO.19.01472</u>. Accessed 14 December 2021.
- 6. Zoberi K and Tucker J. Primary care of breast cancer survivors. Am Fam Physician 2019;99:370-375. Available at <u>https://www.aafp.org/afp/2019/0315/afp20190315p370.pdf</u>. Accessed 14 December 2021.

WAIVER GUIDE Updated: Jan 2016 Supersedes Waiver Guide of Apr 2012 By: Dr. Dan Van Syoc

# CONDITION: Cancers (Misc.) (Jan 2016)

## I. Waiver Considerations.

According to the AF Medical Standards Directory, the history, or presence of, a malignant tumor, cyst or cancer of any sort is disqualifying for aviation and special duties, as well as for retention. Childhood malignancy considered cured may be considered for waiver on a case-by-case basis. To be considered for a waiver, the malignancy needs to be considered cured, or in remission, by applicable clinical standards. The individual must be off all chemotherapeutic agents for long enough to allow for all the intended clinical effects and for all unintended effects to have resolved. The individual must also have no identifiable aeromedically significant side effects from any treatment modality. Each such case must be submitted to the ACS for review prior to waiver action. All contributing lifestyle issues must be resolved. Generally, waiver will not be considered within six months of cessation of definitive therapies.

## II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for *initial waiver* should include the following, at a minimum:

A. History of tumor diagnosis, all treatment performed and any side effects from the tumor and/or treatment. Need good time lines.

- B. All imaging reports (actual images may be required in some cases).
- C. Surgical reports, consults and pathology reports.
- D. Clinically relevant labs.
- E. Oncology consultation stating malignancy is considered cured, or in remission, and the recommended follow-up schedule for the patient.
- F. Tumor board results if accomplished.
- G. MEB results.

The aeromedical summary for <u>waiver renewal</u> should include the following:

- A. Detailed interim history since last waiver submittal.
- B. All applicable labs and imaging studies.
- C. Consult from oncologist.

#### **III. Overview.**

Previously, there were several cancer diagnoses in the waiver guide which have since been removed. The reason for so doing is the paucity of AIMWTS submissions in these categories. Causes for this would include: rarity of the tumor in our aviation population, poor prognosis of the tumor once diagnosed, long duration of chemotherapy and hazards associated with a particular drug regimen, and treatment side effects that are not compatible with aviation duties.

Having said this, there are those folks with many types of cancer who defy the odds and do well after an aggressive approach to their disease. After a thorough evaluation it may be determined that they are fit for waiver consideration.

The following malignancies have a current posted waiver guide:

Bladder Breast Cervical Colorectal Hodgkin Lymphoma Leukemia Malignant Melanoma Non-Hodgkin Lymphoma Pituitary Tumors Prostate Salivary Gland Testicular Thyroid

The following malignancies have been removed from the waiver guide:

Carcinoid Kidney Laryngeal Lung Neurological Tumors Oral cancers Other GI tumors Ovarian Plasma cell dyscrasias Uterine

### **IV. Aeromedical Concerns.**

As with all malignancies, there is concern with recurrence and sudden incapacitation. There is also concern with side effects of treatment such as surgery, radiation, and chemotherapy. An aviator returned to flying duties after treatment for a malignancy must be able to endure all the rigors of his or her aviation environment as well as to safely egress the aircraft in case of an emergency. Depending on the tumor and stage, as well as flyer's aircraft, it may be prudent to have the aviator spin in a centrifuge and/or go through altitude chamber training prior to waiver consideration.





# **Cervical Cancer**

Revised: Aug 2022

Reviewed: Dr. Max Lee (ACS Waiver Guide coordinator), Lt Col Amy Brown (AF/SG OB/GYN consultant), and Lt Col Paul Vu (AFMRA Physical Standards Development Chief)

# **Significant Changes:**

Updates reflective of changes in DoDI 6130.03 V1, updated suggested readings

In trained aviators, abnormal PAP tests are not disqualifying and do not require DNIF unless the flyer has physical or emotional symptoms that warrant grounding until resolved, as determined by their flight surgeon. IAW DoDI 6130.03 V1, new accessions with abnormal cervical cytology within the preceding 3 years (excluding atypical squamous cells of undetermined significance [ASCUS] with human papilloma virus [HPV] and confirmed low-grade squamous intraepithelial lesions [LSIL]) are disqualified for service entry, as is any history of malignancy. All malignant neoplasms (i.e. cancers) require I-RILO processing and are disqualifying for aviation duties. Cervical carcinomas-in-situ without sequelae, after adequate excision as evidenced by pathology report, are exempt from this requirement.

In general, aeromedical waivers are granted for cervical cancers, after meeting clinical and adequate observational timelines. The one exception is Stage IVB disease (distant metastasis), which remains highly unlikely for waiver.

Flying Class (FC)	Disease/Condition	Waiver Authority Waiver Potential	ACS Review/ Evaluation	
	Stages IA1 – IIA	AFRS/CMO Yes ^{2,4}	Yes	
FC I/IA ¹	Stages IIB – IVB	AFRS/CMO Unlikely	No	
FC II/III and	Stages IA1 – IVA	MAJCOM Yes ^{2, 3, 4}	Yes	
ATC/GBO/SWA ¹	Stage IVB	MAJCOM Unlikely	No	

## Table 1: Waiver potential for Cervical Cancer

1. Certification authority for all untrained servicemember is AFRS/CMO.

2. For untrained servicemembers, aeromedical waiver may be considered after <u>five years</u> of remission and asymptomatic.

3. For trained personnel waiver may be considered after <u>six months</u> of completed treatment and are in remission and asymptomatic. For stage IA – IB1 cervical cancers treated with surgical only, without radiation or chemotherapy, and pathology report for low recurrence risk, submit for waiver consideration after appropriate surgical recovery.

4. No indefinite waivers.

# II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. Include: symptoms; pathology; stage; treatment: including date of last treatment, surveillance plan and activity level.
- 2. Current physical exam findings, including but not limited to genital and rectovaginal exam, lymph nodes, and abdomen.
- 3. All consultation reports, including follow-up notes with examination findings after disease resolution.
  - a. Gynecology and Oncology consult reports to include the six-month follow-up visit in accordance with the National Comprehensive Cancer Network (NCCN) guidelines.
  - b. Include tumor board report (military or civilian) if applicable.
- 4. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated).
  - a. Include all follow-up PAP results, frequency per NCCN guidelines.
  - b. Any initial and follow-up labs (minimum of CBC and BUN/Creatinine levels).
- 5. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 6. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 7. Medical evaluation board results (FL4 with RTD and ALC status).
- 8. All operative and/or procedural notes related to cervical cancer.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# B. Renewal Waiver Request:

- 1. Interim history since last waiver submission.
- 2. Current physical exam findings, including but is not limited to genital and rectovaginal exam, lymph nodes, and abdomen.
- 3. All consultation reports, including follow-up notes with examination findings after disease resolution.
  - a. Gynecology and Oncology consult reports to include the six-month follow-up visit in accordance with the NCCN guidelines.
  - b. Include tumor board report (military or civilian) if applicable.
- 4. Reports of any pertinent laboratory studies, imaging studies, copies of images since last waiver.
  - a. Include all follow-up PAP results (frequency per NCCN guidelines).
  - b. Any follow-up labs.

- 5. Discuss the status of any previously identified treatment complications. Include a discussion of any new complications that developed since the previous waiver, information on the functional impact of these complications, and the management plan.
- 6. Any other pertinent information.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

## **III. Aeromedical Concerns**

Cervical cancer is the most common cancer caused by a known preventative pathogen in the United States, and is associated with an infection of the human papilloma virus (HPV), with serotypes 16, 18, 31, 33, 45, and 56 responsible for more than 80% of invasive cervical cancers. Symptoms depend on location and extent of spread of the cancer, but can minimally include invasion of the cervical tissue (causing irregular vaginal bleeding) or can include extension into the surrounding tissue/organs of the vagina, bladder, and GI tract. Risk factors for cervical cancer include early age at first intercourse (age 13 years or younger), multiple sexual partners, multiparity, lower socioeconomic standing, cigarette smoking, history of sexually transmitted diseases, and immunosuppression (e.g. HIV positive, organ transplant patients, and long-term corticosteroid use). Treatment for cervical cancer depends on the stage of the disease, but can include surgical excision, chemotherapy, and/or radiation therapy. The 5-year survival rate for all stages of cervical cancer is close to 68%, but if caught in the early non-metastatic stages, the 5-year survival exceeds 90%. Complications from treatment for cervical cancer vary depending on the type of treatment and their potential for side-effects such as radiation induced proctitis, ulcerations, and strictures, which must be considered when assessing whether an operator is ready to return to duties.

Patients in the U.S. have seen a declining trend over the past 10 years in the number of new cervical cancer cases diagnosed, which has been attributed to the widespread use of primary prevention strategies (sexual abstinence, condom usage, and HPV vaccination) and secondary prevention strategies (improvements in evidence-based screening involving PAP test, cervical cytology, and HPV screening). Cervical cancer is highly preventable utilizing primary prevention recommendations and early detection through cervical cancer screening, treatments have a high rate of success, and the likelihood of returning to flying and operational duties is high. Success of treatment declines as the stage that the cancer is diagnosed increases. It is important to remember that cancer diagnoses of any type may lead to emotional distress. Thus, the member's mental health and emotional wellness should be assessed and managed prior to return to flying or operational duty determination.

Following treatment, the aeromedical concerns primarily surround the sequelae of treatment, the logistics of surveillance, and the potential for local or metastatic disease recurrence. The level of concern increases with advancing stages of disease, and each operator with a diagnosis of cervical cancer needs to be evaluated on a case-by-case basis.

Review of AIMWTS data through July 2022 revealed 7 cases of cervical cancer requiring aeromedical waivers. The breakdown of the number of waivers and number of total cases are tabulated below. The 2 initial FC III disqualifications were related to other medical or administrative conditions.

	Please use only this Cervical Cancer ICD-10 codes for		(# of waivers / total # of cases)			
AIMWTS coding purposes		IFC I/IA	FC II	FC III	ATC	
C53.0	Malignant neoplasm of the endocervix					
C53.1	C53.1 Malignant neoplasm of the exocervix		2/2	2/4	1/1	
C53.8	C53.8 Malignant neoplasm of overlapping site of cervix uteri					
C53.9	Malignant neoplasm of the cervix uteri, unspecified					

## **IV. Suggested Readings**

1. Cervical Cancer. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology; V.4.2019. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf (Free access after sign-up)

2. Straughn JM and Yashar C. Management of early-stage cervical cancer. UpToDate. Feb 11, 2022. Accessed Jul 26, 2022. <u>https://www.uptodate.com/contents/management-of-early-stage-cervical-cancer</u>

3. Frumovitz, M. Invasive cervical cancer: Epidemiology, risk factors, clinic manifestations, and diagnosis. UpToDate. Apr 19, 2022. Accessed Jul 26, 2022. <u>https://www.uptodate.com/contents/invasive-cervical-cancer-epidemiology-risk-factors-clinical-manifestations-and-diagnosis</u>

4. U.S. Preventive Service Task Force. Cervical Cancer: Screening. Aug 21, 2018. Accessed Jul 26, 2022. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening

#### WAIVER GUIDE

Updated: Jan 2018 Supersedes Waiver Guide of May 2013 By: Dr. Dan Van Syoc Reviewed by Lt Col Roger Wood, AF/SG consultant for oncology, Lt Col Thomas Stamp, AF/SG consultant for general surgery, and Lt Col Eric Plott, AF/SG consultant for gastroenterology, and AFMSA staff.

## CONDITION: Colorectal Cancer (Jan 2018)

#### I. Waiver Considerations.

CRC, or a history of CRC, is disqualifying for all classes of flying and special duties in the US Air Force. It is not listed specifically as disqualifying however MSD O1 applies: "Malignant Neoplasms. All malignant neoplasms (except basal cell or squamous cell carcinomas of the skin, and cervical carcinomas-in-situ, after surgical cure) require I-RILO processing." There are no indefinite waivers for this condition.

Flying Class	Condition	Waiver Potential	ACS review/evaluation
(FC)		Waiver Authority	
I/IA	Stages I or II	Yes#	Yes
		AETC	
	Stage IIIA, B, or	No	No
	С	AETC	
		No	No
	Stage IV	AETC	
II/III	Stages I or II	Yes+*	Yes
ATC/GBO/SWA		AFMRA	
	Stage IIIA, B, or	Maybe+*	Yes
	С	AFMRA	
		No	No
	Stage IV	AFMRA	

#### Table 1: Waiver potential of colorectal cancer in FC I/IA, II and III

# For FC I/IA individuals, waiver may be considered after five years of remission, asymptomatic.

+ For trained personnel waiver may be considered as early as six months after treatment completed, in remission, surveillance is ongoing, and asymptomatic.

* For untrained personnel, waiver may be considered after five years of remission.

AIMWTS review in Jan 2018 revealed a total of 47 submitted cases of CRC. Breakdown of the cases was as follows: one FC I case (disqualified), 26 FC II cases (5 disqualified), 18 FC III

cases (4 disqualified), 2 MOD cases (1 disqualified), and 0 ATC/GBC cases. Of the 11 disqualified cases, 7 were disqualified due to advanced disease, 2 for multiple medical problems and the FC I case because it was too soon to consider.

## II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for initial waiver for CRC should include the following:

A. History – initial symptoms, colonoscopy (or CTC) findings, pathology, stage, treatment, surveillance plan, and activity level.

B. Physical – abdominal, rectal, and all imaging studies.

C. GI and surgeon reports to include all follow-up studies, to include a clean colonoscopy..

D. Labs – Serial CBCs and carcinoembryonic-antigen test results; must be normal to be considered for a waiver.

E. Tumor board report, military or civilian, if applicable.

F. Medical evaluation board results.

The AMS of <u>waiver renewal</u> of CRC should include the following:

A. History – brief summary of stage, treatment, frequency of surveillance and results, any symptoms, activity level.

B. Physical – abdominal and rectal exams and imaging studies, if done.

C. Oncology consult(s).

D. Labs - all CBCs and carcinoembryonic-antigen test results since previous waiver.

E. Evidence that the level of follow-up care is consistent with current NCCN standards.

## **III. Overview.**

Colorectal cancer (CRC) is the fourth most common cancer in the US and is the second leading cause of cancer-related mortality. In 2016 an estimated 135,000 new cases of colorectal cancer were responsible for an estimated 49,000 CRC related deaths.^{1, 2, 3} CRC is the third leading cause of cancer deaths in both men and woman. Prior to age 50, men and woman have essentially equal incidence and mortality rates. After age 50, the rates are higher in men. Racial and ethnic groups have differing incidence and mortality rates. African Americans have the highest rates while Hispanics and Pacific Islanders have the lowest.⁴ The overall 5-year survival in the US continues to improve mostly from increased utilization of screening tests.^{4, 5} Unfortunately, the incidence of CRC in persons younger than 50 years of age has been increasing. With current trends, estimates for the 20-34 year old age group are for more than a 120% increase in CRC incidence by 2030.¹ The disease is often insidious in development and common symptoms are fatigue, anemia, altered bowel function, pain and weight loss. The most common acute surgical problem is bowel obstruction.

CRC has been linked to both genetic and environmental factors. Those genetic factors that influence screening recommendations include: hereditary colorectal cancer syndromes such as familial adenomatous polyposis, MUTYH-associated polyposis, and Lynch syndrome, as well as family or personal history of sporadic colorectal cancer. Although inherited susceptibility results in the most striking increases in risk, the majority of CRCs are sporadic rather than familial, with the hereditary syndromes accounting for less than 10% of cases.^{6, 7}

Most CRCs are adenocarcinomas and arise from existing adenomatous polyps. In addition to familial risk, inflammatory bowel disease (ulcerative colitis and Crohn's Disease) is a well-established risk factor for development of CRC.¹ As well, increasing age and male gender are associated with increased risk. Other risk factors include alcohol use and increased body mass index.⁷ There is ongoing research concerning evidence that supports the role of abdominal radiation, acromegaly, renal transplantation, diabetes mellitus and cholecystectomy to an individual's risk of disease. Substantial data exists that a lifestyle with regular exercise, and containing a diet that is high in fruits and vegetables, can lower ones risk for colorectal cancer. More research is necessary before conclusions can be made on calcium, vitamin B6, folic acid, fiber, and fish consumption.⁶

Current screening recommendations are for all Americans to have an initial screening starting at age 50 (45 for African Americans). Options for screening from the US Multisociety Task Force on Colorectal Cancer include: (1) annual fecal occult blood test, (2) flexible sigmoidoscopy every five years, (3) combination of (1) and (2) above, (4) colonoscopy every ten years, and (5) CT colonography every five years. This has led to the reduced mortality for CRC seen in most US populations.⁸ The initial screening colonoscopy should be performed at an earlier age for individuals with genetic, familial, and other risk factors. Surveillance colonoscopy should be performed at increased intervals in individuals with certain pathologic findings on index screening exam.^{9, 10}

Colonic adenomas are the precursors to almost all CRCs and are found in up to 40% of all persons by the age of 60. As most colonic polyps are adenomas and more than 90% of adenomas probably do not progress to CRC, it is not currently possible to reliably identify those polyps that will progress. Larger polyp size and more advanced histologic features are more predictive of progression to invasive cancer.⁹ Identification and removal of these "precancerous" lesions is the primary purpose of screening colonoscopy and mode by which this procedure can reduce incidence of CRC.

Surgery is the cornerstone of therapy for CRC and 70 to 80 percent of patients with tumors can be resected with curative intent. Among patients who have undergone resection for localized disease, the five-year survival rate is 90%. The survival rate decreases to 65% when metastasis to regional lymph nodes is present. Most recurrences occur within three years, and 90% occurs within five years. The most common sites of recurrence are the liver, the local site, the abdomen and the lung.¹¹ Prospective studies have demonstrated that the use of chemotherapy in patients with metastatic disease prolongs survival and enhances quality of life in comparison to palliative care alone. Adjuvant radiation therapy is frequently used for treatment of rectal cancer.

There has been much debate over the years on how best to follow patients post-treatment for CRC. After it has been concluded that the colon is free of cancer and polyps, colonoscopy is recommended at one, three, and every five years thereafter, depending on patient characteristics. Physician visits with targeted exams are recommended every 3 to 6 months for the first three years with decreased frequency thereafter for 2 additional years. There is also consensus that patients be tested every 3 to 6 months for up to 5 years with a carcinoembryonic-antigen test, as most recurrences will first be detected with this lab.¹⁴

While in-depth diagnostic, staging, and treatment regimens associated with CRC are beyond the scope of this document, a staging overview is included below for reference. As well, a succinct presentation of guidelines related to colorectal cancer, screening modalities and specifics, hereditary syndromes, etc. is published by the National Comprehensive Cancer Network and available at https://www.nccn.org.

## Staging of Colorectal Cancer

Stage (T)	Primary Tumor (T)
ТХ	Primary Tumor cannot be assessed
<b>T0</b>	No evidence of primary tumor
Tis	Carcinoma in situ: intraepithelial or invasion of lamina propria
T1	Tumor invades submucosa
T2	Tumor invades muscularis propria
T3	Tumor invades through the muscularis propria into the subserosa, or into non-
	peritonealized pericolic or perirectal tissues
T4	Tumor directly invades other organs or structures, and/or perforates visceral
	peritoneum
	Regional Lymph Nodes
NX	Regional lymph nodes not assessed
NO	No regional lymph node metastasis
N1	Metastasis in 1 to 3 regional lymph nodes
N2	Metastasis in 4 or more regional lymph nodes
	Distant Metastasis
MX	Distant metastasis cannot be assessed
<b>M0</b>	No distant metastasis
M1	Distant metastasis

 Table 2. American Joint Committee on Cancer (AJCC) Colon Cancer Staging System

Stage	Primary	Regional	Distant	Dukes	MAC
	Tumor (T)	Lymph	Metastasis		
		Nodes (N)	(M)		
0	Tis	N0	M0	-	-
Ι	T1	N0	M0	А	А
	T2	N0	M0	А	B1
IIA	T3	N0	M0	В	B2
IIB	T4	N0	M0	В	B3
IIIA	T1-T2	N1	M0	С	C1
IIIB	T3-T4	N1	M0	С	C2/C3
IIIC	Any T	N2	M0	С	C1/C2/C3
IV	Any T	Any N	M1	-	D

**Table 3 Stage Grouping for Colorectal Cancer** 

#### **IV. Aeromedical Concerns.**

Of significant concern with CRC is the potential for sudden incapacitation as the initial presentation; emergent obstruction, or perforation. Chronic anemia presents more insidiously and can cause in-flight problems if undetected. CRC has primarily affected persons over 50 years of age, thereby removing a majority of USAF aviators from the high risk window. As mentioned previously, however, the incidence CRC in the 20-34 age group is on the rise, potentially recapturing those aviators into this risk pool. Regular screening may decrease late presentations and any alarm features, even at a young age, should be carefully considered.

Once diagnosed and treated, the potential for recurrence becomes an important health and aeromedical concern. It has been shown that 80 to 90 percent of all recurrences following curative resection occur within the first 2-3 years and that 95% occur within five years. The five-year survival point can be used as a reliable mark of cure. Among those who undergo curative resection, colonic reanastomosis is common. The presence of colostomy or ileostomy, however, is not compatible with military aviation (MSD I40).

ICD9 Codes	ICD9 Codes for Colorectal Cancer		
153.0	Malignant neoplasm of hepatic flexure		
153.1	Malignant neoplasm of transverse colon		
153.2	Malignant neoplasm of descending colon		
153.4	Malignant neoplasm of cecum		
153.6	Malignant neoplasm of ascending colon		
153.7	Malignant neoplasm of splenic flexure		
153.8	Malignant neoplasm of other specified sites of large intestine		
153.9	Malignant neoplasm of colon, unspecified		
154.0	Malignant neoplasm of rectosigmoid junction		
154.1	Malignant neoplasm of rectum		
154.8	Malignant neoplasm of other sites of rectum, rectosigmoid junction, & anus		

ICD-10 Code	ICD-10 Codes for Colorectal Cancer		
C18.3	Malignant neoplasm of hepatic flexure		
C18.4	Malignant neoplasm of transverse colon		
C7A.023	Malignant carcinoid tumor of the transverse colon		
C18.6	Malignant neoplasm of descending colon		
C7A.024	Malignant carcinoid tumor of the descending colon		
C18.0	Malignant neoplasm of cecum		
C7A.021	Malignant carcinoid tumor of the cecum		
C18.2	Malignant neoplasm of ascending colon		
C7A.022	Malignant carcinoid tumor of the ascending colon		
C18.5	Malignant neoplasm of splenic flexure		
C18.9	Malignant neoplasm of colon, unspecified		
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion		
C18.7	Malignant neoplasm of sigmoid colon		
C7A.025	Malignant carcinoid tumor of the sigmoid colon		
C20	Malignant neoplasm of rectum		
C7A.026	Malignant carcinoid tumor of the rectum		
C18.8	Malignant neoplasm of overlapping sites of the colon		

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## WAIVER GUIDE Updated: May 2015 Supersedes Waiver Guide of Apr 2012 By: Maj Jennifer Wolf (RAM 16) and Dr. Dan Van Syoc Reviewed by Lt Col Roger Wood, AF/SG consultant for Hematology/Oncology

# CONDITION: Hodgkin Lymphoma (May 2015)

## I. Waiver Considerations.

History of Hodgkin lymphoma (HL)is disqualifying for all flying classes. In addition, all malignancies require an I-RILO no more than 90 days after the start of treatment, which necessitates a waiver for all ATC/GBO and SWA personnel with HL who are returned to duty.

Flying Class (FC)	Condition	Waiver Potential	ACS
		Waiver Authority	review/evaluation
I/IA	All stages	Maybe*+	Maybe†
		AETC	
II/III	All stages	Yes*#+	Yes†
	-	AFMRA	
ATC/GBO	All stages	Yes*#+	At the discretion of
SWA	-	AFMRA	the waiver authority

Table 1: Waiver potential for various stages of Hodgkin lymphoma and flying class.

* FC I/IA candidates, as well as untrained FC II, FC III, GBO, ATC, and SWA; waiver may be considered five years after completion of treatment if asymptomatic and in full remission with a favorable prognosis.
# For trained FC II, FC III, ATC/GBO, SWA individuals only, waiver may be considered six months after completion of treatment if asymptomatic and in full remission; the <u>exception</u> is for fighter aircrew who need to wait

12 months prior to waiver consideration if they received bleomycin, otherwise 6 months.

+ No indefinite waivers will be granted.

[†] For high performance (routine use of aviator mask while flying) individuals treated with bleomycin, <u>will no longer</u> require an ACS evaluation unless problems arise and the evaluation is requested by the waiver authority.

Review of AIMWTS in Apr 2015 revealed 31 members with a waiver request for the diagnosis of HL. There were two cases resulting in a disposition of disqualified. Breakdown of the cases was as follows: 13 FC II cases (0 disqualifications), 11 FC III cases (2 disqualifications), 5 ATC/GBC cases (0 disqualifications), and 2 MOD cases (0 disqualifications). One of the DQs was for recurrent disease and the other was due to side effects from treatment.

## II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for *initial waiver* for Hodgkin lymphoma should include the following:

A. History – initial symptoms and signs, staging, treatment (amount and location of radiation and/or amount and type of chemotherapy), current symptoms/signs and activity level.

B. Physical – lymphoid regions, spleen and liver.

C. Hematology/oncology reports to include all follow-up studies consistent with current guidelines in National Cancer Comprehensive Network (NCCN).

D. CT scan results after treatment.

E. Labs – complete blood count (CBC), erythrocyte sedimentation rate (ESR), LDH, liver function tests, albumin, blood urea nitrogen (BUN), and creatinine.

F. Submit ECG and echocardiogram (or MUGA scan) studies if the individual is treated with anthracycline containing regimens.

G. Pulmonary function testing, with spirometry pre and post bronchodilator, lung volumes and DLCO. If there is any DLCO abnormality, exercise oximetry and/or metabolic exercise testing, and follow up DLCO in 3-6 months would be advisable to determine functional status and clinical course.

H. Pathology report.

I. Tumor board results (military or civilian).

J. Medical evaluation board results.

The AMS for <u>waiver renewal</u> for Hodgkin lymphoma should include the following:

A. History – brief summary of stage with risk factors, treatment, review of symptoms for signs of recurrence or complications from treatment (include negatives), activity level.

B. Physical – thyroid, lung, cardiovascular, lymphoid regions, spleen and liver.

C. Hematology/oncology consult.

D. TSH if RT to mantle region.

E. Labs – CBC, platelets, ESR, and chemistry profile.

# **III. Overview.**

HL (formerly Hodgkin's disease) is a neoplasm of lymphoid tissue that accounts for 12-30% of all malignant lymphomas.¹ It has a bimodal distribution with a peak incidence between 15 and 30 years of age followed by another peak among adults over 55 years old and is more common among males.¹ HL will be diagnosed in approximately 9,000 people in 2014 of which 1,180 will die.² HL is divided into two main types by the World Health Organization classification: nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL) and classical Hodgkin lymphoma (CHL). CHL is further divided into four subtypes: nodular sclerosis, mixed cellularity, lymphocyte-depleted, and lymphocyte-rich. CHL predominates in Western countries (95% of cases).² The nodular sclerosis subtype of CHL is more common among young adults (15-35 years old) whereas NLPHL is more common during the fourth decade of life.¹

CHL is defined histopathologically by the presence of the malignant Reed-Sternberg cell in an inflammatory background of lymphocytes and fibrosis whereas NLPHL is characterized by the presence of lymphocyte-predominant cells (popcorn cells) distinguished by giant cells, which express typical B cell lineage.² Among CHL, nodular sclerosis accounts for 50-80% of cases followed by mixed cellularity (20-30%), lymphocyte-rich (5%) and lymphocyte-depleted (<1%).¹⁻⁵

Common presenting features of CHL include painless lymphadenopathy (usually above the diaphragm), cough, fever, night sweats, and weight loss.⁶ The mediastinum is often involoved.¹ NLPHL most often presents with cervical or axillary lymphadenopathy and is distinguished from CHL in that mediastinal lymph nodes and extranodal organs are rarely involved.¹

Several large studies have demonstrated that a prior history of serologically confirmed infectious mononucleosis (in particular elevated titers of Epstein-Barr virus) confers about a three-fold increased risk for HL in young adults.⁷ Of note, EBV is implicated in 40% of CHL cases, most commonly the mixed cellularity subtype.¹ An increased risk for HL among siblings and close relatives supports a genetic basis for increased susceptibility.⁸

The extent of HL is classified using the four-stage modified Ann Arbor classification. Stage I is involvement of a single lymph node region (I) or extralymphatic site (I_E). Stage II is involvement of two or more lymph node regions (II) or extralymphatic sites (II_E) on the same side of the diaphragm. Stage III is involvement of lymph node regions on both sides of the diaphragm (III) or extralymphatic sites (III_E) [Waldeyer's ring of lymphoid tissue in the oropharynx and the spleen both count as nodal sites]. Stage IV is diffuse or disseminated involvement of one or more extralymphatic organs or tissues. Extranodal/lymphatic sites primarily include bone marrow, liver, lungs and bones. The absence or presence of unfavorable factors such as fever, night sweats, and/or unexplained loss of 10% of more of body weight in the 6 months preceding diagnosis are denoted by the suffix letters A or B, respectively. The classic B symptoms are seen in ~25% and denote widespread or locally extensive disease. Fatigue and pruritus can also be seen in HL.²

The workup of HL should include a thorough history focusing on the presence or absence of B symptoms, alcohol intolerance, pruritus, and fatigue; a focused physical exam of the lymph nodes, spleen and liver; laboratory tests including a CBC with differential, platelets, ESR, LDH, albumin, LFT, renal function, chest x-ray, PET/CT and contrast-enhanced CT. The preferred method for diagnosis is by excisional lymph node biopsy although core needle biopsy may be used. The role of fine-needle aspiration (FNA) is controversial and a negative FNA biopsy does not rule out lymphoma. The use of immunohistochemistry is also recommended.²

Prognosis varies depending primarily on stage of disease and histologic subtype, but Hodgkin lymphoma is now curable in 80% of cases as a result of improved management and treatment.² Nodular lymphocyte-predominate HL has the best prognosis, usually (80%) present as asymptomatic, limited stage disease. Nodular sclerosis usually carries a better prognosis than mixed cellularity, which in turn has a better prognosis than lymphocyte depletion.⁵ With regards to prognosis and treatment, patients are classified into three groups: early-stage favorable (stage I-II with no unfavorable factors); early-stage unfavorable (stage I-II with any unfavorable factors); and advanced-stage disease (stage III-IV).² The International Prognostic Factors Project Score (IPS) is used for risk stratification among patients with advanced-stage HL. This score was based on studies that found that patients with advanced-stage CHL (stage III-IV) experienced reduced survival rates 7-8% per year for each of the following factors: age greater than 45 years, male gender, stage IV disease, albumin <4 g/dL, Hgb < 10.5 g/dL, leukocytosis

(>15,000/mm³), lymphocytopenia (<8% of WBC and/or count <  $600/mm^3$ ).^{1,2} Currently, the overall 5-year survival for HL is 81%.¹ B systemic symptoms, mediastinal mass to largest transthoracic diameter ratio >0.33 and extensive tumor burden (≥10 cm largest diameter of any single mass) are other factors that have been repeatedly documented as poor prognostic factors.²

Treatment for HL may involve radiotherapy, chemotherapy, or both, depending on the subtype (CHL vs. NLPHL), stage of disease, and the IPS score.¹ For CHL, the ABVD (doxorubicin [Adriamycin®], bleomycin, vinblastine, and dacarbazine) and Stanford V (doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin and prednisone) protocols are most commonly used with involved field radiation therapy (RT). Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone) can also be used.² PET/CT imaging is used for monitoring therapy and disease response.^{1,2} For NLPHL, a combination of rituximab, multiagent chemotherapy, such as ABVD, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), or CVP (cyclophosphamide, vincristine, prednisone) plus involved field radiotherapy are used.¹ Stem cell transplantation and immunotherapy has been used in refractory HL with limited success. Monoclonal antibodies are currently in Phase II trials and FDA approved as second-line agents.¹ Generally, individuals with limited-stage disease and nonbulky disease are treated with two cycles of ABVD followed by RT or four cycles of ABVD without RT.⁹ Individuals with advanced-stage disease (III-IV) or with B symptoms in any stage receive ABVD until two cycles beyond achieving complete remission. Individuals with bulky disease and in any stage receive ABVD plus RT. More recent studies have indicated that two cycles of ABVD followed by involved-field, moderate-dose radiation can cure most patients.¹⁰

For early stage favorable HL (stage I-II), the 5 year failure rate for treatment (recurrent disease) is 9%.⁵ For early stage unfavorable disease (stage I-II), the failure rate (relapse) is around 15%.⁵ Relapse after successful treatment in advanced-stage occurs in 30% to 47% and most relapses occur within 4 years; about 10% of all relapses occur beyond 5 years.⁵

Although the likelihood of being "cured" of HL is high, overall expectation of survival is not normal.¹ Long-term follow-up studies show that the cumulative treatment-related mortality rate exceeds that of HL itself in 15 years.⁹ The challenge is holding the potential for long-term toxicity to a minimum while successfully treating the disease initially. MOPP (mustargen, oncovin, procarbazine, and prednisone) is associated with infertility, premature menopause and/or leukemia/myelodysplasia. ABVD has less long-term toxicities and has proven therapeutic efficacy. Anthracyclines (e.g., doxorubicin) are associated with cardiomyopathy, bleomycin with pulmonary fibrosis, and alkylating agents with bone marrow failure. RT-induced second malignancies include non-HL, breast, lung or gastrointestinal cancers. RT treatment to the neck area is associated with hypothyroidism and to the chest with cardiac disease. The practice of RT has improved; smaller fields, PET/CT imaging enhanced RT planning and intensity-modulated radiotherapy (IMRT) allows for better targeting and reduced radiation of uninvolved tissues.⁹

Pregnancy, older age (>50 years old), and HIV infection can complicate care and treatment of HL. Among pregnant women, abdominal ultrasound can be used instead of CT/PET and

treatment can sometimes be delayed until after delivery. Older patients with HL experience poorer treatment outcomes due to the toxic effects of treatment. They do, however, benefit from the use of doxorubicin. According to the literature, HIV patients should receive the same treatment as non-infected patients.¹²

### **IV. Aeromedical Concerns.**

As with most malignancies, aeromedical health concerns of HL are based on the disease and the treatment. With HL, the risk for sudden incapacitation is minimal as disease involvement of the CNS or heart is rare. Although the most common presentation of HL is a superficial nontender mass, initial manifestations rarely may include hemoptysis (intrathoracic involvement) or neurologic symptoms from spinal cord compression. However, the greatest concern arises from the potentially rapid (weeks to months) degradation in mental and physical status when the HL and/or treatment protocol is aggressive. Damage to the cardiopulmonary, neurologic, endocrine, and reticuloendothelial systems may occur as a result of disease progression and/or radiotherapy/chemotherapy. In general, flyers can be returned to flight status once all therapy has been discontinued, adverse effects from therapy have resolved, and any hematologic deficits have normalized.¹³

In the past, the use of bleomycin in aviators would have been permanently disqualifying. This was based on the risk of pulmonary fibrosis with exposure to oxygen. The value of bleomycin in the treatment of malignancies is in part a function of its specific toxicity, since it does not induce bone marrow aplasia, and thus does not add to the toxicity that limits most oncologic drugs. Instead, the principal target organ of bleomycin-induced injury is the lung, with acute pulmonary damage occurring in 6-18% of treated patients. The pathophysiology of delayed toxicity of bleomycin is complex. In the medical literature of the last thirty years, a number of patients have been described who, having previously received bleomycin therapy; have developed pulmonary toxicity when undergoing subsequent surgery. Typically, these have been young individuals receiving modest levels of oxygen (33-42%) during long operations (4-8 hours). The true incidence of such delayed toxicity is unknown, since the subsequent literature has largely consisted of isolated case reports or small series.¹⁴ A more cogent argument can be made that the period of risk is primarily in the first year after therapy, since most cases occurred within that time frame. However, it is equally possible that this observation represents a bias related to the timing of operative intervention.

Applicable data had been non-existent, a state of affairs that has been somewhat altered by unpublished data recently supplied by the Duke Hyperbaric Unit.¹⁴ Although it had been the practice in hyperbaric medicine to avoid hyperoxia in bleomycin-treated individuals, the undoubted benefit from hyperbaric oxygen (HBO) in wound healing and osteonecrosis posed against the uncertain risk of delayed bleomycin toxicity led several years ago to a change in policy. Since then, the Duke unit has treated 11 individuals previously exposed to bleomycin with HBO. There was a wide range of time between the last dose of bleomycin and the institution of HBO, ranging from 1 month to 22 years. The range of cumulative bleomycin doses was not noted. Anywhere from 8 to 44 treatments with 100% oxygen at 2 ATA (PiO2 ~ 1475 mmHg) were administered for two hours per treatment, once or twice daily. One individual

experienced significant chest discomfort and a decline in diffusion capacity of 50%; both resolved following a break in treatment, and she successfully completed HBO treatment with a reduction in frequency of her sessions. While the Duke experience does not represent occupational exposure per se, and the number of individuals treated is small, the amount of oxygen exposure from HBO therapy is far in excess of what would be expected in aviation, and suggests that the risk of delayed toxicity outside the operating room may be minimal.

Based on this data, policy was changed for aviators treated with bleomycin. Those aviators returning to non-high performance aircraft would be evaluated as usual, addressing risks of tumor recurrence and potential toxicity from chemotherapy. Assuming they had not developed bleomycin pneumonitis during therapy, then no restrictions from altitude chamber or other sporadic oxygen exposure is warranted. Because it is possible, and biologically plausible, that the common perception of an increased period of risk within the first year is correct, a grounding period of one year from the end of treatment is required before waiver consideration in high performance aircrew. In most cases, this will coincide with the grounding period already recommended as a result of the disease/chemotherapeutic regimen.

There have been case reports of life-threatening pneumonitis developing in patients with a history of bleomycin-induced lung injury, who were later given supplemental oxygen for surgical procedures. Therefore, aviators who have a history of bleomycin-induced lung injury should not be allowed to return to airframes that require routine use of 100% oxygen. Also, they should be exempted from the portions of the altitude chamber qualification that require 100% oxygen use. Use of 100% oxygen during emergencies such as fire or rapid decompression is acceptable and should not be discouraged.

Aviators treated with anthracyclines (e.g. doxorubicin) are at risk of treatment-induced cardiomyopathy. The aeromedical risk due to poor left ventricular function as a result of anthracycline containing treatment regimens requires demonstration of adequate cardiac function. An echocardiogram or Multi-Gated Acquisition (MUGA) scan may be required to demonstrate adequate cardiac function for consideration of returning an aviator to flying following treatment with anthracyclines.

ICD-9 Codes for Hodgkin lymphoma			
201.4	Hodgkin's disease, lymphocytic-histiocytic predominance		
201.5	Hodgkin's disease, nodular sclerosis		
201.6	Hodgkin's disease, mixed cellularity		
201.7	Hodgkin's disease, lymphocytic-depletion		
201.9	Hodgkin's disease (lymphoma), unspecified		

ICD-10 Codes for Hodgkin lymphoma		
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site	
C81.10	Nodular sclerosis classical Hodgkin lymphoma, unspecified site	
C81.20	Mixed cellularity classical Hodgkin lymphoma, unspecified site	

C81.30	Lymphocytic-depleted classical Hodgkin lymphoma, unspecified site
C81.90	Hodgkin's lymphoma, unspecified, unspecified site

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#### WAIVER GUIDE

Updated: Nov 2016 Supersedes Waiver Guide of Feb 2013 By: Capt Daniel Opris, Dr. Chris Keirns and Lt Col Dara Regn (all from ACS Internal Medicine branch) and Dr Dan Van Syoc Reviewed by Lt Col Roger Wood, AF/SG consultant for Hematology/Oncology

### CONDITION: Leukemia (Nov 2016)

#### I. Waiver Consideration.

A history of leukemia is disqualifying for all classes of flying as well as ATC/GBO and SWA duties. The disease is also disqualifying for retention and requires an MEB. Waiver consideration should be delayed until at least one year following completion of active treatment. The patient must be asymptomatic and in remission off all therapies. Due to the heterogeneity of disease and the multitude of factors affecting prognosis and risk, waivers are evaluated on a case-by-case basis by the ACS. Waiver is unlikely to be granted following allogeneic bone marrow transplant, but ACS case review/evaluation is still recommended.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority	ACS review/evaluation
I/IA	All forms of	Yes#†	Yes
	Leukemia	AETC\$	
II, III, SWA,	All forms of	Yes+*†	Yes
ATC, GBO	Leukemia	AFMRA\$	

#### Table 1: Waiver potential for Leukemia.

# For FC I/IA individual waiver may be considered after 5 years of remission, asymptomatic.

+ For trained FC II, FC III, SWA, ATC, GBO personnel, waiver may be considered 12 months after treatment completion if asymptomatic with confirmed remission.

* For untrained FC II, FC III, ATC, GBO, and SWA personnel, waiver may be considered after 5 years of remission.

† No indefinite waivers

\$ All initial waivers requests will be routed to AFMRA.

AIMWTS review in Sep 2016 revealed a total of 33 cases. Seven cases were disqualified (1 FC I, 4 FC II, 1 FC III, and 1 MOD) and 26 were approved for waivers. Six of the seven disqualified cases were primarily disqualified due to the leukemia diagnosis or issues related to the diagnosis. The other case was disqualified for anthropometric reasons.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations. Ensure that the MEB has been completed prior to submitting the waiver.

The AMS for an initial waiver for leukemia should include the following:

A. History – symptoms, pathology, stage, treatment, including date of last treatment, surveillance plan and activity level.

B. Physical exam – focus on CNS, skin, abdominal and chest exams.

C. Hematology/oncology consults to include the six month and twelve month follow-ups - all consistent with National Comprehensive Cancer Network (NCCN) guidelines for the specific type of leukemia. Also recommended is an objective assessment by the oncologist of the ongoing complications of therapy, evidence of recurrence and recommendations for follow-up. D. Labs – all with dates, including bone marrow biopsy.

E. Imaging studies, if obtained.

F. In patients who received prophylactic CNS radiation, a neurology and psychology review is necessary.

G. Tumor board report, military or civilian, if applicable.

H. Medical evaluation board (MEB) disposition.

The AMS for a waiver renewal for leukemia should include the following:

- A. History interim history since last waiver request to include any recent or planned therapy.
- B. Physical exam see above physical exam elements.

C. Hematology/oncology consults.

D. Labs – all test results since previous waiver.

E. Imaging studies since last waiver, if done.

## **III. Overview.**

The leukemias are a diverse set of neoplastic disorders resulting from mutations resulting in malignant transformation of hematologic cells that are classified according to morphological, immunophenotypic, cytogenetic and molecular features. Malignant transformation results in a single mutant hematopoietic progenitor cell that has lost the ability to inhibit proliferation, and is resistant to apoptosis, thereby resulting in malignant, poorly differentiated hematopoietic precursors.¹

All blood cells (Red Blood Cells (RBCs), Platelets and White Blood Cells (WBCs)) are derived from stem cells and are further separated into two pathways, myeloid or lymphoid. Myeloid stem cells can produce RBCs, platelets or myeloblasts, which are the precursors to granulocytes. Lymphoid stem cells can produce non-granulocyte WBCs. In a person with leukemia, the bone marrow produces abnormal WBCs called leukemia cells and leukemic blast cells. As leukemia cells are resistant to apoptosis, the result is a build-up and crowding out of normal blood cells. This can result in secondary anemia, thrombocytopenia or granulocytopenia.^{1,2} Leukemias are divided into myelogenous or lymphocytic based on the origin of the precursor cell. Myelogenous leukemia, also called myelocytic leukemia, arises from granulocytes or monocytes and lymphocytic leukemia arises from lymphocytes. Each type is further divided into acute or chronic forms of disease.

# ACUTE LEUKEMIAS

The clinical presentation of acute leukemia stems from blast cell infiltration of bone marrow or extramedullary sites. As a result, initial symptoms may be due to the presence of anemia, neutropenia, or thrombocytopenia. Nonspecific complaints including weakness, lethargy, fatigue, dyspnea, fever, weight loss, or bleeding may be the first presenting signs of disease. Hepatosplenomegaly or adenopathy may also result from blast cell infiltration of organs or lymph nodes. Bone marrow infiltration can result in bone pain. Mucosal bleeding, petechiae, ecchymosis, and fundal hemorrhages may occur as a result of thrombocytopenia.^{1, 2}

#### Acute Myelogenous (Myeloid, Myelocytic) Leukemia (AML)

AML is a hematopoietic malignancy leading to the infiltration of blast cells in the marrow and the decreased production of normal blood cells; consequently, anemia, neutropenia and thrombocytopenia develop. AML is the most common acute form of leukemia in adults. It represents 35% of all leukemias in the US and is responsible for about 20% of acute leukemia in children and 80% of adult acute leukemia cases. The median age of adults at diagnosis is 65 and the male:female ratio is nearly 5:3.^{3, 4} There are numerous predisposing factors in the development of AML, including genetic abnormalities, environmental factors, and other hematologic diseases, but most patients have no significant exposure.^{1, 3, 5}

Clinical manifestations of AML result either from the proliferation of leukemic cells or from bone marrow failure that leads to decrease in normal cells (complications of pancytopenia). Common symptoms include weakness, fatigue, pallor, infections, palpitations, dyspnea on exertion, bleeding tendency, and bone pain. Blasts may infiltrate organs or lymph nodes, resulting in adenopathy or hepatosplenomegaly. Palpable splenomegaly and hepatomegaly occur in about one third of patients, with testicular infiltration being less common. Definitive diagnosis of AML typically requires bone marrow aspiration and biopsy.^{5,7}

Treatment with induction therapy includes agents such as daunorubicin, cytarabine, idarubicin and mitoxantrone.^{5, 6} Post-induction treatment utilizes allogeneic/autologous bone marrow transplantation or the use of the consolidation chemotherapy after remission is achieved.⁵ Central nervous system involvement (meningeal) occurs in 2% of cases at the time of presentation. In these cases, CNS treatment is recommended; high-dose or intrathecal therapy is more commonly used than cranial radiation due to less toxicity.² Remission is the more accepted term with AML rather than cure and the remission rates have improved dramatically, but remission, 5-year survival, and cure rates are most dependent on the patient's age and cytogenetic/chromosomal findings when AML occurs.²

#### Acute lymphoblastic leukemia (ALL)

ALL is a malignant condition that is characterized by lymphoblast (from either B or T cell lineage) proliferation in the bone marrow and extramedullary sites or "sanctuaries", such as meninges.² ALL is the most common cancer in children younger than 15 years of age; it occurs mainly in children but any age can be affected. There are many subtypes of this form of leukemia. It represents 12% of all leukemias and 20% of adult leukemias. Males are more commonly affected than females. In most age groups, the incidence of ALL is higher in those of European descent than in those of African descent. Cure rates are 80% for children and less than 40% for adults. The majority of adults treated for ALL with current regimens will relapse.^{7, 8} The disease can lead to anemia, thrombocytopenia, and neutropenia.² No specific cause can be identified in most cases, but there is increased risk associated with patients who underwent antineoplastic treatment or those exposed to ionizing radiation and toxins.⁵

Treatment consists of induction therapy, central nervous system-directed treatment or prophylaxis, and consolidation or maintenance therapy. Induction chemotherapy may include glucocorticoids, conventional chemotherapy, and/or targeted therapy. The central nervous system (CNS) may be a site for relapse as it commonly serves as a sanctuary for leukemic cells. To prevent relapse from a CNS source, treatment targeting the CNS is indicated with the use of systemic and intra-thecal chemotherapy or cranial irradiation. Consolidation or maintenance therapy may include conventional chemotherapy or high dose chemotherapy followed by bone marrow transplantation of an allograft from a matched sibling.^{2, 5} In those patients treated with prophylactic CNS radiation as a child, there is concern about the lifetime risk of neurocognitive difficulties, a second cancer and endocrinopathies, as well as problems with bleeding from intracranial vessels. The approach currently has shifted to a more aggressive intrathecal and systemic chemotherapeutic regimen for CNS therapy.

## **CHRONIC LEUKEMIAS**

Patients with chronic leukemia may have a wide range of physical symptoms and laboratory abnormalities at the time of diagnosis. Due to the progressive accumulation of mature and maturing hematologic cells from dysregulated production and uncontrolled proliferation, the overall infiltrative nature of these diseases can cause lymphadenopathy or organomegaly, to B type symptoms (weight loss, fevers, night sweats, fatigue) or a blast crisis, conditions resembling acute leukemia in which myeloid or lymphoid blasts proliferate in an uncontrolled manner.^{9, 10} An important consideration is the large percentage of patients that are asymptomatic at the time of diagnosis (20-50% for CML), with the disease process being considered following evaluation of routine blood tests with incidental findings.¹⁰

#### Chronic lymphocytic leukemia (CLL)

CLL is a malignant proliferation of small mature looking B-lymphocytes in the vascular and lymphatic systems, as well as in the bone marrow. CLL is considered to be identical to the mature B cell neoplasm small lymphocytic lymphoma (one disease with different manifestations).⁹ CLL is the most common adult leukemia in the western world. In the U.S., male incidence is almost twice that of females, and it comprises 30% of all leukemias. The risk increases with age, occurring mostly in the middle-aged and elderly with a median age of onset of 70 years.⁴ It is a disease of unknown etiology with a long clinical course.

Patients may present with a wide range of symptoms, signs, and laboratory abnormalities when diagnosed with CLL. Symptoms may range from no symptoms to persistent lymphadenopathy, unintentional weight loss, fevers with or without infection, night sweats, and extreme fatigue. Signs of CLL include lymphadenopathy, splenomegaly, hepatomegaly, and skin lesions (leukemia cutis). Laboratory findings show typical lymphocytosis in the peripheral blood and bone marrow, mild to moderate cytopenia of all cell lines, and less commonly, hypogammaglobulinemia.⁹

Not all patients with CLL require immediate treatment due to the variable survival rates based on the disease subset, lack of scientific evidence of improved survivability with early treatment, and a low cure rate with current treatment regimens (except possibly for allogeneic hematopoietic cell transplantation). The current recommendation during the asymptomatic phase of CLL, based on several prospective randomized trials, is to observe and not treat. Immediate treatment is recommended for patients with advanced disease, high tumor burden, severe symptoms, or repeated infections. There is no standardized treatment for CLL although there are several options. Choice of treatment regimen is determined by patient characteristics and treatment goals. Overall survival rates vary with the treatment regimen.¹¹

#### Chronic myelogenous (myelocytic, myelogenous, granulocytic) leukemia (CML)

CML is an acquired malignant disorder that is associated with the presence of the Philadelphia chromosome. It commonly results in anemia, granulocytosis, immature granulocytosis, basophilia, thrombocytosis and splenomegaly. CML comprises 15-20% of all adult leukemia cases, with a slightly higher incidence in males compared to females. The median age at presentation is 53. Exposure to high doses of ionizing radiation is known to be the major risk factor and genetic mutations may be a predisposing factor.¹²

Clinical manifestations of CML depend on the phase of the disease at the time of diagnosis: chronic phase, accelerated phase, or blast crisis. Approximately 20-50% of patients are asymptomatic at the time of diagnosis and clues to the disease are found in the peripheral blood. Symptoms, when present, include fatigue, malaise, weight loss, excessive sweating, bleeding tendency, and abdominal fullness. Laboratory findings in CML include white blood cell counts that can rise to the 100,000 micro/L range with predominance of the neutrophilic cell line. Bone marrow aspiration and biopsy show granulocytic hyperplasia with features consistent with the peripheral blood. Ninety to 95% of CML patients have evidence of the Philadelphia

chromosome. The remainder have the BCR-ABL fusion gene, or its product, BCR-ABL fusion mRNA. Several other medical conditions may mimic CML and must be differentiated to determine the appropriate treatment and prognosis. The strongest predictor of prognosis is the stage at which CML is diagnosed: the chronic phase has a much better prognosis compared to the acute phase or blast crisis.¹⁰

Treatment options include potential cure with allogeneic bone marrow transplant, disease control with tyrosine kinase inhibitors (TKI), and palliative therapy with cytotoxic agents. The treatment of choice for the majority of patients in the chronic phase of CML is a TKI, such as imatinib mesylate. Approximately 8% of patients in the chronic phase are either resistant or intolerant to treatment with imatinib mesylate. Monitoring of residual disease after treatment is a key component in managing patients with CML.^{12, 13} The prognosis for these patients has dramatically improved with TKI use and some studies suggest age-adjusted mortality rates similar to the general population.

#### **OTHER LEUKEMIA SUBTYPES:**

#### Hairy cell leukemia

Hairy cell leukemia is an uncommon neoplastic proliferation of B lymphocytic cells that is similar to CLL but the cell has larger cytoplasm with "hairy projections". It represents 2% of all leukemias. It is now considered to be an indolent non-Hodgkin lymphoma. Its prevalence is higher in males with a male to female ratio of 4:1 with a median age of 52. It is three times more prevalent in Caucasians than African-Americans. Predisposing factors are not completely understood, but possible causes include exposure to ionizing radiation, Epstein-Barr virus, and organic chemicals.¹⁴

Patients with hairy cell leukemia may be asymptomatic or present in various ways including splenomegaly, pallor, ecchymosis, weakness, fatigue, or infections. Diagnostic tests may show a characteristic peripheral blood smear with "hairy cells" (usually < 20% of circulating white cells), hyper or hypo cellularity of the bone marrow (the latter causing fibrosis), and pancytopenia.¹⁴ Asymptomatic individuals do not require immediate treatment and can often be observed. Treatment is initiated when they become symptomatic. The first-line treatment option is cytotoxic chemotherapy with purine analogs such as cladribine (2-CdA) and pentostatin. Other treatment options include splenectomy and interferon.^{15, 16} Life expectancy has greatly improved with this disease; newer therapies have led to overall survival rates greater than 95% at four years.²

#### **IV. Aeromedical Concerns.**

ALL or AML are the most commonly encountered leukemias seen in our active duty aviation personnel. Symptoms of acute leukemia include fatigue, lethargy and malaise and can be associated with infections, anemia and/or hemorrhage (cerebral). Other signs and symptoms may develop as the disease progresses and affects other parts of the body, such as abdominal discomfort due to splenomegaly. Although rare, patients may even require splenectomy

secondary to complications of splenomegaly (spontaneous splenic rupture) which would then present an aviator with an added risk for future development of an overwhelming infection. Disseminated intravascular coagulation is also a common complication of ALL as well as a subset of AML and has the potential for causing incapacitating thrombotic and hemorrhagic events. Of note, leukemic involvement of the central nervous system (CNS) at the time of diagnosis is an uncommon finding in AML and ALL. However, CNS preventive therapy with craniospinal radiotherapy or intrathecal chemotherapy may be incorporated into a patient's treatment protocol, particularly for ALL patients. As described above in the ALL subsection overview, CNS radiation has been associated with a number of aeromedically significant long-term complications.

Treatment regimens, both chemotherapeutic and CNS irradiation, for virtually all types of leukemia can have a multitude of side effects and complications that degrade performance and safety; in general, radiation therapy has a limited role in the treatment of most forms of leukemia.¹⁷ Importantly, active leukemia of any type or ongoing therapy is not compatible with flying duties and will not be considered for a waiver.

ICD-9 codes for leukemia				
204-208 (range)	All leukemias			
204	Lymphoid leukemias			
205	Myeloid leukemias			
206	Monocytic leukemias			
207	Other specified leukemias			
208	Leukemia NOS			
204.0	Acute lymphoblastic leukemia			
205.0	Acute myelogenous leukemia			
204.1	Chronic lymphocytic leukemia			
201.1	Chronic myelogenous leukemia			
202.4	Hairy cell leukemia			

ICD-10 codes for leu	kemia			
C91.91	Lymphoid leukemia, unspecified, in			
	remission			
C92.91	Myeloid leukemia, unspecified, in			
	remission			
C93.91	Monocytic leukemia, unspecified, in			
	remission			
C94.81	Other specific leukemias, in remission			
C95.91	Leukemia, unspecified, in remission			
C91.11	Chronic lymphocytic leukemia of B-			
	cell type in remission			
C92.11	Chronic myeloid leukemia,			
	BCR/ABL-positive, in remission			
C91.41	Hairy cell leukemia, in remission			

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#### WAIVER GUIDE

Updated: Apr 2016 Supersedes Waiver Guide of Jul 2015 By: Capt Laura Bridge (ACS Internal Medicine), Dr Christopher Keirns (ACS Internal Medicine), and Dr Dan Van Syoc Reviewed by: Lt Col Jeffrey Bidinger, AF/SG consultant for Dermatology

#### CONDITION: Malignant Melanoma (Apr 2016)

#### I. Waiver Considerations

History of melanoma is disqualifying for all flying classes; as all malignancies require an MEB. The table below outlines the waiver potential for flying class (FC) I/IA, II, and III based on AJCC melanoma staging system.

Flying Class	Melanoma Stage	Waiver Potential	ACS
	Including History of	Waiver Authority‡	<b>Review/Evaluation</b>
I/IA	0	Maybe#† AETC	No
	IA, IB, IIA, IIB, IIC, IIIA, IIIB, IIIC, IV	No AETC	No
II (pilot)	0, IA, IB	Yes† MAJCOM‡	Yes (Stage IA, IB)
	IIA, IIB, IIIA	Maybe* MAJCOM‡	Yes
	IIC, IIIB, IIIC, IV	No MAJCOM‡	No
II (non-pilot) III ATC	0, IA, IB	Yes†\$ MAJCOM‡	Yes (Stage IA, IB)
GBO SWA	IIA, IIB, IIIA, IIC, IIIB, IIIC	Maybe* MAJCOM‡	Yes
	IV	No MAJCOM‡	No

Table 1: Waiver potential based on flying class and melanoma stage.

# Waiver may be considered if no risk factors such as history of dysplastic nevus syndrome (greater than 50 atypical nevi, family history of atypical nevi and family history of melanoma) are present.

[†] Waiver may be considered by waiver authority 6-months post-completion of definitive treatments. No indefinite waivers will be granted except for Stage 0.

\$ Waiver in untrained FC II/III/ATC/GBO/SWA personnel with stage 0, stage IA, or stage IB melanoma may be considered after member has been disease free for three years if no risk factors such as history of dysplastic nevus syndrome (greater than 50 atypical nevi, family history of atypical nevi and family history of melanoma) are present. * Waiver may be considered by waiver authority three years post-completion of definitive treatments, if clinically stable with no evidence of local or distant recurrence.

‡ For all except FC I/IA, AFMRA is the initial waiver authority for malignant neoplasms.

All waivered cases require close follow-up for life, at intervals recommended by the evaluating dermatologist or oncologist, at least annually.

AIMWTS review through Feb 2016 revealed 324 cases of melanoma. Breakdown of these cases revealed: 6 FC I/IA cases (3 disqualified), 209 FC II cases (14 disqualified), 80 FC III cases (11 disqualified), 8 ATC/GBC cases (no disqualifications), and 20 MOD cases (1 disqualified). Of these, 286 (91%) received waivers and 29 (9%) were disqualified; the vast majority approved were Stage 0 or IA.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial waiver</u> should include the following:

A. History – summary of disease course, risk factors, review of systems, and activity level.

B. Physical - special attention to skin and lymph nodes. Need to also exam fundus and conjunctiva.

C. Dermatological consultation (and oncology/surgery consultation if indicated), with specific comments regarding work-up to rule-out metastatic disease.

D. Pathology report, specifically indicating histologic diagnosis of melanoma, presence or absence of tumor ulceration, and tumor thickness (AJCC melanoma staging system).

E. Confirmation of histology, ulceration, and thickness by AFIP or a DoD accredited dermatopathologist, with a copy of report attached.

F. Copies of all laboratory studies, radiological studies, and any other studies.

G. Statement that incision site does not interfere with flying duties and wearing of aircrew flying and life-support equipment.

H. Medical evaluation board (MEB) report.

I. Outline plan for follow-up.

The AMS for waiver renewal should include the following:

A. History – AJCC melanoma staging, interval frequency and results, and review of systems.

B. Physical – skin and lymph node. Need to also exam fundus and conjunctiva.

C. Dermatology consult to include follow-up plan.

# III. Overview.

Melanoma accounts for just 7% of all dermatological cancers and it is curable in early stages, but it causes 73-80% of all deaths from skin cancer.^{1, 2} According to recent data, melanoma is the fifth and sixth most common new cancer diagnosis among men and women in the United States, respectively. In 2014, there were 76,100 new cases of melanoma diagnosed and 9,710 deaths (1.7% of all cancer-related deaths) in the United States.³ It is also the second leading cause of lost productive years among cancers.⁴ The incidence of melanoma include family history of melanoma, fair skin, light eyes, red or blonde hair, a predisposition to sunburns, history of extensive sunlight exposure, a history of at least one episode of a severe sunburn before the age of 18 (two- to three-fold increase in risk), a greater number of common nevi, dense freckling, immunosuppression, and advancing age.³ Melanoma is of particular concern in the aviator population because it is one of the few malignancies that is often diagnosed in young and middle-aged persons. In fact, the incidence of cutaneous melanoma among middle-aged adults increased over the last forty years.⁵

Melanoma is the 3rd leading cause of brain metastasis after lung and breast cancer. Older studies suggested an approximately 13-20% risk of brain metastasis as first site of recurrence among those who eventually relapse.^{6,7} However, a more recent, prospective study of 900 melanoma patients found only a 10% incidence of brain metastasis over the period of the study (Aug 2002-Oct 2008).⁸ Similarly, another retrospective review of the medical records of 211 patients who experienced a first recurrence of melanoma after definitive treatment of the initial malignancy demonstrated that 8% presented with the brain as the initial site of involvement.⁹ In a study of 81 individuals with brain metastasis.¹⁰ In another study of 702 individuals with clinically significant brain metastasis, initial presentation included 39% with focal neurological symptoms, 13% with seizures, 3% with neurological catastrophes, and 2% with behavioral changes, all of which are of major concern in flight.¹¹

Screening for melanoma in high-risk individuals in the primary care setting is considered cost effective and results in earlier diagnosis, which correlates with improved survival.¹² Clinical features used to screen for melanoma include mole **a**symmetry, **b**order irregularity or poor definition, **c**olor variation, **d**iameter larger than 6 mm, and **e**volving features (the ABCDEs). Suspicion is raised when a lesion appears different from other moles or undergoes changes, such as increasing size, asymmetric growth, an irregular pigment pattern or network, development of white, gray, or black areas, bleeding, itching or tenderness within the pigmented lesion.³

Excisional biopsy of the entire suspicious lesion should be performed and tissue submitted to pathology. It is of paramount importance to excise the lesion in its entirety and avoid bisecting any suspicious nevus so that an adequate depth can be assessed on pathologic analysis.³ After melanoma is histologically confirmed, pathologic staging determines prognosis and treatment. The most powerful negative predictors of survival are greater thickness of the lesion, presence of ulceration, and high mitotic index.^{13, 14, 15, 16} Other important factors include microsatellite instability, in-transit metastasis, lymph node involvement, and distant metastasis.^{16, 17} Additional factors that are generally associated with a worse prognosis but are of less certain significance include anatomic site (trunk location worse than extremities), male gender, histologic subtype, presence of lymphovascular invasion or perineural invasion, and regression of the primary tumor. The presence of tumor-infiltrating lymphocytes shows potentially better survival outcomes.¹⁶ If multiple primary melanomas are present, staging is classified according to the primary lesion demonstrating the worst prognostic features.¹⁸ The characteristics of the primary lesion that are more likely to be associated with CNS metastasis are location of the primary lesion in the mucosal, head, neck or trunk area, acral lentiginous or nodular histologic subtypes, presence of lymph node involvement, or metastatic spread to the viscera.¹¹

The 2009 American Joint Committee on Cancer Staging System (AJCC) for Melanoma reflects that the histological features of primary melanoma (thickness, mitotic rate, and ulceration) are important hallmarks for prognosis and staging.^{13, 19}

#### Table 2: TNM, Clinical and Pathologic Staging¹³

Classification	Thickness (mm)	Ulceration Status/Mitoses								
Т										
Tis	NA	NA	Table 2	Anatomio	Stage Grou	uninge f	or Cut	noous M	Volanom	_
T1 ≤ 1.00		a: Without ulceration and mitosis < 1/mm ²								
		b: With ulceration or			inical Stagir	0			ologic Sta	0 0
T2	1.01-2.00	mitoses ≥ 1/mm ² a: Without ulceration		Т	Ν	Μ		Т	Ν	M
12	1.01-2.00	b: With ulceration	0	Tis	NO	MO	0	Tis	NO	M
T3	2.01-4.00	a: Without ulceration	IA IA	T1a	NO	M0	IA	T1a	N0	M
11 C		b: With ulceration	IB	T1b	NO	MO	IB	T1b	NO	M
T4	> 4.00	a: Without ulceration		T2a	NO	MO		T2a	NO	M
		b: With ulceration	AII IIA	T2b	NO	M0	IIA	T2b	N0	M
N	No. of Metastatic Nodes	Nodal Metastatic Burden	1	ТЗа	NO	M0		ТЗа	N0	M
			IIB	T3b	NO	MO	IIB	T3b	NO	M
NO	0	NA	1000 CC	T4a	NO	MO		T4a	NO	M
N1	1	a: Micrometastasis*	IIC	T4b	NO	M0	IIC	T4b	N0	M
		b: Macrometastasis†	111	Any T	N > N0	MO	IIIA.	T1-4a	N1a	M
N2 2-3	a: Micrometastasis*						T1-4a	N2a	M	
	b: Macrometastasis†					IIIB	T1-4b	N1a	M	
	c: In transit metastases/satellites without metastatic nodes						T1-4b	N2a	M	
N3	4+ metastatic nodes, or							T1-4a	N1b	M
	matted nodes, or in							T1-4a	N2b	M
	transit							T1-4a	N2c	M
	metastases/satellites with metastatic nodes						IIIC	T1-4b	N1b	M
М		Serum LDH						T1-4b	N2b	M
IVI	Site	Serum LDH						T1-4b	N2c	M
MO	No distant metastases	NA						Any T	N3	M
M1a	Distant skin, subcutaneous, or nodal metastases	Normal	IV	Any T	Any N	M1	IV	Any T	Any N	Μ
M1b	Lung metastases	Normal	*Clinical stagin							
M1c	All other visceral metastases	Normal	radiologic evalu complete excis	ion of the	primary m					
	Any distant metastasis	Elevated	regional and dis †Pathologic st			etaging	of the	nriman	melano	mala
Micrometas	s: NA, not applicable; LDH, la tases are diagnosed after se stases are defined as clinic		pathologic inform node biopsy) or patients are the lymph nodes.	nation abor complete	ut the regio lymphaden	nal lymr ectomy	oh node . Patho	es after p logic sta	, bartial (ie, age 0 or s	senti stage

The primary treatment for all melanomas is wide local excision. Sentinel lymph node biopsy is recommended in any melanoma with high risk features for improved prognostic staging and to guide additional therapy.³ Systemic adjuvant therapy remains a treatment option for metastatic disease. This includes cytotoxic chemotherapy, immunotherapy, or the combination of both. However, some of these drugs convey significant risk of toxicity with unclear survival benefit.²⁰

# **IV. Aeromedical Concerns.**

Aeromedical concerns in the case of treated malignant melanoma center on both the risk of an inflight incapacitating event and the risk of subtle performance decrement resulting from a recurrence of disease affecting the CNS. Other factors that must be considered prior to granting a waiver include the impact of surgical wounds, scars, or skin grafts on range of motion and proper/comfortable fit of flying/life support equipment.

ICD-9 code for Malignant Melanoma			
172 Malignant melanoma of the skin			
ICD-10 codes for Malignant Melanoma			
ICD IC COUCS			

D03.9 Melanoma in situ
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Updated: Feb 2017 Supersedes Waiver Guide of Aug 2013 By: Lt Col Cindy Harris Graessle (RAM 17) and Dr. Dan Van Syoc Reviewed by Lt Col Roger Wood, AF/SG consultant for Hematology/Oncology

# CONDITION: Non-Hodgkin's Lymphoma (Feb 2017)

#### I. Waiver Considerations.

History of Non-Hodgkin's lymphoma (NHL) is disqualifying for all flying classes in the US Air Force, as well as for ATC/GBC and MOD personnel, and like all malignancies, will require MEB action.

Flying Class (FC)	Condition	Waiver Potential	ACS
		Waiver Authority	review/evaluation
I/IA	All stages	Maybe*+	Maybe†
		AETC	
II/III	All stages	Yes*#+	Yes†
		AFMRA	
ATC, GBO and SWA	All stages	Yes*#+	At the discretion of
	_	AFMRA	the waiver authority

#### Table 1: Waiver potential for Non-Hodgkin's Lymphoma

* FC I/IA candidates, as well as untrained FC II, FC III, GBO, SWA, and ATC; waiver may be considered five years after completion of treatment if asymptomatic and in full remission with a favorable prognosis.

# For trained FC II, FC III, ATC, GBO, and SWA individuals only, waiver may be considered six months after completion of treatment if asymptomatic and in full remission; the <u>exception</u> is for fighter aircrew who need to wait 12 months prior to waiver consideration if they received bleomycin, otherwise 6 months.

+ No indefinite waivers will be granted.

[†] For high performance (routine use of aviator mask while flying) individuals treated with bleomycin, <u>will no longer</u> require an ACS evaluation unless problems arise and the evaluation is requested by the waiver authority.

AIMWTS review in Nov 2016 revealed a total of 46 cases. Breakdown of the cases was as follows: 5 FC I/IA cases (2 disqualified); 21 FC II cases (6 disqualified); 1 RPA case (0 disqualified); 13 FC III cases (4 disqualified); 4 ATC/GBC cases (0 disqualified); and 2 MOD cases (1 disqualified), for a total of 13 disqualified cases, most which were due to the NHL diagnoses.

# II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial waiver</u> for NHL should include the following:

A. History – initial symptoms, pathology, stage, treatment, surveillance plan, and activity level. History should also emphasize past personal or family history of malignancy, radiotherapy, chemotherapy, connective tissue disease, or immune-suppression.

B. Physical exam.

C. Hematology/oncology reports to include all follow-up studies consistent with current guidelines in National Cancer Comprehensive Network (NCCN).⁶

D. Lab/Rad –CBC, peripheral smear, serum creatinine, Complete metabolic panel, hepatitis panel and HIV serology. Serum beta-2 microglobulin levels for individuals with indolent NHL and serum protein electrophoresis for individuals with small lymphocytic lymphoma. Submit bone marrow and CSF studies if clinically indicated and obtained. Chest x-ray and any other imaging studies to include CT, endoscopic photographs, and PET scans should be provided. Submit echocardiogram or MUGA scan studies if the individual is treated with anthracycline containing regimens. Submit completed pulmonary function studies (any additional PFTs will be done in conjunction with the ACS evaluation).

E. Tumor board report, military or civilian, if applicable.

F. Medical evaluation board results (MEB).

The AMS of <u>waiver renewal</u> of NHL should include the following:

A. History – brief summary of stage, treatment, frequency of surveillance with results, symptoms, and activity level.

B. Physical exam.

C. Hematology/oncology consultation reports.

D. Lab/Rad – CBC, peripheral smear, complete metabolic panel, beta-2 microglobulin, and serum protein electrophoresis as clinically indicated.

E. All treatments and follow-up consistent with current guidelines in the NCCN.⁶

F. Any RILO summaries associated with persistent Assignment Limitation Codes.

# **III. Overview.**

NHL is a diverse group of lymphoid malignancies and can range from aggressive to more indolent in behavior. More recent classifications have taken into account genetic information as well as cell morphology to better characterize the behavior of these neoplasms in individual patients. Additionally, it is also recognized that there is a continuum between leukemias and lymphomas and that they can represent the same disease entity.¹ There is an estimated 1 in 47 lifetime risk of being diagnosed with NHL, with approximately 75% of cases diagnosed at age 75 or older. While the incidence of the disease has been increasing, so has the efficacy of the therapies, imparting a 5 year survival rate of 68.1%.²

Abnormal immunologic status, certain viruses and bacteria, occupational exposures, and history of prior lymphoma have all been attributed to an increased risk of NHL. Presentation can include fever, weight loss, and sweats (B symptoms). Often, a patient will be asymptomatic except for an enlarging lymphatic mass.

The physical examination of individuals with suspected NHL should be directed at all lymphoid tissue sites and include special attention to the liver and spleen. Initial laboratory evaluation should include CBC, peripheral smear, complete metabolic panel, protein electrophoresis, hepatitis, and

HIV serology. Beta-2 microglobulin and bone marrow aspirate and biopsy should be obtained if indicated. Cerebrospinal Fluid (CSF) studies may also be indicated in the evaluation of CNS NHL. Biopsy tissue confirmation is essential for definitive diagnosis and therapy.

Initial imaging should include chest x-ray and computed tomography of the chest, abdomen, and pelvis. MRI of the brain is indicated for evaluation of CNS NHL. Positron emission tomography (PET) scanning may be helpful in determining the location of NHL and for monitoring treatment response.

The Ann Arbor Staging System with the Cotswold modifications is the standard for staging of NHL. Treatment is driven not only by staging, but also by molecular genetic factors and individual response to therapy.³

Stage	Area of Involvement
Ι	Single lymph node group
II	Multiple lymph node groups on same side of diaphragm
III	Multiple lymph node groups on both sides of diaphragm
IV	Multiple extranodal sites or lymph nodes and extranodal disease
X	Bulk > 10cm
Е	Extranodal extension or single isolated site of extranodal disease
A (not present)/B (present)	B symptoms: weight loss $> 10\%$ , fever, drenching night sweats

Table 2: Cotswold Modification of Ann Arbor Staging System⁴

Treatment principles take into account the heterogeneous nature of NHL, cell cycle control, drug resistance, and dose intensity. Treatment regimens vary widely from radiation only for indolent early stage disease to aggressive multi-drug regimens with bone marrow transplant for more aggressive NHL. A common feature of current treatment regimens is the use of rituximab. Rituximab is an anti-human CD20 monoclonal antibody that increases the efficacy of other chemotherapeutic regimens but can also be used as monotherapy.⁵ Newer therapies have changed the prognosis of NHL and future prognostic indices will likely be highly individualized. The most up to date treatment guidelines are detailed in the National Cancer Comprehensive Network Clinical Practice Guidelines in Oncology (NCCN).⁶

# **IV. Aeromedical Concerns.**

As with most malignancies, aeromedical concerns of NHL are based on the disease as well as the treatment regimen. With NHL, the risk for sudden incapacitation is minimal as disease involvement of the CNS or heart is rare. Although the most common presentation of NHL is peripheral lymphadenopathy, initial manifestations rarely may include neurologic symptoms from central nervous system involvement or spinal cord compression.

NHL survivors who received chemotherapy have the potential to suffer adverse consequences in relation to their work life and have poor perceptions of their health compared to peers as long as 5 to 15 years after completion of therapy.⁷ They can also suffer from excess fatigue as long as 10 years after diagnosis. The source of this fatigue is multi-factorial and cannot be attributed solely to mode of treatment.⁸ Although treatment regimens can be potentially neurotoxic, there is some

evidence that the long term neuropsychiatric sequelae are minimal.⁹ NHL survivors are at higher risk for second malignancies. This increased risk is likely related to therapy, but genetic predisposition and environmental exposures may also be involved.¹⁰ NCCN follow-up guidelines take into account this increased risk.

In the past, the use of bleomycin in aviators would have been permanently disqualifying. This was based on the risk of pulmonary fibrosis with exposure to oxygen. The value of bleomycin in the treatment of malignancies is in part a function of its specific toxicity, since it does not induce bone marrow aplasia, and thus does not add to the toxicity that limits most oncologic drugs. Instead, the principal target organ of bleomycin-induced injury is the lung, with acute pulmonary damage occurring in 6-18% of treated patients. The pathophysiology of delayed toxicity of bleomycin is complex. In the medical literature of the last thirty years, a number of patients have been described who, having previously received bleomycin therapy; have developed pulmonary toxicity when undergoing subsequent surgery. Typically, these have been young individuals receiving modest levels of oxygen (33-42%) during long operations (4-8 hours). The true incidence of such delayed toxicity is unknown, since the subsequent literature has largely consisted of isolated case reports or small series.¹¹ A more cogent argument can be made that the period of risk is primarily in the first year after therapy, since most cases occurred within that time frame. However, it is equally possible that this observation represents a bias related to the timing of operative intervention.

Applicable data had been non-existent, a state of affairs that has been somewhat altered by unpublished data recently supplied by the Duke Hyperbaric Unit.¹¹ Although it had been the practice in hyperbaric medicine to avoid hyperoxia in bleomycin-treated individuals, the undoubted benefit from hyperbaric oxygen (HBO) in wound healing and osteonecrosis posed against the uncertain risk of delayed bleomycin toxicity led several years ago to a change in policy. Since then, the Duke unit has treated 11 individuals previously exposed to bleomycin with HBO. There was a wide range of time between the last dose of bleomycin and the institution of HBO, ranging from 1 month to 22 years. The range of cumulative bleomycin doses was not noted. Anywhere from 8 to 44 treatments with 100% oxygen at 2 ATA ( $PiO2 \sim 1475 \text{ mmHg}$ ) were administered for two hours per treatment, once or twice daily. One individual experienced significant chest discomfort and a decline in diffusion capacity of 50%; both resolved following a break in treatment, and she successfully completed HBO treatment with a reduction in frequency of her sessions. While the Duke experience does not represent occupational exposure per se, and the number of individuals treated is small, the amount of oxygen exposure from HBO therapy is far in excess of what would be expected in aviation, suggesting that the risk of delayed toxicity outside the operating room may be minimal^{12, 13}.

Based on this data, policy was changed for aviators treated with bleomycin. Those aviators returning to non-high performance aircraft would be evaluated as usual, addressing risks of tumor recurrence and potential toxicity from chemotherapy. Assuming they had not developed bleomycin pneumonitis during therapy, then no restrictions from altitude chamber or other sporadic oxygen exposure is warranted. Because it is possible, and biologically plausible, that the common perception of an increased period of risk within the first year is correct, a grounding period of one year from the end of treatment is required before waiver consideration in high performance aircrew. In most cases, this will coincide with the grounding period already recommended as a result of the disease/chemotherapeutic regimen.

There have been case reports of life-threatening pneumonitis developing in patients with a history of bleomycin-induced lung injury, who were later given supplemental oxygen for surgical procedures. Therefore, aviators who have a history of bleomycin-induced lung injury should not be allowed to return to airframes that require routine use of 100% oxygen. Also, they should be recommended for medical exemption from the portions of the altitude chamber qualification that require 100% oxygen use (in coordination with AOP, A3 and training) from the portions of the altitude chamber qualification that require 100% oxygen use. Use of 100% oxygen during emergencies such as fire or rapid decompression is acceptable and should not be discouraged.

Aviators treated with anthracyclines (e.g. Adriamycin) are at risk of treatment induced cardiomyopathy. The aeromedical risk due to poor left ventricular function as a result of anthracycline-containing treatment regimens requires demonstration of adequate cardiac function. An echocardiogram or Multi-Gated Acquisition (MUGA) scan may be required to demonstrate adequate cardiac function for consideration of returning an aviator to flying following treatment with anthracyclines.⁶

ICD-9 Code	Type of Non-Hodgkin's Lymphoma
202.8	Lymphoma (malignant)
204.9	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
	(CSLL-1)
202.0	Follicular Lymphoma
200.3	Gastric MALT Lymphoma (MALT-1)
200.3	Non-gastric MALT Lymphoma (NGMLT-1)
200.3	Nodal Marginal Zone Lymphoma (NODE-1)
200.3	Splenic Marginal Zone Lymphoma (SPLN-1)
200.4	Mantle Cell Lymphoma (MANT-1)
200.7	Diffuse Large B-Cell Lymphoma (BCEL-1)
200.2	Burkitt's Lymphoma (BURK-1)
200.1	Lymphoblastic Lymphoma (BLAST-1)
202.7	Peripheral T-Cell Lymphoma (TCEL-1)
202.1/202.2	Mycosis Fungoides/Sezary Syndrome (MFSS-1)
200.5	Primary CNS Lymphoma

ICD-10 Code	Type of Non-Hodgkin's Lymphoma	
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site	
C91.90	Lymphoid leukemia, unspecified not having achieved remission	
C82.80	Other types of follicular lymphoma, unspecified site	
C83.80	Other non-follicular lymphoma, unspecified	
C83.87	Other non-follicular lymphoma, spleen	
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites	
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated	
	lymphoid tissue (MALT-lymphoma)	
C83.10	Mantle Cell Lymphoma, unspecified site	
C83.39	Diffuse large B-cell lymphoma, extranodal & solid organ sites	
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites	
C83.70	Burkitt's lymphoma, unspecified site	
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site	
C84.40	Peripheral T-cell lymphoma, not classified, unspecified site	
C84.00	Mycosis fungoides, unspecified site	
C84.10	Sezary disease, unspecified site	

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# WAIVER GUIDE Updated: Aug 2016 Supersedes Waiver Guide of Mar 2012 By: Lt Col Bryant Martin (RAM 2017) and Dr Dan Van Syoc Reviewed by Lt Col Irene Folaron, AF/SG consultant for Endocrinology

# **CONDITION: Pituitary Tumors (Aug 2016)**

# I. Waiver Consideration.

All pituitary tumors, whether benign or malignant, are disqualifying for all flying classes, ATC, GBO and SWA duties, as well as retention. The severity of the condition, the medications required to control the condition and/or complications/results of surgery impact the waiver decision-making process.

Flying	Condition	Waiver Potential	ACS
Class		Waiver Authority	review/evaluation
I/IA	Incidental microadenomas, non- functional, unchanged for 2 years	Yes AETC	Yes
	Nonfunctioning micro or macroadenomas treated with surgery and requiring no pharmacotherapy	Maybe AETC	Yes
	Secreting microadenoma or macroadenoma treated with or	No AETC	No
	<ul><li>without pharmacotherapy or treated with surgery and requiring pharmacotherapy</li><li>Pituitary carcinoma</li></ul>	No AETC	No
II//III ATC GBO	Microadenomas, non-functional	Yes MAJCOM	Yes
SWA	Secreting prolactinoma, asymptomatic requiring no pharmacotherapy	Yes* AFMRA	Yes
	Micro or macroadenomas treated with surgery, in remission and	Maybe* AFMRA	Yes
	requiring no pharmacotherapy Micro or macroadenomas treated with or without surgery and	No AFMRA	No†
	requiring pharmacotherapy Pituitary carcinoma	No AFMRA	No

Table 1. Waiver potential for pituitary tumors.

* Waiver for untrained FC II and III is unlikely.

† If pharmacotherapy is stopped after an interval (12-24 months) and remission is maintained for six months, waiver will be considered after ACS review.

AIMWTS search in Jun 2016 revealed a total of 58 individuals with a diagnosis of a pituitary tumor. There were a total of 11 disqualifications. Breakdown of the cases was as follows: 4 FC I/IA cases (4 disqualifications), 29 FC II cases (1 disqualification), 19 FC III cases (4 disqualifications), 4 ATC/GBC cases (2 disqualifications), and 2 MOD cases (0 disqualifications. All 11 disqualified cases were related to the pituitary diagnosis.

# II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial waiver</u> should include the following:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. Thorough history and physical to identify possible endocrinologic, neurologic, or

ophthalmologic clinical findings with directed evaluation based on findings.

C. MRI of pituitary or CT if unable to perform MRI.

D. Serum PRL level for all pituitary tumors.

E. Endocrinology consult to include need for further hormonal evaluation and management.

F. Neurosurgery consult for evaluation for surgery on any pituitary tumor other than prolactinoma or incidentaloma, or any pituitary tumor with suspected mass effect.

G. Baseline formal visual field testing (Humphrey visual field 30-2), acuity, and dilated

funduscopic exam. If surgery is performed, then repeat testing afterwards.

H. Echocardiogram in GH secreting pituitary adenoma.

I. MEB results.

Note: If steroids are temporarily required after treatment of ACTH pituitary adenoma, see waiver guide on systemic glucocorticoid (steroid) treatment.

The AMS for <u>waiver renewal</u> for pituitary tumor should include the following:

A. History – brief summary of initial work-up, interval signs or symptoms including pertinent negatives.

B. Physical – complete with focus on previous findings.

C. MRI/CT of pituitary annually for first two years, then every two years if stable.

D. Endocrinology consult.

E. Formal visual field testing and acuity testing annually for macroadenomas (not needed if a macroprolactinoma and has responded to therapy), history of surgery/radiation therapy, or increase in tumor size, and more frequently as indicated for any visual complaints.

# **III. Overview.**

Pituitary tumors represent 15% of all primary intracranial tumors and are derived from hormonesecreting adenohypophyseal cells.¹ Primary pituitary tumors are either adenomas or carcinomas. Fortunately, pituitary carcinomas are exceedingly rare with an incidence of less than 0.5% of symptomatic lesions.^{2, 3} Pituitary adenomas are benign anterior pituitary lobe neoplasms that comprise over 90% of pituitary tumors. The annual incidence of pituitary adenoma traditionally has been reported as approximately 1 in 10,000.⁴ However, the prevalence of pituitary adenomas was 16.7% on a recent meta-analysis of autopsy (14.4%) and radiological (22.5%) data.⁵ A more recent study of a population in the UK showed a prevalence of 77.6 per 100,000.^{6,7}

Pituitary adenomas are the most common cause of sellar masses from the third decade on, accounting for up to 10 percent of all intracranial neoplasms.⁸ They are classified by their size and

hormone secreted. Microadenomas are less than 10 mm and macroadenomas are 10 mm or greater.^{9, 10} The five types based on hormone secretion are lactotroph (prolactin [PRL]), gonadotroph (nonfunctioning), somatotroph (growth hormone [GH]), corticotroph (adrenocorticotropic hormone [ACTH]), and thyrotroph (thyroid-stimulating hormone [TSH]). Some pituitary adenomas have multiple hormones released, such as PRL/GH and LH/FSH/TSH.¹ Approximate frequency of adenomas are PRL (35%), nonfunctioning (30%), GH (20%), PRL/GH (7%), ACTH (7%), and LH/FSH/TSH (1%), and TSH (<1%).^{11, 12}

Prolactinoma (lactotroph adenoma), the most common category causes hyperprolactinemia. Common signs and symptoms are amenorrhea/oligomenorrhea with anovulation, galactorrhea, and infertility in females and impotence, infertility, and diminished libido in men.^{13, 14, 15} Gonadotrophs, nonfunctioning adenomas, are the most common macroadenomas due to the late presentation of symptoms secondary to local mass effects.¹⁶ Typical findings would include headache, visual field defects (classically bitemporal hemianopsia from optic chiasm compression), diplopia, hypopituitarism, and hypogonadism.⁴ Although all types of adenomas can present with mass effect findings, primary secretory hormone types usually will present with their hormonal based symptoms earlier. Somatotroph produces hypersecretion of GH and the liver secretes insulin-like growth factor-1 (IGF-1) in response to the GH, which leads to acromegaly in adults. Physical findings include coarse facial features, acral enlargement, prognathism, hirsutism, and osteoarthritis.¹⁷ Corticotrophs produce ACTH, which act on the adrenal gland and lead to hypercortisolemia, also known as Cushing's disease. Most are diagnosed as microadenomas secondary to relatively early clinical findings of truncal obesity, facial plethora, acne, hirsutism, striae, hypertension, osteopenia and muscle weakness.⁴ Thyrotrophs produce TSH, which act on the thyroid gland and cause hyperthyroidism. The clinical findings are goiter, visual impairment, and thyrotoxicosis.¹²

The evaluation of pituitary adenomas involves endocrinological, neurological, ophthalmological, and radiological considerations. The evaluation is driven by clinical findings discussed previously and appropriate screening tests looking for hyposecretion or hypersecretion of related hormones to support clinical findings. These screening tests are summarized in Table 1.^{1, 12}

Condition	Test	Comments
Acromegaly	IGF-I.	Interpret IGF-I relative to age- and gender- matched controls.
Prolactinoma	Serum PRL level	Exclude medications. Magnetic resonance imaging (MRI) of the sella should be ordered if PRL levels elevated.
	24-hr urinary free cortisol.	Ensure urine collection is total and accurate.
Cushing's disease	Dexamethasone (1 mg) at 11 pm and fasting plasma cortisol measured at 8 am.	Normal subjects suppress to $<1.8 \ \mu g/dL$ (sensitivity of 95%). Other cut-offs such as $<$ 3-5ug/dL are used at the expense of sensitivity.
	Late-night Salivary cortisol test. ¹⁸	Normal subjects should be < 145 ng/dL or reference range
Hyperthyroidism	Serum TSH and free thyroxine (T4) levels.	Normal to elevated TSH and elevated free T4 levels.

Table 2. Screening tests for functional pituitary adenomas.³¹

For radiological evaluation of the pituitary, high resolution T-1 weighted MRI in coronal and sagittal planes with and without gadolinium is the gold standard.¹ However, the increasing resolution and availability of MRI and CT in brain imaging has spawned more incidental findings of pituitary tumors (incidentalomas) with these asymptomatic lesions present in 10% of the general population.^{19, 20} The majority of these lesions are microadenoma; in two years of follow-up only two percent showed enlargement as compared to about a third of macroadenomas.²¹ In asymptomatic patients, a single assay for PRL is usually sufficient for hormonal evaluation of an incidentally found microadenoma, although the Endocrine Society suggests an assessment for hypersecretion of prolactin, GH, and ACTH as part of the initial workup.⁴ For microadenomas (less than 1 cm), a sella MRI should be repeated annually for up to 3 years, then less frequently thereafter if there has been no change in the lesion size.²¹

The primary goals of treatment are to normalize excess pituitary secretion, alleviate signs and symptoms, shrink or eliminate compression of vital structures, and preserve or restore normal pituitary function.¹³ These goals are approached by medical therapy, surgery, irradiation, or a combination.

Prolactinomas, the most common of pituitary adenomas, are primarily treated with pharmacotherapy or observation. Observation is a viable option in asymptomatic microprolactinomas because 95% of tumors do not enlarge in four to six years of observation.²² Dopamine agonists such as bromocriptine (Parlodel®) and cabergoline (Dostinex®) are the mainstay of therapy. Bromocriptine is taken two to three times daily compared with the longer acting cabergoline, which is taken twice weekly.^{23, 24} Both drugs are effective in decreasing PRL levels and tumor size reduction in over 90% of patients, with cabergoline demonstrating slightly greater efficacy.²² Withdrawal of dopamine agonists after 1-3 years have shown no recurrence of hyperprolactinemia in 25.8 – 69%; the ideal candidate is one with normal prolactin concentrations while on dopamine agonists and small or no visible tumor on MRI prior to discontinuation of the

dopamine agonist.²² The principal side effects of dopamine agonists are nausea, vomiting, postural hypotension, mental fogginess, and infrequently nasal stuffiness, psychosis, depression, hallucinations, nightmares, insomnia, vertigo, and Raynaud's phenomenon.^{13, 22} Many of the adverse symptoms can be managed clinically with reduction in dose.^{13, 22, 25} Nonetheless, the adverse effects are highly significant from an aeromedical standpoint.

If pharmacotherapy does not control the symptoms of hyperprolactinemia, or shrink a prolactinoma that is exerting mass effect, then surgery is an option.²⁶ For all other pituitary tumors, surgery is the primary treatment modality.¹ Endoscopic pituitary surgery has emerged as the first-line surgical treatment of choice with the exception of prolactinomas.²⁷ Postoperative remission for pituitary adenomas range from 73-96% (lowest GH secreting, highest nonfunctional), recurrence over 10 years is 8-13%. In adenomas which have resulted in visual deficits, visual recovery rates range from 88-92%.⁴ All individuals should have extensive neuro-ophthalmological examination to include visual fields and acuity as well as fundoscopic exam prior to and following surgery.

For nonprolactinomas, other pharmacologic agents may be used as adjuncts to surgery. Acromegaly is treated primarily with somatostatin analogs, such as octreotide (Sandostatin®) and lanreotide (Somatuline®). Somatostatin analogs have been shown to shrink GH-secreting adenomas by 19.4%.²⁸ Somatostatin analogs are limited by side effects to include gallstones and biliary sludging, nausea, cramps, and steatorrhea.^{29,31} Somatostatin analogs have shown good efficacy in TSH-secreting adenomas as well.¹³ Ketoconazole, which inhibits steroid biosynthesis at the adrenal gland, is used as adjuvant therapy in Cushing's disease, both prior to surgery and afterwards if resection fails to result in complete control. Liver enzyme elevations, gynecomastia in men, gastrointestinal upset, and edema are common side effects and ketoconazole is notorious for a wide range of serious drug interactions.¹³

Pituitary radiation is indicated for surgical failure, residual mass effects, persistent hormone hypersecretion, or when surgery is contraindicated. Concerns with pituitary radiation are hypopituitarism (80% within 10 years), other primary brain tumors (< 5% gliomas/meningiomas), optic nerve damage (2%), and brain necrosis (potential cognitive dysfunction, especially memory loss).¹ The introduction of more precise techniques, such as gamma-knife and linear accelerator, should decrease the amount of radiation and collateral impact mentioned previously. Follow up after surgery or radiation should include serial clinical, endocrinologic, ophthalmologic, and radiologic studies. A postoperative MRI should be performed within three months of surgery or treatment and annual evaluations for tumor recurrence or residual.⁴ A summary of the management and control of pituitary adenomas is summarized in Table 2.¹³

Approach	Prolactin- Secreting Tumors	Growth Hormone- Secreting Tumors	ACTH- Secreting Tumors	TSH- Secreting Tumors	Nonfunctioning Tumors
Primary Approach	DA: microadenomas, 80% to 90% response; macroadenomas, 60% to 75% response	Surgery: microadenomas, 70% response; macroadenomas, 50% response	Surgery: microadenoma, 80% to 90% response; macroadenoma, 50% response	Surgery plus irradiation, 67% response	Surgery: improved vision, 70% response
Secondary Approach	Surgery: microadenomas, 55% response; macroadenomas, 20% response	Somatostatin analogues, 60% response; DA, 20% response; irradiation, 50% response (by 12 years)	Irradiation plus cortisol- decreasing drugs	Somatostatin analogues, 75% response	Irradiation
Novel medical developments	Depot long- acting DA, somatostatin receptor subtype-selective analogues	Long-acting somatostatins, somatostatin receptor subtype-selective analogues, growth hormone receptor or GHRH antagonist		Long-acting somatostatins	Gonadotropin- releasing hormone antagonists

Table 3. Management and control of hormone hypersecretion in pituitary adenomas.

ACTH – adrenocorticotropin hormone; DA – dopamine agonists; GHRH – growth hormone releasing hormone; TSH – thyroid-stimulating hormone; Response refers to normalization of hormone secretion or ablation of tumor mass

Long-term monitoring of these conditions is variable, related to the condition and the response of the condition to the medical treatment. In general, normalization of abnormal hormone secretion and prevention of clinical signs and symptoms is the goal. The monitoring of serum markers will be more frequent (every 4-6 weeks) initially until stability is achieved. Pituitary MRI should show stability for 1-2 years before the interval is extended.²⁷

# **IV. Aeromedical Concerns.**

Pituitary apoplexy, a hemorrhage into the pituitary tumor, is likely to cause sudden incapacitation but is exceedingly rare.³² The main concerns for the pituitary tumors are related to hormone hypersecretion, the medications used to treat them, and mass-effect. For prolactinomas the primary concern is the side effects of the centrally-acting dopamine agonists used to treat some of these tumors, such as bromocriptine and cabergoline. These agents commonly cause headache and dizziness, as well as hypotension, syncope, drowsiness, fatigue, and vertigo. Dopamine agonists are

frequently sedating, and reports of sleep attacks, which initially were described in Parkinson's patients, have now been described in other conditions with these agents.³⁴ (Whether these drugs are excitatory or sedating is dependent on dose, time, and individual variance.) Psychosis, predominantly mania, occurs at unpredictable intervals; in one study, the average delay was 13.5 months (range 4-52 months) after inception of therapy.¹¹ Given the role of dopamine antagonism in the mechanism of action of antipsychotic drugs, the occasional occurrence of psychosis with dopamine agonism is not surprising. In addition, therapy with bromocriptine and cabergoline has been clearly associated with impulse control disorders, such as pathologic gambling, hypersexuality, and other behaviors.^{34, 35}

These medications are not compatible with flying. GH-secreting adenomas, which cause acromegaly, are primarily treated with surgery, but somatostatin analogs are used for tumor shrinkage and suppression of GH prior to surgery. Common somatostatin analogs are octreotide and lanreotide and may be used continuously if individual is not a surgical candidate. These agents have common side effects to include biliary dysfunction, hypo/hyperglycemia, hypothyroidism and arrhythmias. The drug preparation requires refrigeration for storage since it is stable for only two weeks at 25°C. These considerations are clearly not compatible with either the flying or the deployed environment. Cushing's disease usually presents with hypersecretion symptoms that are adverse for flying such as hypertension, truncal obesity, hyperglycemia, and bruising.⁴ Surgery is the preferred method of treatment secondary to poor medical response to treatment. These patients typically have a fair response to surgery, but need steroid replacement for up to 12 months after surgery.⁴ Persistent steroid use and high recurrence rates after 5 years make this condition incompatible with aviation. TSH-secreting adenomas are more aggressive and cause all the side effects of hyperthyroidism with visual impairment and goiter. Pituitary carcinomas are extremely aggressive and have very poor prognosis.^{3, 30}

The mass-effect seen with macroadenomas is another concern. Common symptoms related to this include headache and panhypopituitarism. With only a 1 cm gap between the pituitary and the optic chiasm, visual complications are common, and a complete visual workup needs to be done to evaluate for visual defects from compression of the chiasm or diplopia from oculomotor nerve impingement. Neuro-ophthalmologic finding could clearly impact individual performance and mission accomplishment. Except for prolactinomas, surgery is indicated when mass effect is present. If the prolactinoma doesn't respond to therapy, surgery may be indicated if the mass effect is clinically significant (i.e. mass effect on the optic chiasm causing bitemporal hemianopsia). As above, surgery has good remission rates and 10-year recurrence rates around 1% per year. Potential complications of surgery include CSF leak, transient diabetes insipidus, and inappropriate ADH secretion.¹ Adjuvant radiotherapy or radiosurgery results in good control, but high rates of subsequent hypopituitarism. This may lead to issues with hormone replacement in the future.

ICD-9 codes for pituitary tumors		
194.3	Malignant neoplasm in pituitary gland	
227.3	Benign neoplasm of pituitary gland craniopharyngeal duct (pouch)	
242.8	Thyrotoxicosis (overproduction of TSH)	
253.0	Acromegaly and gigantism (overproduction of growth hormone)	
253.1	Other and unspecified anterior pituitary hyperfunction (except ACTH and TSH)	
255.0	Cushing syndrome (overproduction of ACTH)	

ICD-10	ICD-10 codes for pituitary tumors		
C75.1	Malignant neoplasm of pituitary gland		
D35.2	Benign neoplasm of pituitary gland		
E23.6	Other disorders of the pituitary gland		
E22.0	Acromegaly and pituitary gigantism		
E22.8	Other hyperfunction of pituitary gland		
E24.0	Pituitary-dependent Cushing's syndrome		

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# **Prostate Cancer**

Revised: January 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Maj Laura Bridge, and Capt Cody Hedrick (ACS Internal Medicine); Col Christopher Allam (AF/SG Urology Consultant), Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

# I. Waiver Consideration

Any history of a malignant neoplasm, including prostate cancer, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Treatment of any malignancy or the sequelae of either the malignancy or its treatment may be independently disqualifying. For example, post-treatment urinary incontinence may be disqualifying if it meets certain severity criteria, such as the need for follow-up with a specialist more than annually. Additionally, the use of certain phosphodiesterase-5 (PDE-5) inhibitors for post-treatment erectile dysfunction may require 24-hour DNIF after each dose. PDE-5 inhibitors are not approved for daily use, and tadalafil is not approved for use in aircrew. It is recommended that the MSD and the appropriate career field medication list be cross-referenced for any and all treatments, complications, or residual symptoms.

Typically, an aeromedical or operational waiver for prostate cancer is considered after completion of all planned treatment and the establishment of disease-free asymptomatic clinical stability. It is expected that the service member will be in remission and be following a routine schedule of post-treatment surveillance, in accordance with established professional guidelines (e.g., National Comprehensive Cancer Network Guidelines). Any adverse outcomes of the primary malignancy or its treatment should be addressed before requesting a waiver, with clear establishment of clinical, biochemical, and (if applicable) radiographic stability. Generally, a period of at least six months of stable post-treatment surveillance is required prior to consideration of a waiver for a trained asset; whereas five years of surveillance is required prior to consideration of a waiver for an untrained individual. Case-by-case consideration may be given to an earlier waiver in select low-risk cases.

Flying Class	Condition	Waiver Potential ³ Waiver Authority	ACS Review or Evaluation
FC I/IA ¹	Prostate cancer, stages I-IIC	Yes AFRS/CMO	Yes
	Prostate cancer, stages IIIA- IVB	No AFRS/CMO	No
FC II/III ^{1,2}	Prostate cancer, stages I-IIIB	Yes AFMRA ⁴	Yes
	Prostate cancer, stages IIIC- IVB	No AFMRA ⁴	No
ATC/GBO/OSF/ SWA ^{1,2}	Prostate cancer, stages I-IIIB	Yes AFMRA ⁴	No ⁵
	Prostate cancer, stages IIIC- IVB	No AFMRA ⁴	No

 Table 1: Waiver potential for Prostate Cancer

1. Waiver for untrained assets may be considered after five years of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

2. Waiver for trained assets may be considered after six months of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

- 3. No indefinite waivers.
- 4. Certification authority for untrained assets is AFRS/CMO.
- 5. ACS review may be requested at the discretion of the waiver authority.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Fully describe the course of treatment, including dates of each intervention and any side effects, adverse outcomes, or complications.
  - c. Specify presence or absence of any residual symptoms or sequelae following completion of treatment.
  - d. List any current medications, dosages, dates of dose adjustments, and any medication adverse effects.
  - e. Specify current surveillance regimen, including schedule of specialist clinical reevaluation, laboratory testing, and any applicable imaging. Explain any discrepancies in surveillance plan from established post-treatment guidelines.
- 2. Consultation report from all treating specialists, as applicable (e.g., urologist, medical oncologist, radiation oncologist) and all subsequent consultation notes. These notes must include the following:

- a. Summarization of presentation, evaluation, and staging.
- b. Summarization of complete treatment course, including any modifications to initial planned treatments with explanation.
- c. Recent post-treatment follow-up note addressing clinical stability and commenting on presence or absence of residual disease, symptoms, or sequelae of the prostate cancer or its treatment.
- d. Detailed plan of ongoing surveillance for recurrence, including interval of followup and specific monitoring tests planned.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of prostate cancer, including laboratory studies, imaging, pathology results, and any other ancillary studies. The below-listed studies must be included:
  - a. All prostate specific antigen (PSA) levels with dates of measurement.
  - b. Results of all diagnostic, staging, and surveillance imaging studies, as applicable in accordance with established guidelines (e.g., CT, MRI, PET-CT, bone scan).
- 4. Current physical examination, including digital rectal examination (DRE) and examination of external genitalia.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings and a current DRE and examination of external genitalia.
  - b. Complete list of current medications with dates of initiation, dosages, dates of dose adjustments, and all adverse effects.
  - c. Summary of interval surveillance evaluations and studies.
  - d. Updated plan of ongoing surveillance for recurrence.
- 2. All relevant interval consultation reports from specialty providers (e.g., urologist, medical oncologist, radiation oncologist).
- 3. Results of all interval testing performed in the course of ongoing management and surveillance, including all PSA levels with dates of measurement and (as applicable) any other laboratory studies, imaging, and other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# **III. Aeromedical Concerns**

Approximately 95% of prostate cancer is adenocarcinoma. Other histologic types of prostate cancer include small cell, transitional cell, and squamous cell carcinoma. Neuroendocrine tumors and sarcomas of the prostate are rare. Non-adenocarcinoma prostate cancer is beyond the scope of this waiver guide.

The American Cancer Society recommends screening with an annual digital rectal exam (DRE) beginning at age 50 for men at average risk and are expected to live at least 10 more years, and recommends earlier screening (age 45) for men at high risk for prostate cancer, which include African American race and first degree relatives diagnosed with prostate cancer before age 65. Men with multiple first degree relatives diagnosed with prostate cancer before age 65 should consider screening as early as age 40.

At the time of diagnosis, about 90% of prostate cancer is either localized to the prostate gland or its spread is confined to regional lymph nodes. Most prostate cancer is diagnosed prior to the onset of symptoms or complications that would impact aviation or operational duties. Recent literature indicates 15 year metastasis-free survival was near 95% in Grade Group 1 and 85% in Grade Group 2.⁹ The aeromedical risk related to primary prostate cancer is low in cases of early stage disease. For these individuals, aeromedical and operational risk predominantly stems from the complications related to treatment, particularly long-term or late complications of chemotherapy or radiation therapy. Unfortunately, some prostate cancers are aggressive, and about 6% of men demonstrate metastatic disease at the time of initial prostate cancer diagnosis. The most common site of distant metastatic spread is the bone, and individuals with bony metastases may present with bone pain. Other sites of possible metastasis include the lymph nodes, lungs, and liver. Metastatic spread to the brain, adrenal glands, or other distant sites is rare. When metastatic spread occurs, aeromedical risk depends on metastatic burden and the particular organ systems involved.

Treatment for prostate cancer includes active surveillance, radical prostatectomy, external beam radiation, brachytherapy, cryotherapy, hormone therapy (i.e., medical castration), systemic chemotherapy, and systemic immunotherapy. Each intervention is associated with unique adverse effects and complications. Therefore, aeromedical and operational risks are quite individualized. The risk of sequelae of aeromedical or operational significance increases with underlying disease prognostic risk. Occupational risk is also higher for individuals who undergo systemic or combination therapy. Generally, systemic or combination interventions are only utilized in intermediate risk or high risk disease. Suitability for waiver will depend upon the type of treatment(s), outcome, extent and stability of any residual disease, any lasting symptoms or sequelae of the primary tumor or the treatment intervention, burden of surveillance testing, and whether long-term treatment is necessary for disease suppression/prevention of recurrence (e.g., medical castration).

Selection of treatment is guided by risk stratification that considers extent of disease (i.e., stage), histologic grade (i.e., Gleason score and grade group), molecular tumor characteristics (i.e., genomic profile), highest PSA level, comorbid conditions, and the overall health of the individual. Additional considerations when choosing a course of therapy include the potential complications associated with different treatments and patient preference. Numerous pre-treatment risk classification and prognostication tools exist to assist clinicians and patients in shared decision making around an individualized treatment plan. The nuances of these tools and treatment decisions are beyond the scope of this waiver guide, but validated prognostication tools may be utilized during the course of a waiver review to further define individualized aeromedical or operational risk.

Review of AIMWTS data from Dec 2018 through Dec 2021 revealed a total of 31 waiver packages involving prostate cancer. Of that total, 0 was FC I/IA, 23 were FC II (0 disqualified), 8 were FC III (2 disqualified), 0 were ATC/GBO, and 0 were SWA. Both FC III disqualifications were for reasons other than the member's treated prostate cancer.

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
C61	Malignant neoplasm of prostate	
D07.5	Carcinoma in situ of prostate	

#### **IV. Suggested Readings**

- Bekelman JE, Rumble RB, Chen RC, et al. Clinically Localized Prostate Cancer: ASCO Clinical Practice Guideline Endorsement of an American Urological Association/American Society for Radiation Oncology/Society of Urologic Oncology Guideline. J Clin Oncol 2018;36:3251-3258. Available at https://ascopubs.org/doi/pdf/10.1200/JCO.18.00606. Accessed 13 December 2021.
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# **Testicular Cancer**

Revised: Jan 2022

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Significant Changes: Waiver guide restructured, minor edits.

# I. Waiver Consideration

Any history of a malignant neoplasm, including testicular cancer, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Treatment of any malignancy or the sequelae of either the malignancy or its treatment may be independently disqualifying. For example, post-treatment hypogonadism requiring use of exogenous hormone replacement is disqualifying for all flying class, ATC, GBO, and SWA duties. The use of injectable exogenous testosterone is disqualifying for retention. It is recommended that the MSD and the appropriate career field medication list be cross-referenced for any and all treatments, complications, or residual symptoms.

Typically, an aeromedical or operational waiver for testicular cancer is considered after completion of all planned treatment and the establishment of disease-free asymptomatic clinical stability. It is expected that the service member will be in remission and be following a routine schedule of post-treatment surveillance, in accordance with established professional guidelines (e.g., National Comprehensive Cancer Network Guidelines). Any adverse outcomes of the primary malignancy or its treatment should be addressed before requesting a waiver, with clear establishment of clinical and biochemical stability. Generally, a period of at least six months of stable post-treatment surveillance is required prior to consideration of a waiver for a trained asset; whereas two years of surveillance is required prior to consideration of a waiver for an untrained individual. Case-by-case consideration may be given to an earlier waiver in select lowrisk individuals.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority	Evaluation
FC I/IA ¹	Seminoma and non-	Yes	Yes
	seminoma, all stages	AFRS/CMO	
FC II/III ^{1,2}	Seminoma and non-	Yes	Yes
	seminoma, all stages	AFMRA ³	
ATC/GBO/OSF/	Seminoma and non-	Yes	No ⁴
SWA ^{1,2}	seminoma, all stages	AFMRA ³	

 Table 1: Waiver potential for Testicular Cancer

1. Waiver for untrained assets may be considered after two years of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

2. Waiver for trained assets may be considered after six months of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

3. Certification authority for untrained assets is AFRS/CMO.

4. ACS review may be requested at the discretion of the waiver authority.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Fully describe the course of treatment, including dates of each intervention and any side effects, adverse outcomes, or complications. If the treatment regimen included bleomycin, specify whether there were ever any respiratory symptoms or suspicion of possible lung injury/pulmonary toxicity.
  - c. Specify presence or absence of any residual symptoms or sequelae following completion of treatment.
  - d. List any current medications, dosages, dates of dose adjustments, and any medication adverse effects.
  - e. Specify current surveillance regimen, including schedule of specialist clinical reevaluation, laboratory testing, and any applicable imaging. Explain any discrepancies in surveillance plan from established post-treatment guidelines.
- 2. Consultation report from all treating specialists, as applicable (e.g., urologist, medical oncologist, radiation oncologist) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and staging.
  - b. Summarization of complete treatment course, including any modifications to initial planned treatments with explanation.

- c. Recent post-treatment follow-up note addressing clinical stability and commenting on presence or absence of residual disease, symptoms, or sequelae of the testicular cancer or its treatment.
- d. Detailed plan of ongoing surveillance for recurrence, including interval of followup and specific monitoring tests planned.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of testicular cancer, including laboratory studies, imaging, pathology results, and any other ancillary studies. The below-listed studies must be included:
  - a.  $\alpha$ -fetoprotein (AFP) level measured before treatment and at most recent follow-up.
  - b.  $\beta$ -human chorionic gonadotropin ( $\beta$ -hCG) measured before treatment and at most recent follow-up.
  - c. Lactate dehydrogenase (LDH) measured before treatment and at most recent follow-up.
  - d. If treatment included bleomycin or chest radiation, the following must be included: pre- and post-bronchodilator spirometry, full plethysmography, and DLCO.
  - e. Results of all diagnostic, staging, and surveillance imaging studies, as applicable in accordance with established guidelines (e.g., testicular ultrasound, chest x-ray, CT of the abdomen/pelvis, PET-CT).
- 4. Current physical examination, including examination of external genitalia and lymph nodes.
- 5. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 6. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings and a current examination of external genitalia and lymph nodes.
  - b. Complete list of current medications with dates of initiation, dosages, dates of dose adjustments, and all adverse effects.
  - c. Summary of interval surveillance evaluations and studies.
  - d. Updated plan of ongoing surveillance for recurrence.
- 2. All relevant interval consultation reports from specialty providers (e.g., urologist, medical oncologist, radiation oncologist).
- 3. Results of all interval testing performed in the course of ongoing management and surveillance, including (as applicable) laboratory studies, imaging, and any other ancillary tests. Include results of current AFP, β-hCG, and LDH.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

#### **III. Aeromedical Concerns**

Testicular cancer is relatively uncommon, but represents the most common solid tumor in males 20-34 years old. Approximately 95% of testicular cancers present as stage I or II disease, prior to the development of any symptoms or complications of serious aeromedical or operational concern. The five year survival of all testicular cancer is >95%. Although the risk of relapse is high, recurrent disease is typically detected biochemically through regular careful surveillance before the onset of symptoms or physical findings. Therefore, aeromedical and operational risk predominantly stems from the complications related to treatment, particularly long-term or late complications of chemotherapy or radiation therapy. The burden of surveillance testing is also a factor in waiver consideration due to the potential impact of operational tempo on the ability of an individual to complete necessary testing and evaluations and the possibility that surveillance may interfere with a service member's readiness. Due to the high risk of recurrence associated with treated testicular cancer, frequent and timely surveillance in accordance with established evidence-based guidelines (e.g., National Comprehensive Cancer Network) is of critical importance, regardless of initial stage or primary treatment. Follow up schedules depend on the tumor type, staging and elected therapies following orchiectomy (i.e. surveillance, chemotherapy, surgery or radiation therapy). Patient follow schedules range from 2-6 months for several years based on NCCN guidelines.

Individuals with testicular cancer undergo initial surgical resection with orchiectomy which is then followed by either surveillance, chemotherapy, radiation, or retroperitoneal lymph node dissection depending upon the tumor type and stage. The most common chemotherapeutic regimens include bleomycin, etoposide, and cisplatin. Short- and long-term chemotherapy toxicity is a substantial concern in aviation and operational environments. While both etoposide and cisplatin are associated with adverse effects that would increase aeromedical and operational risk (e.g., neuropathy), the greatest aeromedical and operational concern arises from the use of bleomycin.

Historically, the use of bleomycin was permanently disqualifying for aviation duties due to the concern for pulmonary toxicity and the risk for irreversible pulmonary fibrosis after exposure to supplemental oxygen. Acute pulmonary injury occurs in up to 18% of individuals who receive bleomycin. Delayed toxicity is also described in the medical literature, mostly in case reports and small case series. Its true incidence is uncertain. Risk factors appear to include increased age, higher cumulative dose of bleomycin, and renal insufficiency. However, there are documented cases in young individuals previously treated with small cumulative doses of bleomycin following administration of modest levels of supplemental oxygen (33-42%) during the course of surgical operations lasting between 4 and 8 hours. The majority of reported cases occurred within the first year after completion of bleomycin chemotherapy. However, it is unknown if the actual risks decrease over time due to the potential for observation bias.

Several years ago, waiver policy with respect to bleomycin shifted as a result of new data from the Duke Hyperbaric Unit. In a small number of patients with a history of bleomycin treatment, repeated hyperbaric oxygen (HBO) treatments with 100% oxygen in a pressurized chamber did not result in permanent worsened pulmonary function. At least one individual experienced chest discomfort and a decrease in DLCO by 50%, which resolved and did not recur with subsequent

HBO treatments at a reduced frequency. A series of 15 patients previously exposed to bleomycin were successfully treated with HBO without the development of new respiratory symptoms or any significant change in arterial blood gas values, spirometry, or chest x-ray findings. Based on this limited but promising data, aviators in both high-performance and non-high performance aircraft were permitted to return to unrestricted flying duties after receiving bleomycin chemotherapy, provided that there was no evidence of current or previous pulmonary toxicity and there were no other impediments to waiver.

At present, short-duration waivers for individuals with a history bleomcyin pneumonitis requiring return to manned aviation are considered on a case-by-case basis after one year of posttreatment asymptomatic stability. In these instances, ACS evaluation includes thorough pulmonary testing (e.g., pre- and post-bronchodilator spirometry, full plethysmography, diffusion capacity, and high resolution chest CT). Typically, when there is any suspicion of possible pulmonary reaction related to bleomycin, if the individual is otherwise considered suitable for a waiver, the waiver will be restricted to non-high performance aircraft and no routine use of the aviator mask or 100% supplemental oxygen. Likewise, these service members are prohibited from participating in any portion of altitude chamber qualification that requires 100% oxygen use. These restrictions arise from the concern for life-threatening acute pneumonitis provoked by exposure to high oxygen concentrations, based on case reports of such reactions from the surgical literature. Use of 100% oxygen during emergencies such as fire or rapid decompression is acceptable and should not be discouraged. Generally, initial waivers and waiver renewals for individuals with suspicion of past bleomycin toxicity are restricted to one year duration, with repeat pulmonary testing at one and two years of follow-up (i.e., at two and three years after completion of definitive therapy).

Review of AIMWTS data from Dec 2018 through Dec 2021 revealed a total of 63 waiver packages involving testicular cancer. Of that total, 6 were FC I/IA (2 disqualified), 37 were FC II (1 disqualified), 11 were FC III (0 disqualified), 5 were ATC/GBO (1 disqualified), and 4 were SWA (0 disqualified). The two FC I/IA disqualifications were a result of being <1 year removed from treatment. The two disqualifications in trained airmen were also associated with other unrelated or indirectly related conditions and were not disqualifications directly due to the effects of the testicular cancer or treatment.

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended	

# **IV. Suggested Readings**

- Baird DC, Meyers GJ, and Hu JS. Testicular cancer: diagnosis and treatment. Am Fam Physician. 2018;97:261-268. Available at <u>https://www.aafp.org/afp/2018/0215/afp20180215p261.pdf</u>. Accessed 13 December 2021.
- Fung C, Dinh PC, Fossa SD, et al. Testicular cancer survivorship. Journal of the National Comprehensive Cancer Network J Natl Compr Canc Netw 2019;17:1557-1568. Available at <u>https://jnccn.org/view/journals/jnccn/17/12/article-p1557.xml</u>. Accessed 139 December 2021.

- 3. National Comprehensive Cancer Network. Testicular Cancer (Version 2.2021). 13 April 2021. Available at <a href="https://www.nccn.org/professionals/physician_gls/pdf/testicular.pdf">https://www.nccn.org/professionals/physician_gls/pdf/testicular.pdf</a>. Accessed 13 December 2021. (Note: A free account must be created to access this guideline).
- Stephenson A, Eggener SE, Bass EB, et al. Diagnosis and Treatment of Early Stage Testicular Cancer: AUA Guideline. J Urol 2019;202:272-281. Available at <a href="https://www.auajournals.org/doi/pdf/10.1097/JU.000000000000318">https://www.auajournals.org/doi/pdf/10.1097/JU.0000000000000318</a>. Accessed 13 December 2021.
- Stephenson AJ, Gilligan TD: Neoplasms of the Testis. Campbell Walsh Urology10th edition: 837-870; 2011





## **Thyroid Cancer**

Revised: February 2022 Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, Maj Laura Bridge, and Capt Cody Hedrick (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured.

## I. Waiver Consideration

Any history of a malignant neoplasm, including thyroid cancer, is disqualifying for all flying class, ATC, GBO, OSF, and SWA duties, as well as for retention. Treatment of any malignancy or the sequelae of either the malignancy or its treatment may be independently disqualifying. For example, injury to the parathyroid glands may result in transient or permanent parathyroid dysfunction, which is disqualifying for all flying class, ATC, and SWA duties. The use of thyroid hormone replacement or supplementation to correct post-treatment hypothyroidism or to induce thyroid suppression for the purpose of reducing the risk of recurrence is also independently disqualifying for all flying class, ATC, and SWA duties. It is recommended that the MSD and the appropriate career field medication list be cross-referenced for any and all treatments, complications, or residual symptoms.

Typically, an aeromedical or operational waiver for differentiated thyroid cancer is considered after completion of definitive treatment and the establishment of asymptomatic clinical stability. It is expected that the service member will have no or minimal residual disease and be following a routine schedule of post-treatment surveillance, in accordance with established professional guidelines (e.g., National Comprehensive Cancer Network Guidelines). Any adverse outcomes of the primary malignancy or its treatment should be addressed before requesting a waiver, with clear establishment of clinical and biochemical stability. Examples of common sequelae include post-operative hypothyroidism and/or hypoparathyroidism, hypocalcemia, or recurrent laryngeal nerve injury. Generally, a period of at least six months of stable post-treatment surveillance is required prior to consideration of a waiver for a trained asset; whereas two years of surveillance is required prior to consideration of a waiver for an untrained individual. Case-by-case consideration may be given to an earlier waiver in select low-risk cases.

Flying Class	Condition	Waiver Potential ³	ACS Review or
		Waiver Authority	Evaluation
FC I/IA ¹	Differentiated thyroid cancer,	Yes	Yes
	all stages	AFRS/CMO	
FC II/III ^{1,2}	Differentiated thyroid cancer,	Yes	Yes
	all stages	AFMRA ⁴	
ATC/GBO/OSF/	Differentiated thyroid cancer,	Yes	No ⁵
SWA ^{1,2}	all stages	AFMRA ⁴	

#### Table 1: Waiver potential for thyroid cancer

1. Waiver for untrained assets may be considered after two years of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.

- 2. Waiver for trained assets may be considered after six months of stable, asymptomatic surveillance following completion of definitive treatment. An early waiver may be considered on a case-by-case basis in low-risk individuals.
- 3. No indefinite waivers.
- 4. Certification authority for untrained assets is AFRS/CMO.
- 5. ACS review may be requested at the discretion of the waiver authority.

## **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent symptoms and physical findings (positive and negative).
  - b. Fully describe the course of treatment, including dates of each intervention and any side effects, adverse outcomes, or complications.
  - c. Specify presence or absence of any residual symptoms or sequelae following treatment completion.
  - d. List all current medications, dosages, dates of dose adjustments, and any medication adverse effects. Specify thyroid stimulating hormone (TSH) target. Explain any discrepancies in TSH target from established post-treatment guidelines.
  - e. Specify current surveillance regimen, including schedule of specialist clinical reevaluation, laboratory testing, and any applicable imaging. Explain any discrepancies in surveillance plan from established post-treatment guidelines.
- 2. Consultation report from all treating specialists, as applicable (e.g., endocrinologist, surgeon, medical oncologist, radiation oncologist) and all subsequent consultation notes. These notes must include the following:
  - a. Summarization of presentation, evaluation, and staging.
  - b. Summarization of complete treatment course, including any modifications to initial planned treatments with explanation.

- c. Recent post-treatment follow-up note addressing clinical stability and commenting on presence or absence of residual disease, symptoms, or sequelae of the thyroid cancer or its treatment.
- d. Detailed plan of ongoing surveillance for recurrence, including interval of followup and specific monitoring tests planned.
- 3. Results of all testing performed in the course of diagnosis, evaluation, and management of thyroid cancer, including laboratory studies, imaging, biopsies/pathology results, and any other ancillary studies. For medullary thyroid cancer, the following must be included: results of screening for MEN syndromes.
- 4. Results of surveillance laboratory studies on a stable dose of thyroid replacement/suppression, including recent TSH, free thyroxine (free T4), thyroglobulin, and anti-thyroglobulin antibodies. For medullary thyroid cancer, the following must be included: Carcinoembryonic antigen (CEA) and calcitonin.
- 5. Results of surveillance imaging studies, as applicable in accordance with established surveillance guidelines (e.g., neck ultrasound, whole-body scan, MRI, CT, PET-CT).
- 6. Current physical examination, including neck exam.
- 7. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 8. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings and a current neck exam.
  - b. Complete list of current medications with dates of initiation, dosages, dates of dose adjustments, and all adverse effects.
  - c. Summary of interval surveillance evaluations and studies.
  - d. Updated plan of ongoing surveillance for recurrence.
- 2. All relevant interval consultation reports from specialty providers (e.g., endocrinologist, surgeon, medical oncologist, radiation oncologist).
- 3. Results of all interval testing performed in the course of ongoing management and surveillance, including (as applicable) laboratory studies, imaging, and any other ancillary tests. Include results of current TSH, free thyroxine (free T4), thyroglobulin, and anti-thyroglobulin antibodies. For medullary thyroid cancer, the following must be included: CEA and calcitonin.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

## **III. Aeromedical Concerns**

Differentiated thyroid cancer poses little aeromedical or operational risk in the absence of distant metastases. Fortunately, only 10% of individuals diagnosed with differentiated thyroid cancer will develop distant metastases over their lifetime. In the rare event that metastatic spread does

occur, the most frequent site of involvement is the lungs. Spread to the bone or CNS is observed infrequently. Most differentiated thyroid tumors are slow-growing. Even in the case of mild residual disease, the short-term risk to service member health is low when the malignancy is localized. Thus, primary differentiated thyroid cancer itself often poses minimal risk to aviation or operational safety or to mission completion. Rather, the majority of aeromedical and operational risk stems from the treatment of the malignancy and post-treatment sequelae.

The overwhelming majority of individuals with differentiated thyroid cancer undergo surgical resection with either total or sub-total thyroidectomy, with or without lymph node dissection. A subset of individuals will also require radioactive iodine ablation or adjuvant external beam radiation. The most common post-treatment complication is iatrogenic hypothyroidism. There is a small risk of injury to the recurrent laryngeal nerve and parathyroid glands, which may occur intraoperatively or as a result of local tumor invasion into these nearby structures. Following surgery, thyroid suppression is typically utilized to reduce the risk of recurrence. Whether due to post-operative hypothyroidism, a need for thyroid suppression, or both, almost all individuals will require treatment with exogenous thyroid hormone (e.g., levothyroxine). The use of levothyroxine requires careful monitoring and dose adjustments to maintain goal TSH. Over- or under-replacement may result in a hypo- or hyperthyroid state. At suppressive doses, exogenous thyroid hormone induces a mild thyrotoxicosis. There is a slightly increased risk of atrial fibrillation, but the risk of a significant impact on aviation or operational duties is considered minimal.

After hypothyroidism, the most common complications of thyroidectomy are hypoparathyroidism and injury to the recurrent laryngeal nerve. The more extensive the surgery (e.g., total vs sub-total thyroidectomy, thyroidectomy with lymph node dissection vs thyroidectomy alone), the greater the risk of complication. Up to 20% of all individuals who undergo surgical resection of thyroid cancer experience transient hypoparathyroidism. Of individuals who undergo total thyroidectomy, 0.8-3% will sustain a parathyroid injury resulting in a permanent hypoparathyroid state. Whether the hypoparathyroidism is transient or permanent, if it remains undiagnosed and uncorrected, it may cause hypocalcemia and tetany that can range from mild to severe. Mild manifestations of hypocalcemia include perioral tingling, paresthesia of the hands and feet, and muscle cramping. Severe manifestations can be lifethreatening and include laryngospasm and seizures. However, when properly monitored and treated, hypoparathyroidism is amenable to aeromedical and operational waiver. Individuals are educated to recognize early signs and symptoms of hypocalcemia so that it can be corrected with calcium replacement or calcitriol before reaching a level of aeromedical or operational significance.

With regard to iatrogenic or locally invasive recurrent laryngeal nerve injury, waiver consideration depends on the severity of resulting impairment. Unilateral involvement may cause dysphonia and interfere with a service member's ability to communicate, particularly in an environment with a significant level of ambient noise. Waivers for unilateral recurrent laryngeal nerve injury may be considered on a case-by-case basis. Damage to the bilateral recurrent laryngeal nerves may result in aphonia, which is not considered to have waiver potential.

Medullary thyroid cancer is distinct from other forms of thyroid cancer. It is a neuroendocrine tumor that arises from the parafollicular cells, or C cells, of the thyroid gland. Curative treatment depends upon complete surgical resection. Thus, the post-operative considerations for medullary thyroid cancer are the same as those for other differentiated thyroid cancers. Because local invasion is the primary risk, aeromedical concerns center on intraoperative injury and the risk of future recurrence or invasion. Waiver considerations include the burden of residual disease and the risks associated with any sequelae of treatment, as discussed above.

Review of AIMWTS data from Dec 2018 through Dec 2021 revealed a total of 58 waiver packages involving thyroid cancer. Of that total, 1 was FC I/IA (0 disqualified), 40 were FC II (0 disqualified), 13 were FC III (0 disqualified), 2 were ATC/GBO (0 disqualified), and 2 were SWA (0 disqualified).

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
C73	Malignant neoplasm of thyroid gland	

## **IV. Suggested Readings**

- Fagin JA, Wells SA. Biologic and clinical perspectives on thyroid cancer. N Eng J Med 2016;375:1054-67. Available at <u>https://www.nejm.org/doi/full/10.1056/NEJMra1501993</u>. Accessed 13 December 2021. (Note: Requires personal or institutional subscription to access. Available via the AFMS Virtual Library on the AF Knowledge Exchange at <u>https://kx.health.mil/Pages/default.aspx</u>).
- Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid 2016;26:1-133. Available at https://www.liebertpub.com/doi/pdfplus/10.1089/thy.2015.0020. Accessed 13 December 2021.
- National Comprehensive Cancer Network. Thyroid Carcinoma (Version 2.2021). 1 September 2021. Available at <a href="https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf">https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf</a>. Accessed 13 December. (Note: A free account must be created to access this guideline).

## Bell's Palsy (May 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## Significant Changes:

Updated Table 1 and References

## I. Waiver Consideration

An isolated episode of Bell's palsy with full recovery and no clinical or functional residua is not aeromedically disqualifying and does not require waiver. An isolated episode of Bell's palsy with incomplete clinical recovery or recurrent episodes of Bell's palsy is disqualifying for all flying classes, and the flyer will be considered for a waiver based on the outcome of treatment and level of post-treatment residual defects. A history of remote Bell's palsy will not necessarily be disqualifying as there is often complete resolution and affected individuals are not at an increased risk of recurrence.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes ¹	AETC	Yes
FC II/III/SWA	Yes ¹	MAJCOM	Yes
ATC/GBO	Yes ¹	MAJCOM	No

Table 1: Waiver	potential for	Bell's	Palsy
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1. Waiver consideration based on amount of residual symptoms and deficits.

Indefinite waiver recommendation possible with complete resolution or minimal residua.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

## A. Initial Waiver Request:

- 1. Complete history of event detailing all symptoms, treatment (all medications, dosages, and number of days treated) and level of symptom resolution.
- 2. Copies of relevant clinical notes, diagnostic studies, imaging reports and images, and operative reports (if applicable). If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical and neurologic examinations.
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

#### B. Renewal Waiver Request:

- 1 Interval history and level of symptom resolution.
- 2. Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical and neurologic examination findings.
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include effects of any residual symptoms on operational safety and mission effectiveness, and future risk of symptom recurrence. Aviators with Bell's palsy may have eye irritation due to the inability to close the lid, and food and saliva can pool on the affected side of the mouth potentially spilling out from the corner. Vision can be adversely affected due to the dry eyes, speech may be difficult due to facial weakness, and the wear of life support gear, particularly a tight-fitting aviator mask, can be compromised due to facial weakness. These symptoms make flying inadvisable until resolution of the condition. As most cases will be treated with steroids and possibly antiviral agents, the aviator should be grounded during treatment as these medications are not aeromedically-approved and are unlikely to be recommended for waiver.

AIMWTS review in Feb 2019 revealed 42 cases with the diagnosis of Bell's Palsy. Breakdown of the cases revealed: 3 FCI cases, 13 FC II cases, 1 RPA pilot case, 23 FC III cases, and 1 GBC case. There were 4 disqualifications, all FC III. Two of the DQ cases were for a significant nerve deficit and the other 2 for other diagnoses. Two pilots demonstrated very mild facial weakness, one FC I applicant showed a mild hemifacial spasm, a flight surgeon had residual lagophthalmos, and one pilot showed mild facial asymmetry.

ICD 9 codes for Bell's Palsy	
351	Facial nerve disorders
351.0	Bell's palsy
351.9	Facial nerve disorder, unspecified
	· •

ICD-10 codes for Bell's Palsy	
G51.8	Facial nerve disorders
G51.0	Bell's palsy
G51.9 Facial nerve disorder, unspecified	

## **IV. Suggested Readings**

- 1. Reich SG. Bell's palsy. Continuum (Minneap Minn) 2017; 23(2):447-466
- 2. Ronthal M. Bell's palsy: treatment and prognosis in adults. UpToDate, Nov 5, 2019.

3. Ronthal M. Bell's palsy: pathogenesis, clinical features, and diagnosis in adults. UpToDate, Oct 30, 2019.

4. Ropper AH, Samuels MA, Klein JP (Ed). Diseases of the cranial nerves. Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education, 2014:1391-1405.

5. Zandian A, Osiro S, Hudson R, et al. The neurologist's dilemma: A comprehensive clinical review of Bell's palsy, with emphasis on current management trends. Med Sci Monit 2014; 20:83-90.

6. Baugh RF, Basura GJ, Ishii LE, et al. Clinical Practice Guideline: Bell's Palsy. Otolaryngol Head Neck Surg 2013; 149(3S):S1-S27.

7. Gronseth GS, Paduga R. Evidence-based guideline update: Steroids and antivirals for Bell palsy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2012; 79(22):2209-13.





## **Chronic Low Back Pain**

Revised: Feb 2022

Reviewed: Lt Col Mark Dudley (RAM 22), Maj Caleb James, (RAM 22), Dr. Max Lee (ACS Waiver Guide Manager); Col Joseph Stuart (AF/SG Orthopaedics consultant)

Significant Changes: Reformatted with updated references

## I. Waiver Consideration

Recurrent disabling back pain or back pain requiring external support is specifically disqualifying for all flying and operational duties. In addition, chronic back or neck pain, regardless of cause, which requires ongoing duty or deployment restrictions for over a year, or ongoing specialist follow-up more than annually, or frequent duty absences, or chronic/recurrent use of schedule II-IV controlled medications are disqualifying for all flying classes and may require consideration for MEB to meet retention standards.

Flying Class (FC)	Condition	Waiver Potential	ACS Review/
		Waiver Authority	Evaluation
Any Initial FC or	Chronic Pain ²	Yes ¹	No, No
Operational Duty		AFRS/CMO	
Any Trained FC or	Chronic Pain ²	Yes	No, No
Operational Duty		MAJCOM/SGP	

#### Table 1: Waiver potential for chronic low back pain

1. Waiver is unlikely for untrained personnel with active back pain.

2. If member does not meet retention standards (chronic back or neck pain, regardless of cause, which requires ongoing duty or deployment restrictions for over a year, or ongoing specialist follow-up more than annually, or frequent duty absences, or chronic/recurrent use of controlled medications), the waiver authority is AFMRA.

## II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. <u>Initial Waiver Request</u> for chronic low back pain should include the following:

- 1. History Must define the back pain symptomatology to include onset, contributing event, specific etiology along with history of location, radiation, duration, conditions that improve or aggravate the pain, limitations of activities, previous, current, or ongoing treatment(s), and previous, current, or ongoing medication(s).
- 2. Discuss any "Red Flags" such as fever, night sweats, weight loss, bowel and bladder dysfunction, and address all pertinent negatives.
- 3. If present, include history of any social or psychological distress.
- 4. General physical exam including visual inspection, range of motion and neurological examinations consisting of muscle strength, gait, sensation, reflexes, etc.
- 5. All radiological or neurological reports and labs.

- 6. All specialty consultation notes.
- 7. If applicable, MEB results.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

B. <u>Renewal Waiver Request</u> for chronic low back pain should include the following:

- 1. Brief history of initial onset of back as provided in initial AMS. Include the interval history since last waiver with special attention to changes in symptoms, exasperation and occupational and operational impact.
- 2. All interim specialty consultation notes.
- 3. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

## **III. Aeromedical Concerns**

Low back pain (LBP) is the fifth most common reason for visiting a US doctor. Annually, the prevalence of low back pain in the general US adult population is 10–30%, and the lifetime prevalence of US adults is as high as 65-80%. LBP encompasses three distinct sources of pain: axial lumbosacral, radicular, and referred pain. Axial lumbosacral back pain refers to pain in the lumbar (L1-5 vertebral region) and sacral spine (S1 to sacrococcygeal junction region). Radicular leg pain travels into an extremity along a dermatomal distribution secondary to nerve or dorsal root ganglion irritation. Referred pain spreads to a region remote from its source but along a non-dermatomal trajectory.

General risk factors of importance must be considered for appropriate mitigation strategies. LBP can be broken into three categories: acute (4 weeks), subacute (4-12 weeks), and chronic ( $\geq$ 12 week). While most non-chronic back pain presentations are acute with pain that is limited to 6 weeks or less, 10–40% of patients develop symptoms lasting over 6 weeks. The majority of LBP will be non-specific, but serious or concerning causes of back pain must be considered including: spinal cord or cauda equina compression, metastatic cancer, spinal epidural abscess, vertebral osteomyelitis, vertebral compression fractures, radiculopathy, and spinal stenosis.

Operational factors to consider are stress or strain on the musculoskeletal structures by transient high-G states, vibrations, prolonged seated posture, and physically strenuous activities. Differential diagnoses of importance to consider within aerospace and operational personnel include ankylosing spondylitis, osteoarthritis, scoliosis, piriformis syndrome, and SI joint dysfunction. Of note, psychosocial stressors may worsen back pain symptoms or be a cause of non-organic back pain. The aeromedical disposition for mechanical low back pain due to lumbar strain/sprain and degenerative processes is dependent on the degree of functional residual impairment that remains once treatment and rehabilitation are completed. The flight surgeon must ascertain that the aviator can safely perform all flight duties and there should be no significant limitation of motion, loss of strength, or functional impairment that compromises safety during operational control of the aircraft, parachuting duties, during ejection, or egress procedures. If the flyer responds well to therapy and there are minimal recurrences, the aviator may be eligible for

continuation of flight duties. If the back pain is recurrent or disabling, it is disqualifying for all flying and operational classes regardless of the cause. Chronic low back pain due to other causes such as herniated disc, spondylolisthesis, and spinal fractures have unique aeromedical concerns and is discussed in their respective waiver guides.

AIMWTS search from Jan 2015 to November 2021 revealed 91 individuals with waiver dispositions containing the diagnosis of LBP. Of the total, there was 1 FC I/IA case (1 disqualification), 32 FC II cases (6 disqualifications), 50 FC III cases (26 disqualifications), 6 ATC cases (1 disqualification), and 2 GBO cases (1 disqualification).

ICD-9 codes for low back pain	
724.2	Lumbago
724.5 Backache, unspecified	
* ICD-9 to ICD-10 changed October 1, 2015, the last day for ICD-9 began September 30, 2015	

ICD-10 code for low back pain	
M54.40	Lumbago with sciatica, unspecified side
M54.50	Low back pain, unspecified
M54.89	Other dorsalgia

## **IV. Suggested Readings**

1. Wheeler, S., Evaluation of Low Back Pain in adults. *UpToDate*. June 2021. <u>https://www.uptodate.com/contents/evaluation-of-low-back-pain-in-</u> <u>adults?search=low%20back%20pain&source=search_result&selectedTitle=1~150&usage_type=</u> <u>default&display_rank=1</u> (accessed 3 Jan 2022).

2. Urits, I., Burshtein, A., Sharma, M., Testa, L., Gold, P. A., Orhurhu, V., Viswanath, O., Jones, M. R., Sidransky, M. A., Spektor, B., & Kaye, A. D. (2019). Low Back Pain, a Comprehensive Review: Pathophysiology, Diagnosis, and Treatment. *Current pain and headache reports*, *23*(3), 23.

3. DeHart, R. L., & Davis, J. R. (2022). Chapter 11 Musculoskeletal System and Performance. *Fundamentals of aerospace medicine* 5th edition. Philadelphia: Lippincott Williams & Wilkins 4. Posch, M., Schranz, A., Lener, M. et al. Prevalence and potential risk factors of flight-related neck, shoulder and low back pain among helicopter pilots and crewmembers: a questionnaire-based study. *BMC Musculoskelet Disorder* 20, 44 (2019).

5. Chou R. (2014). In the clinic. Low back pain. *Annals of internal medicine*, *160*(11), ITC6–ITC1.

# Guillain-Barré Syndrome (Acute Inflammatory Demyelinating Polyradiculoneuropathy) (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## **Significant Changes:** Updated Table 1 and References

## I. Waiver Consideration

Guillain-Barré Syndrome (GBS) is disqualifying for all flying classes and for GBO and ATC personnel. Per Medical Standards Directory (MSD) L26: "Polyneuritis, whatever the etiology, unless: Limited to a single episode, the acute state subsided at least 1 year before examination, there are no residual effects which could be expected to interfere with normal function in any practical manner." The one-year observation period is specified to allow for maximal functional recovery and because most GBS recurrences or transformation to chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) will occur within this time frame. For flying personnel with GBS, a waiver recommendation is very likely if there is full recovery. An ACS review/evaluation is required to determine eligibility for a return to flying status if residual deficits remain after recovery, but are minor and not felt to interfere with aircrew duties. GBS is not disqualifying for SWA and OSP duties per the MSD.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	Yes ¹	AETC	Yes
FC II/III	Yes ²	MAJCOM	Yes
ATC/GBO	Yes ²	MAJCOM	Yes

#### Table 1: Waiver potential for Guillain-Barré Syndrome

1. IFC I/IA waiver generally not recommended for GBS patients with residual deficits.

2. Trained aviators with GBS and residual deficits are considered for waiver on a case-by-case basis.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Reports of laboratory studies, lumbar puncture, electrodiagnostic studies, imaging studies, and copies of images from any CT/MRI studies. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Neurology consultation reports, including follow-up notes with examination findings after disease resolution.
- 4. Pulmonary function testing after disease resolution.

- 5. If vision was involved, Optometry or Ophthalmology consultation, to include all tests listed in the MSD (stereopsis, ocular motility and alignment testing).
- 6. If obtained, Physical/Occupational Therapy/Rehabilitation Medicine consultation reports.
- 7. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 8. Current physical and neurologic examination findings.
- 9. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

B. Renewal Waiver Request:

- 1 Interval history, with particular emphasis on neurologic examination findings and specific testing as annotated in the initial waiver section.
- 2 Copies of any interim specialty notes, interim diagnostic testing, and images from any interim radiographic studies. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical and neurologic examination findings.
- 4. Comments regarding any current activity limitations.
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include effects of any residual symptoms, signs, and medications used for treatment on operational safety and mission effectiveness, and future risk of symptom recurrence. Within six to twelve months about 85% of GBS patients have fully recovered, with maximal recovery of residual deficits usually seen within 18 months after symptom onset. Persistent minor weakness, areflexia, and paresthesias may remain, and approximately 7% to 15% of patients have permanent neurological sequelae (e.g. foot drop, intrinsic hand muscle wasting, sensory ataxia, painful dysesthesia), which could be aeromedically-significant. The relapse rate for GBS is uncommon and if this occurs, raises the possibility of the diagnosis of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) or other conditions. Most GBS recurrences or transformation to CIDP will occur within 6-12 months of the initial presentation.

AIMWITS search in Jun 2018 revealed a total of 15 cases of GBS. There were 8 FC II cases, 1 RPA pilot case, 5 FC III cases, and 1 MOD case. There were 3 disqualified cases; 1 FC II, 1 FC III, and 1 MOD individual who was disqualified for GBS and concomitant myasthenia gravis.

ICD-9 codes for Guillain-Barré Syndrome	
357.0	Acute infective polyneuritis
357.4	Polyneuropathy in other diseases classified elsewhere
357.8	Other inflammatory and toxic neuropathies

ICD-10 codes for Guillain-Barré Syndrome	
G61.0	Acute infective polyneuritis
G63	Polyneuropathy in diseases classified elsewhere
G61.89	Other inflammatory polyneuropathies

#### **IV. Suggested Readings**

1. Donofrio PD. Guillain-Barré Syndrome. Continuum (Minneap Minn) 2017; 23(5):1295-1309.

2. Allen JA. Chronic demyelinating polyneuropathies. Continuum (Minneap Minn) 2017; 23(5):1310-1331.

3. Vriesendorp F. Guillain-Barré Syndrome in adults: clinical features and diagnosis. UpToDate Dec 4, 2018.

4. Vriesendorp F. Guillain-Barré Syndrome in adults: treatment and prognosis. UpToDate May 21, 2019.

5. Diseases of the peripheral nerves. Principles of Neurology, 10th Edition (Ropper AH, Samuels MA, Klein JP Eds), McGraw-Hill 2014: 1322-1330.

6. Dimachkie MM, Barohn RJ. Guillain-Barre' Syndrome and Variants. Neurol Clin N Am 2013; 31(2):491-510.

7. Walling AD, Dickson G. Guillain-Barré Syndrome. Am Fam Physician 2013; 87(3):191-98.

## Headache (Jan 2021)

Reviewed: Lt Col Aven Ford and Dr. Roger Hesselbrock (ACS Neurology); Dr. Christopher Keirns and Maj Laura Bridge (Technical Editors)

**Significant Changes:** Content updated and revised to reflect current standards of care; information regarding headache management strategies compatible with sustained aeromedical duties added.

## I. Waiver Consideration

In general, all headache syndromes are disqualifying for all flying class, GBO, ATC, and SWA duties. The exception is that occasional tension headaches are not disqualifying. More specifically, any headache or headache syndrome that meets any one of the following criteria is considered disqualifying for all flying duties, ATC duties, GBO duties, and SWA duties:

- A. Impairment in social, vocational, or academic activities, or,
- B. Need for any *abortive* headache intervention or medication other than over-the-counter therapies, **or**,
- C. Need for prescription medication for headache prophylaxis, or,
- D. Associated neurologic dysfunction or deficit, including aura with or without associated headache (i.e., migraine with aura/neurologic dysfunction is disqualifying; typical aura in the absence of headache, also known as acephalgic migraine, is also disqualifying).

A single episode of a severe or incapacitating headache is disqualifying due to the need to exclude a serious underlying cause prior to returning a service member to full operational duties. Finally, any headache disorder that causes frequent absences from duty, mobility restrictions, or frequent specialty follow-up is disqualifying for all flying class, GBO, ATC, and SWA duties, and for retention.

While there is no longer any required minimum observation period before waiver application, a reasonable observation period prior to waiver submission ensures continued headache control and clinical stability. Generally, a waiver may be considered when the following criteria are fulfilled:

- A. Three or fewer disqualifying headaches per year, and,
- B. No associated neurologic dysfunction, deficit, or aura, and,
- C. Negligible or mild functional impairment (i.e., absence of significant social or occupational impairment), nausea, photophobia, or phonophobia, **and**,
- D. No prescription prophylactic or abortive medication is required.

In certain circumstances, a waiver may be considered by the waiver authority when the above criteria are not met. Such requests are reviewed on a case-by-case basis. The waiver authority holds the discretion to obtain an ACS consultation for any headache waiver request.

None of the current FDA-indicated *prophylactic* pharmacologic therapies are formally approved for the specific indication of headache prevention for any flying class, ATC, or SWA duties. There is rare waiver precedent for use of certain prophylactic agents in these personnel, but such cases are typically exceptional (please refer to the "Aeromedical Concerns" section for more information). Calcium channel blockers, beta-blockers, and the antiepileptic medication topiramate are formally approved for headache prophylaxis in GBO personnel. An aeromedical waiver is not required for use of calcium channel blockers for headache prevention in GBO personnel. An aeromedical waiver *is* required for use of beta-blockers or topiramate for headache prevention in GBO personnel. Consult the GBO medication list for details regarding which medications are approved within these classes and for operational prescribing parameters.

When considering *abortive* therapy, the non-injectable formulations of the triptan medication class are approved for all flying class, GBO, ATC, and SWA duties. However, a waiver is required. FC I/IA applicants requiring use of prescription abortive medication are not eligible for waiver consideration. FC II waivers for use of abortive therapy are generally restricted to non-high performance aircraft and duties with another qualified pilot. Consult the aircrew and GBO medication lists for details regarding which medications are approved within the triptan class and for operational prescribing parameters. An example of an operational prescribing parameter is that the use of a triptan requires a 24-hour DNIF/DNIC/DNIA period after each dose to allow for medication clearance and symptom resolution. See the appropriate career field medication list for additional details. When submitting a waiver request for use of pharmacotherapy, it is important to note that the underlying headache diagnosis must be determined to be suitable for a waiver before a waiver will be considered for any medication use.

Flying Class	Condition	Waiver Potential Waiver Authority	ACS Review or Evaluation
FC I/IA ¹	History of migraine with or without aura; typical aura without migraine (acephalgic migraine); or any other headache syndrome meeting disqualification criteria ²	Yes AFRS/CMO	No ⁵
	History of one or more severe/incapacitating headaches	Yes AFRS/CMO	No ⁵
	Headache requiring prescription abortive medication or any prophylactic therapy	No AFRS/CMO	N/A
FC II//III/ ATC/SWA	History of migraine with or without aura; typical aura without migraine (acephalgic migraine); or any other headache syndrome meeting disqualification criteria ²	Yes ³ MAJCOM	No ^{4,5}
	History of one or more severe/incapacitating headaches	Yes MAJCOM	No ^{4,5}
GBO	History of migraine with or without aura; typical aura without migraine (acephalgic migraine); or any other headache syndrome meeting disqualification criteria ²	Yes ³ MAJCOM	No ⁵
	History of one or more severe/incapacitating headaches	Yes MAJCOM	No ⁵

Table 1: Waiver potential for headaches

 1. FC I/IA applicants with a long headache-free interval may be considered for waiver on a case-by-case basis.

- 2. Please refer to the "Waiver Considerations" section for a list of disqualifying criteria.
- 3. Waivers for history of migraine or other headache syndrome are considered for on a case-by-case basis. Waiver for cluster headache is unlikely, except in the setting of prolonged remission.
- 4. Triptan use requires ACS Neurology review.
- 5. ACS Neurology review may be requested at the discretion of the waiver authority.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

**NOTE:** It is required that all original imaging be submitted to ACS Neurology for independent review. Electronic media can be sent via USPS or FedEx to the address below. Please include the service member's name, full social security number, date of mailing, and a POC at the submitting flight surgeon's office with all mailed materials. State in the AMS the date of submission.

Attn: Case Manager for [specify the appropriate MAJCOM] USAFSAM/FECN Facility 20840 2510 Fifth Street Wright-Patterson Air Force Base, OH 45433-7913

#### A. Initial Waiver Request:

- 19. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).
  - b. Age at onset of headache.
  - c. Timing and mode of headache onset, including presence or absence of aura and prodrome.
  - d. Quality of headache, intensity, duration, site of pain, presence or absence of radiating pain.
  - e. Any precipitating or alleviating factors (include statement about effect of activity on headache, whether there is any association to food/alcohol, and any association with environmental factors).
  - f. Any associated symptoms or abnormalities.
  - g. Specify whether there is recent history of any of the following: vision change; trauma; change in weight; alteration in exercise, sleep, or dietary habits; alteration in work or lifestyle.
  - h. For women, specify type of contraception (if applicable), any recent changes in contraception, association with menstrual cycle, and whether there is use of exogenous hormones.
  - i. Frequency of headaches and number of headaches per month.
  - j. Date of last headache attack.
  - k. Current physical and neurological examinations.
  - 1. Family history of headaches.

- 20. Consultation report from any specialty provider and all subsequent consultation notes.
- 21. Results of all testing performed in the course of diagnosis, evaluation, and management of headache, including laboratory studies, imaging, and any other neurologic studies (see note above).
  - a. Must include result of a non-contrasted MRI of the brain (at minimum). If MRI is contraindicated, specify the reason for contraindication.
- 22. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 23. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.
- B. Renewal Waiver Request:
  - 18. Updated AMS with interval history, including:
    - a. Complete updated history and physical examination, including current neurological examination.
    - b. Any changes to the historical information required for initial waiver request.
  - 19. All interval consultation reports from specialty providers.
  - 20. Results of all interval testing performed in the course of ongoing headache evaluation and management, including laboratory studies, imaging, and any other neurologic studies (see note above).
  - 21. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
  - 22. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

## **III. Aeromedical Concerns**

The aeromedical concerns associated with headache relate to the risk of headache recurrence and the potential adverse effects of treatment. Recurrent headaches may occur acutely and be associated with symptoms that would pose a threat to operational safety and mission effectiveness. Examples of symptoms of aeromedical importance include pain, visual disturbances, nausea or vomiting, vertigo, or neurologic deficits such as speech, motor, or cognitive dysfunction. Severity of these symptoms varies between underlying etiologic mechanisms, between individuals, and between headache attacks. At a minimum, the pain from the headache itself or the effects of any associated symptoms may be distracting in an aviation or operational environment. At worst, a recurrent headache may result in sudden incapacitation.

When considering the appropriateness of a waiver, the primary aeromedical and operational concerns are twofold – the individualized risk for future recurrence, and the degree of incapacitation that a recurrent headache is likely to cause. The underlying headache diagnosis is a secondary consideration. In manned aviation, concern is greatest for those flying single-seat aircraft or for those in aircraft where complete crew participation and coordination are essential for mission completion. Similarly, concern is greatest for individuals who are required to function in austere environments without prompt access to medical care or in settings where

there is a lack of redundant personnel capable of assuming essential aviation or operational duties. However, significant concerns exist for any aircrew member, GBO, ATC, or SWA.

Unfortunately, the future recurrence risk for most headache disorders is imprecisely-predictable. Past historical patterns are useful only as an estimate of future activity. A sufficient period of observation may reasonably ensure stability; the length of this observation will vary by the individual and headache type.

Appropriate headache therapy depends upon a correct and complete diagnosis. Nonpharmacologic strategies such as lifestyle modification and behavioral techniques can be useful adjuncts to management. Selected patients may benefit from measures such as dietary supplements, osteopathic manipulation, trigger point injections, or acupuncture. Many FDAapproved headache medications are not formally approved for use in USAF aircrew or operators. Depending upon the medication, its indication (abortive versus prophylactic), and the career field of the service member, use of prescription pharmacotherapy may or may not be amenable to a waiver. For example, waiver precedent exists for pilots of non-high performance aircraft treated with antihypertensive medications for the purpose of headache prophylaxis (i.e., pilots utilizing beta-blockers, calcium channel blockers, angiotensin-converting enzyme inhibitors, or angiotensin II receptor blockers for headache prevention may be considered for a FC IIA waiver). With the exception of topiramate use in GBO personnel, the use of antidepressant or anticonvulsant medications is historically not considered appropriate for any class of waiver due to the adverse effects associated with these medications, as well as the fact that the need for these medications generally indicates a more severe headache syndrome. Similarly, opioid analgesics, benzodiazepines, or musculoskeletal agents with sedative properties are not appropriate for a waiver. Waivers are unlikely for treatment with chemo-denervation (usually with botulinum toxin) or external stimulator devices. When these interventions are successful, a waiver may be entertained on a case-by-case basis. However, the indication for chemo-denervation is very frequent headaches, which may not be compatible with sustained aviation or operational duties. Operational concerns may preclude waivers for external simulators.

Proper diagnosis, recognition of secondary headache disorders, and careful evaluation for provoking factors can facilitate a reduction in headache frequency, duration, and intensity. Given that aeromedical risk is driven by the likelihood of recurrence and the severity of associated symptoms, the optimization of aeromedical risk is contingent upon the implementation of appropriate non-pharmacologic headache management strategies. If pharmacologic therapy is necessary, choosing the agent with the lowest clinical and aeromedical risk profile is essential.

AIMWTS review in Jan 2019 revealed a total of 2301 members with a waiver submissions including the diagnosis of headache. Of these, there were a total of 1211 disqualifications. Breakdown of the cases was as follows: 180 FC I/IA cases (95 disqualified), 439 FC II cases (161 disqualified), 60 RPA pilot cases (13 disqualified), 1000 FC III cases (580 disqualified), 403 ATC/GBC cases (278 disqualified), and 219 MOD cases (89 disqualified). The vast majority of DQ cases were primarily for the headache diagnosis.

#### Please use only these ICD-10 codes for AIMWTS coding purposes

R51.9	Headache, unspecified	
G43.1	Migraine with aura	
G43.0	Migraine without aura	
G44.1	Vascular headache, not elsewhere classified	
G44.20	Tension-type headache, unspecified	
G44.00	Cluster headache syndrome, unspecified	

## **IV. Suggested Readings**

- 1. National Headache Foundation. Available at <u>https://headaches.org/resources/</u>. Accessed 28 October 2020.
- Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalgia 2018;38:1-211. Available at <u>https://ichd-3.org/wp-content/uploads/2018/01/The-International-Classificationof-Headache-Disorders-3rd-Edition-2018.pdf</u>. Accessed 28 October 2020.
- Steiner TJ, Jensen R, Katsarava Z, et al. Aids to management of headache disorders in primary care (2nd edition). J Headache Pain 2019:20;57. Available at <u>https://thejournalofheadacheandpain.biomedcentral.com/track/pdf/10.1186/s10194-018-0899-2</u>. Accessed 28 October 2020.

#### Meningitis and Encephalitis (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

Updated Waiver Consideration, Table 1 and References

#### I. Waiver Consideration

A history of central nervous system (CNS) infection (e.g., meningitis, encephalitis, meningoencephalitis, brain abscess) is disqualifying for flying duties in the US Air Force according to the Air Force Medical Standards Directory (MSD. Waiver requests may be submitted as soon as the individual is symptom free, cleared by Neurology or Infectious Disease consultants, and has normal studies. Encephalitis and abscess cases may require more prolonged observation due to elevated seizure risk. CNS infections are not disqualifying for OSP duties per the MSD.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes ¹	AETC	Yes
FC II/III/SWA	Yes ¹	MAJCOM	Yes
ATC/GBO	Yes ¹	MAJCOM	At discretion of waiver authority

 Table 1: Waiver potential for meningitis and encephalitis

1. Waiver consideration based on amount of residual symptoms and deficits. Encephalitis and non-aseptic meningitis cases may require additional observation due to seizure risk Indefinite waiver recommendation possible in selected cases with complete resolution or minimal non functionally-limiting residua.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

A. Initial Waiver Request:

- 1. Complete history of event detailing all symptoms, evaluation, treatment, current symptoms and activity level.
- 2. Copies of relevant clinical notes (particularly consultation reports from Neurology and [if obtained] Infectious Disease), diagnostic studies (lumbar puncture results, other lab studies, and EEGs if obtained), imaging reports and copies of images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical, mental status and neurologic examination findings
- 4. Audiogram in cases of encephalitis, meningoencephalitis or bacterial, fungal, or parasitic meningitis occurring within the last 3 years.

- 5. Sleep-deprived EEG in cases of encephalitis.
- 6. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

B. Renewal Waiver Request:

- 1 Interval history and level of symptom resolution.
- 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical and neurologic exam findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

#### **III. Aeromedical Concerns**

Aeromedical concerns include the effects of any residual neurologic or cognitive symptoms on operational safety and mission effectiveness, future risk of recurrent infection, and future risk of seizures. Meningitis is an inflammatory process involving the tissues surrounding the central nervous system, while encephalitis involves the brain parenchyma. Some patients have symptoms and signs suggesting involvement of both brain and meninges, blurring the distinction between the two. Acutely, cognitive impairment, obtundation, focal neurological deficits including cranial nerve deficits and hemiparesis, and seizures are significant issues, while residual neurocognitive impairments, movement disorders, and seizures are of future concern. For purposes of aeromedical disposition, aseptic meningitis is defined as no abnormality in brain function (e.g., altered cognitive function, focal neurological deficit), when the CSF findings include a mild pleocytosis (100-1000 cell/mm³ with either mononuclear or polymorphonuclear cell predominance), negative bacterial smears and cultures, normal to mildly elevated protein concentration, and normal to slightly depressed glucose level, and when the clinical course is relatively short. If there is any alteration of cognitive function, obtundation, focal neurological deficit, or complicated hospital or recovery course, then for purposes of aeromedical waiver that is considered to be no longer simple aseptic meningitis but is in the meningoencephalitis or encephalitis continuum. The prognosis is highly variable depending upon the agent responsible for the meningitis or encephalitis. However, in general, simple aseptic (viral) meningitis has an excellent prognosis, although definitive therapy is still somewhat controversial. More complicated forms of viral meningitis, such as West Nile virus or HIV, as well as meningitis secondary to bacterial, fungal, or parasitic agents do not share the same good prognosis. All forms of encephalitis or meningoencephalitis carry a significant risk of chronic neurocognitive or neurological impairment and seizures, and require additional evaluation and observation prior to waiver consideration. Annegers' study from 1988 indicated a 10% risk of seizures over 20 years for viral encephalitis without early seizures, 22% risk with early seizures, 13% risk for bacterial meningitis with early seizures and only 2.4% risk for bacterial meningitis without early seizures.

Late unprovoked seizures may occur in up to 65% of patients following herpes simplex encephalitis. Other neurological complications may be seen, including a high incidence of

neurocognitive and movement disorders in West Nile and Japanese encephalitis. Bacterial brain abscesses carry an increased seizure risk for at least three years post-resolution.

Review of AIMWTS in Dec 2018 showed 104 cases of encephalitis and/or meningitis; 19 FC I/IA, 36 FC II, 2 RPA pilots, 41 FC III, and 6 ATC/GBC. Of the 104, 6 were disqualified (2 FC I and 4 FC III).

ICD-9 Codes for Meningitis and Encephalitis		
047.9	Unspecified viral meningitis	
320.9	Meningitis due to unspecified bacterium	
322.9	Meningitis, unspecified	
323.9	Unspecified cause of encephalitis, myelitis and encephalomyelitis	

ICD-10 Codes for Meningitis and Encephalitis		
A87.9	Viral meningitis, unspecified	
G00.9	Bacterial meningitis, unspecified	
G03.9	Meningitis, unspecified	
B04.90	Encephalitis and encephalomyelitis, unspecified	

## **IV. Suggested Readings**

1. Davis LE. Acute bacterial meningitis. Continuum (Minneap Minn) 2018; 24(5):1264-1283.

2. Lyons JL. Viral meningitis and encephalitis. Continuum (Minneap Minn) 2018; 24(5):1284-1297.

3. Saylor D. Neurologic complications of human immunodeficiency virus infection. Continuum (Minneap Minn) 2018; 24(5):1397-1421.

4. Halperin JJ. Neuroborreliosis and neurosyphilis. Continuum (Minneap Minn) 2018; 24(5):1439-1458.

5. Sejvar JJ. Zika virus and other emerging arboviral central nervous system infections. Continuum (Minneap Minn) 2018; 24(5):512-1534.

6. Gluckman SJ. Viral encephalitis in adults. UpToDate, Oct 30, 2019.

7. Hasbun R. Initial therapy and prognosis of bacterial meningitis in adults. UpToDate, Nov 22, 2019.

8. Tunkel AR. Aseptic meningitis in adults. UpToDate, Sep 26, 2018.

9. Hasbun R. Clinical features and diagnosis of acute bacterial meningitis in adults. UpToDate, Feb 5, 2020.

10. Southwick FS. Treatment and prognosis of bacterial brain abscess. UpToDate, Oct 24, 2019.

11. Ropper AH, Samuels MA, Klein JP (Ed). Infections of the nervous system (bacterial fungal, spirochetal, parasitic) and sarcoidosis. *Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education*, 2014:697-742.

12. Ropper AH, Samuels MA, Klein JP (Ed). Viral infections of the nervous system, chronic meningitis, and prion disease. *Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education,* 2014:743-777.

13. Misra UK, Tan CT, and Kalita J. Viral encephalitis and epilepsy. Epilepsia 2008; 49 (Suppl 6):13-18.

14. Annegers JF et al. The risk of unprovoked seizures after encephalitis and meningitis. Neurology 1988; 38:1407-1410.

## Multiple Sclerosis and Central Demyelinating Disorder (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### Significant Changes:

Updated Table 1 and References

## I. Waiver Consideration

The diagnosis of multiple sclerosis (MS), clinically or radiographically isolated syndrome (CIS/RIS), or other central demyelinating conditions such as optic neuritis, transverse myelitis, and neuromyelitis optica spectrum disorder, is disqualifying for all flying classes. As the diagnosis of MS is disqualifying for retention purposes, all flying and special operational personnel will require a waiver for this diagnosis. Along with submission of aeromedical waiver request, an initial RILO, or MEB as directed, must be performed to determine military service retention. Members who are retained in military service may then be aeromedically considered. Due to disease unpredictability and effects of military/environmental stressors on symptoms, waiver is generally not recommended for aviators with the diagnosis of MS or high-risk CIS/RIS. However, aviators with CIS/RIS and selected aviators with high-risk CIS/RIS or MS with long-term longitudinal stability may be considered for aeromedical waiver on an individual basis.

# Table 1: Waiver potential for multiple sclerosis, CIS/RIS, and other central demyelinating disorders

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	No	AETC	No
FC II//III/SWA	Yes ¹	AFMRA	Yes
ATC/GBO	Yes ¹	AFMRA	Yes

1. If low-risk CIS/RIS, or longitudinally-stable (clinical and radiographic) high-risk CIS/RIS or MS

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

A. Initial Waiver Request:

- 1. A complete discussion of the history of the demyelinating disorder.
- 2. Reports of consultations and diagnostic testing, including: neurology and (as applicable) ophthalmology consultations, reports and images from neuroimaging studies, laboratory testing (including lumbar puncture/cerebrospinal fluid studies, if performed), and sleep study reports (if performed). If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical, mental status and neurologic examination findings.
- 4. Neuropsychological testing if performed. Contact ACS Neuropsychology for questions or further guidance on need for testing and on which tests to administer.
- 5. RILO/MEB results, if obtained.

- 6. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.
- B. Renewal Waiver Request:
  - 1 Interval history and level of symptom resolution.
  - 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
  - 3. Current physical, neurologic and mental status examination findings.
  - 4. RILO/MEB updates as applicable.
  - 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include effects of any residual neurologic or cognitive symptoms and signs and any medication effects on operational safety and mission effectiveness, and future risk of symptom development, which could be subtle and unrecognized. Initial imaging and cerebrospinal fluid findings in CIS/RIS cases can stratify for low or high risk of future conversion to MS. Unfortunately, there are no current clinical, biochemical or radiographic markers to prospectively identify those patients who will have 'benign' MS, and assessment of disease stability is based on retrospective analysis only. Even 'benign MS' patients with 10+ years of disease stability have an over 1% annual risk of developing new symptoms between years 10-20. Cognitive deficits are common and unpredictable effecting approximately 40-60% of MS patients. The incidence of cognitive impairments does not correlate well with the degree of physical deficits, as these may be present in all types of MS and at any stage of the disease. Aeromedically-valid neurocognitive testing can be performed only at a maximum of six month intervals. However, even with this level of monitoring, unpredictable interim neurocognitive changes could still pose a threat to self, crew safety, and mission completion. A further concern with MS is the potential of sleep disturbance that can result in daytime sleepiness, worsening fatigue, depression, and lowered pain threshold. Of particular importance, fatigue is considered the most frequent and often the most disabling symptom of MS, reported by at least 75% of patients at some point during their disease course. Finally, none of the current FDA-approved disease-modifying agents are approved for use in aviators due to their side effect profiles.

AIMWTS search in Jan 2019 revealed 100 cases diagnosed as MS, CIS, or as compatible with demyelinating disease. Breakout of the cases was: 3 FC I/IA cases (2 disqualified); 47 FC II cases (36 disqualified); 34 FC III cases (27 disqualified); 5 RPA pilot cases (2 disqualified); 7 ATC/GBC cases (7 disqualified); and 4 MOD cases (1 disqualified). There are several cases of MS not recommended for waiver by ACS, but granted an Exception to Policy from AF/A3 (continuity of ETPs is handled administratively as waivers from AFMRA).

ICD-9 Codes for MS and CIS		
340	Multiple sclerosis	
377.30	Optic neuritis, unspecified	
341         Other demyelinating diseases of central nervous system		

ICD-10 Codes for MS and CIS		
G35	Multiple sclerosis	
H46.9	Optic neuritis, unspecified	
G37.8, G37.9 Other demyelinating diseases of central nervous system		

#### **IV. Suggested Readings**

1. Solomon AJ. Diagnosis, differential diagnosis, and misdiagnosis of multiple sclerosis. Continuum (Minneap Minn) 2019; 25(3):611-635.

2. Gross RH, Corboy JR. Monitoring, switching, and stopping multiple sclerosis disease-modifying therapies. Continuum (Minneap Minn) 2019; 25(3):715-735.

3. Tonin WO. Management of multiple sclerosis symptoms and comorbidities. Continuum (Minneap Minn) 2019; 25(3):753-772.

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5. Thompson AJ et al. Diagnosis of multiple sclerosis: 2017 revision of the McDonald criteria. Lancet Neurol 2018; 17:162-173.

6. Olek MJ, Howard J. Management of clinically and radiographically isolated syndromes suggestive of multiple sclerosis. UpToDate, Apr 23, 2019.

7. Olek MJ, Howard J. Evaluation and diagnosis of multiple sclerosis in adults. UpToDate, Oct 30, 2019.

8. Olek MJ, Mowry E. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. UpToDate, Jan 2, 2020.

9. Novakova L et al. Monitoring disease activity in multiple sclerosis using serum neurofilament light protein. Neurology 2017; 89:2230-2237.

10. Sartori A, Abdoli M, and Freedman MS. Can we predict benign multiple sclerosis? Results of a 20-year long-term follow-up study. J Neurol, 2017; 264(5):1068-1075.

11. Ropper AH, Samuels MA, Klein JP (Ed). Multiple sclerosis and other inflammatory demyelinating disorders. *Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education*, 2014:915-945.

12. Optic Neuritis Study Group. Multiple Sclerosis Risk After Optic Neuritis: Final Optic Neuritis Treatment Trial Follow-up. Arch Neurol 2008; 65:727-732.

13. Rogers JM and Panegyres PK.. Cognitive impairment in multiple sclerosis: Evidence- base analysis and recommendations. J Clin Neuroscience 2007; 14:919-927.

#### Seizures, Epilepsy, and Abnormal EEG (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### Significant Changes:

Updated Table 1 and References

## I. Waiver Consideration

Medical standards for appointment, enlistment and induction state that epilepsy occurring beyond the 6th birthday is disqualifying, unless the applicant has been free of seizures for a period of 5 years while taking no medication for seizure control, and has a normal electroencephalogram (EEG). Childhood seizures are addressed by stating that "seizures associated with febrile illness before 5 years of age may be acceptable with waiver if recent neurological evaluation, MRI, and EEG including awake and sleep samples are normal". Childhood seizures with prolonged remission may be amenable to waiver consideration on an individual basis. Truly provoked seizures may also be aeromedically-acceptable for waiver consideration on an individual basis. Unprovoked seizures are generally not recommended for waiver due to unacceptably-high recurrence risk. For information on post-traumatic seizures and waiver potential, please consult the Waiver Guide chapter on traumatic brain injury.

For aviators with isolated epileptiform EEG abnormalities and no history of seizure or epilepsy, clinical surveillance is indicated, with categorical waiver recommendation for at least one year, based on data that most non-epileptic adult patients with isolated epileptiform EEG abnormalities who develop seizures will do so within one year of EEG abnormality identification.

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Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	Yes ¹	AFMRA	Yes
FC II//III/SWA/OSF	Yes ^{1,2}	AFMRA	Yes
	1		
ATC/GBO	Yes ¹	AFMRA	Yes
1 11 11	1 1 0	1 1 ' ' '	

Table 1: Waiver potential for seizures, epilepsy and abnormal (epileptiform) EEG findings

1. Waiver usually not recommended for unprovoked seizures or epilepsy. Cases of isolated EEG abnormalities without seizures may be acceptable for waiver on a case-by-case basis after careful review by an epileptologist.

2. Isolated EEG abnormalities not disqualifying for OSF duty.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable. The diagnosis of a seizure is still primarily clinical, and every effort must be made to try and reconstruct what happened before, during and after a suspected seizure event. Special attention should be paid to clinical notes from all who had contact with the patient, such as medical technicians, paramedics, nurses, emergency department personnel, and providers. The medical history should address the relevant period preceding and during the suspected event and include a review of travel, sleep, diet, work and all medications,

whether prescription or over-the-counter. Any ethanol, caffeine and nicotine intake should be listed. Accounts from witnesses must be included in the medical record, either as a written statement from the eyewitness, or as an account documented by a provider. If written accounts were not accomplished initially, then every effort should be made to identify possible witnesses and include their accounts.

A. Initial Waiver Request:

- 1 Historical details as listed above.
- 2 Reports of consultations and diagnostic testing, including: neurology consultations, neuroimaging studies (MRI reports and images), laboratory testing, and EEG reports. Recent brain MRI and EEG studies are needed in cases of remote seizures. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical, mental status and neurologic examination findings.
- 4 Neuropsychological testing if performed. Contact ACS Neuropsychology for questions or further guidance on need for testing and on which tests to administer.
- 5 RILO/MEB results, if obtained.
- 6 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

B. <u>Renewal Waiver Request:</u>

- 1 Interval history and level of symptom resolution.
- 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical, mental status and neurologic examination findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## III. Aeromedical Concerns

Aeromedical concerns include effects of any residual neurologic or cognitive symptoms and signs and any medication effects on operational safety and mission effectiveness, and future risk of seizure occurrence, with resulting sudden incapacitation. For unprovoked seizures in adults, the risk of recurrence is greater than 40% over five years. This aeromedically-unacceptable risk is further increased with other factors such as prior brain lesion or insult causing the seizure, an EEG with epileptiform abnormalities, a significant brain imaging abnormality and nocturnal seizure occurrence. Truly provoked seizures may be amenable to waiver consideration on an individual basis. Sleep deprivation alone is not considered a provocative factor for seizures in neurologically intact individuals. Children with a nonfebrile unprovoked seizure and a normal EEG have a fiveyear recurrence rate of about 21% and recurrences after that time frame are not common. Absence seizures have a repeat seizure rate of 42% over the next 25 years (to include other types of seizures) and are therefore permanently disqualifying. Children with simple febrile seizures generally do not have significant risk for seizure recurrences in adulthood and this diagnosis is amenable to waiver consideration. Brain MRI with attention to medial temporal lobe structures ("seizure protocol") is the most appropriate imaging study to obtain. EEG studies are needed in diagnostic evaluation. These do not prove or disprove the diagnosis of epilepsy, although an unequivocally abnormal EEG

combined with a clinical history compatible with seizure does support the diagnosis. However, EEG studies can be completely normal in known epileptic patients, and a small percentage of the normal population will have apparent epileptiform patterns on EEG. A 1968 review of non-epileptic patients with epileptiform changes on EEG showed that the vast majority of adult patients who developed seizures did so within 12 months of discovery of the EEG abnormalities. In such cases, observation with restricted aviation duties and follow-up EEG studies are usually recommended to determine if a less restrictive waiver might be safely considered in the future. No anticonvulsant medications are aeromedically-approved for use in USAF aviators for management of seizures, although gabapentin and topirimate are approved for use in MOD personnel for non-epilepsy conditions such as pain and migraine.

AIMWTS search in Jan 2019 revealed 329 cases. Breakdown of the cases was as follows: 73 FC I/IA cases (29 disqualified); 84 FC II cases (46 disqualified); 10 RPA pilot cases (1 disqualified), 108 FC III cases (62 disqualified); 34 ATC/GBC cases (24 disqualified); and 20 MOD cases (12 disqualified). The vast majority of the approved cases were for childhood febrile seizures with several provoked seizures as well.

ICD-9 codes for seizures		
345	Epilepsy	
780.3	Convulsions	
780.31	Simple febrile convulsions	
780.32	Complex febrile convulsions	
780.33	Post traumatic seizures	
780.39	Other (unspecified) convulsions	

ICD-10 codes for seizures		
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	
R56.00	Simple febrile convulsions	
R56.01	Complex febrile convulsions	
R56.1	Post traumatic seizures	
R56.9	Unspecified convulsions	
R94.01	Abnormal EEG	

## **IV. Suggested Readings**

1. Schachter SC. Evaluation and management of the first seizure in adults. UpToDate, Aug 11, 2019.

2. Millichap JJ. Treatment and prognosis of febrile seizures. UpToDate, Dec 20, 2018.

3. Bergey GK. Management of a First Seizure. Continuum: Lifelong Learning in Neurology, 2016; 22(1): 38-50

4. Gupta A. Febrile seizures. Continuum: Lifelong Learning in Neurology, 2016; 22(1): 51-59

5. Chen DK and LaFrance WC. Diagnosis and Treatment of Nonepileptic Seizures. Continuum: Lifelong Learning in Neurology, 2016; 22(1): 116-31.

6. Krumholz A, Wiebe S, Gronseth GS, et al. Evidence-based guideline: Management of an unprovoked first seizure in adults: Report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology 2015; 84(16):1705-13.

7. Ropper AH, Samuels MA, Klein JP (Ed). Epilepsy and other seizure disorders. *Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education*, 2014:318-356.

8. Lawn L et al. Are seizures in the setting of sleep deprivation provoked? Epilepsy & Behavior 2014; 33:122-125.

9. Benbadis SR. "Just like EKGs!" Should EEGs undergo confirmatory interpretation by a clinical neurophysiologist? Neurology 2013; 80 (Suppl 1):S46-S51.

10. Salinsky M, Kanter R, Dasheiff RM. Effectiveness of multiple EEGs in supporting the diagnosis of epilepsy: an operational curve. Epilepsia 1987; 28(4):331-334.

11. Robin JJ, Tolan GD, and Arnold JW. Ten-Year Experience with Abnormal EEGs in Asymptomatic Adult Males. Aviat Space Environ Med 1978; 49:732-36.

12. Zivin L and Marson A. Incidence and Prognostic Significance of "Epileptiform" Activity in the EEG of Non-Epileptic Subject. Brain 1969; 91:751-78.

## Transient Ischemic Attack (TIA) and Stroke (Apr 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

Updated References

## I. Waiver Consideration

Irrespective of etiology, stroke and TIA are disqualifying for all flying classes. Waivers are generally not considered unless a correctable cause is discovered and treated. Examples of correctable etiologies might include iatrogenically-induced stroke from catheterization or trauma to the carotid artery without residual injury, and repair of a large patent foramen ovale with intracardiac shunting. Modifiable vascular disease risk factors such as hypertension and hyperlipidemia are not considered correctable etiologies. Additionally, supratentorial strokes leave a potential seizure focus. A 2-3 year seizure-free observation period after stroke and a 1-2 year observation period after TIA are required prior to any potential waiver consideration. Any manned-aircraft pilot waiver recommendations after stroke or TIA are almost invariably limited to non high-performance, multi-crew platforms, often with further restriction of another fully trained pilot to be present during aircraft operation. Stroke is a dynamic field, with evolving evaluation and management guidance.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	Possibly ¹	AFMRA	Yes
FC II//III/SWA	Yes ²	AFMRA	Yes
ATC/GBO	Yes ²	AFMRA	Yes

#### Table 1: Waiver potential for stroke and TIA

1. Waiver recommendation may be considered in exceptional cases if felt secondary to a (treated) correctable cause, and with a suitable observation period

2. Must be 2-3 years post-stroke or 1-2 years post-TIA with no symptoms or clinically-insignificant residua

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

## A. Initial Waiver Request:

- 1. History details of the incident to include the extent of symptoms, physical findings, timing of onset and resolution, and possible precipitating factors (i.e., Valsalva or +Gz preceding symptom onset).
- 2. Reports of consultations and diagnostic testing, including: neurology consultation, imaging studies (reports and images), laboratory testing, cardiac testing (ECG, echocardiogram (report and images), rhythm monitoring), and operative reports if applicable. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical, mental status and neurologic examination findings.

- 4. Neuropsychological testing for all stroke cases. Contact ACS Neuropsychology for questions or further guidance on specific tests to administer.
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.
- B. Renewal Waiver Request:
  - 1 Interval history and level of symptom resolution.
  - 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
  - 3 Current physical and neurologic exam findings.
  - 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include effects of any residual neurologic or cognitive symptoms and signs and any medication effects, on operational safety and mission effectiveness, future risk of recurrence, and future risk of seizures. Literature reports indicate stroke recurrence rate is highest immediately following the initial stroke and continues to remain aeromedically-unacceptably high indefinitely, up to 3-4% annually. However, these rates listed in the literature may overestimate the risk in USAF aviators, as many patients in these studies had significant, sometimes multiple vascular risk factors that are not present in the USAF aviator cohort. Also, strokes with a welldefined and correctable etiology, as well as cryptogenic strokes, may have an aeromedicallyacceptable lower incidence of recurrence and potentially amenable to waiver consideration. The role and management of patent foramen ovale in stroke is evanescent. Current guidelines advise closure in cases of large openings, recurrent vascular events, or with associated atrial septal aneurysm. Prolonged implantable cardiac monitoring to assess for occult atrial arrhythmias should be obtained in cases of cryptogenic stroke. Trans-esophageal echocardiography should also be considered in cryptogenic stroke cases to more thoroughly assess left atrial anatomy. The recentlycharacterized designation of Embolic Stroke of Undetermined Source (ESUS) consists of nonlacunar cryptogenic strokes with likely embolic etiology. Unfortunately, recurrence risk of ESUS is estimated at over 4% annually, and such aviators may not be recommend for aeromedical waiver. Also, atrial fibrillation-associated stroke may have an unacceptably-high recurrence risk for aeromedical waiver consideration. The risk of post-stroke seizures is aeromedically-unacceptably high for at least the first several years following a supratentorial stroke. Supratentorial cortical locations are associated with a higher seizure risk, but seizures also occur following subcortical lacunar strokes. The incidence of new-onset seizures declines over time, with population studies suggesting the risk becomes aeromedically-acceptable after 2-3 years.

Review of AIMWTS through Jan 2019 showed 45 cases of TIA/stroke; 17 were disqualified. Breakdown of the cases revealed: 28 FC II (10 disqualified), 2 RPA pilots (0 disqualified), 12 FC III (6 disqualified), and 3 MOD (1 disqualified).

ICD-9 Codes for transient ischemic attack and stroke				
435.9	Transient cerebral ischemia			
434.0	Cerebral thrombosis			
434.1	Cerebral embolism			
434.9	Cerebral artery occlusion, unspecified			
432.9	9 Unspecified intracranial hemorrhage			
443.21	1 Dissection of carotid artery			
443.24Dissection of vertebral artery				

ICD-10 Codes for transient ischemic attack and stroke				
G45.9	Transient cerebral ischemia attack, unspecified			
I63.00	00 Cerebral infraction due to thrombosis of unspecified precerebral artery			
I63.19	9 Cerebral infarction due to embolism of other precerebral artery			
I66.9	9 Occlusion and stenosis of unspecified cerebral artery			
I62.9	Nontraumatic intracranial hemorrhage, unspecified			
I77.71	Dissection of carotid artery			
I77.74	Dissection of vertebral artery			

#### **IV. Suggested Readings**

- 1. Furie K. Epidemiology and primary prevention of stroke. Continuum (Minneap Minn) 2020; 26(2):260-267.
- 2. Rabenstein AA. Update on treatment of acute ischemic stroke. Continuum (Minneap Minn) 2020; 26(2):268-286.
- 3. Rost NS, Etherton M. Cerebral small vessel disease. Continuum (Minneap Minn) 2020; 26(2):332-352.
- 4. Kamel H. The evolving concept of cryptogenic stroke. Continuum (Minneap Minn) 2020; 26(2):353-362.
- 5. Christensen H, Bushnell C. Stroke in women. Continuum (Minneap Minn) 2020; 26(2):363-385.
- 6. Putaala J. Ischemic stroke in young adults. Continuum (Minneap Minn) 2020; 26(2):386-414.
- 7. Kim AS. Medical management for secondary stroke prevention. Continuum (Minneap Minn) 2020; 26(2):435-456.

8. Wang JZ et al. Incidence and management of seizures after ischemic stroke. Systemic review and meta-analysis. Neurology 2017; 89:1220-1228.

9. Yaghi S, Kamel H, Elkind MSV. Atrial cardiopathy: a mechanism of cryptogenic stroke. Extert Rev Cardiovasc Ther 2017; 15(8):591-599.

10. Hart RG et al. Embolic stroke of undetermined source: a systematic review and clinical update. Stroke 2017; 48:867-872.

## Traumatic Brain Injury (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## Significant Changes:

Updated Waiver Consideration, Tables and References

## I. Waiver Consideration

Traumatic brain injury (TBI) unfortunately occurs too commonly in aviators. A history of TBI is generally disqualifying for all flying classes. Each TBI case has unique characteristics, and waiver consideration is on an individual basis, taking into account all factors. This individual variability makes it quite challenging to comprehensively address TBI in guidance tables. Severity classification is based on the 2007 DoD guidance with additional incorporation of clinical and radiographic information. Recommended post-injury observation periods are evidence-based to allow post-injury seizure risk to become aeromedically-acceptable for waiver consideration. Head injuries without significant sequelae are not disqualifying for OSF personnel per the Medical Standards Directory.

Following discussion with Career Field Managers, the Aeromedical Standards Working Group established a difference in acceptable risk for sudden incapacitation for selected enlisted aircrew and GBO personnel based on AFSC, allowing potential for earlier return to fly following aeromedically-moderate or severe head injury. Table 4 below lists this guidance.

Please contact ACS Neurology and/or Neuropsychology for any case-specific questions.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation		
FC I/IA	Yes	AFMRA	For moderate or severe TBI cases ¹		
FC II/III/SWA	Yes	AFMRA ²	For moderate or severe TBI cases ¹		
ATC/GBO	Yes	AFMRA ²	For moderate or severe TBI cases ³		

## Table 1: Waiver potential for TBI

1. ACS review/evaluation of mild head injury cases on request from the waiver authority

2. AETC is waiver authority for IFC II/III, I-GBO, I-SWA, and I-ATC cases.

3. No waiver required for uncomplicated ATC/GBO cases of aeromedically-mild TBI with normal examination

## II. Information Required for Waiver Submittal

Table 2 applies to head injuries that occurred less than five years from time of waiver request.

Degree of Head Injury	Minimum	Evaluation Requirements
Degree of ficau figury	Observation	
	Time	
Aeromedical Mild	1 month	Flying Class I, IA, II, III, RPA, SWA:
(LOC or amnesia < 30	1	Neurological exam: Complete neurological and mental
minutes; normal MRI)		status examination by a Flight Surgeon
, , , , , , , , , , , , , , , , , , ,		Imaging: noncontrast MRI
		Cognitive Assessment: Clinical interview and screening
		(Montreal Cognitive Assessment or equivalent)
Aeromedical Moderate	6 months	Flying Class I, IA, II, III, RPA, ATC, GBO, SWA:
(LOC or amnesia > 30		Neurological exam: Complete neurological and mental
minutes but < 24 hours		status examination by a Neurologist
or non-displaced skull		<b>EEG</b> : obtain locally if any seizure activity
fracture; normal MRI)		reported/observed
		Imaging: noncontrast MRI
		Neuropsychological evaluation: Local, to include
		assessment of general cognitive functioning and major
		cognitive domains. Contact ACS Neuropsychology for
		guidance on specific testing. Include any test scores with
		waiver package
<b>Aeromedical Moderate</b>	2 years	Flying Class I, IA, II, III ¹ , RPA, ATC, GBO ¹ , SWA:
(LOC or amnesia > 30	for most	Neurological exam: Complete neurological and mental
minutes but < 24 hours	AFSCs,	status examination by a Neurologist
or non-displaced skull	6 months	EEG: obtain locally if any seizure activity
fracture; MRI	for specific	reported/observed
demonstrating	AFSCs ¹	Imaging: noncontrast MRI locally within one month of
evidence of diffuse		injury; follow-up MRI at time of waiver submission
axonal injury or		Neuropsychological evaluation: A local NP evaluation
hemosiderin		during the 3-9 month post-TBI period, to include
deposition/plugs)		assessment of general cognitive functioning and major
		cognitive domains. Contact ACS Neuropsychology for
		guidance on specific testing. Include any test scores with
A anomodiael Savara	2 100 10	waiver package
Aeromedical Severe (LOC or amnesia > 24	2 years	Flying Class I, IA, II, III, RPA, ATC, GBO, SWA: Neurological exam: Complete neurological and mental
hours; normal MRI or		status examination by a Neurologist
MRI demonstrating		<b>EEG</b> : locally or during ACS evaluation
inconsequential		<b>Imaging</b> : noncontrast MRI locally within one month of
hemorrhage or		injury; follow-up MRI at time of waiver submission
evidence of diffuse		<b>Neuropsychological evaluation</b> : A local NP evaluation
axonal injury or		during the 3-9 month post-TBI period, to include
azonai mjul y 01		aumg me 5-7 month post-1 bi period, to metude

 Table 2: Aeromedical Classification and Evaluation of TBIs less than five years from time of waiver request.

hemosiderin		assessment of general cognitive functioning and major
deposition/plugs)		cognitive domains. Contact ACS Neuropsychology for
		guidance on specific testing. Include any test scores with
		waiver package
Aeromedical Severe	5 years	Flying Class I, IA, II, III ¹ , RPA, ATC, GBO ¹ , SWA:
(LOC or amnesia > 24	for most	ACS: evaluation
hours; presence of	AFSCs,	Neurological exam: Complete neurological and mental
subdural hematoma or	2 years for	status examination by a Neurologist
brain contusion; MRI	specific	EEG: locally or during ACS evaluation.
demonstrating more	AFSCs ¹	Imaging: noncontrast MRI locally within one month of
significant		injury; follow-up MRI at time of waiver submission
abnormalities)		Neuropsychological evaluation: A local NP evaluation
		during the 3-9 month post-TBI period, to include
		assessment of general cognitive functioning and major
		cognitive domains. Contact ACS Neuropsychology for
		guidance on specific testing. Include any test scores with
		waiver package
Aeromedical Severe	No waiver	All Flying Classes
(penetrating injury,	possible	
volume loss > 25cc, late		
seizure, shunt,		
significant deficits)	1 1 1	

1. FC III and GBO AFSCs that may be considered for waiver for moderate head injury at 6 months, or for waiver for severe head injury at 2 years, are listed in Table 4.

Table 3 applies to IFC applicants with a remote history of TBI, defined as five years or more postinjury.

Table 3: IFC applicants (all classes) with histo	
Normal exam and imaging at time of injury	Neurological exam: Complete neurological
	and mental status examination by a Flight
	Surgeon
	<b>Imaging</b> : report and images of prior studies.
	Current non-contrast brain MRI if no prior
	MRI was performed
	Neuropsychological evaluation: not required
	unless felt clinically indicated by the Flight
	Surgeon
	<b>Review</b> : AETC/SGP. ACS review at discretion
	of waiver authority
Abnormal exam, imaging or EEG at time of	Neurological exam: Complete neurological
injury	and mental status examination by a Flight
	Surgeon
	<b>Imaging</b> : report and images of prior studies.
	Current non-contrast brain MRI if no follow-
	up neuroimaging was performed
	<b>EEG</b> : report of previous studies.
	Current sleep-deprived EEG if any previous
	EEG study was reported as abnormal
	Neuropsychological evaluation: not required
	unless felt clinically indicated by the Flight
	Surgeon
	Review: AETC/SGP. ACS review at discretion
	of waiver authority
Seizure within 24 hours of time of injury ¹	Neurological exam: Complete neurological
	and mental status examination by a Flight
	Surgeon
	Imaging: report and images of prior studies.
	Current non-contrast brain MRI if no follow-
	up neuroimaging was performed
	<b>EEG</b> : report of previous studies.
	Current sleep-deprived EEG if no previous
	studies were performed or if any previous EEG
	study was reported as abnormal
	Neuropsychological evaluation: not required
	unless felt clinically indicated by the Flight
	Surgeon
	Review: AETC/SGP. ACS review at discretion
	of waiver authority
1 Seizures occurring 24 hours or later following TBL are di	

## Table 3: IFC applicants (all classes) with history of remote (>=5 years) TBI

1. Seizures occurring 24 hours or later following TBI are disqualifying. In such cases, please refer to the Seizures/Epilepsy/Abnormal EEG Waiver Guide chapter for further information.

Table 4 lists FC III and GBO AFSCs that can be considered for <u>earlier</u> TBI waiver (6 months for moderate and 2 years for severe injury).

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	1A2X1	Aircraft Loadmaster
	1A3X1	Airborne Mission Systems
	1A4X1	Airborne Operations
	1A6X1	Flight Attendant
	1A8X1	Airborne Cryptologic Language Analyst
	1A8X2	Airborne ISR Operator
Ī	1B4X1	Cyberspace Defense Operations
	1C6X1	Space Systems Operations
	1T0X1	Survival, Evasion, Resistance, and Escape
	1T2X1	Pararescue
	13BX	Air Battle Manager
	13LX	Air Liaison Officer
	13SX	Space & Missile
	17DX	Cyberspace Operations

Table 4: Specific AFSCs that qualify for earlier TBI waiver consideration

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

A. Initial Waiver Request:

- 1. Historical details of the injury and initial treatment. Include clinical notes from initial evaluation and treatment.
- 2. Evaluation as outlined in Tables 2 and 3 above. Include reports of consultations and diagnostic testing, including: neurology consultations, neuroimaging studies (e.g. MRI reports and images), laboratory testing, any operative reports and EEG reports. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Current physical, mental status and neurologic examination findings.
- 4. Neuropsychological testing results (if performed). Contact ACS Neuropsychology for questions or further guidance on need for testing and on which tests to administer.
- 5. RILO/MEB results, if obtained.
- 6. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## B. <u>Renewal Waiver Request:</u>

- 1 Interval history and level of symptom resolution.
- 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical, mental status and neurologic examination findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include effects of any residual neurologic or cognitive symptoms and signs and any medication effects on operational safety and mission effectiveness, and future risk of seizure with resulting sudden incapacitation. The risk to safety of flight from a fixed neurological deficit is readily apparent. Cognitive deficits may not be readily apparent but can be assessed with appropriate testing. Military aviation stressors such as hypoxia, high +G exposure and sleep disruption may precipitate seizures. Anticonvulsant medications are not currently approved for use in aviators for seizure prophylaxis, primarily due to their central-acting effects on cognition and alertness, and secondarily for the potential of withdrawal seizures following abrupt discontinuation. Interestingly, immediate and early (7 days or less) post-traumatic seizures do not produce an increased future seizure risk, while seizures occurring over 7 days post-TBI do. Annegers' seminal studies indicated the relative risk of seizures following even mild TBI compared to the normal population remains elevated for five years, while the relative risk after moderate or severe TBI remains elevated for over ten years. The actual incidence of seizures, however, becomes aeromedically acceptable much sooner, reflected in recommended observation periods listed in Table 2 above. In one study of USAF aircrew who met waiver criteria, seizures occurred at a rate of 24.53/100,000 person-years. A retrospective study of Vietnam War veterans with penetrating TBIs noted posttraumatic epilepsy in 53% at 15-years; of these 7% experienced their first seizure more than ten years following their trauma. A 0-25 cc volume loss was associated with a 42% seizure incidence while loss > 75 cc was associated with an incidence of 80%. Other imaging findings that increase post-traumatic seizure risk include subdural hematoma, contusions, microhemorrhages and blood breakdown product deposition. As noted earlier, every TBI case is unique, and all information must be taken into consideration when determining aeromedical waiver suitability.

AIMWTS search in Jan 2019 revealed 1337 individuals with a waiver that contained a diagnosis of closed head injury. The breakdown of cases was as follows: 342 FC I/1IA (38 disqualifications), 308 FC II (16 disqualifications), 17 RPA pilot cases, 592 FC III (83 disqualifications), 48 ATC/GBC (11 disqualifications), and 30 MOD (6 disqualifications). There were 154 cases resulting in a disposition of disqualify, and in well over half of the cases the major reason for the disqualification was the head injury.

ICD-9 codes f	ICD-9 codes for traumatic brain injury		
800-801	Skull fracture		
850.1	Concussion with brief loss of consciousness		
854.01	Intracranial injury of other and unspecified nature without open		
	intracranial wound with no loss of consciousness		
854.02	Intracranial injury of other and unspecified nature without open		
	intracranial wound with brief (less than one hour) loss of consciousness		
854.03	Intracranial injury of other and unspecified nature without open		
	intracranial wound with moderate (1-24 hours) loss of consciousness		
959.01	Head injury, unspecified		

ICD-10 codes	for traumatic brain injury
S02.0	Fracture of vault of the skull, closed
S06.0X1	Concussion with loss of consciousness of 30 minutes or less
S06.0X2	
S06.890	Other specified intracranial injury without loss of consciousness
S06.9X1	Unspecified intracranial injury with loss of consciousness of 30 minutes
	or less
S06.9X2	Unspecified intracranial injury with loss of consciousness of 31 minutes
	to 59 minutes
S06.9X3	Unspecified intracranial injury with loss of consciousness of 1 hour to 5
	hours 59 minutes
S06.9X4	Unspecified intracranial injury with loss of consciousness of 6 hours to
	24 hours
S09.80	Unspecified injury of head

#### **IV. Suggested Readings**

1. Evans RW, Whitlow CT. Acute mild traumatic brain injury (concussion) in adults. UpToDate, Mar 8, 2019.

2. Rajajee V. Management of acute moderate and severe traumatic brain injury. UpToDate, Dec 23, 2019.

3. Christensen J. The epidemiology of posttraumatic epilepsy. Semin Neurol 2015; 35:218-222

4. Ropper AH, Samuels MA, Klein JP (Ed). Craniocerebral trauma. *Adams and Victor's Principles of Neurology, Tenth Edition, McGraw-Hill Education*, 2014:885-914.

5. McGuire SA et al. Aeromedical decision making and seizure risk after traumatic brain injury: longitudinal outcome. Aviat Space Environ Med 2012; 83(2):140-43.

6. Christensen JC et al. Long-term risk of epilepsy after traumatic brain injury in children and young adults: a population-based study. Lancet 2009; 373:1105-1110.

7. Agrawal A et al. Post-traumatic epilepsy: an overview. Clinical Neurology and Neurosurgery 2006; 108:433-439.

8. Annegers J, Coan S. The risks of epilepsy after traumatic brain injury. Seizure 2000; 9:453-457.

9. Annegers JF et al. A population-based study of seizures after traumatic brain injuries. N Engl J Med 1998; 338:20-24.

10. Salazar AM, Jabbari B, Vance SC, et al. Epilepsy after penetrating head injury. I. Clinical correlates: A report of the Vietnam Head Injury Study. Neurology 1985; 35: 1406-14.





# **Birth Control**

Revised: Mar 2022

Reviewed: Maj Catherine Blasser (RAM '23), Col Jason Massengill (AF/SG Obstetrics and Gynecology Consultant), Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Updated format and suggested readings.

## I. Waiver Consideration

A waiver is not required for hormonal contraception (oral, vaginal, transdermal, subdermal, subcutaneous, and intrauterine) using <u>approved</u> medications that are well tolerated without significant adverse effects. Additionally, a waiver is not required for long-acting reversible contraceptives methods appropriately placed and well tolerated. Furthermore, non-hormonal methods of birth control, such as the copper intrauterine device, do not require aeromedical waiver. Moreover, a waiver is not required for a history of successful sterilization surgery after full recovery with appropriate follow-up, and without chronic adverse effects. For diagnoses that utilize hormonal contraceptives to regulate symptoms related to the condition (i.e. endometriosis, menstrual migraines, premenstrual dysphoric disorder, polycystic ovarian syndrome) refer to the appropriate aeromedical waiver guide.

## **II. Information Required for Waiver Submittal**

N/A

## **III. Aeromedical Concerns**

Safe and effective contraception that has been appropriately selected and used with the clinical guidance of a flight surgeon can play an important preventive role for the flyer and special duty operator. Choice of birth control method should be determined in a shared decision-making model while recognizing that some forms of birth control may carry increased risks in the aerospace environment. Factors to consider when choosing a contraceptive method include device or medication safety, efficacy, convenience, duration of action, reversibility potential, effect on uterine bleeding, frequency of adverse side effects, protection against sexually transmitted diseases, and a wish for a more permanent solution. Pregnancy, especially when unplanned, can create a variety of considerations for the operational and aviation environments. An unplanned pregnancy prior to or during a deployment can create unexpected risks to an individual and mission, while appropriate knowledge, prevention, and planning can significantly reduce the associated operational risks. Estimates for the general population show that half of all pregnancies are unplanned and in approximately half of these unintended pregnancies, some form of contraception was used.

## Benefits:

The contraceptive and medical benefits of hormonal and non-hormonal contraceptives are well established. Physical or emotional stress can produce physiological responses which have reactionary effects on the pituitary-ovarian hormonal axis. This can result in irregular menstrual

cycles, irregular bleeding, menorrhagia, or amenorrhea during the periods of stress. Hormonal contraceptives can sustain hormonal levels that maintain regular menstrual cycles or amenorrhea. If the flyer is appropriately screened with monitoring during ground trial, there is no aeromedical contraindication for the use of oral contraceptives.

#### Adverse effects:

Distracting symptoms are most common when starting oral, transdermal, or implantable hormonal contraception. Intrauterine devices (IUDs) may be associated with increased menstrual pain, especially during the first cycle. Additionally, IUDs carry the risk of myometrial embedment, uterine perforation, cervical perforation, irregular bleeding, dysmenorrhea, expulsion, and increased incidence of ovarian cysts, all of which could potentially affect mission safety and completion. Irregular spotting or other transient symptoms are more common in the first 1-5 months of a hormonal contraceptive use. Estrogen containing oral contraceptives may be associated with hypertension, headache, nausea, or vomiting. Thus, the treating flight surgeon should council flyers on the risk for adverse events and instruct the operator to report adverse events to the treatment team.

Some hormonal contraceptives such as depot-medroxyprogesterone acetate (DMPA or Depo Provera®) may exacerbate depression. Etonogestrel sub-cutaneous implants and DMPA have been proven effective for control of endometriosis and menstrual conditions but have also been associated with decreased bone mineral density with prolonged use. In addition, there are increased concerns with space travel given the known effects of gravitational unloading on bone health and bone metabolism. Depo-Provera® has a higher association with dysfunctional uterine bleeding which could not only be distracting but can lead to more serious complications, such as anemia. Progesterone-only methods may decrease bone mineral density in some women with long-term use. Other potential adverse effects observed include weight gain, nausea, or vomiting. Of note, oral contraceptives may be beneficial for women with some types of headache, including menstrual migraine, but these estrogen containing oral contraceptives are contraindicated in women with a history of <u>migraine headache with aura</u> due to a significant increased risk of stroke.

The most significant aeromedical concern is related to venous thromboembolism (VTE) in estrogen containing oral contraceptives in high-risk women. Long-duration missions may lead to stasis and increased risk of lower extremity VTE in female aviators. Space travel could pose an even greater risk than aviation due to the alteration in fluid distribution, gravitational unloading, and altered hydrostatic gradients in the body. Women over age 35 and smokers are at increased risk of VTE and that risk is further elevated with the use of estrogen containing contraceptives. For this reason, estrogen containing oral contraceptives are not recommended in this population. Transdermal patches are not recommended for women with a BMI greater than 30 kg/m² and may be less effective in women with a BMI of 25 kg/m². Oral contraceptives with drospirenone (Yaz®, Yasmin®) can induce hyperkalemia in some women through this progestin's spironolactone-like activity and may induce diuretic and anti-androgenic effects.

Contraceptive options:

Vaginal non-hormonal birth control options include condoms, spermicides, diaphragms, cervical caps, and cervical sponges. These options are of variable efficacy depending on ideal usage and combinations of methods. Vaginal non-hormonal birth control options are unlikely to interfere with flying duties in the absence of adverse reactions.

In the US, the combined estrogen-progestin oral contraceptive preparations are the most commonly used effective and reversible method of contraception, with pregnancy rates reported as less than 0.5 per 100 woman-years. While oral contraceptive use is common and effective, it has a higher discontinuation rate within the first year than long-acting reversible devices. Most oral contraceptive compounds include  $35 \ \mu g$  or less of estrogen along with varying types and amounts of progestins. Various progestins include first, second, or third generation forms, with differing profiles relating to their estrogenic effects, progesterone effect, and androgenic effect. Progesterone activity is highest, and estrogenic activity is lowest in the second and third generation progestins. The progestins vary in their beneficial and adverse side effects regarding breakthrough bleeding, acne, bloating, headaches, lipid profiles, and premenstrual mood symptoms. Modifying oral contraceptive use with clinically targeted progestin profile may improve benefits, reduce adverse effects, and increase compliance.

The three currently available long acting reversible contraceptive methods include one contraceptive implant and five intrauterine device (IUD) types. The FDA approved contraceptive implant is the etonogestrel single rod contraceptive implant (Implanon®). This single rod subdermal implant secretes the progestin etonogestrel systemically to suppress ovulation and the endometrium for contraception. This implant may remain in place for three years but requires providers to complete manufacturer training before beginning to insert them in patients. IUDs are the most commonly used method of long-acting reversible contraception because of its high efficacy and safety, ease of use, and cost effectiveness. There are both nonhormonal and hormonal IUDs available. The ParaGard® IUD is a non-hormonal, t-shaped, plastic and copper device that is immediately effective on insertion and can be used as emergency contraception if placed within 120 hours of unprotected sex and can remain in place for up to ten years. It does not contain hormones and does not suppress ovulation. However, ParaGuard® is more often associated with increased bleeding, pain and longer menses than hormone containing IUDs. Levonorgestrel (LNG) IUDs are t-shaped devices made of plastic that slowly release progestin. Several types (Mirena, Skyla, Kyleena, and Liletta) exist that vary in size, amount of progestin secreted, and time approved for contraceptive effectiveness. Noncontraceptive benefits of the higher dose LNG IUDs include reduction in heavy menstrual bleeding, anemia, dysmenorrhea, endometriosis-related pain, endometrial hyperplasia, pelvic inflammatory disease, and cervical cancer. However, higher dose LNG IUDs are more likely to induce menstrual suppression than the lower dose devices. For both category of IUDs, fertility returns immediately upon removal.

Additional options available to women are the transdermal patch (Ortho Evra®) and vaginal rings (NuvaRing® or Annovera). They act similarly to oral contraceptives, but require a lower dose by avoiding the "first pass" hepatic effect. The patch is applied once weekly for three weeks followed by one week without application. The efficacy of the patch has been found to be

similar to oral contraceptives with a high user satisfaction. The contraceptive vaginal ring is a flexible ring inserted into the vagina that releases estrogen and progestin at a constant rate for the three-week period of use. The ring has been found to have an effectiveness rate similar to oral contraceptives, a low incidence of adverse events, and a high satisfaction rate among users. Both of these methods have the additional benefit of easy reversibility after cessation of use. The NuvaRing® requires refrigeration when not in use, where as Annovera® does not. This make Annovera® more preferable for deployment purposes.

For men, two effective methods include condoms and vasectomy. Condoms are convenient in that they are readily available and do not require a prescription. When used correctly, their effectiveness can approach that of hormonal contraceptives with an additional benefit of protection against most sexually transmitted diseases. Vasectomy is the most commonly performed urologic surgical procedure performed in the US, with an estimated 500,000 performed annually. Vasectomy is less expensive and associated with less morbidity and mortality than female tubal procedures. It is employed by nearly 11% of all married couples, but is less prevalent than tubal procedures in women. With an experienced surgeon and a post-vasectomy semen analysis performed to confirm effectiveness, it is unusual to have a pregnancy result months to years after the procedure.

Female or male surgical procedures for permanent sterilization are common and are rarely associated with complications or adverse effects. When a sterilization procedure is uncomplicated and results in a full recovery, no restrictions or waivers are required to return to flight and operational duties.

## **IV. Suggested Readings**

1. Davis, J. R. (2022). Fundamentals of Aerospace Medicine. Wolters Kluwer.

2. Hardeman, J., & Weiss, B. D. (2014, March 15). *Intrauterine devices: An update*. American Family Physician. Retrieved September 10, 2021, from <a href="https://www.aafp.org/afp/2014/0315/p445.html">https://www.aafp.org/afp/2014/0315/p445.html</a>.

3. Saguil, A. (2015, March 1). *Risk of venous thromboembolism with use of combined oral contraceptives*. American Family Physician. Retrieved September 14, 2021, from <a href="https://www.aafp.org/afp/2015/0301/p287.html">https://www.aafp.org/afp/2015/0301/p287.html</a>.

4. Dehlendorf, C. (2022, Jan 26). Contraception: Counseling and selection. UptoDate.com. Accessed February 23, 2022, from <u>https://www.uptodate.com/contents/contraception-</u> <u>counseling-and-</u> <u>selection?search=contraception%20counseling%20and%20selection&source=search_result&sele</u> <u>ctedTitle=1~150&usage_type=default&display_rank=1</u>

## Dysmenorrhea (Apr 2021)

Reviewed: Lt Col Mark B. Dudley (RAM '22), Lt Col Jason Massengill (AF/SG OB/GYN Consultant), and Dr. Max Lee (ACS Waiver Guide Coordinator)

#### **Significant Changes:**

1. Updated language to reflect changes to the DoDI6130.03 V2 and the Medical Standards Directory.

## I. Waiver Consideration

Dysmenorrhea is disqualifying for retention, as well as for all flying classes when symptoms result in an inability to perform duties, cause frequent absences from duty, or require ongoing specialty follow-up more than annually. It is also disqualifying for FC I/IA, II, III, ATC, GBO, OSF, and SWA personnel when it results in other disqualifying conditions (e.g., anemia, osteoporosis, endometriosis, uterine fibroids). Most medications used to prevent or treat dysmenorrhea are compatible with flying duties and the acute use of several NSAIDs (e.g., ibuprofen, naproxen, aspirin) are approved for flying/operational duties and do not require waiver if the underlying condition does not interfere with satisfactory performance.

Flying Class (FC)	Condition ¹	Waiver Potential Waiver Authority	ACS Review/Evaluation
I/IA	Primary dysmenorrhea controlled with NSAIDS (ibuprofen, naproxen, aspirin) and/or hormonal contraceptives.	N/A	No
	Primary dysmenorrhea not controlled on approved NSAIDs and/or hormonal contraceptives.	No AFRS/CMO	No
II, III ATC/GBO/OSD/SWA	Primary dysmenorrhea controlled with NSAIDs and/or hormonal contraceptives.	N/A	No

# Table 1: Waiver potential for dysmenorrhea

Primary	Maybe	No
dysmenorrhea not	MAJCOM	
controlled on	AFMRA ²	
approved NSAIDs		
and/or hormonal		
contraceptives.		

1. For dysmenorrhea resulting from secondary causes see waiver guides for Endometriosis, Uterine Fibroid and Pelvic Inflammatory Disease.

2. Waiver in untrained personnel is unlikely; waiver authority for such cases is AFMRA.

## II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment. History should include the following: age of menarche, onset of pain, relation with onset of menstrual flow, severity, location of pain, additional symptoms, impact on activities, presence of pain not related to menses, prior medical and surgical treatment and effectiveness.
- 2. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated).
- 3. Documentation of a pelvic examination.
- 4. Gynecologic consultation reports, if NSAIDs and/or hormonal contraceptives do not control pain or if abnormal pelvic exam.
- 5. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 6. Current physical examination findings.
- 7. FL4 with RTD and ALC status, if member did not meet retention status.
- 8. Any other pertinent information.
- 9. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.
- B. <u>Renewal Waiver Request</u>:
  - 1. Interval history since last waiver submission.
  - 2. Pelvic examination.
  - 3. Consultation report from the treating physician.
  - 4. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.

## **III. Aeromedical Concerns**

Dysmenorrhea is pain with menstruation which can be categorized into primary and secondary forms. Between 50 to 90 percent of reproductive-age women worldwide describe experiencing painful menstrual periods and most are young and have primary dysmenorrhea with decreased

prevalence with age. Secondary dysmenorrhea is usually associated with other gynecologic conditions. The clinical symptoms of dysmenorrhea include recurrent, crampy, lower abdominal pain that occurs during menses. Symptoms are typically time-predictable and time-limited, beginning one to two days before onset of menses with gradual resolution within 72 hours. Symptoms are often well-controlled with aeromedical approved medications. In most cases, it is not expected to be acutely incapacitating and continued flying should not be problematic. However, in some cases dysmenorrhea can cause menstrual pains severe enough to miss duty, distract, and impair operational performance rather than sudden incapacitation. Other associated symptoms which may be distracting during flying or ground operations may include nausea, vomiting, diarrhea, headaches, dizziness, or low back pain which could jeopardize the safety and health of member and risk mission completion. An oral GnRH antagonist, elagolix, has been recently approved for dysmenorrhea. However, GnRH class of medications are often associated with significant and unpredictable side effects that are aeromedically unacceptable. Therefore, if symptoms are not controlled or require non-approved medications, primary dysmenorrhea is disqualifying for all flying classes.

A review of AIMWTS through Mar 2021 revealed 26 aviators with a diagnosis of dysmenorrhea. There were 2 FC I/IA cases (no disqualifications), 2 FC II cases (no disqualifications), 13 FC III cases (2 disqualified), 2 ATC/GBC cases (no disqualifications), and 3 MOD cases (no disqualifications). Two disqualified cases were due to intractable pelvic pain, not amendable to treatment.

ICD-9 codes for Dysmenorrhea	
625.3	Dysmenorrhea

ICD-10 codes for Dysmenorrhea	
N94.4	Primary dysmenorrhea
N94.5	Secondary dysmenorrhea
N94.6	Dysmenorrhea, unspecified

#### **IV. Suggested Readings**

- 1. Smith RP and Kaunitz AM. Primary dysmenorrhea in adult women: Clinical features and diagnosis. UpToDate. Online version 48.0. Jan 2021.
- Burnett M and Lemyre M. No. 345-Primary Dysmenorrhea Consensus Guideline. Journal of Obstetrics and Gynaecology Canada. 2017; 39(7): 585-595. DOI: <u>https://doi.org/10.1016/j.jogc.2016.12.023</u>
- 3. Osayande AS and Mehulic S. Diagnosis and Initial Management of Dysmenorrhea. Am Fam Physician. 2014; 89(5): 341-346.

- 4. Gorbandt MB and Knittig RA. Women's Health Issues in Aerospace Medicine. In Davis JR, Johnson R, Stepanek J, eds. Fundamentals of Aerospace Medicine, 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2008: 480-490.
- 5. Powell-Dunford, Nicole. Dysmenorrhea: An Aeromedical Clinical Practice Guideline. Capstone, University of Texas Medical Branch. Aug 2008

## Endometriosis (Apr 2021)

Reviewed: Maj M. Tyler Negrey (RAM '21), Lt Col Jason Massengill (AF/SG OB/GYN Consultant), and Dr. Max Lee (ACS Waiver Guide Coordinator)

## **Significant Changes:**

- 1. Updated language to reflect changes to DoDI6130.03 V2 and Medical Standards Directory.
- 2. Edited for clarity, references reviewed, and updated references.

#### I. Waiver Consideration

Any history of endometriosis is disqualifying for FC I/IA and SWA duties. Endometriosis is disqualifying for retention, as well as for all flying and special duty classes when it results in an inability to perform duties, causes frequent absences from duty, or requires the need for ongoing specialty follow ups more than annually.

Flying Class	<b>Medication/Treatment</b>	Waiver	ACS
	Required	Potential	<b>Review/Evaluation</b>
	for Symptom Control of	Waiver	
	Endometriosis	Authority	
I/IA	Any documented history of	No	No
	endometriosis regardless of	AFRS/CMO	
	treatment ¹		
II/III	NSAIDs, estrogen/progesterone	Yes	No
ATC/GBO/SWA	combinations, DepoProvera ²	MAJCOM	
	Danazol, elagolix, or other	No	No
	gonadotropin releasing hormone	AFMRA	
	agonists		
		Yes	No
	Surgery	MAJCOM	

#### Table 1: Waiver potential for endometriosis

 Also applies to SWA personnel with waivers considered on a case-by-case basis similar to trained FC II and FC III personnel.

2. All medications and medication combinations must be used in accordance with the Official Air Force Aerospace Medicine Approved Medications list.

## II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment, to include a complete history of symptoms and degree to which they incapacitate the patient.
- 2. Reports of any pertinent laboratory studies, including the most recent hematocrit.
- 3. Gynecology consultation report, including follow-up notes with examination findingsafter treatment/resolution.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 5. Documentation of return to full physical activity, including specific comments regardingany activity limitations.
- 6. Current physical examination findings.
- 7. FL4 with RTD and ALC status, if member did not meet retention status.
- 8. Any other pertinent information.
- 9. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.
- B. Renewal Waiver Request:
  - 1. Interval history including treatments, tolerance, and any adverse side effects.
  - 2. All applicable labs, particularly most recent hematocrit.
  - 3. Consultation report from gynecologist or primary care physician.
  - 4. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.

#### **III. Aeromedical Concerns**

Endometriosis is a progressive disease and there is little correlation between the physical extent of the disease and severity of reported symptoms. The pain associated with endometriosisusually begins as low grade discomfort and may progress over hours or days to a severe discomfort or pain that may be distracting. The pain may initially be predictable and occur in a cyclic perimenstrual fashion, but may become more persistent over time. Symptoms of endometriosis often require control with aeromedically approved medications, such as oral contraceptives or NSAIDS. At this stage, the symptoms of endometriosis may not be acutely incapacitating and would pose minimal aeromedical risk. However, when the disease progresses and/or is poorly controlled, the pain may be distracting and occur in an unpredictablepattern. In these cases, more aggressive medical therapy or surgical treatment may be required.

Gonadotropin releasing hormone agonists (GnRH) are administered monthly or every three months depending on the dose, but have persistent effects throughout the dosing period. An oral GnRH antagonist, elagolix, has been recently approved for endometriosis and can be utilized for 12 months as initial therapy and if effective, continued therapy up to 24 months. Although elagolix is not always utilized as treatment in preparation for surgery, GnRH class of medications are often associated with significant and unpredictable side effects that are aeromedically unacceptable. Therefore, GnRH are not aeromedically approved and are generally not considered for waiver. A requirement for surgical treatment can be an indicator of the disease severity and failure of medical therapy. Although a history of uncomplicated

surgical treatment for endometriosis is not considered disqualifying for trained aircrew, the severity of the symptoms in these cases would likely be disqualifying. Although hysterectomy or oophorectomy may be therapeutic, hypogonadism caused by oophorectomy carries its own aeromedical concerns. Recurrence of endometriosis symptoms remains possible even after hysterectomy and/or oophorectomy, therefore post-surgical aeromedical monitoring is required. Evaluation of the hematocrit and/or hemoglobin levels is indicated since heavy menstrual bleeding is often associated with endometriosis and can cause anemia. Lastly, it is essential for the treating flight surgeon to ensure the diagnosis of endometriosis was made with objective evidence rather than the diagnosis being used as a substitute to describe dysmenorrhea.

Review of AIMWTS through Apr 2021 revealed 68 aviators with an AMS containing the diagnosis of endometriosis: six FC I/IA (four disqualified), 15 FC II (four disqualified), 42 FC III (20 disqualified), one ATC (disqualified), and two MOD (one disqualified). Of note, some FC I/IA waivers have been approved on a case-by-case basis in individuals with a documented history of endometriosis who are asymptomatic and do not require treatment.

ICD-9 cod	for Endometriosis	
617.9	Endometriosis, site unspecified	

## ICD-10 code for Endometriosis

N80.9	Endometriosis, unspecified

#### **IV. Suggested Readings**

1. American College of Obstetricians and Gynecologists. Management of Endometriosis. ACOG Practice Bulletin Number 114, 2010 (Reaffirmed 2021).

2. Gorbandt MB and Knittig RA. Women's Health Issues in Aerospace Medicine. In Davis JR, Johnson R, Stepanek J, eds. *Fundamentals of Aerospace Medicine*, 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2008:480-490.

3. Rayman RB, et al. Ch. 5 in *Rayman's Clinical Aviation Medicine*, 5th Edition, Castle Connolly Graduate Medical Publishing, LTD, 2013; p. 142-43.

4. Schenken RS. Endometriosis: Pathogenesis, clinical features, and diagnosis. UpToDate. Online version 61.0. Oct2020.

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## Polycystic Ovary Syndrome (May 2020)

Reviewed: Lt Col Clayton Rabens (RAM 21), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), Lt Col Jason Massengill (AF/SG consultant for OB/GYN), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

## Significant Changes:

Updated Table 1 to reflect recent flying and special duty class reorganization; Added MSD references to support disqualification; updated "suggested readings" section.

## I. Waiver Consideration

While not directly identified by name in the MSD, polycystic ovary syndrome (PCOS) is a potentially disqualifying condition for all classes of flying and special duty in the US Air Force. Per the current MSD (MSD, 27 FEB 2020, J59, J61, J64), PCOS is disqualifying when it causes symptomatic persistent ovarian cysts and/or menstrual irregularities that (1) require the use of unapproved aircrew medications and/or (2) results in frequent absences from duty, an inability to fully perform their job duties, or the need for more than annual specialty follow-up.

## Table 1: Waiver potential for Polycystic Ovary Syndrome (PCOS)

Flying Class (FC)	Disease/Condition	Waiver Authority Waiver Potential	ACS Review/ Evaluation
I/IA	PCOS	AETC Yes	No
II/III/ATC/GBO ¹ /OSF/SWA	PCOS	MAJCOM ² Yes	No

1. MOD personnel (AFSC: 13N) require a waiver only if symptomatic.

2. Waiver authority for Initial FC II, FC III, ATC/GBO/SWA candidates is AETC.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

## A. Initial Waiver Request:

- 1. List and fully discuss <u>all</u> clinical diagnoses and medications requiring a waiver.
- 2. A complete history to include a detailed menstrual history and an outline of the onset, duration, and stability of any symptoms of PCOS and its treatment.
- 3. Exam should include assessment of blood pressure, body mass index, careful skin exam, and waist circumference. Include report of a current gynecological exam.
- 4. Labs: HCG, CBC, fasting blood glucose, 2-hour (75g) glucose tolerance test, prolactin, thyroid studies, total/free testosterone, DHEA-S, and any other endocrine studies used to evaluate for PCOS and its complications.
- 5. Radiology: current pelvic ultrasound report and any other pertinent radiological report.
- 6. Statement from treating physician summarizing treatments and intended follow-up.

- 7. FL4 with RTD and ALC status, if member did not meet retention status
- 8. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.
- B. Waiver Renewal Request:
  - 1. Interval history specifically noting any changes in disease course and treatments since the last waiver submission.
  - 2. Documentation of all exam elements.
  - 3. Labs: any completed since last waiver submission.
  - 4. Radiology: reports of pertinent exams completed since last submission.
  - 5. Report of current exam with statement of patient condition from treating physician.
  - 6. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

#### **III. Aeromedical Concerns**

Most symptoms related to PCOS, when mild or well controlled, will usually not be problematic with aviation duties. However, if untreated or unrecognized, PCOS may lead to distracting gynecological problems such as abnormal uterine bleeding or pain, as well as non-gynecological problems such as glucose intolerance/diabetes, obesity, dyslipidemia, sleep apnea, mood disorders, and even atherosclerotic heart disease, all of which can be associated with significant aeromedical risk.

The treatment of PCOS is individualized based on the patient's clinical symptoms and desire for pregnancy. Common treatment options include weight loss for individuals that are overweight, hormonal contraceptives for menstrual irregularities and dermatologic issues, metformin for metabolic manifestations, and clomiphene for infertility. Additionally, surgery, anti-estrogenic medications (e.g. letrozole), and a variety of other less common treatments may also be considered for refractory cases. Please note that not all medications used to treat PCOS are safe or approved for use by the flyer in the US Air Force. Hence, please refer to the most current versions of the aircrew and GBO medication lists for further guidance on medications that might be considered for waivers.

An AIMWTS search in May 2020 revealed 54 submitted cases in the last 5 years that contained an ICD code associated with PCOS. Breakdown of cases revealed: 2 FC I/IA cases (one disqualified), 17 FC II cases, 24 FC III cases (four disqualified), 4 GBO cases, 6 ATC cases (four disqualified), and 1 SWA case. Of the 66 total cases, 13 resulted in a disqualification disposition; 1 FC I/IA, 2 FC II, 7 FC III cases and 3 GBO. Of note, the PCOS diagnosis or the medications utilized were causal in only one of the nine disqualified cases (i.e. disqualification was actually attributable to another diagnosis).

ICD-9 codes for PCOS			
256.4 Polycystic ovaries			
620.2	Other & unspecified ovarian cyst		

ICD-10 codes for PCOS			
E28.2	8.2 Polycystic ovarian syndrome		
N83.20	Unspecified ovarian cyst		
N83.29	Other ovarian cysts		

#### **IV. Suggested Readings**

1. American College of Obstetricians and Gynecologists. Polycystic Ovarian Syndrome. ACOG Practice Bulletin Number 194, 2018.

2. Teede HJ, Misso ML, Costello MF, et al. Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome. Fertil Steril, 2018; 110:364.

3. Moran LJ, Hutchison SK, Norman RJ, Teede HJ. Lifestyle changes in women with polycystic ovary syndrome. Cochrane Database Syst Rev, 2011:CD007506.

4. Rotterdam ESHRE/ASRM-Sponsored PCOS consensus workshop group. Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS). Hum Reprod, 2004; 19:41.

5. Legro RS, Arslanian SA, Ehrmann DA, et al. Diagnosis and treatment of polycystic ovary syndrome: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab, 2013; 98: 4565.

6. Williams, T, Mortada, R, and Porter, S. Diagnosis and treatment of polycystic ovary syndrome. Am Fam Physician, 2016; 94(2):106-113.





## Pregnancy

Revised: May 2022

Reviewed: Lt Col Larissa Weir (AF/SG Chief Women's Health Consultant), Col Amy Hicks (ACS Div Chief), Dr. Max Lee (ACS Waiver Guide Coordinator), and Col Micah Schmidt (AFMRA Chief, Medical Standards Program)

**Significant Changes:** Local clearance process moved to the Kx. Streamlined waiver guide to address the waiver process and updated it to reflect that aircrew members/operators may request waiver at any point in pregnancy IAW DAFMAN 48-123, 8 Dec 2020, para. 5.5.4. and Atch 2.

## I. Waiver Consideration

Pregnancy is a temporary grounding condition for FC I/IA, II, III, OSF, and SWA duties. For FC II, III, and OSF duties, in uncomplicated pregnancy¹ during weeks 12 - 28, local clearance at the base level is possible with certain occupational restrictions (see Table 1). If the member is not eligible for local clearance, waiver may be requested. Additionally, if the flyer wishes to perform flight duties outside the occupational restrictions outlined in Table 1, waiver may be requested. When applicable, ground duties (such as SIM/SOF) should be considered even if the flyer remains DNIF and are generally appropriate during pregnancy. For FC I/IA and SWA duties, local clearance is not an option; waiver may be requested for continued duties. For GBO and ATC duties, uncomplicated pregnancy is NOT grounding, and neither local clearance nor waiver is required for continued duties throughout the duration of the pregnancy. In the setting of high-risk pregnancy², waiver to continue GBO/ATC duties may be requested.

The request to perform flying and operational support duties during pregnancy should be voluntary. Manned flight duties during pregnancy involve exposure to known and suspected hazards to fetal development and maternal health that require individual aircrew member education and risk acceptance. Those members who do elect to perform flying and operational support duties during pregnancy may change their decision at any time. Given that pregnancy is inherently dynamic, regular follow-up throughout the duration of the waiver is important. Both the flight surgeon and the member must be aware of the need to reassess waiver eligibility if new symptoms arise or if any complications develop. Additionally, access to urgent obstetrical care should be considered throughout the pregnancy, and duty modification should be considered as needed based on pregnancy status (for example, in cases where the time to urgent obstetrical care is greater than 2 hours, or other timeframe as specified by the treating obstetrician). Pregnancy is disqualifying for physiological training and hyperbaric/hypobaric duty. Per AFMAN 11-403, *Aerospace Physiological Training Program*, hypoxia training is waived for the duration of the pregnancy.

^{1.} Uncomplicated pregnancy: Singleton, intrauterine pregnancy with no high-risk features; normal prenatal labs and vitas signs; no pregnancy-related medical conditions; pre-existing medical conditions, medications, and waivers should be considered in the context of the pregnancy (many pre-existing medical conditions can increase health risks during pregnancy, see Section III).

^{2.} High-risk/complicated pregnancy: Multiple gestation; age > 35-years-old at time of delivery; in-vitro fertilization (IVF); pre-existing medical conditions such as hypertension, thyroid disease, and autoimmune disease; pregnancy-related conditions such as gestational hypertension, gestational diabetes, pre-eclampsia, previous or current preterm labor or history of preterm birth, or as defined by the treating obstetrician.

<u>Postpartum</u>: After delivery, return to flight/operational duty may be considered after a minimum of six weeks. If physiological training currency was extended to cover pregnancy, refresher training must be accomplished prior to first flight once medically cleared following delivery (see AFMAN 11-403).

Flying Class (FC)	Local Clearance	Waiver Authority
I/IA	No	AFRS/CMO
II//III/OSF	Yes: Uncomplicated pregnancy 12-28 wks gestation ¹	MAJCOM: Uncomplicated pregnancy <12, >28 wks gestation; High-risk pregnancy
GBO	N/A: Uncomplicated pregnancy through delivery (no DNIF/DNIA)	MAJCOM: High-risk pregnancy
ATC	N/A: Uncomplicated pregnancy through delivery (no DNIC)	MAJCOM: High-risk pregnancy
SWA	No	MAJCOM

Table 1: Local Clearance Potential/Waiver Authority for Pregnancy

1. Local clearance should specify the following parameters: non-high performance, non-ejection seat aircraft, altitude restriction <10,000 ft MSL (cockpit altitude pressurized aircraft); with another qualified pilot for non-RPA pilots. Outside these parameters, waiver is needed for continued flying duties.

## **II. Information Required for Waiver Submittal**

Please consult the Kx (<u>https://kx.health.mil/kj/kx4/FlightMedicine/Pages/operationalmedhomeapril2012.aspx</u>) for instruction on the local clearance process. If waiver is required to continue flight/operational duties, the items below should be included in the waiver request. Timely submission of the waiver package should be a priority given the dynamic nature of pregnancy and the potentially limited timeframe for continued flight/operational duties.

## A. Waiver Request:

- 1. The AMS should include the following:
  - a. Date of pregnancy confirmation, date of last menstrual period, estimated current gestational age, and estimated date of delivery (ultrasound-based, if available).
  - b. Pregnancy status uncomplicated (single, intrauterine with no high-risk features) or high-risk/complicated. See definitions on page 1 and item #4 below.
  - c. Date of start of 12th week of gestation and date of end of 26th week of gestation (to assist waiver authority with addressing ICAO provisions relating to pregnancy, which is particularly relevant if waiver is requested for a timeframe outside 12-28 weeks gestation).
  - d. Any significant pregnancy-related symptoms or conditions.
  - e. Past obstetrical history and past gynecological history relevant to the pregnancy. Include past pregnancy dates, delivery types, complications, history of ectopic pregnancy, miscarriages, fibroids, etc.

- f. Past medical and surgical histories, including current status of pre-existing conditions.
- g. List of all current medications.
- 2. Labs/studies required:
  - a. CBC.
  - b. All other routine initial pregnancy labs.
  - c. Obstetric ultrasound report.
- 3. Current physical examination findings:
  - a. Vital signs.
  - b. Visual acuity (reassess every 4 weeks, or sooner if visual symptoms reported).
  - c. Physical examination findings from obstetrical provider.
- 4. Forms:
  - a. "Voluntary Request to Fly While Pregnant and Acceptance of Risk" form signed by aircrew member/operator and by counseling flight surgeon. Located on Kx at: <u>https://kx.health.mil/kj/kx4/FlightMedicine/Pages/operationalmedhomeapril2012.aspx</u>
  - b. "Obstetrician Pregnancy Verification" form (select "aviator" or "operator" version as indicated), signed by the aircrew member/operator and the obstetrician. Located on Kx: <u>https://kx.health.mil/kj/kx4/FlightMedicine/Pages/operationalmedhomeapril2012.aspx</u>

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

- B. Follow-up for duration of waiver request:
  - 1. At least monthly flight surgeon visits in the Flight and Operational Medicine Clinic, ideally timed following OB appointments since the flyer/operator must be cleared before conducting flight/operational duties after OB visits.
  - 2. The FOMC visit should include the following:
    - a. Confirm continued desire to perform flight/operational duties. The aircrew member/operator may request to be grounded at any time.
    - b. Vital signs.
    - c. Visual acuity check for FC II/III/ATC/SWA (confirm vision correctable to 20/20). Not required for GBO or OSF.
    - d. Assess for new symptoms, change in pre-existing medical conditions, development of pregnancy-related conditions or complications, etc.
    - e. Confirm there are no issues that would impact performance of duties, fit and use of life support equipment, or ability to safely egress the aircraft.
    - f. Assess need for access to urgent obstetrical care and appropriate timeframe (such as 2 hours) and consider duty modification as indicated.
  - 3. Waiver eligibility should be reassessed in the setting of new symptoms, conditions or complications.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

#### A. Normal Physiologic Changes of Pregnancy with Aeromedical Relevance

**Cardiovascular:** Cardiac output rises across pregnancy. Early in pregnancy, an increase in stroke volume drives the change in cardiac output. Systemic vascular resistance begins to fall during the first trimester and plateaus at 35-40% below baseline mid-second trimester, reducing afterload to the heart. Additionally, blood volume expands approximately 40% in pregnancy, increasing preload. These changes drive an increase in stroke volume. Heart rate also rises during pregnancy, peaking in the third trimester. The result is a 30-50% increase in cardiac output compared to baseline. There is a 10-fold increase in uterine blood flow during pregnancy, which leads to a shift from 2% of total cardiac output pre-pregnancy to over 17% at term. As pregnancy progresses, the growing uterus exerts pressure on the inferior vena cava, and this effect becomes significant in the supine position. Due to a reduction in venous return to the heart (preload), maternal posture can decrease cardiac output by 25-30%, and 8% of individuals experience supine hypotension with possible syncope. During a normal pregnancy, the average blood pressure begins to decrease by 7 weeks of gestation, reaching a nadir by 24-32 weeks, gradually increasing in the third trimester, and returning to prepregnancy levels following delivery. The cardiovascular and hemodynamic changes that occur during pregnancy can have significant or subtle effects on G-tolerance, endurance, and hypoxia tolerance.

**Endocrine:** The major hormones of pregnancy are human chorionic gonadotropin hormone (hCG), human placental lactogen (hPL), estrogen and progesterone. These hormones are primarily responsible for the physiologic changes described throughout Section III.A of this waiver guide. Pregnancy is associated with insulin resistance, driven by hCG, hPL, progesterone, and other hormones elaborated by the placenta. In those individuals with insufficient pancreatic function to overcome this insulin resistance, relative hyperglycemia or frank (gestational) diabetes develops. In cases of gestational diabetes, control can be achieved with diet, although sometimes insulin is required. Maternal screening for diabetes generally occurs at 26-28 weeks of gestation but may be performed earlier for risk factors or clinical findings. Pregnancies complicated by gestational diabetes are at increased risk of adverse outcomes such as preeclampsia, macrosomia, and polyhydramnios and are classified as "high-risk" pregnancies.

**Gastrointestinal:** During normal pregnancies, high circulating levels of progesterone, a smooth muscle relaxant, cause hypoactivity of the gastrointestinal tract, a decreased transit time, relaxation of the lower esophageal sphincter, and increased vomiting. Pregnancy-associated vomiting occurs most commonly during the first trimester, but can occur throughout the pregnancy. Nausea or vomiting can result in significant aeromedical distractions and contribute to dehydration. Esophageal reflux is more common in pregnancy and may also lead to symptoms distracting in the flight and operational environment.

**Hematologic:** Blood volume increases during pregnancy to accommodate the pregnancy requirements and support placental perfusion. Plasma volume increases by 40%, and red cell mass increases 20-30% over the non-pregnant state. A relative anemia is common in

pregnancy due to the increased ratio of plasma volume to red cell mass and the resulting hemodilution. Iron-deficiency anemia is also common in pregnancy due to the substantial increase in iron requirement for the growing fetus. Changes in maternal pH from respiratory changes cause a right shift in oxygen dissociation of hemoglobin to facilitate oxygenating the fetus. These volume, hemoglobin, and anemia-related circumstances can affect G-tolerance, hypoxia tolerance, and endurance. Pregnancy is a prothrombotic state with a risk of venous thromboembolism increased at least five-fold over the non-pregnant state, although the overall incidence is still low (fewer than 1% of pregnancies). The hypercoagulability of pregnancy is related to several mechanisms, including increases in fibrinogen, von Willebrand Factor, clotting factors (II, VII, VIII, and XII), and reduced activity of fibrinolytic inhibitors such as plasminogen activating inhibitor-1 and -2. In addition, venous stasis is more likely during pregnancy due to decreased systemic vascular tone and compression of the pelvic veins by the enlarging uterus. Periods of inactivity or remaining in a cramped cockpit during flying duties may exacerbate venous stasis and increase the risk of thrombosis. Underlying hypercoagulable states, such as Factor V Leiden, are associated with 20-25% of venous thromboembolism in pregnancy and as such, can add substantially to the venous thrombosis risk. Screening for thrombophilia is not recommended routinely in pregnancy, but may be considered if indicated by clinical or family history.

**Musculoskeletal and Ergonomic Considerations:** As the uterus grows during pregnancy, it emerges from the pelvis after 12 weeks and begins to increase abdominal circumference thereafter. Breast tissue enlarges in response to human placental lactogen (hPL). Localized or generalized edema can occur in normal pregnancies and may increase the circumference of the lower extremities, the upper extremities, and occasionally other areas of the body. Gestational weight gain is also a normal effect of pregnancy. These changes may alter the fit and safety of life support equipment in the aircraft. In addition, the center of gravity changes in pregnancy, while prostaglandins and relaxin increase joint mobility. This increases the risk of falls, especially later in pregnancy. Even minor falls or trauma can lead to significant complications, particularly during the late second trimester and the third trimester.

**Neurologic:** Sleep disturbances during pregnancy are common and can contribute to excess fatigue during pregnancy. These disturbances tend to increase as the pregnancy progresses, resulting in additional aeromedical significance. Neurocognitive changes may also be associated with pregnancy. Subjective symptoms of forgetfulness, poor concentration, and other cognitive changes are reported in up to 80% of pregnancies. Subtle but clinically significant changes on neurocognitive testing have been demonstrated, particularly in the third trimester. However, testing typically remains in the normal range and changes might be noticed only by the individual or those who know them well.

**Ophthalmologic:** Corneal thickening due to edema can occur as early as 10 weeks gestation, and may persist for several weeks postpartum. This change is variable, and can affect visual acuity differently throughout the pregnancy. Visual acuity should be checked every month to ensure vision standards appropriate for flying duties are met. In addition, an immediate assessment should be performed for any visual complaint.

**Pulmonary:** The pulmonary changes of pregnancy may have a significant effect in the aviation environment. There is an increase in maternal oxygen consumption with a 40% increase in tidal volume and a stable baseline respiratory rate, leading to increased minute ventilation (up nearly 50% at term). This results in hyperventilation, hypocapnia, and pH changes. Lung volume is decreased from physiological changes and uterine encroachment. These changes lead to a 20% decrease in functional residual capacity in the second half of pregnancy and can result in early decompensation in the face of infection, or other pulmonary disease. In the flight environment, these changes can affect hypoxia tolerance, especially in the event of rapid decompression.

**Renal:** In pregnancy, renal blood flow increases by 50%, renal plasma flow increases by 60-80%, and glomerular filtration rate increases by 50%. The increased renal function and uterine compression of the bladder result in more urine production during a normal pregnancy. This results in more frequent urination, which may be challenging in the flying environment. If intentional dehydration is used to combat urinary frequency, this can also lead to aeromedically significant symptoms, such as dizziness. The dry flight environment can further induce dehydration. These factors can have significant or subtle effects on G-tolerance, endurance, or hypoxia tolerance. Elevated systemic progesterone decreases the peristalsis of the ureters, which increases the risk of ureteral reflux and ascending urinary tract infections. As such, urinary tract infections must be treated with more vigilance in pregnancy due to the greater risk of pyelonephritis and its higher risk of complications.

## **B.** Exposures in the Aerospace/Operational Environment

**Altitude:** At an altitude of 8,000 ft MSL, SaO₂ is 90-93% for non-pregnant, health volunteers, and at 10,000 ft MSL, SaO₂ in the range of 87%. Normative values in flight during pregnancy have not been established. The effects of short, repeated exposures to increased altitude are unclear. Adverse effects have been found in studies of flight attendants and passengers, but results and methodologies in these studies are inconsistent. Both miscarriage and intrauterine fetal demise were increased in observational studies of flight attendants. A risk of preterm birth has been found in passengers but not flight attendants. Flight altitude restrictions are included for waiver consideration.

**Emergency Egress:** Emergency egress is an unpredictable and potentially violent event that can impact all airframes and aircrew. Flight surgeon familiarity with a flyer's crew position and aircraft is important when counseling the flyer about potential risks associated with egress during pregnancy. Emergency egress can involve operating aircraft doors, climbing, jumping from a variable height, running 200 yards, and donning appropriate survival gear. There are no studies addressing the impact of ejecting from an aircraft on pregnancy or maternal health. However, several studies have demonstrated that the risk of mortality with trauma increases during pregnancy. Pregnancies complicated by trauma also lead to higher incidences of spontaneous abortion, placental abruption, uterine rupture, preterm premature rupture of membranes, preterm birth, cesarean delivery, and stillbirth. Even minor abdominal trauma can lead to significant complications. As such, the member should be made aware of the increased risk to loss of life or miscarriage in an already dangerous situation.

**Heat:** Both the fetus and the metabolic demands of pregnancy generate additional heat above the pre-pregnancy baseline. The flight environment and safety equipment may introduce additional heat burden. This can lead to heat intolerance in the flyer and may also adversely impact fetal development. Elevated core body temperature has been shown to double the risk of neural tube defects in the fetus. The risk of preterm labor and growth restriction may also be increased, although results from epidemiologic studies on this phenomenon are mixed. The National Institute for Occupational Safety and Health (NIOSH) advises that core temperature should not exceed 102°F and that even when core temperature does not exceed 100.4 °F in the workplace, "absolute safety" cannot be assured.

Noise and Vibration Exposure: Noise and vibration exposure during pregnancy have been associated with hearing changes identified in the newborn. Noise is unwanted sound that may induce adverse health effects in the adult human ear if it exceeds a time-weighted average (TWA) of 85 A-weighted deciBels (dBA) over 8 hours (1) or exceeds an impulse level of 140 deciBels (dB). Vibration-creating sounds are usually divided into two groups based on frequency, high and low. The hearing organs are developed around 20 weeks gestation and may be susceptible to damage from both sources. A study of occupational noise exposure during pregnancy found exposure to noise >85 dBA throughout the course of pregnancy (<20 days absence) was associated with an increased risk of pediatric hearing loss (hazard ratio 1.82). During the last 15 weeks of gestation, fetal exposures to high- and lowfrequency sounds may have a significant and sometimes negative effect on fetal behavior and central nervous system development. While higher frequency vibrations up to 20,000 Hz produce sound waves that can be heard by humans, lower frequency vibrations may not be heard but can induce stress in humans. The uterus and abdominal contents provide some noise attenuation, but frequencies less than 250 Hz are more likely to penetrate to the fetus, and sound pressures can be significantly higher in the uterus than outside. Significant noise and whole-body vibration exposure have been associated with preterm labor, as well, although the data are mixed. A reasonable reduction in frequency and duration of exposure can be considered when appropriate.

**Radiation:** Radiation exposure is a potential risk factor for the fetus, with the period of highest vulnerability during organogenesis in the first trimester. Evidence suggests that no adverse fetal effects have been seen with radiation exposures of less than 50 mSv. The average exposure during a 10-hour flight is 0.05 mSv. Population-based studies of commercial airline workers who flew during pregnancy are reassuring. Adverse fetal outcomes associated with radiation exposure in the aviation environment were not demonstrated. However, the commercial environment is not strictly analogous to military aviation.

## C. Pregnancy-Related Medical Conditions

Many pregnancy-specific conditions are aeromedically significant. Examples include, but are not limited to: ectopic pregnancy, spontaneous miscarriage, molar pregnancy, incompetent cervix, vaginal bleeding, preterm labor, spontaneous rupture of membranes,

preeclampsia, hyperemesis gravidarum, gestational diabetes, struma ovarii, uterine anomaly, and fetal conditions such as multiple gestation, birth defects, and growth restriction.

#### D. Pre-existing Medical Conditions and Medication Use Affected by Pregnancy

There are a variety of medical conditions where the disease, the treatment, or both are affected by pregnancy. Such conditions include chronic hypertension, impaired glucose tolerance, diabetes, thyroid disease, inherited thrombophilias, migraines with aura, or history of thromboembolic disease. In many cases, a chronic medication or its dose must be changed. Therefore, preexisting medical conditions and/or stable use of medication previously waived must be re-considered prior to conducting flight and operational duties during pregnancy.

#### E. Postpartum

The postpartum period is characterized by fatigue, sleep deprivation and significant physiological changes. This period is also associated with increased risk of bleeding, infection, depression (generally transient), and hypertension. The prothrombotic state associated with pregnancy persists for up to six weeks, and the highest risk of venous thromboembolism during pregnancy is in the postpartum period. If visual acuity changes develop during pregnancy, these typically resolve by six weeks postpartum.

ICD-10 code for	r Pregnancy
Z33	Pregnant State

## **IV. Suggested Readings**

1. FS Toolkit: https://kx.health.mil/kj/kx4/FlightMedicine/Pages/operationalmedhomeapril2012.aspx

2. ACOG Committee Opinion No. 746: Air Travel During Pregnancy. Obstet Gynecol. 2018 Aug;132(2):e64-e66.

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## Uterine Fibroids (Leiomyomas) (Apr 2021)

Reviewed: Maj Jason Burchett (RAM '21), Lt Col Jason Massengill (AF/SG OB/GYN consultant), and Dr. Max Lee (ACS Waiver Guide Coordinator)

#### Significant Changes:

- 1. Updated language to reflect changes to DoDI6130.03 V2 and Medical Standards Directory.
- 2. Edited for clarity, references reviewed, and updated references.

## I. Waiver Consideration

Asymptomatic fibroids are not disqualifying and as such, require no waiver. Symptomatic uterine fibroids are disqualifying for flying classes (FC) I/IA, II, III, and SWA. The condition is not listed as disqualifying for ATC and GBO duties, nor is it disqualifying for retention purposes, but significant symptoms and/or treatments that require duty restrictions or limitations based on the medication and clinical evaluation are disqualifying for retention standards as well as ATC, GBO, and OSF duties. The use of hormone suppressive medications such as oral contraceptive pills (OCPs), progesterone supplementation, or a progesterone containing intrauterine device do not require a waiver. However, they require a 7 day ground trial to monitor for adverse effects and effectiveness in controlling symptoms. The use of other medications such as gonadotropin releasing hormone (GnRH) agonists/antagonists, aromatase inhibitors, or similar medications are associated with significant and unpredictable symptoms and a ground trial period to monitor adverse effects and effectiveness should be completed prior to waiver consideration. A history of a surgical treatment for symptomatic benign fibroids, such as myomectomy, uterine artery embolization, or hysterectomy, if uncomplicated, fully recovered, asymptomatic, and without evidence of malignancy, does not require waiver for any flying class exams and ACS case review is not required.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority	ACS Review/ Evaluation
I/IA	Medically treated with OCPs, progestin, or NSAIDs Medically treated with GnRH analog ¹	Maybe AFRS/CMO No AFRS/CMO	No
II/III SWA	Medically treated with OCPs,		No

Table 1:	Waiver	potential	for	uterine	fibroids

ATC/GBO ²	Medically treated with OCPs, progestin, or NSAIDs	Yes MAJCOM	No	
	Medically treated with GnRH analog ¹	Maybe MAJCOM	No	

1. GnRH analogs are used for a time limited duration and often in preparation of surgery then discontinued.

2. No waiver required for ATC and MOD personnel unless unable to perform duties or treated with unapproved medications.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment. History should include degree of impairment from the symptomatic uterine fibroids, level of functioning before and after uterine fibroid treatment modalities, presence and/or resolution of anemia/fatigue, treatment modalities used, and treatment option considerations (e.g., future fertility desired).
- 2. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated), including a current complete blood count.
- 3. Gynecology consultation report, including follow-up notes with examination findings after treatment.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated), including a histology report, if applicable.
- 5. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 6. Current physical examination findings.
- 7. Any other pertinent information.
- 8. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.
- B. Renewal Waiver Request:
  - 1. Interval history since last aeromedical summary with emphasis on any symptoms compatible with uterine fibroids.
  - 2. Current complete blood count.
  - 3. Consultation from gynecologist or treating physician.
  - 4. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.

#### **III. Aeromedical Concerns**

Symptomatic fibroids can result in three classes of symptoms, heavy and prolonged menstrual bleeding, bulk related symptoms such as pelvic pressure and pain, and reproductive dysfunction. The first two of the above can have significant aeromedical impact. Heavy and prolonged bleeding can result in significant anemia which may become symptomatic in the hypoxic environment. Bulk symptoms can cause pressure and discomfort that may be distracting, in addition to this significant

bulk can cause bowel and bladder obstruction that may be exacerbated in the hypobaric environment.

There are many aeromedically approved medications for the treatment of fibroids and include hormone suppressive medications such as oral contraceptive pills, progesterone supplementation, or progesterone containing intrauterine devices. The use of non-aeromedically approved medications such as GnRH agonists/antagonists or aromatase inhibitors are often associated with significant and unpredictable side-effects and have an unacceptable aeromedical risk profile for waiver consideration. Additionally, GnRH medications are generally utilized on a temporary basis and often in preparation for surgical treatment. Lastly, due to the associated recovery period and possible complications related to surgical treatments (e.g. myomectomy, uterine artery embolization, hysterectomy) the aviator should be restricted from flying duties until the individual is fully recovered, benign histology report confirmed, and cleared for duty by the treating gynecologist.

A review of AIMWTS through April 2021 revealed 6 aviators with an AMS containing the diagnosis of uterine fibroids; two were FC II and four were FC III (one disqualified). Review of the sole disqualified case showed that the waiver was later approved after appropriate treatment and symptom management.

ICD-9 codes for	r Uterine Fibroids
218	Uterine leiomyoma

## ICD-10 codes for Uterine Fibroids

ICD-10 codes for Oterfine Fibroids		
D25.9 Leiomyoma of uterus, unspecified		
N93         Other abnormal uterine and vaginal bleeding		

## **IV. Suggested Readings**

1. De La Cruz MD and Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. Am Fam Physician, 2017; 95(2):100-107, <u>https://www.aafp.org/afp/2017/0115/p100.html.</u>

2. Mas A, Tarazona M, Dasi Carrasco J, et al. Updated approaches for management of uterine fibroids. Intl J Women's Health, 2017; 9: 607.

3. Vilos G, Allaire C, Laberge P, Leyland N. The Management of Uterine Leiomyoma: SOGC Clinical Practice Guideline. J Obstet Gynaecol Can, 2015; 318:157-178.

4. Stewart EA. Overview of treatment of uterine leiomyomas (fibroids). UpToDate. Online version 44.0 March 2021

#### Cataract, Capsular Opacification, and Intraocular Lens Implant (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

For GBO, only disqualifying for RPA, not RPA SO or MOD. MSD C56, C57, C58.

#### I. Waiver Consideration

Opacities, cataracts, or irregularities of the lens, which interfere with vision, or are considered to be progressive, are disqualifying for all flying classes. Pseudophakia (intraocular lens implantation during cataract surgery) and posterior and anterior capsular opacification are disqualifying for Flying Classes I/IA/II, GBO (RPA Pilot duties only), and SWA. For ATC and Operational Support Flying (OSF) duties, pseudophakia and posterior/anterior capsular opacification are not specifically mentioned as a disqualifying diagnosis, but it would become relevant if the vision was impaired. For all classes, no waiver is required if the lenticular opacity is asymptomatic, visually insignificant, and non-progressive (no potential for progression). Per Air Force policy, opacities, cataracts, or irregularities of the lens interfering with vision, render a member unfit for continued service, and require an I-RILO to evaluate for the possibility of retention.

# Table 1: Waiver potential for Cataracts, Capsular Opacification, and Intraocular Lens Implant.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
I/IA	No	AETC	No
II/III ¹	Yes	AETC or	Yes ³
SWA		MAJCOM ²	
ATC/GBO/OSF ⁴	Yes ⁵	MAJCOM	Only at the request of MAJCOM

1. For initial flying class II and III physicals, waiver is not likely for cataracts deemed potentially progressive. Applicants with a history of cataract surgery will be considered on a case-by-case basis.

AETC will be the waiver authority for Initial Waivers only; MAJCOMs will be the waiver authority for renewals.
 ACS evaluation required initially after diagnosis of symptomatic/visually significant/progressive cataract or

pseudophakia then review only on subsequent renewals.

4. Applies to RPA Pilot only, not RPA SO or MOD.

5. Pseudophakia and posterior and/or anterior capsular opacification are not disqualifying for ATC and OSF duties.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

#### A. Initial Waiver Request:

1. Description of any symptoms associated with condition, any noted progression and any prior medical evaluation or treatment for the condition (including operative note, if applicable).

2. Comment on location and stability of intraocular lens (IOL), model number, and type of IOL used (if applicable).

- 3. Best corrected visual acuities at distance and near.
- 4. Any contact lens or spectacle correction prescriptions.
- 5. Dilated retinal exam.
- 6. Cone contrast test (CCT) scores for each eye individually.
- 7. Humphrey visual field 30-2 testing for each eye.

8. Low contrast acuity testing with Precision Vision 5% acuity chart corrected and uncorrected for each eye.

9. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

#### B. <u>Renewal Waiver Request:</u>

1. Description of any symptoms associated with condition, any noted progression and any prior medical evaluation or treatment for the condition (including operative note, if applicable).

2. Comment on location and stability of intraocular lens (IOL), model number, and type of IOL used (if applicable).

- 3. Best corrected visual acuities at distance and near.
- 4. Any contact lens or spectacle correction prescriptions.
- 5. Dilated retinal exam.
- 6. Cone contrast test (CCT) scores for each eye individually.
- 7. Humphrey visual field 30-2 testing for each eye.
- 8. Low contrast acuity testing with Precision Vision 5% acuity chart corrected and uncorrected for each eye.
- 9 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

**Note:** Aeromedical summaries may not be submitted any earlier than 60 days after extraction and IOL implant. ACS evaluation will not be scheduled until 90 days following the procedure; assuming the aircrew member is stable and off postoperative medications. If just YAG laser surgery is done for a posterior capsule opacification then aeromedical summary may be submitted 30 days after procedure if asymptomatic and off postoperative medications.

#### **III. Aeromedical Concerns**

Aeromedically, lens changes are defined as *opacities* (developmental lens defects that do not progress) and cataracts (lens opacities with the potential to progress and compromise visual function). Developmental opacities of the lens are not disqualifying, whereas cataracts, including congenital polar cataracts, are. Decreased visual acuity, contrast sensitivity, symptoms of glare, acquired color vision deficiencies, and visual field defects associated with cataracts have the potential to adversely affect mission effectiveness and flight safety. Even if a lens change does not significantly impact vision at present, any of those defined as cataracts have the potential to progress, and some may do so relatively quickly. This progression necessitates, at a minimum, monitoring of any potentially progressive cataract to ensure visual functioning remains unaffected. Some cataractous changes may become problematic only under certain environmental conditions, such as in bright lights or at night.

As with any medical problem in USAF aircrew, medical treatment to meet the current standard of care is mandated without the necessity to receive permission from the ACS or waiver authority. However, there are some complicating issues with cataracts in aircrew. Typically, civilian patients are not operated on until the patient deems his or her vision is poor enough to require surgery. Often this level of severity is after the patient's vision has declined significantly below the 20/20 Air Force vision standard. USAF aircrew may require surgery at an earlier point than their civilian counterparts.

Like any medical condition, implanted IOLs have additional concerns in the aviation environment that are not present in typical daily use. A review of FAA records done in 1993 examined the accident risks for pseudophakic pilots versus phakic pilots. This study found a statistically significant increased risk of aviation mishaps associated with pseudophakic pilots. The risk was even greater for pseudophakic pilots under the age of 50. When compared to their corresponding phakic counterparts, pseudophakic pilots under the age of 50 had 3.72 times the risk of having a mishap while the pseudophakic pilots over the age of 50 had 1.41 times the risk.

Another concern for IOLs is the theoretical risk of dislocation of IOLs under the extreme Gforces in the aviation environment. According to ACS records, there has been no known dislocation of an IOL during flight duties in the USAF. Further, study animals with implanted IOLs were subjected to G-forces up to +12 Gz without any signs of dislocation. A case report in August 2000 demonstrated that IOLs may be stable under high G-forces when a pilot with an IOL ejected from a T-6A Texan and the IOL remained stable.⁴

Only certain IOLs are approved for use in aircrew members. The selection of the procedure and the IOL should be coordinated with the Aeromedical Consultation Service (ACS) [DSN 798-3388, (937) 938-3388] for members on or planning to enter flying status. Generally, the preferred procedure is an extracapsular cataract extraction with implantation of a posterior chamber IOL at either the ciliary sulcus or in the capsular bag. The IOL should be a one piece acrylic IOL or have a three piece design with tissue fixable haptics (polypropylene [PP], polyethylene [PE] or polymethylmethacrylate [PMMA]) with a 6-7 mm optic and ultraviolet filtering properties. One piece silicone IOLs are not approved for aircrew use because they do

not fix well to the capsular bag and silicone material has been found to be pro-inflammatory in the post-operative eye. The multifocal IOLs, accommodating IOLs, and the newer extended range IOLs are also <u>not</u> approved for aircrew use. Finally, any IOLs with plate designs and positioning holes are currently still under review by the ACS.

In Feb 2016, blue blocking IOLs were approved for aircrew use as long as the member can successfully pass the CCT. To date, no aircrew have been disqualified for CCT failure due a blue blocking IOL. Numerous reports have confirmed that blue blocking IOLs have no adverse effects on color vision or contrast sensitivity testing in photopic or mesopic conditions. Additionally, even those with moderate color vision deficiency before surgery showed no change in their color vision after implantation of a blue blocking IOL.

In Aug 2016, toric IOLs were approved for use in aircrew given the advances and long successful record of accomplishment of the IOLs. Patients with corneal astigmatism who receive a toric IOL are twice as likely to not need glasses for distance, have improved visual acuity, improved contrast sensitivity, and only 1.1% experience the complication of requiring a second procedure to realign a rotated IOL. The mean misalignment after toric IOL implantation is 1.1°. By lens model IOL rotation of 5 degrees or less occurred with the Tecnis Toric in 94.2%, MicroSil 6116TU in 90%, Acrysof Toric in 81.1%, and in the Staar Toric AA4203 in 62-73%. The Tecnis Toric and Acrysof Toric are the preferred toric IOLs for aircrew due to their stability and that the MicroSil IOL is made of silicone and the Staar Toric is a plate haptic design.

A Sep 2018 AIMWTS search revealed 347 individuals with the diagnosis of cataract and/or cataract with IOL. Of the total, 13 were FC I/IA cases (11 disqualified), 169 FC II cases (26 disqualified), 3 RPA Pilot cases, 154 FC III cases (33 disqualified), 5 ATC/GBC cases, and 2 MOD cases. There were a total of 70 disqualifications dispositions. Fewer than half of the disqualified cases were directly related to the cataract diagnosis and the majority of individuals were disqualified for additional diagnoses.

ICD-9 codes for cataract, cataract surgery	
366	Cataract
379.31	Aphakia
743.30	Congenital cataract
V43.1	Lens replaced by other means
V45.61	Cataract extraction

ICD-10 codes for cataract		
H25.011-	Cataract	
H25.9		
H26.8	Other specified cataract	
H26.9	Unspecified cataract	
H27.0	Aphakia, unspecified eye, right eye, left eye,	
1, 2, 3	bilateral	
Q12.3	Congenital aphakia	
Q12.0	Congenital cataract	

#### **IV. Suggested Readings**

1. Rosenfeld SI, Blecher MH, Bobrow JC, et al. In: *Basic and Clinical Science Course: Lens and Cataract.* American Academy of Ophthalmology. 2013-2014: 52-94.

2. Nakagawara VB and Wood KJ. Aviation Accident Risk for Airmen With Aphakia and Artificial Lens Implants. US Department of Transportation, Federal Aviation Administration. DOT/FAA/AM-93/11. Oklahoma City, OK. July 1993.

3. Tredici TJ and Ivan DJ. Ocular Problems of the Aging Military Aviator. Presented at the RTO HFM Symposium, RTO MP-33, Toulon France, Oct 1999.

4. Smith P, Ivan D, LoRusso F, et al. Intraocular Lens and Corneal Status Following Aircraft Ejection by a USAF Aviator. Aviat Space Environ Med, 2002; 73: 1230-34.

5. Leibovitch I, Lai T, Porter N, et al. Visual Outcomes with the Yellow Intraocular Lens. Acta Ophthalmologica Scandinavica, 2006; 84: 95-99.

6. Yuan Z, Reinach P, and Yuan J. Contrast Sensitivity and Color Vision with a Yellow Intraocular Lens. American Journal of Ophthalmology, 2004; 138: 138-140.

7. Rodriguez-Galietero A, Montés-Micó R, Muñoz G, and Albarrán-Diego C. Blue-Light Filtering Intraocular Lens in Patients with Diabetes: Contrast Sensitivity and Chromatic Discrimination. J Cataract Refract Surg, 2005; 31: 2088-2092.

8. Rodriguez-Galietero A, Montés-Micó R, Muñoz G, and Albarrán-Diego C. Comparison of Contrast Sensitivity and Color Discrimination After Clear and Yellow Intraocular Lens Implantation. J Cataract Refract Surg, 2005; 31: 1736-1740.

9. Raj SM, Vasavada AR, and Nanavaty MA. AcrySof Natural SN60AT versus AcrySof SA60AT intraocular lens in patients with color vision defects. J Cataract Refract Surg, 2005; 31: 2324-2328.

10. Kessel L, et al. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery. Ophthalmology, 2016; 123(2): 275-286.

11. Lubiński W, Kaźmierczak, B, Gronkowksa-Serafin J, and Podborączyńska-Jokdo K. Clinical Outcomes after Uncomplicated Cataract Surgery with Implantation of the Tecnis Intraocular Lens. Journal of Ophthalmology, 2016; Article ID 3257217: 6 pages. <u>http://dx.doi.org/10.1155/2016/3257217</u>

12. Waltz KL, et al. Clinical Outcomes of Tecnis Toric Intraocular Lens Implantation after Cataract Removal in Patients with Corneal Astigmatism. Ophthalmology, 2015; 122: 39-47.

#### **Central Retinal Vein Occlusion (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

New Ground Based Operator (GBO) Standards. MSD C43, C46.

#### I. Waiver Consideration

Central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO) are disqualifying for Flying Class I, IA, II, III, and SWA duties. For ATC, GBO, and Operational Support Flying Duty (OSF) personnel, these conditions would be disqualifying if there are residual visual symptoms such as loss of visual acuity, visual field defects, or loss of color vision below standards. An Aeromedical Consultation Service (ACS) evaluation is required for aviators for all initial waivers for CRVO/BRVO. The probability of waiver approval is dependent on the final visual acuity, visual field, and absence of other significant pathology or complications. Any underlying contributing pathology must also be waiverable for the individual to be returned to flight status. For waiver renewals, ACS review is required. Depending on the results of local work-up, an ACS evaluation <u>may be required</u> prior to waiver renewal.

Flying Class	Waiver Potential	Waiver Authority	ACS
(FC)			<b>Evaluation/Review</b>
I/IA	Maybe ^{1, 2}	AETC	Yes
II/III	Yes ²	MAJCOM	Yes
SWA			
ATC/GBO/OSF	Yes ^{2, 3}	MAJCOM	At the discretion of the
			waiver authority

Table 1: Waiver potential for Retinal Vein Occlusion

1 No waiver potential for RVO with residual visual defects in initial FC I/IA applicants.

2 Visual outcome needs to have returned to baseline without presence of any recognized risk factors. The Waiver Authority for untrained aircrew is AETC.

3 Waiver only required if RVO residual symptoms are disqualifying (visual field defect, color vision loss, etc.)

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. Consideration of any potentially underlying disease etiologies, to include hypertension, heart disease, diabetes, hematologic disease, or collagen vascular disease with appropriate work-up and lab testing results.
- 2. List and fully discuss all clinical diagnoses requiring a waiver.
- 3. History of disease, including treatment modalities attempted.
- 4. Full ophthalmology exam to include:
  - a. Presence or absence of any visual symptoms.
  - b. Best corrected visual acuities at distance and near.
  - c. Examination of fellow eye with pertinent findings.
  - d. Cone contrast testing (CCT) for each eye.
  - e. Best corrected 5% Precision Vision (low contrast) acuity testing, if available.
  - f. Humphrey visual field 30-2 and 10-2 testing for each eye, if available.

g. Specialist report must comment on the presence or absence of macular edema, retinal hemorrhage, neovascularization, and glaucoma. Include Optical Coherence Tomography and/or Fluorescein Angiography, if available.

- 5. Lab testing results for fasting blood glucose, A1C, CBC + differential, PT/PTT, ESR, CRP, Lipids, ANA, Treponemal AB, and homocysteine.
- 6. If the local base cannot provide all of the above information, an explanation needs to be given to the MAJCOM as to why not.
- B. Renewal Waiver Request:
  - 1 Interim history since last waive and ACS visit.
  - 2 Ongoing treatment modalities
  - 3 Full ophthalmology exam to include items as noted above.
  - 4 If the local base cannot provide all of the above information, an explanation needs to be given to the MAJCOM as to why not.
  - Note: if above items are not available, member must come for full ACS evaluation.

# **III. Aeromedical Concerns**

The primary aeromedical concerns with CRVO/BRVO are loss of best-corrected visual acuity, loss of visual field, decreased night vision, loss of color vision, loss of low contrast vision, and loss of stereopsis. Other concerns include persistent complications such as neovascular glaucoma, macular edema, as well as ensuring proper management of any predisposing medical conditions. The risk of BRVO developing in the non-affected eye is approximately 10% within three years of initial presentation. The risk of fellow eye involvement in CRVO cases is 1% per year based on published data. A common complication following RVO is the development of neovascular glaucoma in eyes with ischemic CRVO, which approaches 40% over one year. Persistent, chronic macular edema is not waiverable due to the risk of worsening of this condition during flight and associated reduced visual function. Even if vision is adequately restored to meet vision standards, the underlying systemic conditions leading to RVO may pose potential serious risks to safe flight. Therefore, investigation of the underlying cause is critical to

both management and aeromedical disposition. Also of aeromedical concern is exposure to the hypoxic environment of altitude. A small case report series discussed the implications of highaltitude as a possible cause to RVO. Though these patients were typically exposed to the highaltitude environment for several weeks, one patient did develop BRVO while driving to altitude. These occurrences create some concern specifically for recurrence of events especially in light of literature suggesting decreased oxygen saturation in the venous circulation of the retina up to three months following the acute event.

AIMWTS review in Jan 2019 revealed 24 cases containing the diagnosis of retinal vein occlusion. There were no FC I/IA cases, 14 FC II cases and 10 FC III cases. There were three cases disqualified, one FC II and two FC III.

ICD 9 Codes for Retinal Vein Occlusion		
362.35	Central Retinal Vein Occlusion	
362.36	Branch Retinal Vein Occlusion	

ICD-10 Codes for Retinal Vein Occlusion		
H34.81	Central Retinal Vein Occlusion, Right, Left,	
1, 2, 3, 9	Bilateral, Unspecified	
H34.83	Branch Retinal Vein Occlusion, Right, Left,	
1, 2, 3, 9	Bilateral, Unspecified	
H34.9	Unspecified Retinal Vascular Occlusion	

# **IV. Suggested Readings**

1. Ehlers JP and Fekrat S. Retinal Vein Occlusion: Beyond the Acute Event. Surv Ophthalmol, 2011; 56(4): 281-299. 53(2): 112-20.

2. Hardarson SH and Stefánsson E. Oxygen Saturation in Central Retinal Vein Occlusion. Am J Ophthalmol, 2010; 150(6): 871-75.

3. Gupta A, Singh S, Ahluwalia TS, and Khanna A. Retinal Vein Occlusion in High Altitude. High Altitude Med Bio, 2011; 12(4): 393-97.

#### **Central Serous Chorioretinopathy (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

**Significant Changes:** New Ground Based Operator (GBO) Standards. Oral eplerenone can speed recovery of CSR. Half dose photodynamic therapy should be considered for members who do not respond to oral eplerenone. MSD C43.

## I. Waiver Consideration

Central Serous Chorioretinopathy (CSR) is disqualifying for all FC I/IA, II, III, and SWA duties and requires ACS evaluation for waiver consideration. CSR is not specifically disgualifying for ATC, GBO (RPA Pilot, RPA SO, and MOD), and OSF duties, but will be disqualifying if it results in visual acuity problems or significantly alters color vision. Although CSR is not disqualifying for these members, they should still get referred to an ophthalmologist for diagnosis and treatment to speed resolution and ensure preservation of good vision. After documented resolution of CSR by a fundus exam and optical coherence tomography (OCT), a waiver may be requested. Even if the aviator's vision returns to 20/20 or is correctable to 20/20, a local eye specialist must demonstrate that the sub-retinal fluid has resolved prior to waiver request submission. Waivers may be requested for aviators with best-corrected vision less than 20/20 or residual visual symptoms (metamorphopsia, color vision deficits), however, the visual acuity and visual symptoms must be stable (not improving or worsening). If photodynamic therapy (PDT) or laser photocoagulation is performed, the airman must remain DNIF for 30 days following the procedure and requires a full local ophthalmologic exam to include a dilated fundus exam and Humphrey visual field 30-2 testing prior to waiver request submission. The eye exam must demonstrate resolution of the sub-retinal fluid by fundus exam and OCT. If CSR recurs in an aviator with a known history of prior CSR, it is treated the same as an initial occurrence. The aviator will require a new waiver request to be submitted prior to return to flight status with a possible ACS review/evaluation.

Current literature supports initiating oral mineralocorticoid receptor antagonists (spironolactone or eplerenone) earlier after diagnosis to speed recovery.^{1,2,3} Given the side effect profile of spironolactone, eplerenone use is preferred and should be started at a dose of 50 mg daily for one week and then increased to 50 mg BID until fluid resolves (typically 1-2 months). Once the fluid is resolved, eplerenone may be tapered to daily for one to two weeks and then stopped. Hyperkalemia is a known side effect and potassium levels should be monitored for any member who requires eplerenone use longer than two months in duration. Members who do not respond to medical treatment should be considered for half-dose photodynamic therapy (PDT).

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review/Evaluation
I/IA	No	AETC	No
II/III/SWA	Yes ¹	MAJCOM	Yes
ATC/GBO/OSF	N/A	N/A	N/A

## Table 1: Waiver potential for Central Serous Chorioretinopathy.

1. Waiver in untrained FC II and III individuals is unlikely but will be considered on a case-by-case basis.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

# A. Initial Waiver Request:

- 1. Complete history of symptoms (negatives included), medical or laser treatment, and residual visual complaints.
- 2. Medical History including possible contributing factors such as steroid use, HCTZ use, or Obstructive Sleep Apnea.
- 3. Attach studies (optical coherence tomography [OCT], fluorescein angiograms [FA] or indocyanine green angiograms) if performed.
- 4. Full ophthalmology exam to include:
  - a. Documentation of resolution of CSR by fundus exam and an OCT.

b. Documentation of visual acuities at or better than 20/20 in each eye or documented stability of a visual acuity less than 20/20.

- c. Results from Amsler grid testing.
- d. Results of CCT for each eye individually.
- e. OVT-DP results, if not within standards then AO Vectograph results.
- f. Humphrey visual field 30-2 testing for each eye if laser photocoagulation was

performed (waiver request may not be submitted until 30 days after the procedure).

5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority

# B. Renewal Waiver Request:

- 1 A brief medical history summarizing the initial occurrence of the CSR, any recurrences and any treatment, as well as a full description of any residual visual complaints.
- 2 Full ophthalmology exam to include:
  - a. Documentation of continued resolution of CSR by fundus exam and an OCT.
  - b. Visual acuity in each eye, uncorrected and corrected.
  - c. Results from Amsler grid testing.
  - d. CCT scores from each eye individually.
- 3 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

## **III. Aeromedical Concerns**

Normal visual function is crucial in the aerospace environment. Central serous chorioretinopathy (CSR) can adversely impact visual function with symptoms of metamorphopsia (distortion of vision), micropsia (smaller visual images), scotomata (areas of the visual field missing or blurred), blurred vision, color desaturation (reduced brightness of colors), or sub-standard visual acuity. A 1988 Aeromedical Consultation Service (ACS) study that examined 47 rated airmen with 55 eyes affected by CSR found that all but one of the patients was returned to flying status. Fifty-one percent of airmen had recurrent episodes, 86% had better than 20/20 visual acuity after resolution of the CSR, 87% had normal color vision and 90% had normal stereopsis. A current study is pending legal review and IRB approval to review the current outcomes of the CSR Management Group.

The effect of the aerospace environment on active CSR is currently unknown. The presence of sub-retinal fluid introduces new dynamics into the eye that are not present otherwise. The effect of applying G-forces or relative hypoxia upon the pathophysiologic process of CSR is unclear. Further, sub-retinal fluid indicates active disease, which introduces the possibility of fluctuating visual acuity and could have an adverse impact on flight safety. Because of the aeromedical implications of these variables, aircrew members will not be considered for return to flight status until complete resolution of the sub-retinal fluid occurs as demonstrated by ophthalmologic exam and ancillary studies.

For aircrew members that have a history of CSR, regular follow-up care and monitoring are critical for flight safety and continued ocular health. If contributing medical factors such as steroid use, HCTZ use, or a history of Obstructive Sleep Apnea are identified, these should be addressed to minimize recurrences and to hasten resolution of the subretinal fluid. Self-administered Amsler grid testing is the primary method for aircrew to assess for recurrence or worsening of CSR. Aircrew members should obtain an Amsler grid from the local optometrist office and test each eye individually daily for the first year following the CSR. Any new distortion of the lines (metamorphopsia) or missing parts of lines (scotomas) should be immediately reported to the local flight surgeon with subsequent referral to ophthalmology. If no recurrence has occurred within the first year, then weekly Amsler grid testing is appropriate. In addition to Amsler self-testing, aircrew members with a history of CSR require annual full local ophthalmology evaluations as follow-up. These exams should specifically note visual acuity, Amsler grid testing, OVT depth perception testing, CCT color testing, and dilated funduscopic examination results. The result of these exams should be included in the AMS with submission for waiver request.

AIMWTS search in Jan 2019 revealed 164 members with a diagnosis of CSR. Breakdown of the cases reveals: 3 FC I/IA cases (3 disqualified), 98 FC II cases (8 disqualified), 5 RPA pilot cases (1 disqualified), 55 FC III cases (9 disqualified), and 3 ATC/GBC cases (1 disqualified).

ICD-9 code for	central serous chorioretinopathy
362.41	Central serous retinopathy

ICD-10 code for central serous chorioretinopathy		
H35.71	Central serous retinopathy, right, left,	
1, 2, 3, 9	bilateral, unspecified eye	

# **IV. Suggested Readings**

- 1. Bousquet E, et al. Mineralocorticoid Receptor Antagonism in the Treatment of Chronic Central Serous Chorioretinopathy: A Pilot Study. Retina 2013; 33:2096-2102.
- 2. Zucchiatti I, et al. Eplerenone Versus Observation in the Treatment of Acute Central Serous Chorioretinopathy: A Retrospective Controlled Study. Ophthalmol Ther 2018; 7:109-118.
- 3. Kapoor KG and Wagner AL. Mineralocorticoid Antagonists in the Treatment of Central Serous Chorioretinopathy: A Comparative Analysis. Ophthalmic Res 2016; 56:17-22.
- 4. Green RP, Carlson DW, Dieckert JP, and Tredici TJ. Central Serous Chorioretinopathy in US Air Force Aviators: A review. Aviat Space Environ Med, 1988; 59(12): 1170-75.

#### **Color Vision Deficiencies (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons, (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

**Significant Changes:** None. Despite the change in Flying Class categories, the RPA, RPA SO standard remains at CCT-55 minimum, and the MOD remains at CCT-35. MSD C80.

## I. Waiver Consideration

Moderate and Severe color vision deficiencies are disqualifying for FC I/IA, II, III, ATC, SWA, and GBO personnel. Severe color vision deficiency is disqualifying for MOD personnel. A normal score on the CCT is 75 or better. A score of 55 or better is required for FC I/IA, II, III, ATC, SWA, RPA and RPA SO duties and a score of 35 or better is required for MOD duties. Untrained aircrew will not be considered for waiver below the MSD standard. Trained aircrew may be considered for a waiver for defective color vision. ACS review/evaluation is required as part of the waiver consideration for trained aircrew. Waiver recommendations and management are primarily dependent on the etiology, severity of the color deficiency, and are made on a case by case basis. Indefinite waivers for color vision deficiency are authorized. CCT testing is required once at initial qualification. A CCT score of 55-74 is considered mild color deficiency; a score of 35-54 is moderate color deficiency, and a score < 35 is considered severe color deficiency.

Flying Class	Passing	Waiver Potential	<b>ACS Review/Evaluation</b>
	Score		
FC I/IA,	CCT - 55	No	No
Initial FC II/III, ATC, SWA,			
GBO (RPA, RPA SO)			
Initial MOD	CCT - 35	Maybe ¹	Yes
Trained FC II /III	CCT - 55	Yes	Yes - At the discretion of
ATC, SWA, GBO (RPA,		FCIIC ²	MAJCOM.
RPA SO)			
MOD	CCT - 35	Yes ¹	Yes - At the discretion of
			AFMRA ¹

Table 1: Waiver potential for Color Vision Deficiencies.

1 MOD waivers are unlikely but will be considered on a case-by-case basis, with inputs from the career field manager and AFMRA if needed.

2 Flying Class IIC waiver restricted to all previously flown aircraft. If selected to cross train into a new airframe, or assigned to a previous airframe that has undergone a significant cockpit upgrade that requires interpretation of different color symbology, an operational evaluation is recommended to verify capability to accurately recognize and respond to all display information. This operational evaluation should be performed by an instructor pilot in the new airframe.

AIMWTS search in Jun 2018 revealed a total of 3467 individuals with an AMS containing a diagnosis of color deficiency. Of that total, 1536 were disqualified. Breakdown of the cases was as follows: 501 FC I/IA (476 DQ), 785 FC II (41 DQ), 52 RPA pilots (34 DQ), 1509 FC III (592

DQ), 372 ATC/GBC (226 DQ), and 248 MOD (167 DQ). Within the DQ category, there were 13 ETP cases (3 FC I, 9 FC III, and 1 MOD). Of this total, 11 were denied and 2 were granted (both FC III).

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

## A. First-time (Indefinite) Waiver Request:

- 1. History history of previous color vision testing results (MEPS, commissioning, initial flying physicals, preventive health assessments), family history of color vision defects, medications, and any impact on job/daily life.
- 2. Physical Full eye exam to include funduscopic results and current color testing results on the most recent CCT version (ensure proper positioning and alignment with correction to at least 20/20 at distance and near or best corrected if member does not have 20/20 vision potential).
- 3. Optometry or ophthalmology consultation report.

## **III. Aeromedical Concerns**

Color deficient individuals are at a distinct disadvantage in terms of receiving and processing information in an efficient manner in the aviation and occupational environment. This can be demonstrated in aviation history as witnessed in the FedEx mishap in 2002, where color vision was found to be a contributing factor. Several other examples have been cited in a work on military aviation history and color vision. With regards to aviation, color defectives are more vulnerable to low-light and hypoxic effects on color vision than normals. Additionally, one must consider the compounding effects induced by certain required protective or performance enhancing optical appliances that can potentially degrade existing levels of color perception even further. These currently include blue-blocker sunglasses, yellow high-contrast visors, and assorted laser eye protection devices. While these devices cause changes in color perception with color normal subjects, the impact is far more profound with subjects who have an underlying color deficit. This finding is the basis for restriction from use of the yellow high contrast visor by color defective members, as stated in AFI 48-123. In addition to concerns with flying members, color vision can pose a significant risk for ground personnel. Color discrimination is an integral capability in the function of many ground based duties, to include remotely piloted aircraft operations and air-traffic control duties. Previous studies have demonstrated the importance of normal color vision in performing crucial tasks in air-traffic control. In light of changing technology both in operational symbology and color vision screening, the Operational Based Vision Assessment (OBVA) lab and ACS Ophthalmology are testing to determine if any updates on color vision requirements can be made for the various career fields. However, the current device being investigated by OBVA, the Konan CCT-HD, has not been validated for accuracy and consistency at scoring for a 55 cutoff and is not approved for initial flying class physical exam testing. Additionally, Innova is now selling

tablets to various flight medicine clinics for color vision testing to be held anywhere from 18-24 inches from the tester. As a result, there is a surge of applicants who are able to pass on the tablet at the local base by holding the screen closer (which makes the image larger), but ultimately fail at MFS when the approved NCI test at 36 inches and confirmatory ancillary testing are properly administered. Therefore, the Konan CCT-HD and the Innova are not approved or recommended for initial flying class physical exams.

In general, most color vision screening tests involve one of three types: pseudo-isochromatic plates [or PIP (e.g. Ishihara)], an arrangement test (e.g. D-15 or FM-100), or an operationally derived test (e.g. FALANT). While these tests are appropriate for screening purposes, they are highly dependent on proper administration and they are not designed to quantify severity of color deficiencies. To address these concerns, USAF School of Aerospace Medicine scientists developed the computer-based Rabin Cone Contrast Test (CCT). A study with aircrew applicants demonstrated that the CCT significantly improves sensitivity relative to pseudoisochromatic plates and provides quantification on the level of color deficiency. Due to these advances, the CCT is now the only acceptable device for evaluating color vision of USAF aircrew and applicants to aircrew positions. A normal score on the CCT is 75 or better. A passing score on the CCT is now 55 or greater (mild deficiency or better) for the red, green, and blue cone types with each eye (35 or better is required for MOD duties). To ensure the most accurate results, testing should be accomplished with the patient corrected to 20/20 at distance and near or best corrected if member does not have 20/20 vision potential. It is appropriate to use a reading lens for the test distance (36 inches) for presbyopic patients as needed. Alignment of the monitor should be confirmed using the alignment tube and the patient should not be allowed to move their head during the test sequence (refer to the KX for further guidance). Improper test administration can result in false positive and false negative results.

ICD-9 codes for color vision deficiency		
368.51 Protan defect		
368.52 Deutan defect		
368.59 Color vision deficiencies, unspecified		

ICD-10 codes for color vision deficiency		
H53.54	Protanomaly	
H53.53	Deuteranomaly	
H53.50	Unspecified color vision deficiencies	
H53.59	Other color vision deficiencies	

## **IV. Suggested Readings**

1. National Transportation Safety Board. Collision with Trees on Final Approach Federal Express Flight 1478... Aircraft Accident Report NTSB/AAR-04/02. Washington, DC. 2004.

2. Hovis J, Milburn N, and Nesthus T. Trichromatic and Dichromatic Relative Sensitivity to Green Light in a Mild Hypoxic Environment. Aviat Space Environ Med, 2013; 84(11): 1125-30.

3. Hovis JK, Lovasik JV, Cullen AP, and Kothe AC. Physical Characteristics and Perceptual Effects of "Blue-Blocking" Lenses. Optom and Vision Sci, 1989; 66 (10): 682-89.

4. Mertens H and Milburn N. Performance of Color-Dependent Air Traffic Control Tasks as a Function of Color Vision Deficiency. Aviat Space Environ Med, 1996; 67(10): 919-27.

5. Rabin J, Gooch J, and Ivan D. Rapid Quantification of Color Vision: The Cone Contrast Test. Investigat Ophthalmol Vis Sci, 2011; 52(2): 816-20.

## Dry Eye Syndrome (Keratoconjunctivitis Sicca) (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

**Significant Changes:** None since last review. Grading is <u>post-treatment</u> when considering waiver potential. MSD C24.

# I. Waiver Consideration

Dry eye is disqualifying for Flying Class I, IA, II, III, and SWA duties. Quality of vision can easily be compromised with chronic dry eye syndrome, so visual acuity standards apply. Generally, Grade 1 Dry Eye Syndrome does not require waiver action as it is easily controlled by lid hygiene and occasional use of artificial tears. Grade II and III dry eyes would require waiver action if only controlled with artificial tears, topical medications, or punctual plugs. Grade IV Dry Eye Syndrome would generally not be waiverable on maximal medical therapy. There is no disqualification for ATC, GBO, or OSF personnel with Dry Eye Syndrome. However, if the dry eye affects visual acuity to a level that the member cannot meet vision standards, then that is disqualifying. Dry Eye Syndrome is not disqualifying for retention.

Flying Class (FC)	Waiver Potential	<b>ACS Review/Evaluation</b>
	Waiver Authority	
FC I/IA	Yes – Grade 1 only (may not be considered disqualifying) No – Grade 2 or worse on tears for at	At the request of AETC
	least 3 months AETC	
FC II/III	Yes – Grade 2 and 3	At the request of the
SWA	No – Grade 4 on treatment (tears, Restasis®, Xiidra®) MAJCOM	MAJCOM
ATC/GBO/OSF	N/A	N/A

# Table 1: Waiver potential for Dry Eye Syndrome

AIMWTS review in Jun 2018 revealed a total of 96 cases submitted for waiver consideration with the diagnosis of dry eye with 84 cases approved for waiver. Breakdown of the cases revealed 7 FC I/IA cases (1 disqualification), 44 FC II cases (4 disqualifications), 7 RPA cases (1 disqualification), 33 FC III cases (4 disqualifications), and 7 ATC/GBC cases (1 disqualifications).

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

# A. Initial Waiver Request:

- 1. List and fully discuss all clinical diagnoses requiring a waiver.
- History history of all dry eye symptoms; any underlying causative factors, all treatments attempted and effectiveness of the therapy (medical and surgical), and any impact on job/daily life. History of contact lens use, including length and pattern of wear must be included in history. Specific description of medical interventions tried, and current treatment regimen if applicable.
- 3. Physical full eye exam to include visual acuity measurement, an external examination, and slit-lamp examination. In addition, include results of the tear film break-up time, ocular surface dye testing, and the Schirmer test.
- 4. Ophthalmology consultation report (cornea specialist preferred).
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

# B. Renewal Waiver Request:

1 Interval AMS with particular attention to clinical changes on Ophthalmologist Consultation.

# **III. Aeromedical Concerns**

The aeromedical issues relate to the subjective annoyance of dry eye symptoms and also with visual performance decrements. In more severe cases individuals can have significant visual impairment and should not participate in military aviation duties. The dry air of most cockpits will exacerbate symptoms in most affected airmen. The increase in use of contact lens among aircrew has significantly increased the incidence of dry eyes, and it is vitally important that new dry eye medications are not inappropriately used to treat contact lens intolerance or contact lens related dry eyes. Most artificial tear drops are safe in the aviation environment, as are punctal plugs if declared stable by the treating ophthalmologist.

An attempt to grade severity of dry eye symptoms is depicted in Table 2. The results of this grading scheme may drive the level of treatment. However, symptoms of dry eye syndrome do not necessarily reflect the severity of the disease. The lack of concordance between signs and symptoms presents a problem not only in the diagnosis but also in the construction of a treatment plan and when designing adequate clinical trials.²

Dry Eye Severity level		2	3	4
Discomfort, severity,	Mild and/or	Moderate,	Severe,	Severe and/or
and frequency	episodic; occurs	episodic, or	frequent, or	disabling and
	under	chronic; stress	constant	constant
	environmental stress	or no stress	without stress	
Visual Symptoms	None or	Annoying	Annoying,	Constant and/or
	episodic mild	and/or activity-	chronic,	possibly
	fatigue	limiting,	constant	disabling
		episodic	limiting activity	
Conjunctival injection	None to mild	None to mild	Mild	Moderate to
				Severe
Conjunctival staining	None to mild	Variable	Mild to	Marked
			Moderate	
Corneal	None to mild	Variable	Marked central	Severe
staining(severity/				punctuate
location)				erosions
Corneal tear signs	None to mild	Mild debris,	Filamentary	Filamentary
		decreased	keratitis, mucus	keratitis, mucus
		meniscus	clumping,	clumping, $\uparrow$ tear
			increased tear	debris,
			debris	ulceration
Lid/Meibomian	MGD variably	MGD variably	Frequent	Trichiasis,
glands	present	present	_	keratinization,
	-			symblepharon
TBUT (seconds)	Variable	<u>&lt;</u> 10	<u>&lt;</u> 5	Immediate
Schirmer score (mm	Variable	<u>&lt;</u> 10	<u>&lt;</u> 5	<u>≤</u> 2
tears/5 minutes)				
MGD = Meibomian gland disease				
TBUT = tear film break-up time				

ICD-9 code for Dry Eye Syndrome		
375.15	Dry eye syndrome	

ICD-10 code for Dry Eye Syndrome		
	Dry eye syndrome of lacrimal gland	

# IV. Suggested Readings

1. Galor A, Feuer W, Lee DJ, et al. Prevalence and Risk Factors of Dry Eye Syndrome in a United States Veterans Affairs Population. Am J Ophthalmol, 2011, 152(3), 377-84.

2. Lemp MA. Advances in Understanding and Managing Dry Eye Disease. Am J Ophthalmol, 2008; 146: 350-56.

## Glaucoma and Ocular Hypertension (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Michael Parsons (Deputy Chief, Aerospace Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## Significant Changes: New Ground Based Operator (GBO) Standards. MSD C6, C7, C8.

## I. Waiver Consideration

Glaucoma is disqualifying for all flying classes (except GBO and OSF), and for retention. There is no waiver potential for *initial* aircrew applicants. Glaucoma is most simply defined as an acquired and progressive optic neuropathy, often associated with raised intraocular pressure over time. However, glaucoma is disqualifying for all flying classes including GBO and OSF duties if there are demonstrable changes in the optic disc or visual fields or if the condition is not amenable to treatment. Additionally, initial GBO and OSF applicants with the diagnosis of glaucoma who do not meet the retention standard (only C7 applies) will require a waiver to commission or access into the Air Force prior to flying or special operational duty consideration. The waiver authority for those cases is the Air Education and Training Command (AETC) and each applicant will be considered on a case-by-case basis.

Glaucoma in *trained* aircrew (all flying classes) is potentially waiverable, provided the following conditions are met. First, that there is stable glaucoma controlled by medications or aeromedically approved laser treatment modalities, without aeromedically significant visual field defect within the central 30 degrees of either eye. Second, a full binocular visual field is documented. Finally, no evidence of visual or systemic medication side effects. The degree of systemic beta-blockade resulting from ophthalmic timolol is proportionately much less than oral, with perhaps a 20-30% reduction in reflex cardiovascular responses at the plasma levels achieved with such therapy. All topical eye drop medication are aeromedically approved after an uneventful one-week ground trial. Laser surgical procedures such as argon laser trabeculoplasty (ALT), selective laser trabeculoplasty (SLT), peripheral iridotomy (PI), or iridoplasty may be performed on aviators with demonstrated uncontrolled OHT or progressive glaucoma. Waiver request for these procedures should be submitted following successful laser treatment once the treated eye/s have stabilized (usually at least one month), IOP is controlled and topical post-op steroids have been discontinued. Incisional surgery such as trabeculotomy or glaucoma shunt surgery has no waiver potential for aircrew trained or untrained.

By definition, the diagnosis of Ocular Hypertension (OHT) requires <u>absence of</u> optic nerve damage (as defined by normal 30-2 visual fields, no retinal nerve fiber layer (RNFL) or ganglion cell layer (GCL) thinning, and non-progressive optic nerve cupping). Ocular Hypertension (OHT) is disqualifying for *initial* FC I/IA, II, III, ATC, and SWA applicants provided the following conditions are met: either the intraocular pressure (IOP) is greater than 26mm Hg <u>or</u> the corneal thickness is less than 540um with an IOP greater than 21. Otherwise, this condition meets standards for both initial and trained aircrew. Waiver request and Aeromedical Consultation Service (ACS) case review is not required for symmetric or asymmetric physiologic (normal variant) enlargement of the optic nerve cup.

			· ·
Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
II/RPA Pilot/III	Yes	MAJCOM	Yes
ATC/SWA	Yes	MAJCOM	Yes
GBO/OSF ³	N/A	N/A	N/A

Table 1: Waiver potential for Glaucoma (trained aircrew only)^{1, 2}

1. There is no waiver potential for initial applicants with Glaucoma or Ocular Hypertension with an IOP greater than 26 mmHg or corneal thickness less than 540 um with an IOP greater than 21 mmHg.

2. Glaucoma for the setting of waiver criteria is defined as any history of an IOP of 30 or greater or the presence of glaucomatous optic neuropathy. Only trained aircrew will be considered for a waiver recommendation.

3. Only disqualifying if there is glaucoma progression NOT amenable to treatment (C6)

 Table 2: Qualification Matrix for Ocular Hypertension (initial aircrew only)¹

Corneal Thickness	IOP = 21-26  mmHg	IOP > 26 mmHg
> 540 um	Yes	No
< 540 um	No	No

1. Ocular Hypertension (IOP greater than 21 mmHg, but less than 30 mmHg with normal OCT and visual field) in *trained* aircrew is *not* disqualifying.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

## A. Initial Waiver Request:

- 1.Aeromedical summary with a thorough review of past medical history and family history. Past ocular history should include a review of eye injuries, surgery, previous infectious or inflammatory eye disease, intraocular pressure history, previous visual field findings and presence or absence of associated risk factors including family history of glaucoma.
- 2. Complete eye examination to include:
  - a. Refraction to best visual acuity.
  - b. Humphrey visual field testing (30-2).
  - c. Applanation tonometry with diurnal measurements (at least three measurements, performed two hours apart).
  - d. Dilated funduscopic exam, and retinal nerve fiber layer analysis by optical coherence tomography (OCT) results.
  - e. OHT and glaucoma examination should also include central corneal thickness by ultrasound or with other computerized devices, such as Pentacam or anterior segment OCT (if available), and include optic disc photographs (if available).
- 3. Results of ophthalmology consultation (if required).
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

ACS review is required for all flying classes for waiver recommendation of OHT and glaucoma as part of the Ocular Hypertension/Glaucoma Management Group. A Medical Evaluation Board (MEB) is required for glaucoma if there are changes in the optic disc, visual field defects, or the condition is not amenable to treatment. An MEB is not required for ocular hypertension.

B. Renewal Waiver Request:

- 1 Summary of any changes with a review of history and a list of quarterly measurements of intraocular pressure by applanation tonometry, unless the treating specialist specifies less frequent assessment.
- 2 A complete eye examination to include: retinal nerve fiber layer analysis by optical coherence tomography (OCT), dilated funduscopic exam with optic disc photographs, and Humphrey visual field exam (30-2) of each eye separately (if OCT abnormal).
- 3 Results of ophthalmology consultation (if required).
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

# **III. Aeromedical Concerns**

Enlarged optic nerve cupping and OHT may be indicators of early glaucoma. Elevated IOP may result in difficulty with night vision secondary to the appearance of halos and flares around lights, and decreased contrast sensitivity. Left undiagnosed or inadequately treated, glaucoma can cause acquired changes in color vision, loss of central or peripheral visual fields, loss of visual acuity, and blindness. All of these visual disturbances have the potential to impair the aviator's visual performance and may present a significant safety hazard or adversely impact mission effectiveness. Glaucoma associated visual degradation occurs insidiously without subjective complaints which makes the screening program even more vital.

AIMWITS search in Jun 2019 for the previous five years revealed 444 members with an aeromedical summary with the diagnoses of glaucoma or intraocular hypertension. There 48 disqualifications. Breakdown of the cases revealed: 41 FC I/IA cases (18 disqualified), 170 FC II cases (5 disqualified), 16 RPA pilot cases (1 disqualified), 178 FC III cases (23 disqualified), 33 ATC/GBC cases (0 disqualified), 3 MOD cases (0 disqualified), and 3 SWA cases (1 disqualified).

ICD-9 codes for optic nerve cupping, intraocular hypertension, and glaucoma		
743.57	Specified anomalies of optic disc (increased cup-to-disc ratio)	
365.04	Ocular Hypertension	
365	Glaucoma	

ICD-10 codes for optic nerve cupping, intraocular hypertension, and glaucoma		
Q14.2	Congenital Malformation of optic disc	
H40.05	Ocular Hypertension, right eye, left, bilateral, unspecified	

1, 2, 3, 9	
H40.9	Unspecified glaucoma
H40.10X0	Unspecified open-angle glaucoma, stage unspecified

# **IV. Suggested Readings**

1. Leisegang TJ, et al. American Academy of Ophthalmology. Basic and Clinical Science Course, 2007-2008, Section 10: *Glaucoma*.

2. Saeedi OJ, Ramulu P, and Friedman DS. Epidemiology of Glaucoma. Ch. 10.1 in *Yanoff: Ophthalmology*, 4th ed., Saunders, 2013.

3. Mims JL, Tredici TJ. Ocular Hypertension and Chronic Open-Angle Glaucoma in USAF Pilots and Navigators. National Technical Information Service. December 1974. TR-74-48.

4. Gordon MO, Beiser JA, Brandt JD, et al. The Ocular Hypertension Treatment Study: baseline factors that predict the onset of primary open-angle glaucoma. Arch Ophthalmol. 2002; 120(6):714-720.

## Implantable Collamer Lens (ICL) Surgery (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Lt Col Richard Townley (SG Consultant for Refractive Surgery), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

**Significant Changes:** ICL surgery is now authorized for trained USAF aircrew. Refractive error limits must be within waiver tolerances of other laser refractive surgical procedures. MSD C33, 34, and 59.

# I. Waiver Consideration

Implantable collamer lens implantation surgery is disqualifying for Flying Class I, IA, II, III, GBO (RPA Pilot only), and SWA duties. There is waiver potential for FC II (non-pilot), FC III, GBO (RPA Pilot), and Special Warfare Airfare Airmen (SWA). ICL implantation surgery is not yet approved for FC II (pilots). It is not disqualifying for ATC, GBO (RPA SO and MOD), and Operational Support Flying Duty (OSF) personnel. No waivers will be considered for FC I/IA at this time, regardless of outcome. Implantation of phakic intraocular lenses other than the ICL is not authorized.

For ATC, GBO (RPA SO and MOD), and OSF personnel, a history of ICL surgery is only disqualifying if the surgical outcome results in the member's inability to meet visual standards for the career field.

Active duty members may have surgery at any DoD Refractive Surgery center. Members not eligible for TRICARE medical benefits (ANG/AFRC) may go to a civilian provider. Please submit for waiver once the member is one month post-op from surgery, meets vision standards, and all complications (if any) are appropriately managed and resolved.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review/Evaluation
FC I/IA	No	AETC	No
FC II (pilot)	No	MAJCOM	No
FC II (non-pilot)/ SWA/FC III	Yes	MAJCOM	Yes
ATC/GBO/OSF	N/A ¹	MAJCOM	No

# Table 1: Waiver potential for ICL surgery

1. ICL surgery is only disqualifying for ATC/GBO/OSF if the surgical outcome results in the member's inability to meet established vision standards or interferes with the member's ability to perform his/her duties.

Table 2. TTE-TCL Cyclopiegic Kenacuve Error Linnts		
Myopia (Most myopic meridian)	$\leq$ -10.00 Diopters	
Hyperopia (Most hyperopic meridian)	$\leq$ +4.00 Diopters	
Astigmatism	$\leq$ 3.00 Diopters	

## Table 2: Pre-ICL Cycloplegic Refractive Error Limits^{1,2}

 ICL surgery is NOT authorized outside of these refractive error limits, however members who have a preexisting waiver for refractive error beyond these limits will be considered for ICL surgery on a case-by-case basis.
 ICL implant choice must be a currently FDA approved implant (ICLs for hyperopia are not yet FDA approved).

Examination	Waiverable Results
Best corrected visual acuity (OVT)	20/20 or better each eye
Precision Vision 5% low contrast chart	20/50 or better each eye
Refractive error	Stable, no more than 0.50 diopter shift in
	manifest sphere or cylinder refractive power
	between two readings at least 2 weeks apart
Intraocular Pressure	$\leq$ 21 mmHg
Depth perception (OVT-DP)	Line B or better. If fails, refer to defective depth
	perception/stereopsis waiver guide.
ICL Vault	Greater than or equal to 20% corneal thickness
	based on slit lamp measurements or 100 microns
	based on anterior segment OCT measurements.
Slit Lamp Exam	Open angles and no cataract formation.
Fundus Exam	No new or previously unrecognized retinal
	pathology.

## Table 3: Waiverable Examination Results

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

To be eligible for ICL surgery, the member must first be disqualified for PRK/LASEK/LASIK surgery and be granted a permission to proceed letter from the Aviation Program Manager (APM) located at Wright-Patterson AFB. The member must then be examined by an ophthalmologist who has been certified in ICL surgery to make the final determination of surgical candidacy. After the surgery, the surgeon will evaluate the member for their one day, one week, and one month examinations. The three month, six month, and twelve month follow-up appointments, may be accomplished by a refractive surgeon or certified optometric co-manager to meet RS standard of care requirements. Any abnormalities or concerns found should be immediately reported to the surgeon to expedite evaluation and intervention. After the 12 month postoperative appointment, annual routine Flight or Special Operational Duty Qualification (PHA) and vision (optometry or ophthalmology) exams will be required. Waiver submission may be accomplished once the member is one month post-op from surgery, meets vision standards, and all complications (if any) are appropriately managed and resolved.

The aircrew member will be placed on non-mobility status, restricting the individual from deployment via AF Form 469 for a minimum of one month after surgery, even if no longer on steroid eye drops.

A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. Pre-op cycloplegic refraction.
  - b. Surgical procedure, date, location.
  - c. Assessment (negative and positive) of post-op symptoms of glare, halos, reduced night vision and diplopia.
  - d. Eye medications usage, past and current, include discontinuation date
- 2. Physical (Current):
  - a. Uncorrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.
  - b. Best corrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.
  - c. Cycloplegic refraction and dilated fundus exam.
  - d. Two post-op refractions at least 2 weeks apart that shows stability (no more than 0.50 diopter shift in **manifest** sphere or cylinder power).
  - e. Slit lamp exam.
  - f. Intraocular pressures (IOPs).

g. Depth perception (OVT-DP). (If fails and previously waived for defective depth perception using AO Vectograph, then include AO Vectograph).

h. ICL vault determine by slit lamp measurement and/or anterior segment OCT.

i. Endothelial cell count (pre-operative and post-operative measurements), if available.

- 3. Attach copy of "Permission to Proceed" letter.
- 4. Attach copy of the operative report for each eye treated, post-RS evaluations (1, 3, 6, 12 months post-op and annually, and any other additional follow-ups) and any RS-related incidents.
- 5. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

# B. <u>Waiver Renewal Request:</u>

- 1 History:
  - a. Pre-op cycloplegic refraction.
  - b. Surgical procedure, date and location.

c. Assessment (negative and positive) of post-op symptoms of glare, halos, reduced night vision and diplopia.

d. Eye medications usage, past and current.

2 Physical (current):

a. Uncorrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.b. Best corrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.

c. Manifest refraction

d. Slit lamp exam noting stability of the lens, patency of the peripheral iridotomy, and presence or absence of postoperative cataract formation.

e. Intraocular pressures (IOPs)

f. Depth perception (OVT-DP). (If fails and previously waived for defective depth perception using AO Vectograph, then include AO Vectograph).

- g. ICL vault determine by slit lamp measurement and/or anterior segment OCT.
- h. Endothelial cell count (pre-operative and post-operative measurements), if available.
- 3 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

#### **III. Aeromedical Concerns**

Implantable collamer lens implantation is a refractive surgery involving implantation of an artificial lens on top of the natural lens for individuals who are not candidates for traditional laser refractive surgical procedures (PRK, LASEK, or LASIK). While the FDA has approved much higher levels of myopia, current Air Force policy allows treatment with ICL surgery in aircrew with refraction from -3.00 D to -10.00 D. With ICL surgery, the major concerns are quality of visual outcome, postoperative cataract formation, pupillary block glaucoma, and endothelial cell loss causing corneal edema.

An independent Air Force Surgeon General directed review was conducted at Wilford Hall to determine the safety and efficacy of the ICL in Air Force personnel from 2016-2018. Even though the implantable collamer lenses used at the time did nothing to correct for astigmatism, 100% achieved uncorrected vision 20/30 or better without glasses. In terms of cataract formation, a meta-analysis reviewed 15 studies involving a total of 1,387 eyes and found an overall incidence of 0.3%.

The risk of pupillary block glaucoma is mitigated by proper ICL sizing to ensure a vault less than 1000 microns as well as the creation of a peripheral iridotomy for current FDA approved models. Newer models, such as the EVO (pending FDA approval), have a central port created in the lens, which negates the need for a peripheral iridotomy.

Endothelial cell loss is a known complication of intraocular surgery and happens to a greater extent the closer a lens implant is placed in relation to the endothelial cells. The initial FDA trials indicated an annual endothelial cell loss as high as 2.47% per year that was felt to continue indefinitely. More recent studies demonstrate cumulative losses are lower than the earlier FDA trials and indicate no corneal adverse events were noted in any of the studies, which indicates that this risk is not as concerning as it initially appeared.

ICD-10 Co	ICD-10 Codes for Corneal Refractive Surgery		
H52.0	Hypermetropia, right, left, both		
1, 2, 3			
H52.1	Myopia, right, left, both		
1, 2, 3			
H52.20	Unspecified astigmatism, right, left, both, unspecified		
1, 2, 3, 9			
Z96.1	Presence of intraocular lens		

# **IV. Suggested Readings**

1. Dougherty PH and Priver T. Refractive outcomes and safety of the implantable collamer lens in young low-to-moderate myopes. Clin Ophthalmol, 2017: 11: 273-77.

2. Packer M. Meta-analysis and review: effectiveness, safety, and central port design of the intraocular collamer lens. Clin Ophthalmol, 2016; 10: 1059-77.

3. Sander DR. Anterior Subcapsular Opacities and Cataracts 5 Years After Surgery in the Visian Implantable Collamer Lens FDA Trial. JRefract Surg, 2008: 24(6): 566-70.

4. Zeng Q, Xie X, Chen Q. Prevention and management of collagen copolymer phakic intraocular lens exchange; causes and surgical techniques. J Cataract Refract Surg, 2015; 41: 576-84.

5. Food and Drug Administration. Summary of safety and effectiveness data, STAAR Visian ICL. Date of Notice of Approval: December 22, 2005. Available from:

http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030016b.pdf. Accessed July 2, 2019.

6. Moya T, Javaloy J, Montes-Mico R, et al. Implantable Collamer lens for myopia: assessment 12 years after implantation. J Refract Surg, 2015; 31(8): 548-56.

7. Igarashi A, Shimizu K, and Kamiya K. Eight-Year Follow-up of Posterior Chamber Phakic Intraocular Lens Implantation for Moderate to High Myopia. Am J Ophthalmol, 2014; 157(3): 532-39.

8. Alfonso JF, Baamonde B, Fernandez-Vega L, et al. Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow-up. J Cataract Refract Surg, 2011: 37(5): 873-80.

# Keratoconus, Abnormal Corneal Topography, and Corneal Collagen Crosslinking (Nov 2020)

Revised: November 2020 Authors/Reviewers: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Dr. Christopher Keirns (ACS Waiver Guide Coordinator), and Lt Col Ric Speakman (AFMRA Physical Standards Development Chief)

**Significant Changes:** Updated to reflect new Ground Based Operator (GBO) MSD Standards. MSD C25, C30.

## I. Waiver Consideration

Keratoconus (KCN), including similar ectatic corneal disorders to include Pelucid Marginal Degeneration (PMD) and Keratoglobus, is a disqualifying condition for all flying classes in the Air Force, to include GBO, ATC, and SWA. (MSD C25 if progressive, C30 if stable). A FC I/IA, IFCII, and IFCIII waiver for abnormal corneal topography (MSD C30), which is a topography that is not normal but also not diagnostic of KCN, is possible and will be considered on a case-by-case basis with ACS review. Abnormal corneal topography alone is not disqualifying for ATC, GBO, or OSF duties.

Contact lenses, if worn, must be fitted appropriately and achieve adequate wearing times prior to use while flying. Trained aircrew diagnosed with KCN require frequent evaluations and management to ensure that they are adequately corrected to mitigate the optical side effects of the condition. Although contact lenses, particularly rigid lenses, are frequently required to optimize vision performance in these cases, aircrew must also be adequately corrected with spectacle back-ups. A key element in correction of KCN is to ensure adequate stereopsis with both contact lenses and spectacles. Trained aircrew who require specialty contact lenses (e.g. rigid gas permeable, hybrid, scleral lens) to meet stereopsis standards may be granted a IIC waiver (restricted to flying with another qualified pilot) and must carry a back-up pair of both contact lenses and spectacles on person at all times while flying. Specialty contact lenses for KCN are fitted and dispensed by the ACS.

As discussed above, historically, treatment of KCN typically consists of correction of refractive error with spectacle or contacts (soft, rigid, or hybrid) until the patient no longer can be corrected with these modalities; that member may then require penetrating keratoplasty (corneal transplant surgery). A more recent treatment procedure was developed and FDA approved (2016) which utilizes Riboflavin (Vitamin B2) and ultraviolet light to polymerize stromal collagen and induce corneal stiffening, with the goal to halt progression of KCN. This method is known as collagen cross-linking (CXL) and has widespread use in Europe since 2003. Several studies have shown very promising results with reduction in corneal steepness, improved corrected visual acuity, and halting of progression of KCN.

There is a gain of one to three lines of best-corrected visual acuity ranging from 21-54% after CXL. In terms of safety, there is a loss of best-corrected visual acuity at a rate of 0-2.9% and

failure rates ranging from 0-7.6%. Larger studies have shown the overall failure rate to be at 1%.⁷ Corneal haze can be seen after this procedure at a rate as high as 8.6%. However, Scheimpflug analysis following the natural history of post-CXL haze shows this to peak at one month postop with the majority of the return within the first three to six months and a near return to baseline by one year. This pattern of healing is very similar to that of PRK. Therefore, CXL shows incredible promise to help aircrew with keratoconus to see better while having an acceptable risk profile. The ACS will follow waived aircrew who have had CXL in a study group to determine if the aviation environment impacts the ultimate outcome and the best time postoperatively to return to flying status.

Flying Class (FC)	Waiver Potential	Waiver Authority ²	<b>ACS Review or Evaluation</b>
FC I/IA, initial FC	Mavbe ¹	AETC	Yes
II, initial FC III	właybe	ALIC	105
FC II/FC III, SWA	Yes	MAJCOM	Yes
ATC, GBO, OSF	Maybe ³	MAJCOM	Yes

 Table 1: Waiver potential for Keratoconus (MSD C25 if progressive, C30 if stable)

Cases will be considered as a case by case basis and keratoconus must be stable for at least one year for initial applicants and at least two years if the member has not already been assessed/commissioned in the USAF.
 Cases that are progressive, require long-term treatment, surgical intervention or results in spectacle corrected visual acuity below that specified in the MSD require AFMRA waiver after RILO/MEB.

3. Condition only disqualifying if demonstrates progression, requires long term treatment or surgical intervention, or does not meet best spectacled correction standards; requires RILO/MEB prior to waiver submission.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I	Yes, if meets REACT Study Criteria	AETC	Yes
FC IA, IFC III	Maybe ¹	AETC AFMRA	Yes
Initial FC II (FS), FC II, FC III, SWA	Yes ¹	MAJCOM	Yes
ATC, GBO, OSF	N/A	N/A	N/A

 Table 2: Waiver potential for Abnormal Corneal Topography (MSD C30)

1. Any corneal findings that exceed the following criteria should be submitted for waiver: I-S > 1.4, corneal pachymetry < 475 microns by any device, steepest K > 48 diopters by any measurement, pachymetry progression > 1.2 on Belin-Ambrósio Enhanced Ectasia. Waivers will be considered on a case by case basis.

Examination	Waiverable Results
Best corrected visual acuity (OVT)	20/20 or prior waivered baseline vision*
Precision Vision 5% low contrast chart	20/50 or prior waivered baseline vision*
Slit lamp exam	No more than trace corneal haze*
Refractive error	Stable, no more than 0.50 diopter shift in
	manifest sphere refractive power between two
	readings at least 2 weeks apart*
Keratometry	Stable, no more than 0.50 diopter shift in
	steepest keratometry reading on CT or tangential
	view of pentacam.*
Preoperative Corneal Pachymetry	Corneal pachymetry $\geq$ 400 microns
Fundus exam	No new or previously unrecognized retinal
	pathology†
Depth perception (OVT-DP)	Line B. If fails, see substandard stereopsis
	waiver guide.

 Table 3: Waiverable Postoperative CXL Examination Results

* If outside these limits, refer to local eye care provider and/or treating surgery center prior to referral to ACS to ensure member is ready for ACS evaluation.

[†] Work-up and submit waiver request for new diagnosis

AIMWTS review in Jul 2018 revealed 434 aircrew with waiver dispositions for keratoconus or abnormal corneal topography. There were 94 FC I/IA cases, 157 FC II cases, 16 RPA pilot cases, 143 FC III cases, 16 ATC/GBC cases, and 8 MOD cases. There were a total of 141 disqualifications; 65 were FC I/IA, 9 FC II, 4 were RPA pilots, 56 FC III, 4 were ATC/GBC, and 3 were MOD.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations. First-time waiver for KCN in trained aircrew or for abnormal corneal topography in aircrew or applicants requires an in-person ACS evaluation. Following first-time waiver, trained aircrew with KCN will be followed at the ACS every 1-3 years depending on clinical and optical stability. For those enrolled in the REACT study, an annual corneal evaluation including corneal topography and Orbscan or Pentacam,OVT-DP stereopsis, refraction to best visual acuity, and ultrasound central pachymetry (corneal thickness) is required with an ACS review prior to waiver renewal. If KCN or abnormal corneal topography demonstrates progression, requires long term treatment, surgical intervention or results in spectacle corrected visual acuity below the level specified in item MSD C2, MSD C25 applies(which also is a retention standard), and RILO/MEB results are required for inclusion into AMS submission.

#### A. Initial Waiver Request:

21. History of previous refractions and progression of astigmatism (if available) and other visual symptoms.

- 22. Family history of KCN and any impact on job/daily life.
- 23. Full eye exam to include:
  - a. 5% Precision Vision chart.
  - b. Manifest Refraction to best visual acuity.

c. Corneal Topography. Submissions should be formatted in **Axial** view using a standard dioptric scale (39.0 to 50.0 Diopter range, 0.50 Diopter increments) and standard color palette. The **OD/OS Display** with an **Axial Map** and an **Axial Numeric View** is preferred. All ATLAS topographies should display the **Axial I-S** value.

- d. Retinoscopy findings (+/- scissoring).
- e. Slit Lamp Exam with comment on positive/negative findings in the cornea.
- 24. Orbscan or Pentacam (Holladay and Belin-Ambrósio), if available.
- 25. Ophthalmology consultation report in advanced cases.
- 26. Pre-operative, operative, and post-operative ophthalmology notes if crosslinking performed to include:
  - a. All requirements listed above.
  - b. Preoperative corneal pachymetry.
  - c. Cycloplegic refraction and dilated fundus exam.
  - d. Two post-op refractions at least 2 weeks apart that shows stability (no more than 0.50 diopter shift in **manifest sphere**).
  - e. Keratometry readings pre and post-surgery.
- 27. f. Slit lamp exam which must include grading of haze, if present. RILO/MEB results, if member demonstrates progression, requires long term treatment, surgical intervention (to include corneal collagen crosslinking), or results in spectacle corrected visual acuity below the level specified in item MSD C2.
- B. Renewal Waiver Request:
  - 19. An interval AMS with particular attention to clinical changes and disease stability.
  - 20. Interval eye exam results to include:
    - a. Manifest Refraction Slit Lamp Exam
    - b. Corneal Topography (with parameters as above)
    - c. Slit Lamp Exam
    - d. Pentacam (if available).

# **III. Aeromedical Concerns**

Keratoconics frequently have poor quality of vision. Optical correction mitigates those effects somewhat, but many cases eventually require hard contact lenses to optimize correction. These contact lens fittings, however, are complicated and not always successful. Blurred vision, distorted images, decreased contrast sensitivity, degradation in stereopsis, monocular diplopia, and optical side effects caused by KCN are undesirable and detrimental to flight safety. It is imperative that aircrew carry a set of backup spectacles (and backup contacts if used) on all missions in the event problems arise with contacts making removal necessary.

In addition, corneal hydrops is a known complication in approximately 2-3% of KCN patients.⁹ Corneal hydrops is the development of acute and significant corneal edema following a break in

Descemet's membrane and endothelium, producing corneal clouding and vision loss. This complication typically only occurs in severe cases of KCN but would be a significant event if it occurred during operations. However, the risk of simultaneous bilateral corneal hydrops is considered to be low and is aeromedically acceptable. Fortunately, hydrops has rarely been observed within the USAF flying population. This may be due to the fact that hydrops is typically associated with younger patients who develop a severe form of KCN that presents at an early age. These individuals would likely be aware of their impaired visual condition and self-select out of an occupation with strict vision requirements. Additionally, as described above, the aeromedical risks of CXL specifically include loss of best corrected vision, treatment failure (progression despite treatment), and corneal haze. However, treating earlier in the disease process and proper patient selection can greatly reduce these risks.

ICD 9 code for keratoconus			
371.6 Keratoconus			
ICD-10 code for keratoconus			
H18.609	8.609 Keratoconus, unspecified, unspecified eye		
ICD-10 code for abnormal corneal topography			
H18.899	Other specified disorders of cornea, unspecified eye		

#### **IV. Suggested Readings**

1. Asri D, Touboul D, Fournié P, et al. Corneal Collagen Crosslinking in Progressive Keratoconus: Multicenter Results From the French National Reference Center for Keratoconus. J Cataract Refract Surg, 2011; 37: 2137-43.

2. Caporossi A, Mazzotta C, Baiocchia S, and Caporossi Tl. Long-term Results of Riboflavin Ultraviolet A Corneal Collagen Cross-linking for Keratoconus in Italy: The Siena Eye Cross Study. Am J Ophthalmol, 2010; 149(4): 585-93.

3. Hersh PS, Greenstein SA, and Fry KL. Corneal Collagen Crosslinking for Keratoconus and Corneal Ectasia: One-year results. J Cataract Refract Surg, 2011; 37(1): 149-60.

4. Agrawal VB. Corneal collagen cross-linking with riboflavin and ultraviolet – a light for keratoconus: results in Indian eyes. Indian J Ophthalmol. 2009; 57(2): 111–14.

5. Janov MR, Jovanovic Vm Nikolic L, et al. Corneal Collagen Cross-linking. Middle East Afr J Ophthalmol, 2010; 17(1): 21-27.

6. Koller T, Mrochen, and Seiler T. Complication and failure rates after corneal crosslinking. J Cataract Refract Surg, 2009; 35: 1358-62.

7. Raiskup-Wolf F, Hoyer A, Spoerl E, and Pillunat LE. Collagen cross-linking with riboflavin and ultraviolet-A light in keratoconus: Long-term results. J Cataract Refract Surg, 2008; 34(5): 796-801.

8. Greenstein SA, Fry KL, Bhatt J, and Hersh PS. Natural history of corneal haze after collagen crosslinking for keratoconus and corneal ectasia: Scheimpflug and biomicroscopic analysis. J Cataract Refract Surg, 2010; 36(12): 2105-14.

9. Gaskin JCF, Patel DV, and McGhee CNJ. Acute Corneal Hydrops in Keratoconus-New Perspectives. Am J Ophthalmol, 2014; 157(5): 921-28.

10. Al Suhaibani AH, Al-Rajhi AA, Al-Motowa S, and Wagoner MD. Inverse relationship between age and severity and sequelae of acute corneal hydrops associated with keratoconus. Br J Ophthalmol, 2007; 91(7): 984–85.

11. Tuft SJ, Gregory WM, and Buckley R. Acute Corneal Hydrops in Keratoconus. Ophthalmology, 1994; 101(10): 1738-44.

## Lattice Degeneration (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: LD and low risk atrophic retinal holes with refraction  $\leq$ -5.50 is not disqualifying. Waiver potential for LD and low risk atrophic retinal holes with refraction from - 5.75 to -8.00. MSD C42.

# I. Waiver Consideration

Lattice degeneration (LD) is disqualifying for Flying Class I, IA, II, III, and SWA duties when refraction exceeds -5.50. Lattice degeneration is not disqualifying for ATC, GBO, and OSF personnel, nor is it disqualifying for retention purposes. LD is considered high risk if there is a retinal hole present with subretinal fluid or vitreous traction. No waivers are currently being recommended for LD with high-risk characteristics for FC I/IA. The ACS is currently studying the axial length (length of the eye) to determine a better association with lattice degeneration, refractive error, and retinal detachment risk. Current members of the ACS Lattice Degeneration Management Group may be asked to come to the ACS for data collection, but generally, waiver recommendation is made by ACS case review only.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	Yes ¹	AETC	Yes
FC II/III	Yes ^{1,2}	MAJCOM	Yes
SWA	Yes ^{1,2}	MAJCOM	MAJCOM
ATC/GBO/OSF	N/A	N/A	N/A

Table 1: Waiver potential for lattice degeneration and low risk atrophic retinal holes

1. LD and low risk atrophic retinal holes may be waived for FC I/IA, as well as initial FC II, SWA, and FC III, if the member has been evaluated by an ophthalmologist or retinal specialist, who has ruled out the presence of untreated high risk peripheral holes or breaks, retinal traction or sub-retinal fluid, and native refractive error (pre-corneal surgery, if applicable) does not exceed -8.00 diopters. ACS review/evaluation required for initial waivers and at the discretion of the MAJCOM for waiver renewals. LD and low risk atrophic retinal holes with refraction  $\leq$ -5.50 are not disqualifying.

2. Waiver for history of retinal detachment is possible if treatment results in stable vision that is within accepted standards.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request:

- 1. List and fully discuss all clinical diagnoses requiring a waiver.
- 2. Symptoms, degree of lattice degeneration, degree of myopia (pre-refractive surgery, if applicable), and axial length of both eyes.
- 3. If there is a history of retinal detachment; discuss fully to include all treatments and post-treatment results (visual acuity, visual fields, status of other eye).
- 4. Details of complete ophthalmologic exam, to include presence and location of retinal holes, presence or absence of subretinal fluid, and presence or absence of vitreo-retinal traction.
- 5. Comprehensive ophthalmologist exam (Retinal specialist exam if there is a history of retinal detachment).
- 6. Copies of any photos, if they exist (photograph or digital).
- 7. Medical Evaluation Board results, if applicable.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

# B. Renewal Waiver Request:

- 1 Interim history specifically discussing any recurrences or any changes in the disease pattern and vision status.
- 2 Details of complete ophthalmologic exam.
- 3 Comprehensive ophthalmologist exam to include presence and location of retinal holes, presence or absence of subretinal fluid, and presence or absence of vitreo-retinal traction (Retinal specialist exam if there is a history of retinal detachment).
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

# **III. Aeromedical Concerns**

Retinal detachment is the primary aeromedical concern. This can result in decreased or loss of vision, visual field changes, abnormal stereopsis, and proliferative vitreoretinopathy. All of these conditions can compromise visual function to such a degree that continued aviation duty is not possible. Detachment is usually sudden and without warning and can be quite incapacitating.

Although LD remains stable in most cases (97%), it can cause, or be associated with RD, especially in higher degrees of myopia. LD is the direct cause of RD in 21% of cases, and is present in 41% of all RD cases. Seventy percent of RD, associated with LD, occurs in patients younger than 40 years of age. LD is more common in myopia; 70% of RD are seen in myopic eyes, with 75% of those RD in myopes with refractive error of -3.00D or greater. The risk of RD in association with any amount of LD increases with the degree of myopia, especially when the refractive error is greater than -5.00D.

In 1989, two major studies were conducted regarding the incidence of retinal detachment in myopic patients with LD. One was a retrospective study observing the characteristics of 176 retinal detachments. Using an annual RD risk of 0.38% and assuming an average lifespan of 79 years, they extrapolated a lifetime RD risk of 35.9% in patients with lattice degeneration and

myopia greater than -5.00, whereas those with lesser myopic refractive errors between -1.00D and -3.00D incurred a 5.3% lifetime RD risk. The other major study at that time observed 423 eyes over 1-25 years (mean 10.8 years) and found three clinical retinal detachments with an overall rate of 0.7%. This translates to a 0.07% annual risk of retinal detachment over the average observed time. This study further followed patients out up to 25 years and no patients had additional clinical retinal detachments. More recently, a study in Japan found a cumulative risk of retinal detachment from atrophic holes at a rate of 1.5% by age 40.

To take the most conservative approach possible, prior waiver recommendations were made on the most concerning statistic available, which was the 35.9% lifetime RD risk. However, this statistic was an estimation and the majority of the retinal detachments occurred at a mean age of 52, which is much older than the typical active duty pilot population. Other studies have subsequently shown a much lower 10-year RD risk ranging from 0-1.4%. To rectify this difference, the ACS has been tracking progression to retinal tears or retinal detachments in aviators with lattice degeneration through the Lattice Degeneration Study Group. While only 4.6 years into the 10 year study, preliminary data shows an annual rate of retinal tears of 0.48% and retinal detachment of 0.08%. This aligns much better with the other studies quoted and supports a much more favorable aeromedical risk profile.

There is no specific treatment for lattice degeneration, but high-risk atrophic holes or breaks can be treated by cryothermy, laser photocoagulation, or diathermy. In an evidence-based analysis of prophylactic treatment of asymptomatic retinal breaks and LD, a panel of vitreoretinal experts reviewed the ophthalmology literature. They concluded that there was insufficient information to strongly support prophylactic treatment of lesions other than symptomatic flap tears. If the condition leads to a retinal detachment, the vast majority can be repaired permanently, allowing the flyer to return to aviation duty due to a lack of increased further risk of retinal detachment.

A theoretical concern with LD is an increased risk of open angle glaucoma, specifically from pigment dispersion. It is recognized that various types of pigmentary disturbances can be seen in up to 80% if LD cases, particularly in cases with high myopia.

Review of AIMWTS data in Sep 2019 revealed 1046 cases since 1 Jan 2014 with a listed diagnosis of lattice degeneration. There were a total of 171 FC I/IA cases (21 disqualified), 372 FC II cases (13 disqualified), 56 RPA pilot cases (11 disqualified), 415 FC III cases (48 disqualified), 8 ATC/GBC cases (0 disqualified) 20 SWA cases (0 disqualified), and 4 MOD cases (1 disqualified).

ICD-9 codes for Lattice Degeneration		
362.6	Peripheral retinal degenerations	
362.63	Lattice degeneration	

ICD-10 codes for Lattice Degeneration			
H35.40	Unspecified peripheral retinal degenerations		
H35.411	Lattice degeneration of retina, right eye, .412 left eye, .413 bilateral, .419 unspecified		

## **IV. Suggested Readings**

1. Burton TC. The Influence of Refractive Error and Lattice Degeneration on the Incidence of Retinal Detachment. Trans Am Ophthalmol Soc, 1989; 87: 143-57.

2. Byer N.E. Long-term Natural History of Lattice Degeneration of the Retina. Ophthalmology, 1989; 96(9):1396-1401.

3. Sasaki K, Ideat H, Yonemoto J, Tanaka S, Hirose A, Oka C. Risk of Retinal Detachment in Patients with Lattice Degeneration. Jpn J Ophthalmol. 1998; 42(4):308-313.

4. Lewis H. Peripheral Retinal Degenerations and the Risk of Retinal Detachment. Am J Ophthalmol, 2003; 136:155-160.

5. Steel D and Fraser S. Retinal Detachment. Clin Evidence, 2010; 11: 710-746.

6. Wilkinson CP. Evidence-Based Analysis of Prophylactic Treatment of Asymptomatic Retinal Breaks and Lattice Degeneration. Ophthalmology, 2000; 107: 12-18.

7. Green RP and Chou TY. Retinal Detachment in US Air Force Flyers. Aviat Space Environ Med, 1996; 67:874-79.

8. Rahimi M. Relationship between retinal lattice degeneration and open angle glaucoma. Med Hypothesis, 2007; 64: 86-7.

## **Ocular Histoplasmosis Syndrome (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## **Significant Changes:**

New Version. MSD C44.

# I. Waiver Consideration

Patients who have active OHS lesions are disqualified for all flying class duties. In these cases, waivers will not be considered until the disease has resolved or the active lesions have been adequately treated. If an active lesion is treated by laser photocoagulation or PDT, patients should have at least one follow-up evaluation completed by the treating ophthalmologist 3-4 weeks post therapy prior to waiver submission. Follow-up examination must indicate extent of choroidal neovascularization (CNV) eradication and if residual disease is present requiring further therapy. Inactive lesions which allow the airman to meet vision standards will be waived on a case by case basis. Local ophthalmology evaluation to include visual acuity, Amsler grid testing, Humphrey 10-2 visual fields, stereopsis and funduscopic evaluation are required. Submit any ophthalmologic imaging obtained including optical coherence tomography (OCT) and fluorescein angiography. All cases will need to be reviewed or seen by ACS Ophthalmology. In addition, any disease, injury, infection process, or sequelae involving the eye that is resistant to treatment and/or results in: distant visual acuity that cannot be corrected to the retention vision standards listed in Item C2, and/or a central field of vision defect in the better eye that reduces the field of view less than 20 degrees from fixation in any direction is disqualifying for retention and will require an MEB.

Flying Class (FC)	Waiver Potential ^{1,2,3}	Waiver Authority ⁴	ACS Review/Evaluation
I/IA II/III (untrained)	Yes	AETC	Yes
II/III SWA	Yes	MAJCOM	Yes ⁵
ATC/GBO/OSF	N/A	N/A	N/A

	Table 1: Waiver	potential for	<b>Ocular Histo</b>	plasmosis Syn	drome
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1. History of macular disease or CNV in an initial applicant will not be waived.

2. Must meet retention and Flying Class-specific vision standards. Must not be expected to progress or recur. No active or reactivated disease are waiverable.

3. No indefinite waivers.

4. If individual does not meet retention standard outlined in MSD, then waiver authority becomes AFMRA.

5. For initial waiver consideration, AMS goes to AFMRA and subsequent requests may go to MAJCOM.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

1. List and fully discuss all clinical diagnoses and diagnoses requiring a waiver.

2. Eye exam to include:

a. Visual acuity

b. Humphrey visual fields (30-2 and 10-2)

c. Stereopsis testing.

3. Ophthalmology consultation report to include all follow-up reports.

4. If active lesions are part of the history and were treated by laser photocoagulation, intravitreal injections, or PDT, patients should have at least one follow-up evaluation, at least 3-4 weeks post therapy, completed by the treating ophthalmologist prior to waiver submission.

5. Ophthalmologic imaging test results to include fundus photos, OCT, and fluorescein angiography.

6. MEB results, if required.

7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

B. Renewal Waiver Request:

1. Interim History since last waiver and ACS visit.

2. Ongoing treatment modalities.

3. Full ophthalmology exam to include Amsler grid, dilated fundus exam, and OCT of the maculae.

4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

# **III. Aeromedical Concerns**

The primary aeromedical concern in OHS is its potential to affect central and peripheral vision. Patients with peripheral inactive disease without evidence of macular involvement will maintain excellent visual acuity and have a good visual prognosis. Some of these patients may have residual visual field defects, but most are minor and do not have substantial effects on peripheral vision. For those patients who develop macular disease, the prognosis is more guarded. Progression of disease with loss of vision depends upon the size and location of the lesion, development of CNV, and subsequent scaring. After three years, more than 75% of patients with subfoveal CNV will have a best-corrected visual acuity of 20/100. If the patient is less than 30 years of age and has a small subfoveal CNV lesion with no visual loss secondary to OHS in the other eye, a visual acuity of 20/40 or better may be retained in up to 14% of eyes. Currently, available treatments may preserve vision, although treating the macular area with laser therapy may degrade visual acuity. If subfoveal or juxtafoveal lesions are present, treatment should involve intravitreal anti-VEGF injections, PDT, or a combination of these two.

Review of AIMWTS in Jan 2019 identified 29 cases of OHS submitted for waivers. Of the 29 waivers, 3 were for FCI (1 disqualified), 18 were for FCII (3 disqualified), 2 were for RPA pilots, and 6 were for FCIII (1 disqualified). The waivers returned as medically acceptable all had inactive disease and met vision standards.

ICD-9 codes	ICD-9 codes for Ocular Histoplasmosis		
115.02	Ocular histoplasmosis syndrome		
115.9	Histoplasmosis unspecified without manifestation		
115.92	Histoplasmosis retinitis, unspecified		
115.99	Histoplasmosis unspecified with other manifestation		

ICD-10 codes for Ocular Histoplasmosis		
B39.4	Histoplasmosis capsulati, unspecified	
B39.9	Histoplasmosis, unspecified	
H32	Chorioretinal disorders in diseases classified elsewhere	

# **IV. Suggested Readings**

Moorthy RS. Histoplasmosis. Ch. 7.10 in Yanoff & Duker: Ophthalmology, 3rd ed., Mosby, 2008.

### **Optic Nerve Head Drusen (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, Aerospace Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

Significant Changes: New Ground Based Operator (GBO) standards. C54.

## I. Waiver Consideration

Optic nerve head drusen is a disqualifying condition for flying classes I/IA, II, III, and SWA personnel. It is not listed as a disqualifying diagnosis for ATC, GBO (RPA Pilot, RPA SO, and MOD), or OSF personnel, but for ATC/GBO personnel, it would be disqualifying if it results in a visual field defect. Aeromedical Consultation Service (ACS) evaluation is required for initial waiver of optic nerve head drusen for cases eligible for waiver. FC I/IA candidates with optic nerve head drusen are not eligible for waiver. Optic nerve head drusen in untrained FC II and FC III are also typically not eligible for waiver. ACS review is required for waiver renewal; depending on the results of local work-up, an ACS evaluation may be required. Waiver potential is based upon ophthalmologic examination including visual acuity, color vision, stereopsis, absence of transient visual loss, and an absence of aeromedically significant visual field defect.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review/Evaluation
I/IA	No	AETC	No ¹
II/III/SWA	Yes ²	MAJCOM	Yes
ATC/GBO	N/A ³	N/A	N/A
OSF	N/A	N/A	N/A

## Table 1: Waiver potential for Optic Nerve Head Drusen.

1. ACS evaluation only required if diagnosis is in question.

2. Waiver for untrained flying class II and III is unlikely but will be considered on a case-by-case basis.

3. Waiver will be required if the condition causes loss of visual acuity, visual field, or color vision.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

## A. Initial/Renewal Waiver Request:

1. Complete aeromedical history to include pertinent positives and negatives (e.g. headaches, pulsatile tinnitus, hypertension, diabetes, family history of drusen, etc.)

2. Presence or absence of visual symptoms and their operational impact (e.g. transient visual obscurations, perceived scotomas or metamorphopsia)

3. Results of complete optometric or ophthalmologic eye examinations to include:

- a. Refraction to best Snellen visual acuity
- b. Intraocular pressure by applanation tonometry
- c. CCT results for each eye individually
- d. Amsler grid
- e. Humphrey visual field testing (preferably 30-2)
- f. Ocular coherence tomography (OCT) of the retinal nerve fiber layer (RNFL)
- g. Stereoscopic optic disc evaluation.

4. Diagnostic test(s) supporting diagnosis (e.g. ophthalmic B-scan ultrasound, computed tomography of the orbit, or autofluorescence.)

a. Confirmatory diagnostic testing is only required for the initial diagnosis. Images and report of at least one confirmatory test must be included in the initial waiver request.

b. Waiver renewal requires items #1 through #3 be performed. The results of the testing in item #4 used for the initial waiver should be included in the AMS with the date and results of the initial testing performed. Confirmatory diagnostic testing is not required for each waiver renewal.

5. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

#### **III. Aeromedical Concerns**

Clinically and aeromedically, the main concern with optic disc drusen is their propensity to induce slowly progressive visual fields loss. As high as 87% of individuals with optic nerve head drusen can expect to have visual field abnormalities. Furthermore, transient disturbances in central acuity and visual field may occur in association with optic nerve head drusen. Color vision anomalies have also been described in 41% of USAF aviators with ODD in preliminary data collected at the Aeromedical Consultation Service. ODD have also been associated with retinal hemorrhage in 2-10% of patients, though most cases are incidental findings without visual impairment.¹

Once the diagnosis of drusen is established, careful evaluation of optic nerve function is imperative. This should include visual acuity, visual field testing, Amsler grid, and color vision testing. Visual field loss has the most potential for aeromedical grounding and as such, visual field testing should be performed on a regular basis to ensure visual function remains adequate and consistent with mission effectiveness and flying safety. In addition, applanation tonometry should be completed in cases with known visual field or RNFL and GCC loss on OCT. This recommendation comes due to the risk of hypoxic nerve injury. Ischemia is the cause of the visual field loss and optic nerve damage associated with optic nerve head drusen. In a normal healthy optic nerve, the redundancy of blood supply allows aircrew to have adequate blood flow to the optic nerve in most instances, to withstand the hypoxia associated with flight. The optic nerve of a member with drusen is already a compromised nerve. As reported above, even in the civilian population, 71-87%, have ischemic related optic nerve injury even without the hypoxia risk. Optic disc photodocumentation should be obtained for comparison during future monitoring. It is also important for patients to self-monitor their vision periodically with Amsler Grid testing. Periodic surveillance to assess visual function in aircrew with optic nerve head drusen is appropriate, since drusen-related optic nerve problems are often asymptomatic. Routine cases should be monitored every six to twelve months.

AIMWTS search revealed a total of 140 members with an AMS containing the diagnosis of optic nerve head drusen. There were 51 disqualifications in that total. Breakdown of the cases revealed:

24 FC I/IA cases [22 disqualified (2 FC I/IA waivers exist in AIMWITS; both cases were misdiagnosed at the time of waiver submission as optic nerve head drusen and the diagnosis remained. However, subsequently no disc drusen were definitively identified following full ophthalmology evaluation in these individuals)], 54 FC II cases (1 disqualified), 58 FC III cases (26 disqualified), 4 ATC/GBC cases (2 disqualified), and no MOD cases.

ICD-10 Codes	for Optic Nerve Head Drusen
H47.329	Drusen of optic disc, unspecified eye

## **IV. Suggested Readings**

1. Auw-Haedrich C, Staubach F, Witschel H. Optic Disk Drusen. Survey of Ophthalmology, 2002; 47(6): 515-532

## **Optic Neuritis (Mar 2020)**

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## Significant Changes:

New Version. MSD C49.

## I. Waiver Consideration

Optic neuritis (ON) is disqualifying for flying classes I/IA, II, III, and SWA duties. It is not specifically listed as disqualifying for GBO, ATC, and OSF duties, unless MS has also been diagnosed, in which case the member is disqualified. If the ON is visually symptomatic (decreased visual acuity or visual field defect), it would then be disqualifying for ATC, GBO, and OSF duties.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation		
I/IA	No	AETC	No		
II/III/SWA ^{1,2}	Yes	MAJCOM ³	Yes		
ATC/GBO/OSF ²	Yes	MAJCOM ³	Maybe		

#### Table 1: Waiver potential for Optic Neuritis.

1. In untrained FC II and III, waiver recommendation is unlikely.

2. All waivers are recommended to be valid for only one year. ACS evaluations should be "in person" for initial waiver after a normal MRI and a normal repeated MRI 3 months later. Waiver renewal may be performed by review or evaluation.

3. If the case also demonstrates positive MRI/CSF or definitive Multiple Sclerosis, the waiver authority is AFMRA.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

### A. Initial Waiver Request:

- 1. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.
- 2. A complete discussion of the history of the optic neuritis.
- 3. Results of consultation from Ophthalmology AND Neurology
- 4. Visual Field (30-2) results at initial diagnosis and 3 months later.
- 5. Labs: If lumbar puncture clinically indicated by a neurologist, submit cerebrospinal fluid results including oligoclonal bands and myelin-basic protein.
- 6. Brain T1 and T2-weighted MRI with gadolinium and FLAIR sequences at initial presentation and 3 months later. Send report(s) and images to the ACS. Images may be mailed to ACS on CD or uploaded to the USAFSAM ECG Library PICOM servers.
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

## B. <u>Renewal Waiver Request:</u>

- 1 Interval history.
- 2 Interval labs (if indicated).
- 3 Interval brain T1 and T2-weighted MRI with gadolinium and FLAIR sequences. Send report(s) and images to ACS. Images may be mailed to ACS on CD or uploaded to the USAFSAM ECG Library PICOM servers.
- 4 Optical Coherence Tomography (OCT) of the retinal nerve fiber layer (RNFL).
- 5 Interval Threshold 30-2 Visual Field Studies.
- 6 Follow-up consultations from Ophthalmology and Neurology.
- 7 If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

## **III. Aeromedical Concerns**

The primary aeromedical concerns with isolated ON (as defined by the absence of radiologic or clinical criteria for MS) are variable decreases in visual performance that are unpredictable by either clinical exam or imaging study and may go unrecognized by aircrew member with or without treatment. These visual changes include decreased visual acuity, degradation in color vision, visual field defects, and photopsias. Symptoms can present over a period of hours and may increase under physiologic stresses such as dehydration, hypoxia, fatigue, or increases in body temperature. Additionally, Uhthoff's phenomenon, which is a decrease in vision associated with a rise in body temperature, was a common observation amongst USAF aircrew with ON. Military operational extremes characterized by increased heat exposure, such as in desert operations and in hot closed cockpits/crew stations, may place military personnel at an increased risk for Uhthoff related functional impairments.

The risk of relapse from typical isolated ON with normal brain CSF and MRI findings is low enough, as evidenced by the Optic Neuritis Treatment Trial (ONTT), that disease modifying immunomodulatory treatment is not recommended, and waiver is possible. Treatment with high dose intravenous methylprednisolone may be considered to hasten visual return in severe cases with possible earlier return to duty with isolated ON. However, this must be balanced with the risks of such therapy since long term visual performance is not changed. When ON is not isolated, the risk of relapse is very high. Unfortunately, the reduction in relapses seen with treatment is insufficient for aviation purposes and immunomodulatory therapy for MS is not currently approved for waiver. Thus, the issue of treatment is largely irrelevant for aeromedical purposes at this time.

AIMWTS search in Jan 19 revealed 41 cases with the diagnosis of ON. There were 0 FC I/IA cases, 16 FC II cases (8 disqualifications), 22 FC III cases (9 disqualifications), 2 RPA pilot cases (1 disqualification), and 1 ATC/GBC case.

ICD 9 code for Optic Neuritis			
377.30	Optic neuritis, unspecified		
ICD 10 code	e for Optic Neuritis		
<b>ICD 10 code</b> H46.9	e for Optic Neuritis Optic neuritis, unspecified		

## **IV. Suggested Readings**

1. Clark D, Kebede W, and Eggenberger E. Optic Neuritis. Neurol Clin, 2010; 28: 573-80.

2. Optic Neuritis Study Group. The Clinical Profile of Optic Neuritis: Experience of the Optic Neuritis Treatment Trial. Arch Ophthalmol, 1991; 109(12): 1673-78.

3. Gerling J, Meyer JH, Kommerell G. Visual field defects in optic neuritis and anterior ischemic optic neuropathy: distinctive features. Graefes Arch Clin Exper Ophthalmol, 1998; 236: 188-92.

4. Keltner JL, Johnson CA, Cello KE, et al. Visual Field Profile of Optic Neuritis: A Final Followup Report From the Optic Neuritis Treatment Trial From Baseline Through 15 Years. Arch Ophthal, 2010; 128: 330-37.

5. Ivan DJ, Tredici TJ, Burroughs JR, et al. Primary Idiopathic Optic Neuritis in U.S. Air Force Aviators. Aviat Space Environ Med, 1998; 69(2): 158-65.

6. The Optic Neuritis Study Group. Visual Function More Than 10 Years After Optic Neuritis: Experience of the Optic Neuritis Treatment Trial. Am J Ophthalmol, 2004; 137: 77-83.





# **Excessive Refractive Error**

Revised: Feb 2022

Reviewed: Col(s) Jonathan Ellis (Chief, ACS Ophthalmology), Dr. Max Lee (ACS Waiver Guide Coordinator), and Maj Paul Vu (AFMRA Physical Standards Development Chief)

**Significant Changes:** Correction of Waiver Authority. Per Note 8 of Table One of the MSD, standards for refraction and anisometropia only apply to initial aircrew applicants.

# I. Waiver Consideration

Refractive errors standards are listed in Section C, TABLE ONE of the Medical Standards Directory for all flying classes and special operational duty. Excessive refractive error is not listed specifically as disqualifying for ATC, GBO (RPA SO and MOD), and SWA duties. Members must correct to 20/20 in each eye at distance and near for ATC and SWA duties. Members must correct to 20/20 in the better eye and 20/400 in the worse eye for GBO. SWA personnel must also meet sister service standards IAW AR40-501 and NAVMED 15-102/105. For trained assets without other disqualifying conditions listed in the MSD, waiver renewals are not required. Assets training into a new careerfield must meet initial waiver requirements appropriate for the new flying class or operational duties.

The following tables cover the different flying classes, waiver potential, and ACS review/evaluation for myopia, hyperopia, astigmatism, and anisometropia. If refractive errors are greater than those listed in the tables below for FC I/IA, no waiver will be granted.

Flying Class	<b>Refractive error</b>	Waiver Potential	Waiver Authority	ACS review/evaluation
FC I	> -3.00	No	AFRS/CMO	No
FC IA	> -4.50	No	AFRS/CMO	No
FC II(non-pilot)/FC III/GBO (RPA Pilot)	> -5.50	Yes	AFRS/CMO	No
ATC/GBO (RPA SO/MOD)	N/A	N/A	N/A	N/A
SWA	> -8.00	No	AFRS/Army/Navy	No

Table 1: Myopia

#### Table 2: Hyperopia

Flying Class	<b>Refractive error</b>	Waiver	Waiver Authority	ACS
		Potential		review/evaluation
FC I	> +2.00 but $\leq$ +3.00 ¹	Yes	AFRS/CMO	Yes
	$> +3.00$ but $\leq +4.00^{-2}$			
FC IA	$>+3.00$ but $\leq+4.00^{-1}$	Yes	AFRS/CMO	Yes
	> +4.00 but $\leq$ +5.50 ²			
FC II(non-pilot)/FC III	>+5.50 ¹	Yes	AFRS/CMO	Maybe ³
GBO (RPA Pilot)	>+5.50	Yes	AFRS/CMO	Yes
ATC/GBO (RPA	N/A	N/A	N/A	N/A
SO/MOD)				
SWA	>+8.00	No	AFRS/Army/Navy	No

1. If waiverable degradation in stereopsis, (meets waiver criteria for defective depth perception, see waiver guide on stereopsis), then waiver potential exists.

2. If no degradation in stereopsis, then waiver potential exists.

3. Hyperopes with defective depth perception may be referred to the ACS at the discretion of the waiver authority.

Tab	le 3	: Astigma	atism	
1.11	•	0		

Flying Class	<b>Refractive Error</b>	Waiver	Waiver	ACS
		Potential	Authority	review/evaluation
FC I/IA	>3.00	No	AFRS/CMO	No
FC II/FC III	>3.00	Yes	AFRS/CMO	Yes
GBO (RPA Pilot)				
ATC/GBO (RPA	N/A	N/A	N/A	N/A
SO/MOD)/SWA				

#### Table 4: Anisometropia

Flying Class	<b>Refractive Error¹</b>	Waiver	Waiver	ACS
		Potential	Authority	review/evaluation
FC I	> 2.00	Yes	AFRS/CMO	Yes
FC IA	> 2.50	Yes	AFRS/CMO	Yes
FC II(non-pilot/FC III	> 3.50	Yes	AFRS/CMO	No
GBO (RPA Pilot)				
ATC/GBO (RPA	N/A	N/A	N/A	N/A
SO/MOD)/SWA				

1. If normal stereopsis or waiverable degradation in stereopsis and no asthenopic symptoms or diplopia. Waiverable degradation of stereopsis means meets waiver criteria for defective depth perception (see waiver guide on subject).

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

## Myopia

Initial Waiver Request:

- 1. Cycloplegic refraction (Initial FC II/III/GBO-RPA Pilot applicant) to 20/20 each eye and manifest refraction to best corrected visual acuity each eye.
- 2. Optometry/ophthalmology exam to include a dilated peripheral retina exam of each eye.
- 3. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## Hyperopia

## Initial Waiver Request:

- 1. Cycloplegic refraction (FC I/IA and initial FC II/III/GBO-RPA Pilot applicant) to 20/20 each eye and manifest refraction to best corrected visual acuity each eye.
- 2. Stereopsis testing (OVT).
- 3. Optometry/ophthalmology exam to include:
  - a. Ductions, versions, cover test and alternate cover test in primary and 6 cardinal positions of gaze.
  - b. AO Vectograph stereopsis and suppression tests at 6 meters
  - c. Randot or Titmus stereopsis test (near stereopsis tests).
  - d. Red lens test.
  - e. Four-diopter base-out prism test at 6 meters.
- 4. History of asthenopic (eye pain/fatigue) symptoms, diplopia.
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## Astigmatism

Initial Waiver Request:

- 1. Cycloplegic refraction (Initial FC II/III/GBO-RPA Pilot applicant) to 20/20 each eye and manifest refraction to best corrected visual acuity each eye.
- 2. Corneal topography imaging. All corneal topography (CT) submissions should be formatted in Axial view using a standard dioptric scale (39.0 to 50.0 Diopter range, 0.50 Diopter increments) and standard color palette. The OD/OS Display with an Axial Map and an Axial Numeric View is preferred. All ATLAS topographies should display the Axial I-S value.
- 3. Corrected visual acuity with spectacles, and contact lenses if applicable, each eye.
- 4. Corrected low contrast acuity (PV 5% chart) with spectacles, and contact lenses if applicable, each eye.
- 5. Stereopsis testing (OVT).
- 6. Optometry/ophthalmology exam to include slit lamp and fundus exam.

7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## Anisometropia

Initial Waiver Request:

- 1. Cycloplegic refraction (FC I/IA and initial FC II/III/GBO-RPA Pilot applicant) to 20/20 each eye and manifest refraction to best corrected visual acuity each eye.
- 2. Stereopsis testing (OVT).
- 3. Optometry/ophthalmology exam to include:
  - a. Ductions, versions, cover test and alternate cover test in primary and 6 cardinal positions of gaze.
  - b. AO Vectograph stereopsis and suppression tests at 6 meters
  - c. Randot or Titmus stereopsis test (near stereopsis tests).
  - d. Red lens test.
  - e. Four-diopter base-out prism test at 6 meters.
- 6. History of asthenopic (eye pain/fatigue) symptoms, diplopia or fusional problems, to include negative responses.
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

**Note:** For all FC I/IA applicants, confirmation that individual has discontinued wear of soft contacts for at least 30 days or hard/rigid gas permeable contact lenses for at least 90 days at the time of exam is required.

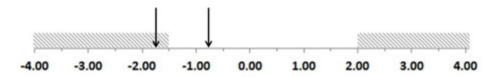
## **III. Aeromedical Concerns**

Aeromedical refractive error is based on the cycloplegic refraction for all initial flying class exams. The authorized cycloplegic exam technique uses 1% cyclopentolate (Cyclogyl), 2 drops each eye, 5 to 15 minutes apart, with examination performed no sooner than one hour and no later than two hours after the second drop. The cycloplegic refractive error is the minimum refractive power needed to achieve 20/20 visual acuity in each eye. The refractive error standard for aeromedical purposes is that produced following transposition. The rules of transposing are: (1) <u>Algebraically</u> add the cylinder power to the sphere power to determine the transposed power of the sphere (2) Change the sign of the cylinder (3) Change the axis by 90 degrees (do not use degrees greater than 180 or less than 0). Note: 180 degrees is used in place of 0 degrees.

	Sphere	Cylinder		Axis
Example 1:	-0.75	-1.00	Х	179
Transposed	-1.75	+1.00	Х	089
Example 2:	-4.25	-1.25	Х	068
Transposed	-5.50	+1.25	Х	158

By transposing a refractive error, the most plus and most minus meridians can easily be determined. In example 1, -0.75 is the most plus meridian and -1.75 is the most minus meridian. When applying aeromedical standards and waiver criteria, both of these values must fall within the allotted range based on the flying class. If the candidate in example 1 was applying for FCI,

Table One of the Medical Standards Directory (MSD) would show that the most plus meridian can be no greater than +2.00 and the most minus meridian can be no less than -1.50. Graphically, this would be represented as shown below, and it is apparent that this refraction would exceed the standard for myopia.



Astigmatism may be represented by either a positive or negative cylinder value depending on the axis referenced. When applying aeromedical standards and waiver criteria, the sign of the value is irrelevant as the physical meaning of astigmatism is simply a difference between two points.

Improper or unbalanced correction with spectacles or contact lens can degrade stereopsis and contrast sensitivity as well as induce generalized ocular pain and fatigue (asthenopia). Myopia is more likely to progress, with respect to the degree of myopia, regardless of age, while hyperopia tends to remain static over time. In addition, myopes may see halos or flares around bright lights at night and are also at risk for worsening vision under dim illumination and with pupil enlargement, a phenomena known as "night myopia." Myopes also have an increased risk of retinal detachment, open angle glaucoma and retinal degenerations, such as lattice.

Hyperopes, especially those with greater than +3.00 D of correction, will experience greater problems with visual acuity after treatment with atropine or topical cycloplegic agents. They have a greater predisposition for tropias, microstrabismus, and phorias that can decompensate under the rigors of flight. They also have a higher prevalence for amblyopia due to the accommodative esotropia and anisometropia. Moreover, hyperopes have more problems with visual aids, such as night vision goggles, as they develop presbyopia at earlier ages compared to myopes. Lastly, hyperopes are more likely to develop angle closure glaucoma than myopes.

Higher levels of astigmatism or progressive astigmatism can be associated with potentially progressive corneal conditions, such as keratoconus, that can degrade image quality and visual performance during productive years of flying career. Anisometropias have greater association with diplopia, fusional discrepancies (e.g. defective stereopsis), and amblyopia, especially when greater than 2.00 D refractive error difference between the two eyes.

In general, corrective measures presently available to correct refractive errors include spectacles, contact lenses, and corneal refractive surgical techniques such as PRK, LASIK, and ICL implantation. Spectacles impose an additional optical interface between the aircrew's eyes and the outside world. This increases the risk of internal reflections, fogging, as well as reduction in the light reaching the retina leading to visual distortion. These phenomenon are especially more common in high myopes and in higher levels of astigmatism. Finally, spectacle frames interfere with the visual field, cause potential hot spots, and displace under G forces. Depending on nature and magnitude of the refractive error, the lenses themselves can induce optical blind spots (scotomas), optical image size changes, and can create unacceptable effects on other visual performance parameters, such as stereopsis. Contact lenses share some of these same problems,

but reduce some of the drawbacks of spectacles, such as changes in image size, peripheral vision interference, hot spots from frames, fogging, and blind spots. However, contact lenses introduce their own unique aeromedical problems particularly related to maintenance and wear. In addition, further concern exists with the risk of acutely having to perform without the corrective lenses, such as after spontaneous lens loss, e.g. after ejection or during a deployment without adequate backups. See corneal *Refractive Surgery* and *Implantable Collamer Lens* Waiver Guides for further discussion on advantages and risks of refractive surgery.

AIMWTS review of each of these four diagnoses produces a large number of cases. In 2015, there were 8420 cases of myopia, 496 cases of hyperopia, 2079 cases of astigmatism and 153 cases of anisometropia. It is no longer necessary to do new searches that will produce even larger numbers. These are common diagnoses in the aviation population, but it is important that we continue screening our aviators for quality of vision.

ICD-9 Codes for Refractive Errors	
367.0	Нурегоріа
367.1	Муоріа
367.2	Astigmatism
367.31	Anisometropia

ICD-10 Codes for Refractive Errors		
H52.0, 1, 2, 3	Hypermetropia, right, left, both	
H52.1, 1, 2, 3	Myopia, right, left, both	
H52.20, 1, 2, 3, 9	Unspecified astigmatism, right, left, both, unspecified	
H52.31	Anisometropia	
H52.7	Unspecified disorder of refraction	

## **IV. Recommended Readings**

No external references were used in producing this waiver guide.

# **Refractive Surgery (Nov 2020)**

Revised: November 2020 Authors/Reviewers: Lt Col Jonathan Ellis (ACS Ophthalmology Branch Chief), Dr Christopher Keirns (ACS Waiver Guide Coordinator), and Lt Col Ric Speakman (AFMRA Physical Standards Development Chief)

**Significant Changes:** SMILE and ICL surgery now approved but requires a waiver prior to return to flying and operational duties.

# I. Waiver Consideration

Uncomplicated Refractive Surgery is not disqualifying for all classes of flying duties and Aviation and Aviation Related Special Duty (AASD) if pre-refractive Surgery Cycloplegic refractive error limits were met (Table 3). Waiver is required only if complications occurred or if surgery was performed beyond the standards but does not exceed waiver limits (Table 4). Members who don't require a waiver are managed locally with a DNIF and may return to flying duties once cleared by the flight surgeon, co-managing optometrist, and surgeon (if needed). All LASIK flap dislocations need to be evaluated in person at the ACS even if treated promptly and deemed healed by the treating ophthalmologist. There is a risk in such cases of quality of vision deficits. Return to Flying Duties/Waiver may be initiated as early as 30 days postop for LASIK and 6 weeks postop for PRK if the surgery and/or complication has been managed appropriately with return of good visual acuity (Table 2). In cases where no waiver is necessary (within standards as stated in Table 3 and without complications), member may return to flying duties two weeks after surgery at the earliest, but not until they can pass vision standards with at least two weeks of stability (Table 2).

The currently approved laser refractive surgery procedures include LASIK, PRK, and SMILE. LASIK and PRK are generally not disqualifying and do not require a waiver unless one of the above conditions are met. SMILE is a newer procedure and requires a waiver prior to return to flying duties. ICL surgery is the only approved intraocular refractive surgery for aircrew and also requires a waiver prior to return to flying duties (see ICL Waiver Guide).

For ATC, GBO and SWA personnel, a history of refractive surgery is only disqualifying if the surgical outcome results in the member's inability to meet visual standards for the career field.

Steroid eye drops used to treat or prevent inflammation after approved CRS do not automatically lead to DNIF. The member should remain DNIF until cleared by flight surgeon, optometrist, and surgeon once the member meets vision standards, and is deemed clear, as outlined in Table 2. Members may need anti-inflammatory drops after they have been deemed clear to return to flight status, but do not need to be DNIF during the rest of their time using these drops.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
I/IA	Yes	AETC	Yes
II/III	Yes	MAJCOM	Yes
ATC, GBO, SWA	Yes	MAJCOM	Yes

 Table 1: Waiver potential for Refractive Surgery with Complications

Table 2. Whatam	Ctandanda fan Datam		
I able 2: Vision	Standards for Ketur	n To Fiving Duties or to	o Initiate Waiver (if required)

Examination	Waiverable Results
Best corrected visual acuity (OVT)	20/20 or better each eye
Precision Vision 5% low contrast chart	20/50 or better each eye
Refractive error	Stable, no more than 0.50 diopter shift in
	manifest sphere or cylinder refractive power
	between two readings at least 2 weeks apart
Slit lamp exam	LASIK – no visually significant striae or flap
	complications
	PRK – no visually significant corneal haze
Fundus exam	No new or previously unrecognized retinal
	pathology
Depth perception (OVT-DP)	Line B or better. If fails, refer to defective
	depth perception/stereopsis waiver guide.

#### Table 3: Pre-RS Cycloplegic Refractive Error Limits (AASD)

Myopia (Most myopic meridian)	$\leq$ -8.00 Diopters
Hyperopia (Most hyperopic meridian)	$\leq$ +3.00 Diopters
Astigmatism	$\leq$ 3.00 Diopters

#### Table 4: Pre-RS Cycloplegic Refractive Error Limits (Exceeds AASD and Requires Waiver)¹

<b>Refractive Error</b>	Untrained Applicants	Trained Applicants
Myopia (Most myopic	$\leq$ -10.00 Diopters	$\leq$ -10.00 Diopters
meridian)		
Hyperopia (Most hyperopic	$\leq$ +5.00 Diopters	$\leq$ +4.00 Diopters
meridian)		
Astigmatism	$\leq$ 6.00 Diopters	$\leq$ 3.00 Diopters

1. Applicant/Member may not qualify for a waiver for surgery in excess of AASD standards unless member had a good outcome and is able to meet other vision standards. Special warfare airmen must meet sister service standards while training with sister services.

		PRK ^{8, 9}	LASIK ^{7, 9}	Hyperopia ^{6,9}
		Plano to $\leq$ -8.00	Plano to <u>&lt;</u> -8.00	Plano to $\leq +3.00$
Trained	Surgery	Any DoD RS Center/Civilian ¹	Any DoD RS Center/Civilian ¹	Any DoD RS Center/Civilian ¹
Aircrew	1-year post-op exam	Local Eye Clinic/Civilian ¹	Local Eye Clinic/Civilian ¹	Local Eye Clinic/Civilian ¹
	Waiver Authority ⁵	MAJCOM	MAJCOM	MAJCOM
D:1-4	Surgery	USAFA/Civilian & Any DoD RS Center ¹	USAFA/Civilian & Any DoD RS Center ¹	USAFA/Civilian & Any DoD RS Center ¹
Pilot Applicants ²	Exam requirement for initial waiver ³	USAFA/ACS at time of MFS	USAFA/ACS at time of MFS	ACS ⁴ /ACS at time of MFS
	Waiver Authority	AETC	AETC	AETC ⁴
RPA Pilot	Surgery	Any DoD RS Center/Civilian ¹	Any DoD RS Center/Civilian ¹	Any DoD RS Center/Civilian ¹
Applicants	Initial follow-up for waiver	Local Eye Clinic/Civilian ¹	Local Eye Clinic/Civilian ¹	USAFA/ACS at time of MFS

Table 5: USAF Corneal Refractive Surgery Clinical Guidelines (AADS CRS Program and Standards)

If not eligible for TRICARE medical benefit (e.g. civilian, ROTC & most ANG/AFRC), will go to civilian provider.
 AD pilot applicants are considered Warfighters until selected for training [they must have a qualified physical exam (pending MFS) <u>before</u> selection]. They must meet the AASD or waiver criteria.

3. Post-op exam for initial FC I application must be at least three months after date of surgery (e.g. history of PRK or LASIK no sooner than three months ago). Applicants must be one year after surgery for hyperopic treatments.

4. For USAFA cadets, ACS review/evaluation is required prior to waiver (no "contingent on MFS" waivers) if there was a complication.

5. Waiver authority for initial and renewal, if the surgery was in excess of AASD standards and/or complications were experienced.

6. For both PRK and LASIK.

 Members who have LASIK should have a minimum two-week DNIF period, however, it may take up to 1 month to fully stabilize following LASIK. Initial waiver can be requested once applicable vision standards are met and refractive stability is established if the surgery was in excess of AASD standards and/or there was a complication.
 Members who have PRK should have a minimum two-week DNIF period, however, it may take up to 2-3 months for

enough corneal healing to occur to meet applicable vision standards and for refractive stability to occur.

9. All initial waivers must meet other set vision standards and meet the waiver criteria in Table 4 above.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations. Waiver potential and waiver limits are outlined in Tables 1, 2, 3, and 4. The essential elements of the USAF Refractive Surgery Program are outlined in Table 5 above.

If the <u>trained aircrew member</u> has an uncomplicated postoperative course, meets applicable vision standards, and met pre-refractive cycloplegic refractive error limits in Table 3, member may resume flying duties once cleared by their flight surgeon, co-managing optometrist, and surgeon (if necessary). All follow-up appointments, including the 12-month post op evaluation should still be accomplished to meet RS standard of care requirements. Annual routine PHA vision exams will be required after this point. Complicated cases, cases that exceed AASD standards, or cases not meeting vision standards post-operatively should be referred to the ACS for review.

While on anti-inflammatory (steroid) eye drops, the aviator will be placed on non-mobility status, restricting the individual from deployment via AF Form 469. For LASIK, the aircrew member will similarly be placed on non-mobility status, restricting the individual from deployment via AF Form 469 for a minimum of one month after surgery, even if no longer on steroid eye drops.

Any complications that arise will require waiver after the complication is successfully managed.

A. Initial Waiver Request for trained AASD members:

28. History

- a. Pre-op cycloplegic refraction.
- b. Surgical procedure, date, location, complication, and management of the complication. c. Assessment (negative and positive) of post-op symptoms of glare, halos, reduced night vision and diplopia.
- d. Eye medications usage, past and current, include discontinuation date.

29. Physical (current):

a. Uncorrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.

b. Best corrected visual acuity high contrast (OVT) and Precision Vision 5% low contrast.

c. Cycloplegic refraction and dilated fundus exam.

d. Two post-op refractions at least 2 weeks apart that shows stability (no more than 0.50 diopter shift in **manifest** sphere or cylinder power).

- e. Slit lamp exam, which must include grading of haze, if present.
- f. Intraocular pressures (IOPs).

g. Depth perception (OVT-DP). (If fails and previously waived for defective depth perception using AO Vectograph, then include AO Vectograph).

- 30. Attach copy of "Permission to Proceed" letter.
- 31. Attach copy of the operative report for each eye treated, post-RS evaluations (1, 3, 6, 12 months post-op and annually, and any other additional follow-ups) and any RS-related incidents (this will meet the requirement to send this info to the USAF-RS APM). The following is a link to the post-RS evaluation form to be utilized:

https://kx.health.mil/kj/kx1/AFRefractiveSurgery/Pages/home.aspx or

https://kx.health.mil/kj/kx1/AFRefractiveSurgery/Documents/Forms/ShowFolders.aspx?Roo tFolder=/kj/kx1/AFRefractiveSurgery/Documents/New%20CRS%20PDF%20forms&Folder CTID=0x01200042E4CD4D09D1524EB5B8D337F9AD1615&View=%7bD5DE7241-B6EB-4E3D-A94E-D3E74D33084D%7d

32. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

## B. Initial Waiver Request for untrained AASD applicants:

21. History/Physical:

a. Address whether all clinical criteria prior to RS were met. If not, describe exceptions in detail.

b. Description of other surgical or post-operative complications (e.g. corneal haze, flap striae, ocular hypertension, etc.)

c. Must be 6 months post-RS, at minimum, for application consideration (one year for hyperopic treatments).

d. All other items required for History and Physical for trained AASD members above in section A.

Attach copy of the operative report for each eye treated, post-RS evaluations and any RS-related incidents (this will meet the requirement to send this info to the APM. The following is a link to the post-RS evaluation form which should be used:

https://kx.health.mil/kj/kx1/AFRefractiveSurgery/Pages/home.aspx or

https://kx.health.mil/kj/kx1/AFRefractiveSurgery/Documents/Forms/ShowFolders.aspx?RootFolder =/kj/kx1/AFRefractiveSurgery/Documents/New%20CRS%20PDF%20forms&FolderCTID=0x0120 0042E4CD4D09D1524EB5B8D337F9AD1615&View=%7bD5DE7241-B6EB-4E3D-A94E-D3E74D33084D%7d

- 1. Initial waiver term of validity may be indefinite at the waiver authority's discretion; however, AASD applicants are not eligible for waiver until the complication has been managed and member has stabilized and otherwise meets vision standards. Post-RS evaluations are desired at 1, 2 (if PRK), 3, 6, and 12 months post-op. All examination documentation obtained to date is required for submission for the initial waiver.
- 2. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

## **III. Aeromedical Concerns**

These elective surgical procedures, although highly successful in general, are not risk free and represent an investment by the patient and his/her squadron initially. Topical steroids are required following RS to control the healing response and reduce the risk of corneal haze and scarring. However, topical steroids may increase the risk of infection, produce elevated intraocular pressure in some individuals, and may cause development of cataracts. To date, two aircrew members have sustained permanent visual field defects and vision loss because of topical steroid related complications. Therefore, frequent monitoring of intraocular pressure and close follow-up is required.

AASD personnel are restricted from deployment as long as steroid eye drops are in use; however, if waiver required, the aircrew member may be waived by the MAJCOM waiver authority to return to local flight duties in order to maintain qualifications. Participation in flight simulator and altitude chamber training while on steroid eye drops is permissible after initial waiver is granted by the waiver authority. An aeromedical summary submitted to MAJCOM waiver authority must provide evidence that all applicable vision standards are met, any post-operative complications have resolved, and the refraction is stable (two refractions separated by at least two weeks with no more than 0.50D change.) When the aviator has been directed to discontinue steroid eye drop use, the member may be returned to world-wide-qualified status for deployment purposes.

Degradation in the quality of vision following RS can affect operational visual performance, despite a finding of high contrast visual acuity (standard vision charts) that meets flight standards. Significant complications include dry eye symptoms, corneal haze, glare, halos, diplopia, reduced low contrast sensitivity, unaided night vision, and night vision goggles (NVG) performance. Recovery from RS complications may require extended recuperation time extending to a year or more. Under- and over-corrections of refractive errors can result from both PRK and LASIK treatments. Refractive surgery enhancement (secondary treatment) or requirement to wear traditional correction (spectacles or contact lenses) may be required. UV protection is required post-RS to reduce UV-induced phototoxic damage than can potentiate corneal haze.

LASIK procedures uniquely present flap complication risks. Intra-operative complications, while rare, include thin flap, incomplete flap, buttonhole flap or free flap. In addition, flap striae (wrinkles) can develop intra-operatively or at any time during the convalescent period. Surgical

intervention is usually required to address striae complications if visual acuity is affected. The risk of corneal flap displacement by high Gz forces or ejection sequences is low. The effect of chronic, low-grade hypoxia on visual performance following LASIK has not been completely studied. A single study at sea level (normobaria) with simulated hypoxic environment equivalent to 25K feet revealed no reduction in vision.¹ The effects of altitude up to 35K feet in an aviation environment following both PRK and LASIK has been studied with no adverse effects noted. Infectious keratitis can occur during the immediate postoperative period, which can be vision threatening. Best-corrected visual acuity may decrease by two or more lines in up to 3.6% of patients if keratitis occurs.

Flight surgeons should encourage post-RS aircrew to prepare for long duration flights and pending deployments. A bottle of sterile lubricating eye drops assists aviators in managing dry eye symptoms (a common post-RS complication) and thus minimizes rubbing of the eyes, which can precipitate corneal abrasions or LASIK flap dislocation. Post-operatively, aircrew must continue to be alert and vigilant in the use of eye protection in both operational and recreational environments, especially after LASIK.

Recently, a change was made to allow waivers for members in excess of AASD limits (Table 4). This change was recommended based on nearly two decades of success of the USAF refractive surgery program as well as numerous studies showing the continued safety of the procedures. For myopia, the most feared complication is that of retinal tears and retinal detachment. A retrospective review of 1554 eyes who underwent LASIK for refractive error between -8.00 to -27.50 showed only four retinal detachments (0.25%). The rate of retinal detachment in aircrew in the excessive myopia management group (members who had refractive surgery from -5.50 to -8.00 diopters) was found to be 0.08% and was 0.22% for retinal tears. With hyperopic treatments, the concern is the quality of vision and risk of regression. Current literature on modern laser platforms show 86% of eyes +0.50 to +8.50 have best corrected acuity of 20/20 one year after procedure and there is a 2.13% loss of two lines or more of best corrected visual acuity. Another study looking at a sixth generation laser platform found outcomes to be very stable with regression of only 0.14 diopters reported over a one year period. Therefore, even in more extreme refractive errors, it does seems reasonable to offer refractive surgery, especially as these are the members with the most to gain from having surgery.

A newer laser refractive surgical procedure called SMILE (SMall Incision Lenticule Extraction) was approved for aircrew in March 2020. This procedure involves the use of a femtosecond laser to cut an intralamellar (within the cornea) lenticule that is removed through a small incision created with the laser. This procedure was first performed in the Air Force at Wilford Hall Ambulatory Surgical Center (WHASC) in Dec 2018. An unpublished internal review of 213 procedures on 117 patients at WHASC revealed that with SMILE, 16.67% of patients had 20/15 UCVA and 97.60% had 20/20 UCVA by 6 months after surgery. The 5% PV showed that SMILE did not perform as quite as well as LASIK and PRK, but 100% of patients saw 20/40 or better. Additionally, 94.6% of patients were within 0.50 D of the intended postoperative refraction. Based on these results, SMILE was approved as an alternative to LASIK and PRK for USAF aircrew. However, since this is a newer procedure and has not specifically been studied in the aviation environment, a waiver will still be required prior to return to flying duties for members who have had SMILE.

A waiver may be granted by the waiver authority at initial waiver following **complicated approved refractive surgery, uncomplicated surgery in excess of AASD limits, or for members who underwent SMILE surgery** once the aircrew member is off all medications and meets post-op stability and vision criteria.

ICD-10 Co	ICD-10 Codes for Corneal Refractive Surgery		
H52.0	Hypermetropia, right, left, both		
1, 2, 3			
H52.1	Myopia, right, left, both		
1, 2, 3			
H52.20	Unspecified astigmatism, right, left, both, unspecified		
1, 2, 3, 9			
08Q8XZZ	Repair right cornea, external approach		
08Q9XZZ	Repair left cornea, external approach		

### **IV. References**

1. Larys RP. LASIK at high altitude – a study of the worst-case mission scenario. Presented at the International Military refractive Surgery Symposium, February 5-7, 2007 in San Antonio, Texas.

2. Tutt RC, Baldwin JB, Ivan DJ, et al. Simulated altitude and G-force tolerance after photorefractive keratectomy (PRK). Brooks City Base, TX: USAF School of Aerospace Medicine; 2005 June. Report No: SAM-FE-BR-TR-2005-0002.

3. Aaron M, Wright S, Gooch J, et al. Stability of Laser-Assisted In Situ Keratomileusis (LASIK) at Altitude. Aviat Space Environ Med, 2012; 83: 958-61.

4. Ruiz-Moreno JM, Perez-Santonja, JJ, and Alio JL. Retinal Detachment in Myopic Eyes After Laser In Situ Keratomileusis. Am J Ophthalmol, 1999; 128(5):588-594.

5. Sandoval HP, Donnenfeld ED, Kohnen T, et al. Modern Laser In Situ Keratomileusis Outcomes. J Cataract Refract Surg 2016; 42:1224-1234.

6. Gharaibeh Villanueva A, Mas D, et al. Corneal Stability Following Hyperopic LASIK with Advanced Laser Ablation Profiles Analyzed by a Light Propagation Study. J Ophthalmol, vol. 2018, Article ID 3060939, 10 pages, 2018.

### Retinal Holes, Retinal Tears, Retinal Detachment, and Retinoschisis (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons, (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col Ian D. Gregory (AFMRA Physical Standards Development Chief)

## Significant Changes:

New Ground Based Operator (GBO) Standards. MSD C39-42.

## I. Waiver Consideration

Bilateral retinal detachment is disqualifying for all classes and for retention. Unilateral retinal detachment from organic progressive disease or with persistent defects may be disqualifying for all classes and for retention. Retinal breaks and retinoschisis are only disqualifying for Flying Classes I/IA, II, III, and SWA. Low risk atrophic retinal holes with a refraction less than or equal to -5.50 are not considered disqualfying. Waiver potential exists for low risk atrophic retinal holes with refraction from -5.75 to -8.00 diopters.

 Table 1: Waiver potential for Retinal Holes, Retinal Tears, Retinal Detachment, and Retinoschisis.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
I/IA	Maybe ¹	AETC	Yes
II/III	Yes ²	MAJCOM	Yes
ATC/GBO/SWA/OSF	Yes ^{3,4}	MAJCOM	Yes

1 Low risk features for retinal detachment are defined as absence of symptoms (flashes or floaters), no prior history of retinal detachment, no subretinal fluid, myopia between -5.75 to -8.00 diopters, and no evidence of vitreo-retinal traction. In addition, there should be no retinal breaks at the edge or outside the area of lattice degeneration, except in the case of operculated peripheral retinal hole.

2. Untrained FC II/III treated similar to FC I/IA.

3. Not disqualifying if treated and/or determined to be stable by a vitreo-retina specialist.

4. No waiver potential if bilateral retinal detachment or unilateral retinal detachment resulting from organic progressive disease, and/or associated with diplopia, field of view <20 degrees, or loss of acuity below standards.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations; MEB may be required for retinal detachment. If the treating ophthalmologist or retinal specialist determines surgical treatment is required then waiver submission should occur after adequate recovery time without complications and adequate pigment changes in the post-laser scar has occurred (one month minimum). If no treatment is required, then the 1 month waiting period prior to waiver submission is not required. All initial waivers (or recurrence of retinal tear or detachment) require an ACS evaluation/review.

A. Initial Waiver Request:

- 1. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.
- 2. Complete aeromedical history to include pertinent negatives (trauma, myopia, lattice degeneration, etc.), high-risk features, or treatment(s), if applicable.
- 3. Optometric exam to include:
  - a. Manifest refraction (previous refraction if underwent CRS)
  - b. Visual acuity
  - c. Humphrey 30-2 visual field
  - d. Amsler grid
  - e. CCT results from each eye individually (if macular involvement)
- 4. Ophthalmology or retinal specialist consultation to include: history, positive risk factors, exam findings, treatment(s), and surgical outcome.
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.
- B. <u>Renewal Waiver Request:</u>
  - 1 Interval history to include presence or absence of current visual symptoms and operational impact of condition.
  - 2 Results of interval ophthalmology exams.
  - 3 Summary of any interval medical or surgical treatments (if required).
  - 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

## **III. Aeromedical Concerns**

Retinal holes and tears can lead to retinal detachment. Retinal detachment can result in loss of visual acuity, loss of stereopsis, visual distortion, visual field loss, relative night blindness, reduced color vision, and lowered contrast sensitivity. The specific visual impact depends on the area and extent of the retina involved and the success of any reattachment surgery. In 90% of cases, eyes with no macular detachment present can be expected to have 20/40 vision or better following surgery. Consideration must also be given to the risk of progression, recurrence or involvement of the fellow eye based on the mechanism of retinal pathology, or type of retinal detachment. Although routine exposure to G-forces has not been shown to increase the risk of retinal detachment, the risk is increased with pre-existing vitreoretinal abnormalities, especially in the case of tractional retinal detachment, and this should be considered in the case of unrestricted waivers. All patients with documented retinal holes or breaks should have their manifest refractions included in the Aeromedical Consultation Service (ACS) referrals (these should be pre-corneal refractive surgery measurements if applicable), as higher levels of myopia lend to a higher risk of retinal detachment as discussed above. This risk is due to the fact that myopic eyes tend to have longer axial lengths, which is the real risk factor for retinal detachment. The ACS Ophthalmology Branch is currently investigating this association and its applicability to aeromedical standards. All retinal breaks need careful examination to identify the types of holes present and to determine if active vitreo-retinal traction or other signs of impending retinal detachment are present. This can be accomplished by any ophthalmologist or vitreo-retinal subspecialist (retinal detachment) but should also be reviewed by the ACS once the underlying disease process has stabilized.

AIMWTS search in Sep 2019 back to 1 Jan 2014 revealed 241 members with an AMS containing one of the above retinal diagnoses. There were 21 cases that were disqualified. Breakdown of the cases revealed: 23 FC I/IA cases (3 disqualified), 106 FC II cases (3 disqualified), 7 RPA pilot cases (2 disqualified), 92 FC III cases (11 disqualified), 4 ATC/GBC cases (0 disqualified), 6 SWA cases (1 disqualified), and 3 MOD cases (1 disqualified).

ICD-9 codes for retinal hole, retinal detachment, and retinoschisis		
361.3	Retinal holes	
361.31		
361.0	Retinal detachment	
361.2		
361.8		
361.9		
361.1	Retinoschisis	

ICD-10 codes f	ICD-10 codes for retinal hole, retinal detachment, and retinoschisis		
H33.309	Unspecified retinal break, unspecified eye		
H33.329	Round hole, unspecified eye		
H33.2	Serous retinal detachment		
0, 1, 2, 3			
H33.8	Other retinal detachments		
H33.10	Unspecified retinoschisis		
0, 1, 2, 3			

## **IV. Suggested Readings**

1. Greven CM. Retinal Breaks. Ch. 6.37 in Yanoff: Ophthalmology, 4th ed., Saunders, 2013.





# Substandard Stereopsis Formerly Defective Depth Perception

Revised: Apr 2021.

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology),

Dr. Austen Tanner (Optometrist, ACS Ophthalmology), Lt Col Amy Hicks (ACS Division Chief), Dr. Max Lee (ACS Waiver Guide coordinator), and Lt Col Ric Speakman (AFMSA Physical Standards Development Chief)

# Significant Changes:

- 1. New Special Warfare Airmen Standards added.
- 2. Indefinite SWA waiver will be considered for members/applicants who can consistently demonstrate proficiency at 120 arc seconds.
- 3. AO Vectograph administration instructions have been added.

# I. Waiver Consideration

The Medical Standards Directory (MSD) sets the standards for stereopsis as OVT line "B" (40 arc sec) is the standard for FC I/IA/II/III, and SWA. All FC I/IA with VTA-DP or OVT-DP failure (unable to consistently read line B) who are otherwise qualified will require a depth perception waiver workup and are required to either have a case review or in-person evaluation by the Aeromedical Consultation Service (ACS).

All FC II and FC III aircrew positions that require depth perception for scanning duties to safely clear their aircraft or themselves from objects or other aircraft in the air or on the ground within 200 meters (i.e. boom operators, flight engineers, loadmasters, and military free fall) who fail the annual required depth perception testing (VTA or OVT), or who have failed in the past (using the 40 arc sec standard) and never been evaluated at the ACS for defective stereopsis are required to have an ACS records review and/or in-person evaluation before waiver consideration. The Monofixation-Microtropia and the Prospective Defective Stereopsis management groups have been closed as the requisite data has been collected and interpreted.

If the trained aviator has previously failed the VTA or OVT during the annual flight physical but has an existing ACS review or evaluation with **indefinite** waiver, and can pass the VTA or OVT with a score of 4/4 (60 arc sec) on the AO Vectograph distance stereopsis test, or achieve a previously waivered baseline score on the AO Vectograph (as determined by the ACS), no further workup is needed until next annual flight physical. Do **NOT** retire the indefinite waiver unless advised by ACS after a review of current and prior testing results. If depth perception capability has declined from the previously waivered level or if binocular fusional control has diminished, i.e. onset of diplopia, previous waiver is nullified and a full workup should be accomplished as outlined below in the Information Required for Waiver Submission section. If spectacles or contact lenses were needed to pass depth perception testing, regardless of unaided visual acuity i.e. 20/20, then spectacles are required for aviation duties, to meet depth perception standards.

Defective depth perception requirement is outlined in the Air Force Officer and Enlisted Classification Directories (AFOCD/AFECD) and generally is not waiverable for initial FC III applicants for the following career fields: 1A0 (Boom Operators), 1A1 (Flight Engineers), 1A2 (Loadmasters), 1A3 (Airborne Mission System Operators), and 1A7 (Airfield Managers). More extensive work up for waiver submission will only be required for FC I/IA/II, SWA, FC III and GBO career fields that carry a depth perception requirement as outlined in the AFOCD/AFECD.

There is no depth perception standard for ATC or GBO personnel. Initial RPA Pilot applicants will meet FAA Third Class Medical Certificate standards for Undergraduate RPA Training if they do not have a history of strabismus or diplopia. Additionally, SERE technicians, who otherwise fall under SWA standards, have no depth perception requirement to perform operational duties.

SWA personnel other than SERE technicians must meet the stereopsis standard of 40 arc sec on the OVT-DP line "B" to qualify for SWA duties. If the member or applicant fails to meet this standard, they should have a refraction exam performed by an optometrist or ophthalmologist and repeat testing on the OVT-DP once adjusted to the new prescription. If the member still fails, an indefinite waiver can be considered if the member is able to pass 3 out of 4 lines on the AO Vectograph (120 arc seconds). No alternative testing methods are currently accepted for waiver consideration with the exception of a 120 arc second slide for the OVT-DP obtained from the ACS for use at the high volume initial SWA exam locations. A waiver will not be considered for any SWA personnel or applicants unable to pass this standard with or without best corrected lenses.

Flying Class (FC)	Waiver Potential	Required ACS
	Waiver Authority	<b>Review/Evaluation</b>
FC I/IA	Yes ²	Yes
	AFRS/CMO	
FC II	Yes ²	Yes
FC III ¹	MAJCOM	
SWA	Yes ²	Yes, review only
	MAJCOM	
ATC/GBO/OSF	N/A	N/A

Table 1: Waiver potential for Defective Depth Perception

1. Aircrew positions that require depth perception for scanner duties (i.e. boom operators, flight engineers, loadmasters, and military freefall) will require work up for waiver submission.

2. If spectacles or contact lenses were needed to pass depth perception testing, regardless of unaided visual acuity, i.e. 20/20, then spectacles are required for aviation duties, to meet depth perception standards.

Flying Class (FC)	OVT-DP / VTA-DP	AO Vectograph (requires waiver)
FC I/IA/II/III	Line "B" (40 arc secs)	4/4 (60 arc secs) or 3/4 (120 arc secs) only by ACS review / evaluation
SWA	Line "B" (40 arc secs)	3/4 (120 arc secs) or ACS 120 arc sec slide
ATC/GBO/OSF	N/A	N/A
Initial FC III for AFSC 1A0, 1A1, 1A2, 1A3 or 1A7	Line "B" (40 arc secs)	Not waiverable.

A review of AIMWTS through Jun 2018 showed 5,438 aeromedical summaries containing a diagnosis of substandard stereopsis. There were a total of 904 cases disqualified, the majority which were either for another unrelated diagnosis or for untrained assets. There were 888 FC I/IA cases, 1,442 FC II cases, 163 RPA pilot cases, 2,713 FC III cases, 213 ATC/GBC cases, and 19 MOD cases.

Previous retrospective analysis conducted by the Ophthalmology Branch of the ACS found 524 aviators were evaluated for defective stereopsis/depth perception. The final ACS diagnosis underlying defective stereopsis/depth perception the aviators in this group was as follows: vergence issue or phoria in 31%, microesotropia in 29%, monofixation in 24%, microexotropia in 10% and vertical microtropia in 1%.²

A 2017 reviewed 753 subjects from the prospective ACS Defective Stereopsis Study Group established in 1997. Of those, 540 were analyzed with 213 excluded from analysis for not having follow-up exams (178), not meeting study criteria (32), or uninterpretable findings (3). Of the 540 analyzed, 536 documented stability over an average period of 7.7 years (0.7-18.8). There were 4 subjects who decompensated, which occurred over an average period of 6.6 years (0.9-10.9). Therefore, 4 of 540 (0.7%) decompensated over 7.7 years, resulting in an annual rate of <0.1%.²

## **II. Information Required for Waiver Submittal**

The most common cause of an acquired depth perception defect is uncorrected refractive error. Depth perception testing should not be attempted until optimal correction has been achieved. Failure of depth perception with best corrected visual acuity is disqualifying, but may be considered for waiver.

After initial ACS evaluation or review for stereopsis failure, **an indefinite waiver may be recommended**. Annual flight PHA demonstrating a decrease in stereopsis status will nullify existing waiver and require ACS review or evaluation.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using the best current clinical guidelines and recommendations. Underlying conditions such as microtropia (8 diopters or less), monofixation syndrome, and anisometropia that are identified during evaluation by the local

Table 2: Passing Scores

optometrist or ophthalmologist should be listed as a separate disqualifying condition along with a diagnosis of defective stereopsis. It should be noted that if after a thorough examination, no underlying diagnosis is found, a disqualifying diagnosis of defective stereopsis is sufficient for AMS submission.

A complete AMS with a local ophthalmologist or optometrist work-up to include all of the following is required for **indefinite waiver** consideration:

 Complete ocular history noting particularly any history of eye patching, spectacle wear at an early age, strabismus, eye surgery, and previous depth perception testing performance.
 Ductions, versions, cover test, and alternate cover test in primary and six cardinal positions of gaze.

3. Optimal refraction with further testing, including repeat VTA-DP or OVT-DP, to be accomplished with best optical correction of any refractive errors, regardless of unaided visual acuity.

- 4. AO Vectograph stereopsis test at 6 meters. (4 line version) (distant stereopsis)*
- 5. AO suppression test at 6 meters.
- 6. Randot or Titmus stereopsis test (near stereopsis tests).
- 7. Red lens test.
- 8. Four-diopter base-out prism test at 6 meters.
- 9. Direct/indirect macula and optic nerve exam.

*Note: Use only the American Optical (AO) version of the vectograph projection slide graded in 60 arc sec increments (60, 120, 180, 240 arc sec). Isolate each line of the slide and present them multiple times in random order. The lines must also be shortened to four circles and also presented in isolated vertical columns to increase randomization. Line four (60 arc sec) is tested a minimum of six times in various presentations. A correct response must be given for every presentation of a line in order to be given credit for that line. Displaying all four lines of the stereopsis test at one time is not a valid way to administer the test.

## **III. Aeromedical Concerns**

Stereopsis is generally not considered to be a factor in the perception of depth beyond 200 meters, as monocular cues tend to prevail at these distances. In aviation, accurate perception of spacing or depth within 200 meters is critical in a number of situations, such as aerial refueling, formation flying, holding/hover rescue-type operations, taxiing, and parking. Stereopsis also facilitates closure maneuvers and rejoins. Microtropia and monofixation syndrome may be intermittent in nature and susceptible to decompensation in the aerospace environment due to such exposure as relative hypoxia and fatigue over time.³

The analysis from the 1997-2017 Defective Stereopsis (Prospective) Study Group demonstrated an annual risk of decompensation of <0.1% per year. While there is a chance of decompensation, it is well below the acceptable aeromedical risk threshold. All aviators must continue to have stereopsis testing at their flight physical and monitor for changes.

Fourth cranial nerve (superior oblique) palsy, as with other forms of vertical phorias and tropias, has been shown by ACS experience to more likely decompensate over time in aircrew with

resultant diplopia than the horizontal microtropias. Therefore, a waiver for this diagnosis will generally NOT be recommended.

ICD-9 Code fo	or Defective Stereopsis (Depth Perception)
368.3	Other disorders of binocular vision

ICD-10 Codes	for Defective Stereopsis (Depth Perception)
H53.30	Unspecified disorder of binocular vision
H53.34	Suppression of binocular vision

### **IV. Suggested Readings**

1. Steinman SB, Steinman BA, Garzia RP. (2000) Foundations of Binocular Vision: A Clinical perspective. McGraw-Hill Medical.

2. Parsons, M, Wright S, Ellis, J. Stereopsis testing in the US Air Force: Where we have been and where we are going. Ramstein Aerospace Medicine Summit NATO STO Technical Course, 2018, poster session.

3. Hunt MG, Keech RV. Characteristics and course of patients with deteriorated monofixation syndrome. J AAPOS, 2005; 9: 533-6.

### Uveitis (Mar 2020)

Reviewed: Lt Col Jonathan Ellis (Chief, ACS Ophthalmology), Lt Col Michael Parsons (Deputy Chief, ACS Ophthalmology), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator) and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## **Significant Changes:**

New Ground Based Operator (GBO) Standards. MSD C38

## I. Waiver Consideration

Acute, chronic or recurrent inflammation of the uveal tract, except for healed traumatic iritis is disqualifying for flying classes I/IA, II, III, and SWA duties. For all initial flying classes, waivers will be considered if the uveitis was a single episode that occurred greater than one year ago, was nongranulomatous, unilateral, and did not result in recurrent episodes or ongoing visual symptoms or sequelae. Trained assets will be considered for a waiver. If the uveitis is secondary to a systemic disease, waiver consideration will also depend on the status of the causative systemic disease, see applicable waiver guides. While not specified in either AFI 48-123 or the MSD as disqualifying for ATC and GBO personnel, uveitis should be disqualifying if it is recurrent or chronic, leads to frequent absences from duty, or results in decrease or loss of vision.

Table 1. Walver poter			
Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review/Evaluation
I/IA or II/III (untrained)	Maybe ¹	AETC	Yes
II/III (trained) SWA	Yes	MAJCOM	Yes
ATC/GBO/OSF	N/A	N/A	N/A

#### Table 1: Waiver potential for Uveitis

1. For all initial flying classes, waiver recommendation will be considered if the uveitis was a single episode that occurred greater than one year ago, nongranulomatous, unilateral, and did not result in recurrent episodes or ongoing visual symptoms or sequelae.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request (Items 4-6 required for granulomatous, recurrent, or bilateral cases):

- 1. History signs, symptoms, duration, treatment and must include pertinent review of system negatives.
- 2. Physical complete.
- 3. Ophthalmology consultation.
- 4. Chest x-ray to rule out sarcoidosis and tuberculosis.
- 5. Labs: Syphilis serology, Lyme titer, HLA-B27, erythrocyte sedimentation rate (ESR).

- 6. IPPD.
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

## B. <u>Waiver Renewal:</u>

- 1. History signs, symptoms, duration, treatment and must include pertinent review of system negatives.
- 2. Physical complete.
- 3. Ophthalmology consultation.
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

## **III. Aeromedical Concerns**

For the flight surgeon, uveitis of any etiology is of concern due to possible complications and sequelae. The acute condition can cause distracting pain. Floaters and blurred vision can impair performance and affect flight safety. Long-term sequelae include pupillary abnormalities, cataract, glaucoma, retinal scarring, retinal detachment, keratopathy, and loss of vision. The flight surgeon also needs to be concerned with possible underlying disease processes which may require aeromedical disposition as well.¹

A review of the AIMWTS database in May 2015 revealed 137 cases of uveitis; 19 were disqualified. There were 0 FC I/IA cases, 72 FC II cases (5 disqualifications), 57 FC III cases (11 disqualifications), 6 ATC/GBC cases (2 disqualifications), and 2 MOD cases (1 disqualification). Of the 19 disqualified, all but 2 were secondary to the uveitis symptoms.

A review of the AIMWTS database in Jan 2019 revealed 109 cases of uveitis; 18 were disqualified. There was 1 FC I/IA cases (1 disqualified), 52 FC II cases (4 disqualified), 1 RPA pilot case, 47 FC III cases (10 disqualified), 6 ATC/GBC cases (2 disqualified), and 2 MOD cases (1 disqualified). Of the 18 disqualified, all but 2 were secondary to the uveitis symptoms.

ICD-9 Codes	for Uveitis
364.3	Unspecified iridocyclitis
363.2	Unspecified forms of chorioretinitis and retinochoroiditis
360.12	Panuveitis

ICD-10 Code	es for Uveitis
H20.9	Unspecified iridocyclitis
H30.93	Unspecified chorioretinal inflammation
1, 2, 3, 9	
H44.11	Panuveitis
1, 2, 3, 9	

## **IV. Suggested Readings**

1. Rayman R, Hastings J, Kruyer et al. Ophthalmology: Uveitis. Ch. 9 in *Rayman's Clinical Aviation Medicine*, 5th ed., Castle Connolly Graduate Medical Publishing, Ltd; 2013: 280-83

### WAIVER GUIDE

Updated: May 2017 Supersedes Waiver Guide of Jan 2011 By: Lt Col Cindy Harris Graessle (RAM 2017) and Dr Dan Van Syoc Reviewed by: Dr. Edwin Palileo and Lt Col Eddie Davenport (Chief Cardiologist ACS)

## **CONDITION:** Valve Surgery - Replacement or Repair (May 2017)

## I. Waiver Consideration.

Cardiac valve replacement or repair by surgery or catheter-based technique is disqualifying for all classes of flying duties as well as retention in most cases. ACS review/evaluation is required for initial and renewal waiver considerations. The ACS will make recommendations based on the successfulness of the procedure/surgery and residual valve hemodynamics and cardiac function.

### Herniated Nucleus Pulposus (HNP) and Spinal Fusion (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), Lt Col James Dunlap (AF Ortho Spine Specialist), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

### **Significant Changes:**

Updated Waiver Considerations, Tables 1-3, Aeromedical Concerns and References

## I. Waiver Consideration

A history of HNP or surgery for it is disqualifying for FC I/IA/II/III and requires a waiver under MSD K6. All flying classes and OSD personnel require a waiver when they fall under MSD K5: "Herniation of nucleus pulposus, when symptoms and associated objective findings are of such a degree as to require repeated hospitalization, significant duty limitations, or frequent absences from duty." MSD K5 is disqualifying for retention standards, so would also require an MEB or RILO. If surgical intervention is contemplated, note that cervical disc arthroplasties (artificial disc replacements) are not routinely aeromedically-approved for high-performance aircraft operation waiver, and may also be duty-limiting for personnel on jump status.

Aviation personnel must fulfill all of the following applicable qualifying criteria for the initial waiver request:

- Need to be asymptomatic or with non functionally-limiting symptoms or signs
- Need to have adequate waiting period after treatment see Table notes
- Please note difference in waiting times for different categories.

Table 1: Waiver potential for HNP treated conservatively, or surgically without fusion	or
disc replacement	

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II	Yes ^{1,2}	MAJCOM	Yes ³
FC III	Yes ^{1,2}	MAJCOM	No
ATC, GBO, SWA	Yes ¹	MAJCOM	No

1. Minimum observation period post-treatment: 6 months if on jump status, otherwise 3 months

2. Multi-level cervical spine surgery waivers restricted to non high-performance aircraft

3. For cases with over 4 years stability, ACS review is not required, and is at the discretion of the waiver authority

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II	Yes ^{1,2}	MAJCOM	Yes ³
FC III	Yes ^{1,2}	MAJCOM	No
ATC, GBO, SWA	Yes ¹	MAJCOM	No

Table 2: Waiver potential for HNP treated with spinal fusion, with or without hardware	Table 2: Waiver po	otential for HNP trea	ited with spinal fusion,	, with or without hardware
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1. Minimum observation period post-treatment: 6 months for FC II, 4 months for FC III/GBO

2. Multi-level cervical fusion waivers restricted to non high-performance aircraft

3. For cases with over 4 years stability, ACS review is not required, and is at the discretion of the waiver authority

Table 3: Waiver potential for HNP treated with artificial disc replaceme
--------------------------------------------------------------------------

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II	Yes ¹	AFMRA	Yes ²
FC III, ATC, GBO, SWA	Yes ¹	AFMRA	Yes ²

1. Minimum observation period post-treatment: 6 months

2. Cervical disc arthroplasty waivers currently routinely restricted to non high-performance aircraft

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. Detailed history of back/neck pain and previous treatments; surgical history; any specialty consultative reports and follow-up notes.
- 2. Current physical, musculoskeletal (spinal) and neurological examinations.
- 3. Operative report (if surgically treated).
- 4. Consultant statement clearing member for unrestricted activities or flying duties
- 5. Follow-up dynamic (flexion-extension) radiographs to confirm stability if treated with spinal fusion, instrumentation, hardware or disc replacement.
- 6. Reports and images from all relevant imaging studies performed. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

#### B. <u>Renewal Waiver Request:</u>

- I Interval history, to include any residual signs and symptoms, current symptoms, current medications, current treatment, current pain level, and any activity limitations.
- 2 Physical musculoskeletal (spinal) and neurological exam.
- 3 Copies of any interim specialty consultations, follow-up notes, imaging studies and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

#### **III. Aeromedical Concerns**

Aeromedical concerns include effects of any current symptoms or signs on operational safety and mission effectiveness, and future risk of symptom development, especially with stressors of high-performance aircraft operations or aircraft ejection, which could be of sudden onset and severe intensity. Following surgical treatment of HNP, concerns also include potential for vertebral joint stability and hardware failure. There are documented cases of disc herniations, vertebral fractures, and neck injuries with high-G maneuvers and ejections. After spinal fusion, there is concern over the possibility of repeat injury to a fused spine as a result of ejection and rapid-onset Gz-forces. The normal acceleration magnitude during ejection from the ACES II seat is 12-14 +Gz, but may vary with flight parameters and weight of occupant. Parachute opening shock can range from 10 to 20 +Gz, especially if outside the ejection envelope. Vertebral fracture occurs frequently with forces of greater than 20 +Gz, but with poor positioning, forces as low as 10 +Gz have caused fractures. Non-waiverability of multi-level cervical fusions for high-performance and ejection seat aircraft is based on the concern of increased stress concentration at adjacent non-fused vertebral joints during flexion, extension, and rotation. Multi-level lumbar or thoracic fusions may be considered for waiver in ejection seat aircraft as the thoracolumbar joints are not generally as mobile as the cervical joints, resulting in less severe focal stress concentrations at adjacent non-fused levels, and a lumbar fracture or other injury is far less likely to result in permanent neurological impairment. In cases of fusion, it is essential to establish successful complete fusion prior to consideration of returning to fly, particularly in high-performance aircraft operations. This can take up to 12 months in some cases. Artificial disc replacement devices have not been adequately assessed for stability with anticipated stressors experienced in high-performance aircraft operations, and cervical spine disc arthroplasties are currently not routinely recommended for such waivers. Further studies are needed to demonstrate equivalence or superiority of disc arthroplasty vs. fusion in both cervical and lumbar regions, and studies demonstrating device stability under sustained high-performance aircraft operation conditions.

AIMWTS search in Mar 2019 revealed 838 members with a diagnosis of HNP and/or spinal fusion since Jan 2014. There were 97 cases resulting in disqualification. Breakdown of the cases demonstrated: 13 FC I/IA cases (8 disqualified), 442 FC II cases (30 disqualified), 18 RPA pilot cases (1 disqualified), 344 FC III cases (50 disqualified), 19 ATC/GBC cases (8 disqualified), and 2 MOD cases (0 disqualified).

ICD-9 Codes for HNP and Spinal Fusion		
722	Intervertebral Disc Disorders	
81.0	Spinal Fusion	
81.3	Refusion of Spine	
84.60	Insertion of Spinal Disc Prosthesis, NOS	

ICD-10 Codes for HNP			
M50.20	Other cervical disc displacement unspecified cervical		
	region		
M51.26	Other intervertebral disc displacement, lumbar region		

## **IV. Suggested Readings**

1. Rayman RB. *Rayman's Clinical Aviation Medicine*, 5th Ed., Castle Connolly Graduate Medical Publishing, LTD, 2013; 293-94.

2. Wahezi SE, Lederman L, and Elowitz EH. Conservative Versus Operative Management for Lumbosacral Radiculopathy With Motor Deficit. Phys Med Rehab 2015; 7(7):770-76.

3. Zarkadis NJ et al. Outcomes following multilevel cervical disc arthroplasty in the young active population. Military Medicine 2017; 182:e1790

4. Garcia R Jr et al. Lumbar total disc replacement for discogenic low back pain: two-year outcomes of the activL multicenter randomized controlled IDWE clinical trial. Spine 2015; 40:1873-1881.

5. Gao S, Geng X, Fang Q. Spontaneous disappearance of large lumbar herniation. JAMA Neurology 2018; 75(1):123-124.

6. Kisher S. Degenerative disc disease. Medscape Mar 15, 2019. Link: http://emedicine.medscape.com/article/1265453-overview

7. Robinson J, Kothari MJ. Treatment and prognosis of cervical radiculopathy. UpToDate, Aug 31, 2018.

8. Levin K, Hsu PS, Armom C. Acute lumbosacral radiculopathy: treatment and prognosis. UpToDate, Jun 3, 2019.





# RETAINED ORTHOPÆDIC DEVICE AND JOINT REPLACEMENT

Revised: February 2022

Authors/Reviewers: Lt Col Jeffrey Kinard (RAM '22), Col Joseph Stuart (AF/SG Orthopædic Consultant), and Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

Individuals with fractures are grounded until evidence of bone healing and return of full function can be documented. For fractures with retained fixation devices, waiver is required for FC I/IA, II, III, and SWA personnel when there is obstruction of motion or if easily irritated or painful when hit or pressure applied to the affected area. Medical Evaluation Board (MEB) and waiver for all flying duties are required for all joint replacements and prosthetics if it results in ongoing duty or deployment limitations for over a year, requires ongoing specialist follow up more than annually, or causes frequent absences from duty. An unrestricted FC II and III waiver may be considered for joint prosthetics. Joint prosthetics are NOT considered waiverable for FC I/IA, untrained FC II, III, and SWA duties. Joint replacements without complication are disqualifying for flying duties and require waiver for FC I/IA, II, III, and SWA personnel.

Flying Class	Condition Waiver Potential	
		Waiver Authority
I/IA	Retained orthopædic device with no	No waiver required,
Untrained	pain or limitation of motion (able to	medically qualified
II/III/SWA	lead physically active lifestyle)	
	Retained orthopædic device with	Maybe
	obstruction of motion or if easily irritated/painful when hit/pressure applied	AFRS/CMO
	Joint replacement	No
		AFRS/CMO
II/III/SWA	Retained orthopædic device with no	No waiver required,
ATC/GBO	pain or limitation of motion (able to lead physically active lifestyle)	medically qualified
	Retained orthopædic device with	Maybe
	obstruction of motion or if easily irritated/painful when hit/pressure applied	MAJCOM
	Joint replacement, minimum four	Yes ²
	months post-op. ¹	MAJCOM
Individuals with	Retained orthopædic device with no	No waiver required,
parachuting	pain or limitation of motion (able to	medically qualified
duties (not	lead physically active lifestyle)	
including		
emergency	Retained orthopædic device with	Maybe
bailout)	obstruction of motion or if easily irritated/painful when hit/pressure applied	MAJCOM
	Joint replacement	No MAJCOM

Table 1: Summary of Clinical Conditions and Waiver Potential

If history of affected joint dislocation, ACS review is required. A waiver is more likely if total hip arthroplasty dislocation occurred within the first 6 weeks, but it will require a minimum of 6 months post dislocation.
 This includes "minimally invasive" hip replacement procedures.

# **II. Information Required for Waiver Submission**

The aeromedical summary should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

- A. Initial Waiver Request for Retained Orthopædic Device:
  - 1. History brief summary of trauma, surgery and recovery, complications, symptoms, current activity level, and medications.
  - 2. Physical addressing range of motion, muscle strength, and point tenderness.
  - 3. Operative reports.
  - 4. X-ray documenting radiographic healing.
  - 5. Orthopædic consult that addresses device, muscle strength, range of motion of proximal and distal joint, and limitations in activities.
  - 6. If functionality is reduced, include a statement regarding performance of routine and emergency duties in aircraft.
- B. <u>Waiver Renewal Request for Retained Orthopædic Device</u>:
  - 1. History brief summary of trauma, surgery and recovery, complications, symptoms, current activity level, and medications.
  - 2. Physical addressing range of motion, muscle strength, and point tenderness.
  - 3. Orthopædic consult, if symptoms have changed.
- C. Initial Waiver for Prosthetic Joint:
  - 1. History of symptoms, limitations prior to surgery, summary of surgery and recovery, present level of activity, medications, and limitations.
  - 2. Physical addressing range of motion, and muscle strength.
  - 3. Orthopædic consult range of motion, muscle strength, activity level, and limitations.
  - 4. Operative reports.
  - 5. X-rays documenting radiographic healing.
  - 6. Include a statement regarding performance of routine and emergency duties in aircraft.
  - 7. Medical evaluation board (MEB) results if required.
- C. <u>Waiver Renewal for Prosthetic Joint</u>:
  - 1. History and physical to include summary of surgery and recovery, present level of activity, medications, and limitations.
  - 2. Orthopædic consult.
  - 3. X-rays results.

# **III. Aeromedical Concerns**

Fractures requiring open reduction and internal fixation (ORIF) are fairly common among our active aircrew and operators. Less common are degenerative joint diseases requiring prosthetic joint implants due to the relatively young population served. Fixation devices in the spine and artificial intervertebral disks are considered separately in the Herniated Nucleus Pulposus and Spinal Fusion waiver guide.

#### RETAINED ORTHOPÆDIC DEVICE:

Retained device(s), except in the case of joint replacement, consist primarily of screws, plates, wires, and intramedullary rods (nails). These components are placed to stabilize the fracture and allow for adequate healing. Fracture healing time depends on the nature of the fracture (amount

of energy involved in creating the fracture, disruption of soft tissue around the fracture, and the particular bone involved).¹ In the vast majority of fractures, medical standard of care no longer dictates removal of fixation devices. In some cases after adequate bone regeneration, implanted hardware removal may be indicated because of patient preference or to restore skeletal strength (usually in children). Additional removal may be required if the device causes pain, device migration such as loose screws, or reduction in function.

For fractures with retained device, waiver is required when there is obstruction/limitation of motion or if the device is easily irritated/painful when hit or when pressure is applied in common activities. These symptoms can become distracting in the aeromedical environment. Limitations in motion can also preclude safe operation of the aircraft or ability to egress in a safe and timely manner in the event of an emergency. Removal of the device may rectify symptoms resultant from retained hardware. Waiver is required in such cases when the aviator has aeromedically significant limitations or pain and the device can't be removed or if the individual declines removal.

# JOINT REPLACEMENT:

Total knee arthroplasties (TKAs) are a common surgery in the US, with over 600,000 operations performed annually.² The most frequent indications are severe osteoarthritis (OA) or inflammatory arthritis conditions. The average age of knee replacement patients is 65-years-old, limiting the utility of available information on outcomes in a population more representative of military aircrew. Despite these limitations, the procedure is becoming more common in younger populations (defined as patients under 45 years old). Younger patients experience higher rates of joint loosening, leading to more revisions than the general population (8% versus 6%).^{3,4} This is one of the reasons surgeons historically were more reserved in performing TKA on younger patients. Results are also mixed regarding any variation in outcomes among post-traumatic arthritis TKAs versus in traditional OA TKA patients. However, both groups consistently report improvements in overall pain and function following TKA.⁵

Total hip arthroplasties (THAs) are also quite common among the general population, with over 370,000 surgeries performed annually in the US.⁶ As with TKAs, a THA is indicated when a patient fails conservative therapies and continues to have debilitating pain or functional limitations. A 2014 study in THA patients under 30 demonstrated similar joint survivability to older patients (90% at 10 years).⁸ Similar to TKA, higher THA revision rates are reported in younger populations due to joint loosening. Early loosening is more often associated with rheumatoid arthritis or congenital diseases that may be associated with musculoskeletal deformations or deficiencies that impact the stability of surgical implants.⁸ Of note, "minimally invasive" replacement procedures, such as hip resurfacing or procedures that decrease the incision size still have extensive soft tissue trauma, require experienced orthopædic surgeons, and recovery times for these procedures are not necessarily shorter. One of the most concerning aeromedical issues for THA patients is the risk of joint dislocation. There is a 1% risk of dislocation in the first month after THA, and 2% in the first year. That figure increases 1% every five years to a rate of 7% after 25 years based on a 2004 study by Dargel, Oppermann, et al.⁹ Dislocation risk is much greater following hip revisions, with rates as high as 28%.⁹ History of dislocation of THA suggests that the individual's hip is unstable and will continue to be unstable,

or that the individual is non-compliant with hip precautions and adversely affect flight safety or mission accomplishment.

Although dislocations and failures of joint replacement are of significant aeromedical concern, the most likely risks for TKA and THAs center on distracting discomfort or pain as well as functional limitations that impede the member's abilities to safely perform aviation duties or aircraft egress. However, certain roles, such as parachute duties, are not conducive to the post-TKA or THA patient as the physical stresses risk catastrophic failure of the joint and sudden incapacitation of the member. Wear and tear from parachute operations also likely decreases the expected lifetime of the joints, with high numbers of knee and hip injuries reported among military parachutists at baseline.¹⁰ While G-forces sustained in an ejection would also place significant strain on artificial joints, the likelihood of ejection is very low, not considered to be a routine operational event. Therefore, joint replacement is considered acceptable in the absence of other concerns.

Aeromedical risks can either be exacerbated or mitigated by overall physical activity levels and selection of appropriate activities in the post-TKA or THA patient. Physical activity is key for overall health, as well as improving bone health and reducing the risk of early TKA or THA loosening and need for revision.¹¹ It is important to understand factors such as wear, joint load, and activity intensity when generating an exercise regimen. Lastly, a TKA or THA also impacts the stability and function of other anatomic areas, and this information needs to be incorporated when building the overall aeromedical risk profile of aircrew with a TKA or THA. Replacing a hip or knee can place additional strain on the opposing hip or knee and increase the likelihood of musculoskeletal injury or arthritis in other joints.¹² This risk is magnified in those with underlying inflammatory or congenital pathologies. Similarly, the mechanics of the hip and pelvis are complex, and bilateral THAs generate additional and different stressors than unilateral THA and need to be considered when determining potential risks to crew safety and mission completion.

Review of AIMWTS through March 2021 showed 38 cases of retained orthopædic device with a total of 4 disqualifications (1 FC I, 1 FC II, and 2 FC III). Breakdown of the cases was as follows: 1 FC I/IA, 19 FC II, 17 FC III, and 1 ATC case. Of the 4 disqualifications, 1 was an IFC 1 with retained cranial device, and 3 were trained assets with other medical issues.

Review of AIMWTS through March 2021 showed 30 cases of TKA with 3 disqualifications (1 FC II and 2 FC III). There were 17 FC II cases and 13 FC III cases. One of the disqualification was due to CAD, and the other two were for multiple medical issues.

Review of AIMWTS through March 2021 showed 78 aviators with an AMS containing the diagnosis of THA with 3 disqualifications (2 FC II and 1 FC III). Breakdown of the cases was as follows: 50 FC II cases, 25 FC III cases and 3 ATC/GBC cases. Two disqualifications were due to unrelated medical conditions and the third case was disqualified secondary to pain after surgery and persistent inflammatory arthritis symptoms.

ICD-10 codes for Joint Replacement		
0SR9	Hip joint, right	
0SRA	Hip joint, acetabular surface	
0SRB	Hip join left	
0SRC	Knee joint, right	
0SRD	Knee joint, left	

ICD-10 codes for Retained Orthopædic Device		
Z96.9	Presence of functional implant, unspecified	
Z47.2		

#### **IV. Suggested Readings**

1. Graves MF. Principles of Internal Fixation. Ch. 8 in Browner: Skeletal Trauma: Basic Science, Management, and Reconstruction, 5th ed., Saunders, 2015.

2. Martin GM and Harris I. Total knee arthroplasty. UpToDate. Feb 2021.

3. Castagnini F, Sudanese A, Bordini B, Tassinari E, Stea S, Toni A. Total Knee Replacement in Young Patients: Survival and Causes of Revision in a Registry Population. J Arthroplasty. 2017 Nov; 32(11):3368-3372.

4. Pabinger C, Berghold A, Boehler N, Labek G. Revision Rates After Knee Replacement. Cumulative Results from Worldwide Clinical Studies Versus Joint Registers. Osteoarthritis and Cartilage. 2013: 21(2): 263-268.

5. Shearer DW, et al. The Predictors of Outcome in Total Knee Arthroplasty for Post-Traumatic Arthritis. Knee. 2013 Dec; 20(6):432-436.

6. Erens GA, Walter B, Crowley M. Total Hip Arthroplasty. UpToDate. Jan 2021.

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# Spinal Curvature, Abnormal (Kyphosis, Scoliosis, and Lordosis) (Sep 2019)

Reviewed: Lt Col David Navel (RAM 20), Maj Andrew Long (RAM 20), Dr. Van Syoc (ACS Waiver Guide coordinator), Col Brandon Horne (AF/SG orthopedic surgery consultant), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

# Significant Changes:

Table 1 updated to reflect MSD change of item K10 and minor corrections made to Table 1.

# I. Waiver Consideration

For FC I/IA, FC II, FC III, and SWA, lumbar scoliosis (LS)  $>20^{\circ}$  or thoracic scoliosis (TS)  $>25^{\circ}$  by Cobb method, any abnormal curvature producing pain, interference with function, or noticeable deformity when dressed, or abnormal curvature which is progressive are disqualifying IAW the MSD K11. Further, according to K10 of this MSD, LS  $>30^{\circ}$ , TS  $>30^{\circ}$ , kyphosis or lordosis (K/L)  $>50^{\circ}$  K/L or any spinal deviation interfering with function, vocation or wear of the military uniform or equipment is disqualifying for retention as well as all flying and special operator duties. Table 1 explains the aeromedical waiver potential for all flying classes.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority
FC I/IA	Lumbar Scoliosis (LS): >20° or Thoracic Scoliosis (TS): >25° or Kyphosis/Lordosis (K/L): >50° or	No AETC
	Any abnormal curvature producing noticeable deformity when dressed, pain, interference with function, or which is progressive.	No AETC
FC II/III/ SWA	Asymptomatic LS: >20 and <30° or Asymptomatic TS: >25 and <45°	Yes ¹ MAJCOM
	Asymptomatic LS: $\geq 30^{\circ}$ or Asymptomatic TS: $\geq 45^{\circ}$ or Asymptomatic K/L: $\geq 50^{\circ}$	Yes ^{1,2} MAJCOM
	Any abnormal curvature producing noticeable deformity when dressed, pain, or which is progressive.	Yes ^{1,3,4} MAJCOM
ATC/ GBO	Lumbar or Thoracic Scoliosis $\geq 30^{\circ}$ or Kyphosis/Lordosis (K/L): $>50^{\circ}$ or Any abnormal curvature interfering with function, vocation, or wear of military uniform.	Yes ^{3,5} MAJCOM

Table 1: Waiver potential for flying class and degree of scoliosis kyphosis and lordosis

1. No waiver for untrained applicants.

2. Trained FC II personnel will be restricted from ejection seat airframes and waiver authority is AFMRA.

3. Trained personnel may be eligible for waiver on a case-by-case basis.

4. Any abnormal curvature that interferes with function, vocation, or wear of military uniform is also disqualifying for retention and waiver authority is AFMRA for trained personnel.

5. Untrained assets may be eligible for waiver on a case-by-case basis and waiver/certification authority is AETC.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

#### A. Initial Waiver Request:

- 1. Summary of presentation, course, and any treatment.
  - a. History when deformity first noticed, who discovered, symptoms, treatment.
  - b. Physical document gait, range of motion, motor and sensory testing of lower extremities, including reflexes.
- 2. X-ray results of the spine by the Cobb Method.
- 3. Orthopedic consult, including any follow up notes.
- 4. Document full physical activity, or include any specific activity limitations.

- 5. FL4 with RTD and ALC status, if member did not meet retention standards.
- 6. Any other pertinent information.
- 7. The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.
- B. <u>Renewal Waiver Request:</u>
  - 1 Summary noting any interval change.
    - a. History symptoms and activity level.
      - b. Physical document gait, range of motion, motor and sensory testing of lower extremities, including reflexes.
  - 2 X-ray results if symptoms develop (back pain, neurologic, etc.).
  - 3 Orthopedic consult if there are symptoms or evidence of progression.
  - 4 Any other pertinent info.
  - 5 The above list is not an absolute requirement list. If there is a valid reason for not including an important item in medical care, document why.

# **III. Aeromedical Concerns**

Abnormal spinal curvature includes excessive scoliosis, kyphosis, and lordosis. Although scoliosis is defined as a Cobb angle  $>10^{\circ}$ , progression is likely in adolescents with Cobb angles  $>20^{\circ}$ . In those who have stopped growing, scoliosis  $<30^{\circ}$  is considered stable but scoliosis  $>30^{\circ}$  may be expected to progress  $1^{\circ}$  per year. Treatments may include physical therapy, bracing or surgery. Orthopedic referral is typically indicated when back pain is refractive to conservative therapy, when there is any neurological abnormality, or when the Cobb angle is:

- 1)  $>20^{\circ}$  for the lumbar curve, or
- 2)  $>25^{\circ}$  for the thoracic curve, or
- 3)  $>55^{\circ}$  for thoracic kyphosis or lordosis.

Primary aeromedical concerns involve the increased risk of fracture or other spinal injuries. Additional risks of sudden incapacitation, critically distracting symptoms, or functional limitations during flight may accompany clinically significant or progressive spinal curvatures.

Abnormal spine curvature increases risk of spine fracture during high-G exposures, particularly with ejection seat use or hard landings in rotary wing aircraft. Vertebral fractures frequently occur at loads exceeding the set ejection seat exposure limit of 20G but can occur with forces as low as 10-12Gs when the spine is not vertical. The upper body center of gravity is anterior to the spine and kyphoscoliosis shifts the center of gravity further forward out of vertical alignment. This deviation increases the risk for flexion compression fractures.

Review of AIMWTS in Jun 2019 for the previous 5 years revealed 49 submitted waivers for abnormal spinal curvature. Breakdown of the cases revealed: 8 FC I/IA cases (5 disqualified), 11 FC II waivers (0 disqualified), 7 RPA waivers, 20 FC III cases (7/20 disqualified, 1 with significant pain and 1 with concurrent disqualifying conditions), and 1 GBC case (1/1 disqualified with a concurrent disqualifying condition).

ICD-9 codes for	ICD-9 codes for Disease/Condition		
737.20	Lordosis (acquired) postural		
737.29	Other Lordosis acquired		
737.30	Scoliosis (& Kyphoscoliosis)		
737.34	Thoracogenic scoliosis		
737.39	Other Kyphoscoliosis & scoliosis		
737.42	Lordosis associated with other conditions		
737.43	Scoliosis associated with other conditions		

ICD-10 codes for Disease/Condition		
M40.40	Postural lordosis, site unspecified	
M40.50	Lordosis, unspecified, site unspecified	
M41.9	Scoliosis, unspecified	
M41.30	Thoracogenic scoliosis, site unspecified	
M41.80	Other forms of scoliosis, site unspecified	
M41.50	Other secondary scoliosis, site unspecified	

# **IV. Suggested Readings**

1. Negrini S, Donzelli S, Aulisa AG, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis and Spinal Disorders, 2018; 13(3).

2. Horne JP, Flannery R, and Usman S. Adolescent Idiopathic Scoliosis: diagnosis and Management. Am Fam Physician, 2014; 89(3): 193-98.

3. Scherl SA. Adolescent idiopathic scoliosis: Management and prognosis. https://www.uptodate.com/contents/adolescent-idiopathic-scoliosis-management-and-prognosis. Updated April 29, 2019. Accessed June 10, 2019.

4. Ernsting F, King P. Aviation Medicine, 4th ed. Butterworths, Boston. 2006; 24:379.

5. Vasishta VG and Pinto LJ. Aviation Radiology: Teaching series. Ind J Aerospace Med, 2003; 47(2): 42-44.

# **Spinal Fracture Mar (2020)**

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

Updated Waiver Considerations and References

# I. Waiver Consideration

Fractures or dislocations of the vertebrae are disqualifying for US Air Force FC I, II and III aircrew, as well as for SWA airmen. Fractures or dislocations of the vertebrae are not disqualifying for ATC or GBO personnel. Transverse or spinous process fractures are not disqualifying if asymptomatic following recovery. Ejection/high Gz waiver limitation recommendations are based on severity of fracture, time since injury, treatment, and functional status of the aviator. For compression fractures with vertebral body height loss less than or equal to 25%, an unrestricted waiver recommendation is possible. For vertebral body fractures with greater than 25% compression, pilots and navigators may be considered for categorical FC IIB waiver, but FC I/IA applicants will typically not be considered for a waiver. If, after adequate healing time, there are residua such as chronic pain, decreased mobility, neurological injury, or other medical disease, aeromedical disqualification may be appropriate. Surgically-treated compression fractures normally heal well and are usually recommended for categorical waiver. Traumatic thoracolumbar compression fractures treated with vertebroplasty (VP) or balloon kyphoplasty (BKP) may be considered for unrestricted waiver after six months. VP is injection of bone cement into a vertebral body and BKP is placement of a balloon into the vertebral body, followed by an inflation/deflation sequence to create a cavity prior to cement injection. These procedures primarily address neurologic instability-related pain symptoms and do not affect mechanical stability. The use of a biologic-based cement agent is recommended, as this does allow the potential for new bone deposition.

Burst fractures managed nonoperatively can be aeromedically managed as a compression fracture for waiver consideration. Waived burst fracture aviators should have annual radiographs with interim evaluation to ensure no progression of kyphosis, until they are demonstrated to be stable. Spinous process fractures are commonly seen with direct trauma involving sudden deceleration and forced flexion, and tend to be stable. Parachutists who have fully healed from an uncomplicated and non-surgical spinal fracture should have at least one year post-injury/surgery observation and recovery before waiver consideration.

For cases of spinal fracture with an associated herniated nucleus pulposus, please consult the Waiver Guide chapter on Herniated Nucleus Pulposus and Spinal Fusion, and apply the more restrictive waiver criteria.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	No	AETC	No
FC II	Yes ¹	AFMRA	Yes
FC III	Yes ¹	MAJCOM	At MAJCOM Request
Parachute	Yes ^{1,2}	MAJCOM	At MAJCOM Request
SWA	Yes ^{1,2}	MAJCOM	At MAJCOM Request

#### Table 1: Waiver potential for spinal fracture

1. Compression fractures with >25% vertebral body height loss are usually recommended for restricted waiver.

2. Spinal fractures treated with hardware in parachutists are generally disqualifying for continued parachute duties.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

A. Initial Waiver Request:

Waiver Request:

- 1. Minimum observation times before aeromedical waiver consideration:
  - a. Compression fractures:
    3 months for FC II/FC III managed conservatively
    6 months for FC II/FC III if treated with BKP or VP

1 year for parachute duties

- b. Burst fractures:6 months for FC II/FC III
  - 1 year for parachute duties
- 2. History of injury, immediate exam results, and treatment.
- 3. Reports of consultations, diagnostic testing, imaging, procedures or operations as applicable, and images from initial and current radiographic studies.
- 4. Reports and images from current dynamic (flexion-extension) radiographs and also, if applicable, current MRI or CT studies. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 5. Consultant note clearing the aviator for return to duty, listing any specific activity limitations.
- 6. Current spinal and neurologic examination findings.
- 7. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.
- B. Renewal Waiver Request:
  - 1 Interval history and level of symptom resolution.
  - 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.

- 3 Current spinal and neurologic examination findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

# III. Aeromedical Concerns

Aeromedical concerns include the effects of any residual neurologic or cognitive symptoms on operational safety and mission effectiveness, future risk of new symptom development, and future risk of recurrence. Even after healing, ejection or high Gz load stressors may predispose to repeat fracture and, more ominously, spinal cord damage. Limited mobility after cervical fracture healing, fusion, or fixation can limit scanning from the cockpit and performance under Gz loading with neck rotation. Thoracolumbar fractures can also limit mobility or distract due to pain, but are generally not as limiting for aviation duties. A fully healed uncomplicated spinal fracture should tolerate the traumatic forces from military parachuting.

Review of AIMWTS through Jan 2019 revealed a total of 364 cases submitted with a diagnosis of spinal fracture. Of this total, 45 were FC I/IA (14 disqualified), 150 were FC II (14 disqualified), 6 were RPA pilots (0 disqualified), 151 were FC III (31 disqualified), 10 were ATC/GBC (3 disqualified), and 2 were MOD (0 disqualified).

ICD-9 Codes for Spinal Fractures		
805	Fracture of vertebra without mention of cord injury	
806	Fracture of vertebra with spinal cord injury	

ICD-10 Codes for Spinal Fractures		
S12.0 - S12.9	Fracture cervical vertebra	
S22.0	Fracture of thoracic vertebra	
S32	Fracture of the lumbar spine	

# **IV. Suggested Readings**

1. Kaji A. Evaluation and acute management of cervical spinal column injuries in adults. UpToDate, Oct 0, 2019.

2. Kaji A, Hockberger RS. Spinal column injuries in adults: definition, mechanisms and radiographs._UpToDate, Apr 11, 2018

3. Kaji A, Hockberger RS. Evaluation of thoracic and lumbar spinal column injury. UpToDate, Aug 30, 2018.

4. Amorosa LF, Vaccaro AR. Subaxial Cervical Spine Trauma. Ch. 34 in *Skeletal Trauma: Basic Science, Management, and Reconstruction*, 5th ed., Saunders, 2015.

5. Wood KB, Li W, Lebl DR, and Ploumis A. Management of thoracolumbar spine fractures. Spine J, 2014; 14: 145-64.

6. McBratney CM, Rush S, and Kharod CU. Pilot Ejection, Parachute, and Helicopter Crash Injuries. J Spec Oper Med 2014; 14:92-94.

7. Pavlovic M, Pejovic J, Mladenovic J, et al. Ejection experience in Serbian Air Force, 1990-2010. Vojnosanit Pregl 2014; 71(6):531-33.

8. Manen O, Clément J, Bisconte S, and Perrier E. Spine Injuries Related to High-Performance Aircraft Ejections: A 9-Year Retrospective study. Aviat Space Environ Med 2014; 85:66-70.

9. Papanastassiou ID, Phillips FM, Van Meirhaeghe J, et al. Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies. Eur Spine J 2012; 21:1826-43.

# Spondylolysis and Spondylolisthesis (Feb 2019)

Reviewed: Lt Col Ross Semeniuk (RAM 2020) Dr. Dan Van Syoc (ACS waiver guider coordinator), Col Brandon Horne (AF/SG consultant for orthopedic surgery), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

#### **Significant Changes:** Table change

# I. Waiver Consideration

Spondylolysis is a defect involving the pars interarticularis of the vertebrae. Spondylolisthesis is a condition in which there is anterior slipping of a vertebrae. The most common location for these conditions occurs at the lower lumbar vertebrae.

Symptomatic spondylolysis or spondylolisthesis that requires repeated hospitalizations, duty restrictions, or frequent absences from duty is disqualifying for all flying classes, ATC, GBO and SWA duties, as well as for retention. Spondylolysis and spondylolisthesis are often associated with other spinal pathologies (e.g. spina bifida, disc protrusion, spinal stenosis, disc disease) that are also disqualifying.

If spondylolysis or spondylolisthesis is treated with surgery, refer to the waiver guide on herniated nucleus pulposus (HNP) and spinal fusion for additional waiver considerations.

Flying Class	Condition	Waiver Potential	ACS
(FC)		Waiver Authority	<b>Review/Evaluation</b>
Ì/IA	Symptomatic spondylolysis and/or Symptomatic grade I/II spondylolisthesis	Yes AETC	No
	Symptomatic spondylolysis and/or symptomatic spondylolisthesis, or asymptomatic spondylolisthesis grade III or higher (treated or not)	No AETC	No
II/III ATC, GBO, SWA	Symptomatic spondylolysis and/or symptomatic spondylolisthesis controlled only with exercise or NSAIDs	Yes ^{1, 2,3} MAJCOM	No
	Spondylolysis and/or spondylolisthesis treated with surgery	Maybe ² AFMRA/MAJCOM ⁴	No
	Spondylolysis or spondylolisthesis, when symptoms and associated objective findings require repeated hospitalization, duty restrictions or frequent absences from duty	Maybe AFMRA	No

 Table 1: Waiver potential for Spondylolysis and/or Spondylolisthesis

1. If spondylolisthesis is grade III or greater waiver unlikely for untrained FC II and FC III individuals.

2. Waiver unlikely for untrained FC II and FC III personnel.

3. Not disqualifying for ATC and GBO personnel.

4. See HNP and spinal fusion waiver guide.

# II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial Waiver Request:

- 1. History Presentation, course, and a thorough back history including:
  - a. any adolescent sports injuries; and
  - b. vehicular accidents.

If aviator had past or present symptoms, document nature of pain and treatment received.

- 2. Orthopedic spine or neurosurgical consultation report.
- 3. Diagnostic imagining –X-ray (AP, LAT, obliques), and CT/MRI results.

- 4. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 5. Current physical examination spine (range of motion), extremities (range of motion, strength, sensation, and reflexes).
- 6. Any other pertinent information. MEB result, if required.
- 7. If the above items are not available, it is necessary to explaining reasoning to the waiver authority.

B. Renewal Waiver Request:

- 1 Interval history Describe circumstances of any back pain, severity, limitations, treatment, duration of symptoms, and DNIF period; current activity level.
- 2 Current physical examination spine (range of motion), extremities (range of motion, strength, sensation, and reflexes).
- 3 Diagnostic imagining –X-ray (AP, LAT, obliques) if recurrent symptoms.
- 4 Orthopedic spine or neurosurgical consultation report.
- 5 MEB updates, if applicable.
- 6 If the above items are not available, it is necessary to explaining reasoning to the waiver authority.

# **III. Aeromedical Concerns**

Spondylolisthesis and spondylolysis represent structural abnormalities of the lumbar spine and may be manifested by low back pain. Such pain is unlikely to cause sudden incapacitation but can cause distraction during flight operations.

Spondylolysis may be caused by a stress fracture and lead to occasional or chronic low back pain. Additionally, the affected portion of the spine may be particularly vulnerable to accelerative stress.

Spondylolisthesis can be secondarily caused by degenerative disc disease or spondylolysis. It may also cause low back pain as well as sciatica. The aviator's response to continued exposure to vibration and accelerative forces should be considered. However, an AF Aerospace Medical Research Laboratory report on spinal column considerations for flight physical standards noted that there were no proven demonstrations in which the aggravation of spondylolisthesis was shown in the course of time.

A Feb 2019 review of AIMWTS revealed 193 members with a waiver disposition for spondylolysis or spondylolisthesis. Of this total, 31 were disqualified. Breakdown of the cases revealed: 8 FC I/IA cases (2 disqualified), 93 FC II cases (8 disqualified, of which 5 had a previous waiver), 2 RPA pilot cases, 80 FC III cases (18 disqualified, of which 7 had a previous waiver), 7 ATC/GBC cases (3 disqualified), and 3 MOD cases. The majority of the disqualified cases were due to vertebral concerns.

ICD-9 Codes for Spondylolysis and Spondylolisthesis	
738.4	Acquired spondylolisthesis/spondylolysis
756.11	Spondylolysis (congenital)
756.12	Spondylolisthesis (congenital)

ICD-10 Codes for Spondylolysis and Spondylolisthesis	
M43.10	Spondylolisthesis site unspecified
M43.00	Spondylolysis, site unspecified
Q76.2	Congenital spondylolisthesis

# **IV. Suggested Readings**

1. North American Spine Society. *Diagnosis and treatment of degenerative spondylolisthesis*. 2nd edition. 2014. Retrieved from: https://www.spine.org/Portals/0/Deguments/PeggarahClinicalCare/Guidelings/Spondylolisthesis.pd

https://www.spine.org/Portals/0/Documents/ResearchClinicalCare/Guidelines/Spondylolisthesis.pdf ?ver=2016-04-12-134623-410

2. Evans N and McCarthy M. Management of symptomatic degenerative low-grade lumbar spondylolisthesis. EFORT Open Rev, 2018 Dec 19; 3(12): 620-31.

3. Syrmou E, Tsitsopoulos PP, Marinopoulos D, et al. Spondylolysis: a review and reappraisal. Hippokratia, 2010; Jan; 14(1): 17-21.

4. Kazarian LE and Belk WF. (1979). Flight physical standards of the 1980's: spinal column considerations. Aerospace Medical Research Laboratory (AMRL) Technical Report (TR)-79-74; October 1974.

#### Allergic Rhinitis (Mar 2021)

Authors/Reviewers: Dr. Christopher Keirns, Maj Luke Menner, and Maj Laura Bridge (ACS Internal Medicine); Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

#### I. Waiver Consideration

Allergic rhinitis is disqualifying for all flying class, ATC, OSF and SWA duties unless it is mild in degree, controlled on approved medications, and unlikely to limit duty performance. If symptoms are controlled on medications that are approved for the specific career field (e.g., selected second-generation antihistamines, montelukast, or nasal corticosteroids), then a waiver is not required. Nasal azelastine (Astelin®) is approved for use with a waiver. Likewise, treatment with allergen immunotherapy (i.e., desensitization or "allergy shots") requires a waiver for all flying class, ATC, and SWA duties. Considered in isolation, treatment with allergen immunotherapy is not disqualifying for GBO and OSF duties; however, the severity of the allergic rhinitis itself may be disqualifying for ATC or OSF duties. The use of any medication that is not approved for the specific career field is disqualifying, and a waiver may be considered on an individualized basis.

It is recommended that the MSD and the appropriate career field medication list be crossreferenced with the MSD. Please note that at the time of the revision of this Waiver Guide chapter, allergen immunotherapy was not disqualifying for ATC duties per the MSD; however, it *was* disqualifying per the *Official Air Force Aerospace Medicine Approved Medications* list. Therefore, barring changes to either the MSD or medication list, the use of allergen immunotherapy *does* require an aeromedical waiver for continued ATC duties.

This waiver guide chapter addresses allergic causes of rhinitis. Sinusitis, non-allergic rhinitis, vasomotor rhinitis, Eustachian tube dysfunction, and other related conditions are not discussed but may be disqualifying. Please refer to the MSD for additional information about potentially disqualifying related conditions. Additionally, please refer to the Aerospace Medicine Waiver Guide chapters on *Eustachian Tube Dysfunction* and *Sinusitis*.

Flying Class	Condition	Waiver Potential	ACS Review or
		Waiver Authority	Evaluation
FC I/IA	Allergic rhinitis (controlled	N/A	N/A
	with approved medications		
	that do not require waiver)		
	Allergic rhinitis (controlled	Yes	$No^5$
	with immunotherapy,	AFRS/CMO ^{3,4}	
	medication requiring waiver,		
	or non-approved		
	medication) ²		
FC II/III/	Allergic rhinitis (controlled	N/A	N/A
ATC/SWA ¹	with approved medications		
	that do not require waiver)		
	Allergic rhinitis (controlled	Yes	No ⁵
	with immunotherapy,	MAJCOM ^{3,4}	
	medication requiring waiver,		
	or non-approved		
	medication) ²		
GBO ¹	Allergic rhinitis (controlled	N/A	N/A
	with approved medications		
	that do not require waiver,		
	including immunotherapy)		
	Allergic rhinitis (controlled	Yes	No ⁵
	with medication requiring	MAJCOM ^{3,4}	
	waiver or non-approved		
	medication)		

Table 1: Waiver potential for allergic rhinitis

1. Untrained assets may be eligible for waiver on a case-by-case basis. Certification authority for untrained assets is AFRS/CMO.

2. Submit waiver requests for allergen immunotherapy only after the treated individual reaches the maintenance phase of therapy. If waiver is approved, a mandatory four-hour DNIF is required after each injection.

3. Waivers for the use of non-approved medications may be considered on a case-by-case basis. The waiver authority for any non-approved medication is AFMRA.

4. Indefinite waivers may be considered, except in cases requiring immunotherapy.

5. ACS review may be requested at the discretion of the waiver authority.

#### **II. Information Required for Waiver Submission**

Submit the aeromedical summary (AMS) only after the clinical disposition is finalized and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

#### A. Initial Waiver Request:

- 7. Information to include in history:
  - a. Complete description of presenting features, including full history and all pertinent physical findings (positive and negative).

- b. Specify presence or absence of pertinent symptoms, including any impact on both quality of life and occupation.
- c. Document all comorbidities (e.g., food allergies, asthma, eczema, etc.).
- d. Specify current treatment regimen. Include dosages, and comment on tolerance of treatment.
- 8. Consultation report from the treating specialist (e.g., allergist, otolaryngologist) and all subsequent consultation notes. These notes must include the following:
  - a. Discussion of current treatment (e.g., allergen avoidance, allergen immunotherapy, antihistamines, glucocorticoid nasal sprays, etc.) including dose, frequency, and formulation, as applicable.
  - b. Recommendations for ongoing specialist follow-up, if any.
- 9. If applicable, results of all testing performed in the course of diagnosis, evaluation, and management of allergic rhinitis, including laboratory studies, imaging, and any other ancillary studies.
- 10. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 11. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

B. <u>Renewal Waiver Request</u>:

- 1. Updated AMS with interval history, including:
  - a. Complete updated history and physical examination. Include report of any new subjective symptoms or objective findings.
  - b. Complete list of current medications with dates of initiation, dosages, and all adverse effects.
  - c. Plan for monitoring of recurrence.
- 2. All relevant interval consultation reports from specialty providers (e.g., allergist, otolaryngologist).
- 3. Results of all interval testing performed in the course of ongoing evaluation and management, including (as applicable) laboratory studies, imaging, and any other ancillary tests.
- 4. Form FL4 with return to duty and ALC status, if service member did not meet retention standards.
- 5. If any of the substantiating documentation listed above is not included in the waiver package, document and explain to the waiver authority the reason for omission.

# **III. Aeromedical Concerns**

Clinically, allergic rhinitis is often considered to be relatively benign. However, in the unique environment of aviation or under the physiologic stress of military operations, uncontrolled or under-controlled allergic rhinitis can lead to serious consequences for individual health and mission success. Allergic rhinitis is of aeromedical concern due to the symptoms and complications of the condition itself as well as the adverse effects of its common treatments. For example, the symptoms of allergic rhinitis are expected to worsen at altitude, which may result in

uncomfortable distracting symptoms at a minimum or incapacitation due to serious ear and sinus barotrauma at worst. Likewise, exposures to allergens or irritants during the course of military operations may cause duty-limiting symptoms that could affect individual safety and mission completion. Such symptoms include, but are not limited to, severe nasal and sinus congestion impacting breathing; impaired olfaction or anosmia; impaired hearing due to congestion; headaches; and cough due to post-nasal drip. Although not often reported by the affected individual, impaired sleep, fatigue, and cognitive impairment are frequent when symptoms of allergic rhinitis are not adequately controlled. Distracting symptoms such as rhinorrhea and sneezing may be of particular concern during high speed, low level flight. Eustachian tube dysfunction from post-nasal drainage can lead to prolonged periods of flying restriction, reducing operational readiness. Additionally, many of the widely-available over-the-counter (OTC) products that successfully treat the symptoms of allergic rhinitis also result in fatigue or other adverse effects of significant degree that their use poses serious risks in the aviation and operational setting.

Though the standard medications used to treat allergic rhinitis are generally safe, they may all cause adverse effects of aeromedical and operational importance. Consult the appropriate career field medication list for details regarding approved medications and their operational prescribing parameters. Whenever a new mode of therapy is initiated, it is critical to both exclude idiosyncratic reactions/significant adverse effects and ensure complete symptomatic control prior to flight status or, if necessary, submission of an aeromedical waiver request. The second-generation antihistamines that are included in the approved medications lists (i.e., loratadine and fexofenadine) are associated with the lowest risk for sedation compared to alternative agents within their class. However, they are not completely free of sedative effects. Therefore, a minimum ground trial of 72 hours is required prior to operational use.

Cetirizine is not approved for aviation or operational use due to its increased sedative properties compared to other oral antihistamines and the availability of alternative medications with less risk of sedation within the same class. The topically-administered antihistamine azelastine is a second-generation H1-receptor antagonist with a sedation risk that approaches that of cetirizine. However, azelastine offers advantages over oral antihistamines that justifies its approval for aeromedical and operational use. Specifically, azelastine displays one of the fastest onsets of action among all allergic rhinitis medications currently on the market (15 minutes). Furthermore, it demonstrates superior efficacy compared to other therapeutic options in individuals with inadequate response to oral antihistamines. Due to the increased rate of sedation or drowsiness associated with azelastine, a waiver is required for its use in FC I/IA/II/III and ATC personnel. To mitigate the aeromedical and operational concerns related to sedation, pilot waivers for azelastine are typically restricted to aviation duties with another qualified pilot.

Allergen immunotherapy is associated with an ongoing risk for systemic reaction including anaphylaxis. Due to the greater likelihood of such reactions during the build-up phase, waivers are generally not considered until an individual demonstrates stability at maintenance dosing. After a waiver is granted, aviators require a 4-hour verbal DNIF after each dose administration prior to engaging in any aviation or operational duties. Review of the AIMWTS database from Mar 2016 through Mar 2021 revealed 617 cases with a diagnosis of allergic rhinitis. A breakdown of the cases was as follows: 36 FC I/IA cases (10 disqualified), 254 FC II cases (14 disqualified), 220 FC III cases (30 disqualified), 40 ATC cases (4 disqualified), 52 GBO cases (9 disqualified), and 15 SWA cases (2 disqualified). Of the 59 disqualified cases involving trained individuals, nearly all were disqualified for reasons other than the allergic rhinitis.

Please use <i>only</i> these ICD-10 code for AIMWTS coding purposes		
J30.9	Allergic rhinitis, unspecified	

#### **IV. Suggested Readings**

- Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngol Head Neck Surg 2015;152:S1-43. Available at <u>https://journals.sagepub.com/doi/pdf/10.1177/0194599814561600</u>. Accessed 24 March 2021.
- Wise SK, Lin SY, Toskala E, et al. International Consensus Statement on Allergy and Rhinology: Allergic Rhinitis. Int Forum Allergy Rhinol 2018;8:108-352. Available at https://onlinelibrary.wiley.com/doi/pdf/10.1002/alr.22073. Accessed 24 March 2021.
- Dykewicz MS, Wallace DV, Amrol DJ, et al. Rhinitis 2020: A practice parameter update. J Allergy Clin Immunol 2020;146:721-767. Available at <u>https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Rhinitis</u> -2020-A-practice-parameter-update.pdf.





# Cholesteatoma

Revised: Aug 2022

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**Significant Changes**: Formatting change to waiver demographics table, updated references with hyperlinks, new format for previous waiver dispositions

# I. Waiver Consideration

History of cholesteatoma or history of surgical removal of cholesteatoma is specifically disqualifying for flying classes I/IA, II, III, OSF, and SWA duties. Cholesteatoma is not specifically disqualifying for GBO or ATC duties, unless it is associated with otitis media or mastoiditis that interferes with satisfactory job performance, requires more than annual specialist follow up, or results in H-3 or worse hearing. Due to the requirement for long-term follow-up, it is recommended that initial waivers be limited to one year. Patients with cholesteatoma will require regular and prolonged follow-up with otolaryngology while on flying status as recurrence is best managed when caught early. Indefinite waivers will be uncommon.

Flying Class (FC)	Disease/Condition	Waiver Potential Waiver Authority	ACS Review/ Evaluation
FC I/IA and FC II/III/SWA (initial)	Cholesteatoma	Maybe ^{1,2} AFRS/CMO	Yes
FC II/III SWA (trained)	Cholesteatoma	Yes ^{1,2} MAJCOM	Yes
ATC GBO	Cholesteatoma	N/A	N/A

# Table 1: Waiver potential for Cholesteatoma

 For FC I/IA, initial FC II/III, surgery for cholesteatoma must have occurred at least two years previous to waiver submission with documentation indicating the cholesteatoma was completely removed; hearing profile must be H-1. AFRS/RSG is the certification authority for all untrained assets except for MOD candidates which go to AFGSC. Indefinite waiver may be considered for cases that occurred years prior to consideration if there has been no recurrence and hearing is excellent.

2. IFC I/IA candidates need to wait a minimum of two years post treatment before consideration of waiver. For all others, after 6 months, individuals must demonstrate normal Eustachian tube function (i.e., a normal valsalva), and a stable or waiverable hearing profile (if a conductive hearing loss is present). For non-trained assets an H-2 hearing profile requires waiver submission, and for trained assets an H-3 requires waiver. Individuals will need close otolaryngology/flight surgeon observation during the first year post-op.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

# A. Initial Waiver Request:

- 1. History of risk factors (i.e., Eustachian tube dysfunction, pressure equalization (PE) tubes, age at first and subsequent PE tube placement, a history of other ear surgeries, episodes of otitis media, smoking status, etc.). Symptoms, including pertinent negatives, should be addressed, (e.g., dizziness, vertigo, facial paralysis, Eustachian tube dysfunction, etc., treatments, and prognosis).
- 2. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated).
- 3. Physical exam: Valsalva results, status of tympanic membrane.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 5. Audiogram. (If an audiogram profile is not H-1, a full audiology evaluation is needed).
- 6. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 7. Otolaryngology consultation; attach referral report FL4 with RTD and ALC status.
- 8. Copy of operative report.

Note: For any of the above listed conditions, specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. Renewal Waiver Request:

- 1. Assessment for recurrence (e.g., otorrhea, otalgia, hearing loss, etc.).
- 2. Physical exam: Valsalva results and status of tympanic membrane.
- 3. Audiogram. (If an audiogram profile is not H-1, a full audiology evaluation is needed).
- 4. Otolaryngology consultation; attach referral report.

Note: For any of the above listed conditions, specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# **III. Aeromedical Concerns**

Cholesteatomas are typically defined as keratinzed masses in the middle ear, mastoid, or temporal bones that are benign, expanding, and locally destructive lesions. They are typically classified based upon their pathogenesis, being either acquired or congenital. Acquired cholesteatomas are the most common form of cholesteatoma found in the general population and in USAF aircrews. Acquired cholesteatomas may be further subdivided into primary or secondary. Primary acquired cholesteatomas, which account for up to 80% of all middle ear cholesteatomas, usually occur behind an intact TM. They occur as a consequence of tympanic membrane retraction, where the uncontrolled growth of squamous keratinized epithelium in the middle ear damages the ossicles, as it progresses into the aditus ad antrum and mastoid. Secondary acquired cholesteatomas, which account for 18% of middle ear cholesteatoma, seem to "grow" into the middle ear through a

#### Cholesteatoma

perforated TM. Congenital cholesteatomas are rare, and account for only about 2 to 4% of all middle ear cholesteatomas.

The pathogenesis of acquired cholesteatoma has been debated for over a century, but the most commonly agreed upon etiological factors include chronic Eustachian tube dysfunction, poor pneumatization of the middle ear and mastoid process, and inflammatory conditions (e.g., chronic otitis media with effusion) with subsequent retraction pocket formation.

Aeromedical concerns regarding cholesteatomas include hearing loss, vertigo, facial paralysis, intracranial suppurations, recurrence, persistent Eustachian tube dysfunction, and otalgia which may be aggravated with headset or helmet use. The growing mass can cause a mass effect as it impinges parts of the ear/outer skull, including ossicles, cranial nerves, and mastoid cavity spaces. Although improved surgical techniques have decreased morbidity and mortality from this disease, patient outcome depends on the extent of the disease at the time of surgery, how much damage has already been done, and the skill of the surgeon. Although many patients will have normal ear function for decades after surgical excision, cholesteatomas may recur and require multiple operations resulting in hearing loss. In most patients, the underlying cause, such as Eustachian tube dysfunction, will persist.

A review of AIMWTS from Jun 2017 to Jun 2022 looking revealed a total of 32 cases with an AMS containing the diagnosis of cholesteatoma, only 1 of these cases resulted in a disqualification disposition in a Ground Based Controller. The breakdown of the number of waivers and number of total cases are tabulated below.

Please use only these ICD 10 codes for Cholesteatoma		(# of waivers / total # of cases)			
for AIM	for AIMWTS coding purposes		FC II	FC III	ATC
H71.9	Unspecified cholesteatoma, right, left, bilateral				
0, 1, 2, 3					
H71.0	Cholesteatoma of attic, unspecified ear, right,				
0, 1, 2, 3	left, bilateral				
H71.1	Cholesteatoma of tympanum, unspecified ear	4/4	9/9	16/16	2/3
H71.2	Cholesteatoma of mastoid, unspecified ear,				
0, 1, 2, 3	1, 2, 3 right, left, bilateral				
H71.30	Diffuse cholesteatoma, unspecified ear				
H95.00	Recurrent cholesteatoma of				
	postmastoidectomy cavity, unspecified ear				

# **IV. Suggested Readings**

- Basic Otorhinolaryngology: A Step-by-Step Learning Guide, 2nd Edition. (2018). *ProtoView*, 2018(9), ProtoView, Vol.2018(9). https://books.google.com/books?id= tTKXJ8OY0QC&printsec=frontcover#v=onepage&q&f=false
- Kennedy KL, Singh AK. Middle Ear Cholesteatoma. [Updated 2021 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <u>https://www.ncbi.nlm.nih.gov/books/NBK448108/</u>
- 3. Lustig, LR, Limb CJ. Chronic otitis media, cholesteatoma, and mastoiditis in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc., <u>https://www.uptodate.com/contents/chronic-otitis-media-cholesteatoma-and-mastoiditis-in-adults</u>
- Spilsbury K, Miller I, Semmens JB, and Lannigan FJ. Factors Associated With Developing Cholesteatoma: A Study of 45,980 Children With Middle Ear Disease. *Laryngoscope*, 2010; 120: 625-30. <u>https://onlinelibrary.wiley.com/doi/10.1002/lary.20765</u>

#### WAIVER GUIDE

Updated: Jan 2018 Supersedes Waiver Guide of Aug 2013 By: Dr Dan Van Syoc Reviewed by Col LaKeisha Henry, AF/SG consultant for otolaryngology and Lt Col Samuel A. Spear, AF neuro-otologist and AFMSA Staff

# **CONDITION: Eustachian Tube Dysfunction (Jan 2018)**

#### I. Waiver Consideration.

Acute Eustachian tube dysfunction (ETD) secondary to a transient illness (e.g. viral URI or SAR) requires no waiver but is grounding for flyers until resolution. However, chronic ETD is disqualifying (MSD D6) and requires a waiver for FC I/A, FC II, FC III, OSF, and SWA duties. Also any surgical procedure for correction of ETD (MSD D7) is disqualifying for FC I/A, FC II, FC III, OSF, and SWA duties. It needs to be emphasized that resolution of ETD and adequacy of ET function are to be assessed on a case by case basis and that no one treatment or procedure, per se, will lead to waiver approval. Regardless of cause or treatment modality, ET functionality must be demonstrable for a waiver to be granted. In general, the permanent use of PE tubes in flyers is not advisable, but it is a fact that adults tend to tolerate chronic use of PE tubes better than children. What is important is the operational necessity of using the tubes and the clinical judgment of the flight surgeon and treating otolaryngologist.

For GBO and ATC personnel, ETD is not listed specifically as disqualifying. However, per AFI 48-123 on general and miscellaneous conditions and defects, retention standards are in play when satisfactory performance of duty is prevented or there is a requirement for extensive and prolonged treatment. If these conditions exist, the member will need a waiver if returned to duty after MEB.

Flying Class (FC)	Condition	Waiver Potential	
		Waiver Authority	
I/IA	ETD/OM, regardless of	Maybe*	
	cause, controlled with nasal	AETC	
	steroids and/or approved		
	oral antihistamines.		
	ETD/OM, regardless of	Maybe*#	
	cause, controlled via	AETC	
	surgical correction.		
II/III	ETD/OM, regardless of	Yes*	
SWA	cause, controlled with nasal	MAJCOM	
	steroids and/or approved		
	oral antihistamines.		
	ETD/OM, regardless of	Yes*#	
	cause, controlled via	MAJCOM	
	surgical correction.		
ATC/GBO	ETD/OM, regardless of	N/A	
	cause.		

 Table 1: Waiver potential for ETD

* Waiver in FC I/IA and untrained FC II/III requires at least 12 months of symptoms controlled on medication before waiver.

# Waiver may be considered if at least 6 months after surgery, symptoms entirely resolved, clearance by ENT physician. ENT clearance is mandatory as different surgical procedures (e.g. PET vs. cholesteatoma resection) have dramatically different recovery periods and associated complications. Further, any surgical complications (e.g. hearing loss) require evaluation and waiver of their own accord.

A review of AIMWTS through Jan 2018 revealed 207 cases with the diagnosis of ETD with 117 cases disqualified. Breakdown of the cases was as follows: 6 FC I/IA cases (4 disqualified), 50 FC II cases (17 disqualified), 135 FC III cases (94 disqualified), 8 RPA Pilot cases (0 disqualified), 7 ATC/GBC cases (2 disqualified), and 1 MOD case (0 disqualified). In every case, except two (optic drusen and migraines), the disqualifying diagnosis was the ETD/inadequate or absent Valsalva. In almost every case where the ETD was treated with aeromedically waiverable medications and/or surgical correction (e.g. PET, adenoidectomy, cholesteatoma resection, nasal polypectomy, etc.), the waiver was granted in the presence of subsequently demonstrated pressure equalization (e.g. altitude chamber). In only one case was a granted waiver subsequently denied due to recurrent ETD.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for initial waiver for ETD should include the following:

A. History – symptoms (flying and on ground), duration, and treatment.

- B. Physical HEENT including Valsalva.
- C. ENT consultation report to include any surgical reports if applicable.
- D. Audiology with Impedance test consultation report.

E. Altitude chamber flight results (Altitude chamber ride up to 8-10,000ft with rapid decompression is required. If treated with surgery, altitude chamber ride no earlier than 6 weeks after surgery or when cleared by ENT physician, whichever is later). This only applies to those whose duties are at altitude

The AMS for <u>waiver renewal</u> for ETD and/or surgery should include the following:

A. History - interim summary of any symptoms (flying and on ground), treatments, or

recurrences/exacerbations since last waiver.

B. Physical – HEENT including Valsalva.

C. ENT consultation if symptoms recurrent.

D. Audiology consult if symptoms recurrent.

E. Status report of ET functional capacity in flight (i.e. any in-flight symptoms?).

#### **III. Overview.**

Eustachian tube dysfunction (ETD), which is most easily recognized as difficulty clearing one's ears, is often the cause for grounding of airmen. While most occupations require only normal hearing, a normal otoscopic exam, and absence of an ear disease history, the requirements for flight duty are far more rigorous.¹ Sudden changes in atmospheric pressure, as are often experienced by aviators, demand tubal equilibrating capacity to be in optimal working order. Failure to equilibrate to rapid changes in atmospheric pressure can lead to the sudden onset of "ear block" – (barotrauma resulting in severe ear pain due to the inability to equilibrate pressures in the middle ear).² This sudden onset of severe pain may be incapacitating and pose great risk to safety of flight.

Our knowledge and understanding of the functions and diseases of the eustachian tubes (ET) are due to the pioneering works of men such as Bartolomeus Eustachius (16th century anatomist), Antonio Valsalva (18th century anatomist), and Adam Politzer (19th century otologist). As an outgrowth of their endeavors, we now realize that the ET serves three physiologic functions: 1) pressure regulation, 2) protection of the middle ear from pathogens/foreign material in the nasopharynx, and 3) clearance of the middle ear space.³ Failure of the tubal mechanism can disrupt any and/or all of these functions. This altered tubal function may then lead to a multitude of complications which vary from mild and transient (i.e. causing temporary DNIF) to severe and debilitating (i.e. permanently disqualifying). For example, the transient difficulty clearing ears

caused by viral upper respiratory tract infections (URIs) and/or seasonal allergic rhinitis (SAR) may only cause mild and/or fleeting symptoms. However, ETD has also been linked to the development of chronic otitis media and secondary cholesteatoma (trapping of squamous debris in the middle ear and mastoid).

In its resting state, the ET remains closed and only opens when necessary to equalize pressure. In flight, ascent usually causes little trouble even in the absence of any active ear clearing maneuvers. This is due to the passive escape from the middle ear of expanding air as it exceeds the opening pressure of the ET. However, 10-17% of airmen have reported vertigo during ascent which is believed to be secondary to asymmetry between the right and left side (i.e. alternobaric vertigo-causing a differential input to the vestibular system).^{1, 2} This is more frequently seen on descent which requires the active passage of air into the middle ear space. This is normally accomplished by the tubal musculature associated with deglutition and/or jaw movements.¹ The most well-known example of this is the Toynbee's maneuver: displacement of air by the movement of the eardrum when swallowing with the nose closed.¹ Should such maneuvers fail, air can be forced into the middle ear by increasing nasopharyngeal pressures via the Valsalva maneuver: displacement of air by the movement of the eardrum caused by forceful expiration against a closed nose.⁴ Many authorities suggest as safer alternatives the Toynbee or *Frenzel* maneuvers: open the jaw, fill mouth with air, pinch the nose, purse the lips, and then close the jaw while displacing air posteriorly by pushing the tongue up and back.⁴ In a minority of cases. anatomic, hormonal, and disease factors cause the ET to be remain open continuously (i.e. a patulous ET). This often leads to auditory complaints including autophony (hearing one's own breathing).

There are myriad etiologies of ETD and not all are understood in their entirety. Many mechanisms are easily understood. For example, the initiation of swelling, inflammation and/or drainage within the ET caused by entities such as viral URI, chronic sinusitis, and/or allergic rhinitis is a rather straightforward cause. Further, obstructive mechanisms such as adenoid hypertrophy, deviated nasal septum, or nasal polyposis are also well known. Less well appreciated, however, are other causes of ETD such as the decreased tubal function associated with tobacco smoke (decreased ciliary function), reflux disease (nasopharyngeal exposure to gastric contents), and congenital abnormalities (location/angle of tube, cleft palate, reduced mastoid air cell system).³ It is now felt that there are three subtypes of ETD: dilatory, barochallenge induced, and patulous.⁵

Any history of fullness or clogging of the ears, otalgia, hearing loss, tinnitus or dizziness should prompt an evaluation for ETD. A common complaint is that no amount of yawning, swallowing, chewing or attempted Valsalva maneuver alleviates the symptoms. Several methods are available to assess the function of the ET in the office. Otoscopic observation of tympanic membrane (TM) mobility caused by the Toynbee, Frenzel, Valsalva maneuvers and/or pneumatic otoscopy is good evidence of a functional/patent ET. Likewise, a normal tympanogram attests to the normal transmission of energy through the middle ear space.³ However, studies have not shown good correlation between a normal tympanogram and any predictive value for barotrauma.² The 7-Item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) was designed by McCoul et al. as a disease-specific instrument for the assessment of

symptoms related to obstructive dysfunction of ET.⁶ This validated questionnaire can be helpful in assessing the degree of ETD as well as treatment response. The limiting factor for all of these assessment tools; however, is that none of them assess ET function during the dynamic changes in atmospheric pressure experienced by aviators. However, the ETDQ-7 has shown to discriminate between patients with baro-challenge-induced ET dysfunction and healthy controls and may be helpful in the aeromedical community.⁷ Such complex function should be tested during simulated flights in a pressure chamber.¹ Even this assessment, however, short of expensive and invasive pressure manometer placement, is dependent upon the subjective report of the aviator. Seeking the best combination of cost, non-invasiveness and accurate surrogacy for the dynamic flight environment has led the USAF to select demonstration of a normal Valsalva maneuver and successful completion of a pressure chamber flight as criteria for pilot selection and training.¹ The main predictors of barotrauma continue to be a previous history of nasal or otologic disease and/or abnormal otoscopy.²

Treatment of ETD should be directed at the underlying etiology, if known, as well as any resultant complications.⁸ Review of the medical literature reveals no clear consensus on the efficacy of common treatment modalities for ETD.⁹ While there are studies showing promising results from treating inflammatory, congestive and allergic causes for ETD with the appropriate oral/topical decongestant, antihistamine or nasal steroid, there are also studies which do not duplicate such promising outcomes.¹⁰⁻¹³ Likewise, success rates following surgical correction for ETD have varied. Insertion of pressure equalization tubes (PET) has long been the mainstay of surgical treatment for ETD. However, several investigators have found that while the pressure differential between the middle ear and the external auditory canal may be immediately resolved, the function of the ET itself does not change following PET insertion. Other procedures such as adenoid resection and laser eustachian tuboplasty have also shown a mix of success and failure in treating ETD.³ Thus, regardless of whether medically or surgically treated, and regardless of specific etiology, the outcome of any treatment for ETD needs to be evaluated on a case by case basis to determine the presence of acceptable ET function. This is especially true in the aviator population.

Recently, balloon dilation of the cartilaginous ET (BDET) has shown encouraging results and was approved by the FDA for use in 2016. Published results have shown that BDET can effectively improve ET function in ears with ETD, OME or atelectasis.¹⁴⁻¹⁶ The procedure, which usually requires general anesthesia in the OR, is generally well tolerated and without significant complications. International studies on BDET demonstrated to be effective in 70% of a large cohort of patients affected by obstructive ET dysfunction.^{14, 15} In a prospective study with moderately long-term follow-up, it showed significant improvement in aeration of the middle ear and ability to perform a Valsalva maneuver. Patients with presumably irreversible disease, but having had their underlying etiology adequately managed, appear to be candidates for the procedure and it is now commonly performed in military treatment facilities by ENT surgeons/otologists.¹⁶

ETD and otitis media (OM), another common disorder of the middle ear, are closely related. Historically, the pathophysiology of OM has always been linked with abnormalities of ET function. As previously reviewed, the ET performs the three classic functions of aeration,

clearance, and protection of the middle ear. Traditional teaching has held that the ET function of aeration was limited and that this was the underlying cause of most acute otitis media (AOM). More recent investigation, however, has suggested that AOM is the result of bacterial entry into the middle ear (i.e., failure of protection). In either case, that there is a relationship between ETD and the development of OM is clear. Whether or not ETD precedes AOM, the finding of ETD in patients with AOM is nearly universal.¹⁷ While space here does not permit a separate treatise on OM and its many variants, the following five principles derived cooperatively by the Centers for Disease Control and the American Academy of Pediatrics should help to guide OM-related diagnosis and treatment decisions: 1) the diagnosis of OM should not be made unless fluid is present in the middle ear, 2) OM should be classified as AOM or otitis media with effusion (OME) on the basis of the presence or absence of signs and symptoms of acute illness, 3) in contrast to AOM, OME should not be treated with an antibiotic, 4) effusion is likely to persist after the treatment of AOM and does not require repeated treatment, and 5) antibiotic prophylaxis for AOM should be used only in accordance with strict criteria.¹⁸

For questions regarding the complication of cholesteatoma, please refer to the waiver guide on that topic.

#### **IV. Aeromedical Concerns.**

ETD may result in the failure to equilibrate middle ear pressures and lead to pain, impairment of hearing, and vertigo, with or without rupture of the tympanic membrane, resulting in compromised aircraft safety if a member of the crew is incapacitated in this way.¹ ETD may only be minimally symptomatic at ground level. However, such tubal dysfunction can block the flow of air in and out of the middle ear space. In the presence of ETD, dynamic perturbations of atmospheric pressure may result in acute barotrauma, resulting in sudden, incapacitating pain. Should such an event occur immediately prior to or during landing procedures, it could lead to sudden incapacitation and an aircraft mishap. Treatment should consist of returning to altitude to allow slower equilibration of the middle ear, the use of oxymetazoline nasal spray (Afrin®), and if the block persists on landing, the use of a Politzer bag to assist in ventilating the middle ear. Aviators need to take caution with the use of such nasal sprays. Overuse can lead to inhibition of normal smooth muscular tonality of the vascular nasal mucosa, leading to rhinitis medicamentosa, which results in mucosal swelling and secretions; the exact opposite of the desired outcome.

There is no quick test to ensure the ET is patent prior to flight; but, being free of sinonasal and URI symptoms and being able to Valsalva and prior successful completion of altitude chamber training are a close approximation. Further, any middle ear disturbance (e.g. ETD or OM) raises concern for decreased and/or loss of hearing, disequilibrium, and the development of more extensive disease.

There are some concerns about the chronic use of PE tubes in aviators. Most patients requiring prolonged PE tubes will end up with a large central perforation which tends to remain as long as the ear is not being ventilated. Also, the PE tubes can fail. They get plugged, extrude, cause granulation tissue which then causes bleeding and infection, and can cause perforations of the

TM. They can also act as a conduit for fluids getting in the middle ear especially soapy fluids with low surface tensions that then can cause a chemical irritation of the middle ear and subsequent otorrhea/infection. The other challenge is that it sometimes takes a microscope and other specialized otologic instrumentation to accurately evaluate and mediate PE tube problems, so a deployed FS evaluating with an otoscope may not be able to discern what is happening with the tube or TM.

ICD-9 codes for Eustachian Tube Dysfunction and Otitis Media				
381.5	Eustachian salpingitis			
381.6	Obstruction of the Eustachian tube			
381.7	Patulous Eustachian tube			
381.8	Other disorders of the Eustachian tube			
381.9	Unspecified Eustachian tube disorder			

ICD-10 codes for Eustachian Tube Dysfunction and Otitis Media				
H68.00	Unspecified Eustachian salpingitis, right ear, left, bilateral, unspecified			
1, 2, 3, 9	ear			
H68.10	Unspecified obstruction of the Eustachian tube, right ear, left, bilateral,			
1, 2, 3, 9	unspecified ear			
H69.0	Patulous Eustachian tube, unspecified ear, right, left, bilateral			
0, 1, 2, 3				
H69.8	Other specified disorders of the Eustachian tube, unspecified ear, right,			
0, 1, 2, 3	left, bilateral			
H69.9	Unspecified Eustachian tube disorder, unspecified ear, right, left,			
0, 1, 2, 3	bilateral			

#### V. References.

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3. Seibert JW, and Danner CJ. Eustachian Tube Function and the Middle Ear. Otolaryngol Clin N Am, 2006; 39: 1221-35.

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# Hearing Loss, Asymmetric Hearing Loss, and Use of Hearing Aid(s)

Revised: Mar 2022 Reviewed: Dr. Max Lee (ACS Waiver Guide Coordinator), Lt Col Brandon Tourtillott (AF/SG Audiology consultant)

Significant Changes:

Updated references

# I. Waiver Consideration

Hearing loss that precludes safe, effective performance of duty despite use of hearing aid(s) (i.e. H-4) is disqualifying for all flying and special duty personnel, as well as retention. Use of a hearing aid is disqualifying but may be waiverable for FC I/IA, II, III, ATC, GBO, and SWA duties. Initial applicants for FC I/IA, II, III, ATC, and SWA must be H-1 for selection; initial applicants for GBO and OSF personnel require H-2 or better hearing threshold. Trained FC II, FC III, ATC, GBO, and SWA with H-2 hearing threshold require evaluation for conductive or retrocochlear pathology (includes comprehensive audiologic evaluation and potential otolaryngology evaluation). Restriction from flying duties are not required during this work-up. No waiver is required for H-2 hearing threshold for trained personnel unless indicated by audiology and/or otolaryngology findings. All trained flyers and special duty personnel with H-3 profiles or asymmetric hearing loss are disqualified and require aeromedical waiver. Table 1 outlines the definition for H-1, H-2, H-3, and H-4 hearing. Hearing profiles are based on an unaided audiogram (no hearing aids) and removal from hazardous noise for at least 14 hours.

	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz
H-1 Profile If no single value exceeds (dB)	25	25	25	35	45	45
H-2 Profile If no single value exceeds (dB)	35	35	35	45	55	
H-3 Profile	Any hearing loss exceeding at least one value for H-2 profile, but does not qualify for H-4.					
H-4 Profile	Hearing loss sufficient to preclude safe and effective performance of duty, regardless of level of pure tone hearing loss, and despite use of hearing aids.					
*Hearing Proficiency Validation	Written validation of ability to safely perform all assigned aircrew duties in flying environment signed by flying SQ/CC or Operations Officer, <i>supplemented by</i> the flight surgeon's written memo for record stating that Speech Recognition Levels (from the audiology report) are adequate to perform flying duties (>70%).					
Asymmetry	25 d di erence c mparin le t and ri t ear at an t c nsecuti e frequencies. ¹					

#### Table 1: Hearing profile standards and asymmetry definition.

1. Asymmetry at 3000 Hz is considered by recent studies to be an important predictor of retrocochlear pathology.

Waivers are valid for no greater than three years or until a shift of 10 dB or greater on the average of 2,000, 3,000 and 4,000 Hz in either ear from the previous waiver's audiogram, whichever occurs first. Indefinites hearing waivers will not be granted. If the cause of the hearing loss is secondary to acoustic neuroma, cholesteatoma, eustachian tube dysfunction, otosclerosis, or a peripheral vertiginous disorder, refer to the respective waiver guides.

Flying Class	Hearing Loss	Waiver Potential Waiver	ACS Review/ Evaluation ⁷	
		Authority		
I/IA	H-1 with asymmetry	Yes AFRS/CMO	No	
	H-2 with or without asymmetry	Maybe ¹ AFRS/CMO	No	
	H-3/H-4 with or without asymmetry	No AFRS/CMO	No	
	Hearing aids	No AFRS/CMO	No	
II/III ATC/GBO SWA	Н-2	Initial/untrained – Maybe ² Trained – N/A ³ MAJCOM	As Above	
	Н-3	Initial/untrained – No Trained – Maybe ⁴ MAJCOM	As Above	
	H-4	No MAJCOM		
	Asymmetry	Initial/untrained – Maybe ⁵ Trained – Maybe MAJCOM	As Above	
	Hearing aids	Initial/untrained – No Trained – Maybe ⁶ MAJCOM	As Above	

Table 2: Degree of hearing loss and waiver potential.

1. Waiver for FC I/IA may be considered if H-2 due to one frequency in one ear.

2. Waiver for initial/untrained FC II and III may be considered if H-2 due to one frequency in one ear. H-2 is qualifying for GBO applicants.

3. For trained FC II, FC III, GBO, ATC, and SWA, no waiver or grounding required but must have comprehensive audiologic work-up.

4. For inactive flyers, hearing proficiency validation/waiver may be delayed; FC IIC or modified FC III waivers may be granted by the waiver authority (must have hearing proficiency validation, inflight test or letter from SQ/CC or DO, before flying).

5. Waiver for initial/untrained FC II and III with H-2 may be considered if H-2 due to one frequency in one ear; no waiver for initial/untrained FC II and III with H-3.

6. If flyer has H-3 and does not wear hearing aids performing flying duties, they must pass hearing proficiency validation without hearing aids.

7. Review by ACS is not required, but may be requested on a case-by-case basis by the waiver authority.

Note: No indefinite waivers will be granted for asymmetric hearing loss or H-3; maximum duration of waiver is 3 years.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial/Renewal Waiver Request:

- 1. Summary of presentation, course, and treatment. Include history related to hearing loss (including noise exposure history). If hearing aids are used, include if worn while flying and address the ability to wear hearing protection.
- 2. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated), including baseline and latest audiograms.
- 3. Any consultation reports, including follow-up notes with examination findings after disease resolution. Include documentation of complete and current, within 12 months of waiver submission, audiology evaluation. Consider otolaryngology evaluation if there is any concern for conductive or retrocochlear disease.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 5. Validation of hearing proficiency for H-3 waivers (initial waivers and waiver renewals with a shift of 10 dB or greater on the average for 2,000, 3,000 and 4,000 Hz from the previous waiver's audiogram).
  - a. In-flight hearing test available at <u>https://apps.dtic.mil/sti/pdfs/AD0767586.pdf</u> or,
  - b. Written validation of ability to safely perform all assigned aircrew duties in flying environment signed by flying SQ/CC or Operations Officer, supplemented by the flight surgeon's written MFR stating that Speech Discrimination Levels (from the audiology rep rt are ade uate t per rm 1 in duties
- 6. If the local base is not able to provide any of the above listed information, they should document why, explaining reasoning to the waiver authority.

# III. Aeromedical Concerns

It is essential that aviators have hearing adequate to recognize and understand verbal communications and warning tones. This includes adequate binaural hearing in aircraft with warning tones presented specifically to the left or right sides. Significant tinnitus associated with hearing loss may interfere with communications as well as sleep. Hearing loss can be an early symptom of other medical problems, for example, a vestibular schwannoma which could directly affect vestibular function and flight safety. Lastly, aviators with noise induced hearing loss will likely experience some degree of worsening hearing loss secondary to continued noise exposure.

If the design of the hearing aid allows the proper fit of hearing protection devices, and are programmed appropriately to minimize feedback, hearing aids may be worn during flight. It is important to emphasize that hearing aids are not a substitute for hearing protection. Lack of proper hearing protection in hazardous noise places an individual at risk for increased hearing loss. In noisy environments where double hearing protection is required, hearing aids are not allowed. Cochlear implants or implantable amplification devices are not allowed in any

hazardous noise environment and thus not allowed in aviators. Hearing aid battery life varies, with the shortest being about 4 days; due to the potential disruption incurred related to changing batteries during flying and special missions duties, hearing aid batteries should be changed prior to flying if hearing aids are worn while performing aircrew duties.

Individuals with otosclerosis or other causes of conductive hearing loss may have a paradoxical improvement in hearing in a noisy environment. This is due to a phenomenon called the Paracusis of Willis where the low frequency background noise is sometimes filtered and allows the individual to perceive communications better in the higher frequency range. In this unique situation, hearing aids may be used on the ground but not recommended or needed in flight.

Review of AIMWTS from Apr 2019 through Mar 2022 revealed 935 waivers for H-2 or greater hearing loss. There were 58 FC I/IA cases (13 disqualified), 398 FC II cases (1 disqualified), 328 FC III cases (28 disqualified), 49 GBO cases (4 disqualified), 33 ATC/GBC cases (4 disqualified), 49 GBO/MOD cases (4 disqualified), and 69 SWA cases (6 disqualified). Of the 56 disqualified cases, 22 had other aeromedically significant conditions that resulted in aeromedical disqualification.

ICD-10 Codes for Hearing Loss and Hearing Aids				
H90.0, H90.2	Conductive hearing loss, bilateral, unspecified			
H90.3, H90.5	Sensorineural hearing loss, bilateral, unspecified			
H90.6, H90.8	Mixed conductive and sensorineural hearing loss, bilateral,			
	unspecified			
Z97.4	Presence of external hearing-aid			

## **IV. Suggested Readings**

- 1. Weber PC. Evaluation of hearing loss in adults. UpToDate. Jan 19, 2021. Accessed Mar 2, 2022. https://www.uptodate.com/contents/evaluation-of-hearing-loss-inadults?search=evaluation%20of%20hearing%20loss%20in%20adults&source=search_result&selectedTitle=1~15 0&usage_type=default&display_rank=1
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# **Motion Sickness**

Revised: Sep 2022 Reviewed: Lt Col Jeffrey Harris (RAM 22), Dr. Max Lee (ACS Waiver Guide coordinator), Lt Col James Davis (USAF physiologist), and Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

# **Significant Changes:**

Updates in accordance with DAFMAN 48-123 (8 Dec 20), AFMAN 11-402 (24 Jan 19), AETCI 36-2605V1 (17 Sep 19), and AETCI 48-102 (7 Mar 19), new format for previous waiver dispositions

# I. Waiver Consideration

Motion sickness experienced in aircraft, automobiles, or watercraft after the age of 12 with any significant frequency in applicants for undergraduate pilot training (UPT), undergraduate navigator training (UNT) (FC I/IA), and Special Warfare training requires a waiver. Any history of motion sickness occurring before age 12 does not specifically require a waiver, but does require exploration. A thorough history of motion sickness should be discussed in the aeromedical summary. Airsickness is *not* disqualifying for FC II or FC III personnel, unless there is medical evidence of organic or psychiatric pathology.

UPT (FC I), UNT (FC IA), and non-rated aircrew (FC III) trainees and who have intractable airsickness after completing, or attempting to complete, the Airsickness Management Program are handled administratively in accordance with AFMAN 11-402 because they are unable to meet syllabus requirements and/or demonstrated "lack of adaptability" to the flying environment. Prior to administrative actions, these cases should be evaluated by an experienced aeromedical provider to rule out an organic or psychiatric etiology. Trained aircrew who remain symptomatic after repeated exposures to the flying environment and fail desensitization training are dispositioned through a Flying Evaluation Board (FEB).

Airsickness requiring pharmacologic therapy beyond the Airsickness Management Program is disqualifying.

Flying Class (FC)	Disease/Condition	Waiver Authority Waiver Potential	ACS Review/ Evaluation
	History of Motion Sickness age >12 yrs ¹	AFRS/CMO Maybe	No
IFC I/IA, SWA (initial)	Airsickness/Motion Sickness during UPT/UNT/Special Warfare training	MAJCOM Maybe	No
FC II, III, SWA (trained)	Airsickness with medical evidence of organic or psychiatric pathology ²	MAJCOM Maybe	Maybe
	History of Motion Sickness	N/A	N/A
ATC, GBO	Simulator/Motion Sickness during training	N/A	N/A
	Simulator/Motion Sickness with evidence of an organic or psychiatric pathology	N/A	N/A

Table 1: Waiver potential for Motion Sickness

1. History of motion sickness before the age of 12 that has resolved does not require a waiver, but should be completely explored.

2. There is no specific MSD disqualification requirement for FC II and III without organic or psychiatric pathology, however an AMS may be submitted for MAJCOM review on a case-by-case basis.

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

### A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. Childhood and adolescent history of any type of motion sickness.
  - b. History of vestibular disorders.
  - c. Motion sickness risk factors.
  - d. Treatments/medications attempted with results.
    - e. How symptoms affect mission and/or training.
- 2. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 3. If vision was involved, Optometry or Ophthalmology consultation, to include all tests.
- 4. If concerns for anxiety manifestations or motivation, include Mental Health consultation.
- 5. Current physical examination findings (specific focus on CNS and ENT exams)
- 6. Any other pertinent information.
  - a. Include notes and results from all Airsickness Management Program training.
  - b. Include a statement from the aerospace physiologist regarding training and conditioning.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Motion sickness is a common, even normal, physiologic response by an unadapted individual to unfamiliar movement with significant variation in susceptibility by individuals. The term 'motion sickness' includes airsickness, seasickness, car sickness, simulator sickness, space motion sickness, as well as other related entities. It is not typically considered a medical disorder and can be induced in anyone with an intact vestibular system given the right type and duration of provocative stimuli. The effects of motion sickness range from subtle performance deficit and distraction to incapacitation. Motion sickness is thought to occur as a result of conflicting inputs to the brain from visual, vestibular, proprioceptive, and rarely, auditory systems. The terms "airsickness" and "motion sickness" are used interchangeably in this waiver guide.

It is possible to experience characteristic symptoms in the absence of motion, as in the case of "simulator-sickness," "virtual-reality- sickness," or "visually induced motion sickness" (VIMS). While there is no MSD disqualification for a GBO with motion sickness, an individual could theoretically be ineffective at their job due symptoms of VIMS. In such cases, the flight surgeon should apply aeromedical judgment in the context of personnel and mission safety when determining aeromedical risk not specifically addressed in the MSD.

The USAF has defined two types of airsickness: active and passive. Passive airsickness can include pallor, cold sweats, dizziness, headaches, belching, nausea, apprehension, hyperventilation, lightheadedness, drowsiness, apathy, and sopite syndrome. Active airsickness progresses to retching and vomiting. The affected individual may become distracted even by passive symptoms, leading to a decreased situational awareness and performance degradation. Some individuals may experience significant improvement after vomiting, while others may continue to experience symptoms, including lethargy, fatigue, and drowsiness, long after the motion has stopped. Motion sickness is most commonly encountered among personnel early on in flight training, although it may still occur in more experienced aircrew, especially when switching aircraft types, or when returning to flying after an extended period of non-flying. It is thought that adaption is almost completely retained for 1 month and partially retained for 1 year.

Prevention education and early intervention through the Airsickness Management Program have proven to be effective in helping aviator students to overcome motion sickness. The role for pharmacologic intervention is limited in flyers, and may only be utilized early on in pilot training with coordination between the Flight Surgeon and the Aerospace Physiologists per Airsickness Management Program guidelines. Medication usage is not approved for solo flight, or within 5 sorties of solo flight.

Approved medications, used as part of the Airsickness Management Program, can be found in the Aircrew Med List on the KX and are not approved for use in trained aviation personnel. Medication use, efficacy, and side effects should be documented clearly in the medical record and in the Airsickness Management Program reporting tools with the final outcome of each case documented and tracked for annual reporting to AETC/SGP. For more information about the AMP and medication usage, reference AETCI 48-102. Bases without physiology support may request assistance in identifying resources from their MAJCOM/SGP.

It is important to consider the aeromedical and safety concerns related to airsickness, as the effects can range from mild distraction to near-incapacitation. The corresponding degradation of situational awareness and performance is incompatible with flying duties. Most affected aircrew will adapt with repeated exposures to the flying environment, so it is important to keep flying them as often as possible, while doing so in a safe manner (e.g. with an IP). Trained aircrew who experience their first episode of airsickness should be evaluated by the aeromedical provider to rule out an organic or psychiatric etiology. If no such etiology is found, the affected individual should be enrolled in the Airsickness Management Program at the local base prior to determining a final aeromedical disposition.

AIMWTS search for Motion Sickness waivers within the past 5 years found 65 total waiver cases with a diagnosis of motion sickness. Majority of cases not waived were due to other disqualifying diagnoses also in the waiver package, or a DQ recommendation by the local flight surgeon for ARMA-UNSAT. Only a few DQs were truly due to severely debilitating motion sickness unresponsive to therapy.

ICD-10 code for Motion Sickness		(# of waivers / total # of cases)				
		IFC I/IA FC II FC III OSF S			SWA	
T75.3XXA	Motion sickness, initial encounter					
T75.3XXD Motion sickness,		17/21	4/5	6/30	2/2	5/7
T75.3XXS	Motion sickness, sequelae					

### **IV. Suggested Readings**

1. Parmet AJ and Ercoline WR. Spatial Orientation in Flight. Ch. 6 in *Fundamentals of Aerospace Medicine*, 4th ed. Williams and Wilkins, Philadelphia, 2008: 195-203.

2. Murdin L, Golding J, and Bronstein A. Managing Motion Sickness. BMJ, 2011; 343: 1213-17. https://www.bmj.com/content/343/bmj.d7430.long

3. Shupak A and Gordon CR. Motion Sickness: Advances in Pathogenesis, Prediction, Prevention, and Treatment. Aviat Space Environ Med, 2006; 77: 1213-23.

4. Hu S and Stern RM. The Retention of Adaptation to Motion Sickness Eliciting Stimulation. Aviat Space Environ Med, 1999; 70(8): 766–68.

5. Zhang LL, Wang JQ, Qi RR, Pan LL, Li M, Cai YL. Motion Sickness: Current Knowledge and Recent Advance. CNS Neurosci Ther. 2016 Jan;22(1):15-24. doi: 10.1111/cns.12468. Epub 2015 Oct 9. PMID: 26452639; PMCID: PMC6492910. <u>https://onlinelibrary.wiley.com/doi/epdf/10.1111/cns.12468</u>

6. AETC Instruction 36-2605, Vol 1, *Formal Flying Training Administration and Management*, Ch 3.4, 17 Sep 2019. <u>https://static.e-publishing.af.mil/production/1/aetc/publication/aetci36-2605v1/aetci36-2605v1.pdf</u>

7. AETC Instruction 48-102, *Medical Management of Undergraduate Flying Training Students*, Ch 15, 7 Mar 2019. <u>https://static.e-publishing.af.mil/production/1/aetc/publication/aetci48-102/aetci48-102.pdf</u>

8. AETC Instruction 36-2605, Vol 1, Formal Flying Training Administration and Management, Chapter 3.3, 16 Feb 2016.

9. AETC Instruction 48-102, *Medical Management of Undergraduate Flying Training Students*, Chapter 15, 7 Mar 2019.





# **Otosclerosis/Stapedectomy**

Revised: Sep 2022

Reviewed: Dr. Max Lee (ACS Waiver Guide Coordinator), Lt Col Brent Feldt (AF/SG Otolaryngology Consultant), and Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

**Significant Changes:** Minor revisions and updated references with hyperlinks, new format for previous waiver dispositions

# I. Waiver Consideration

Otosclerosis is an ankylosis involving the stapes footplate and the surrounding bone of the inner ear. Otosclerosis is addressed in the MSD and is disqualifying for all flying and special operations duties when it interferes with normal hearing. Any surgical procedures in the middle ear, including stapedectomy, are disqualifying for FC I/IA, II, III, OSF, and SWA duties.

There are various medical and surgical treatments that may be considered to address the condition. The most common surgical procedures are a total or partial stapedectomy, or stapedotomy. In addition to meeting the hearing standards, an ACS review is recommended for operators in single seat and high performance aircraft following stapes surgery.

Flying Class (FC)	Waiver Potential ¹ Waiver Authority	ACS Review/Evaluation
I/IA	Yes AFRS/CMO	ACS review necessary if stapes surgery performed
II/III/SWA	Yes MAJCOM	ACS review necessary if stapes surgery performed ²
ATC/GBO	Yes MAJCOM	No

### Table 1: Waiver potential for Otosclerosis/Stapedectomy

1. No indefinite waivers.

2. Single seat high performance aircrew only.

# II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should be submitted after diagnostic evaluation has been completed and appropriate treatments have been initiated using best current clinical guidelines and recommendations.

# A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment for all clinical diagnoses.
- 2. Complete history to include all hearing and vertiginous symptoms along with impact on activities of daily living and aviation duties. Discuss all attempted treatments (e.g. hearing aids).
- 3. Otolaryngologist and audiologist consultation reports, including follow-up notes with examination findings after disease resolution.

- 4. Complete audiologic exam to include:
  - a. Air conduction threshold measurement;
  - b. Bone conduction threshold measurement (if indicated);
  - c. Speech reception threshold;
  - d. Speech discrimination testing;
  - e. Acoustic impedance testing; and
  - f. Electronystagmography if clinically indicated.
- 5. All surgical reports to include:
  - a. Details of technique used;
  - b. Type of prosthesis; and
  - c. Type of graft used.
- 6. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 7. Any other pertinent information.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### B. Renewal Waiver Request:

- 1. If any abnormalities surface in the interim, they will need to be addressed appropriately.
- 2. Interim history to include any change in hearing, any side effects such as vertiginous symptoms, and any operational issues.
- 3. Exam: Otolaryngology and audiology evaluations.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

## **III. Aeromedical Concerns**

The chief aeromedical concerns of otosclerosis relate to progressive hearing loss. In addition, otosclerosis may result in vestibular symptoms significant enough to impact flight safety.

Most aviators with otosclerosis will present with a chief complaint of hearing loss as the pathologic process affects the speech range frequencies. Although it is important to consider the impact of Paracusis of Willis, an improved perception of speech in a noisy environment, hearing loss will eventually impair communication leading those affected to seek surgical or audiometric remediation. Corrective surgery is highly successful in restoring the aviator's auditory acuity. However, there are post-operative risks, which although rare, include; injury to the facial nerve, inner or middle ear infection, meningitis, disturbances of equilibrium, conductive hearing loss, persistent perforation of the tympanic membrane, and perilymphatic fistula; each of which may prevent the proper use of safety equipment or cause incapacitation through loss of hearing or decreased situational awareness.

Previously, medical waivers post-stapedectomy were rarely recommended. Fortunately, the majority of known complications of stapes surgery become evident within the first one or two months following the procedure. Only disturbances in equilibrium and delayed sudden hearing loss are believed to present beyond the first few weeks, although there are reports of chronic perilymphatic fistulas. Perilymphatic fistula is the most serious long-term complication for

aviators due to the potential for vertigo as the cabin or ambient barometric pressures can rapidly change with military aviation, jump, and dive duties. On account of extensive post-operative data and altitude chamber experience, there is consensus that after an appropriate waiting period to rule out immediate post-operative complications, return to flying status after stapedectomy can meet aeromedical risk tolerance.

AIMWTS search for otosclerosis, stapedectomy, or stapedotomy from Jan 2018 – Jul 2022 revealed 20 adjudicated cases. The breakdown of the number of waivers and number of total cases are tabulated below.

ICD 10 Codes for Otosclerosis and Stapedectomy		(# of waivers / total # of cases)				
		IFC I/IA	FC II	FC III	OSF	SWA
H80.83	Other otosclerosis, bilateral					
H80.93	Unspecified otosclerosis, bilateral				- 1-	
19.1	Stapedectomy	0	12/12	4/4	2/2	1/2
19.19	Other stapedectomy					
19.9	Stapedotomy					

## **IV. Suggested Readings**

1. American Academy of Otolaryngology. Position Statement: Management of Otosclerosis. 2014 July. <u>https://www.entnet.org/resource/position-statement-management-of-otosclerosis/</u>

2. Cureoglu S, Schachern PA, Ferlito A, et al. Otosclerosis: Etiopathogenesis and histopathology. Am J Otolaryngol, 2006 Sep-Oct; 27(5): 334-40. https://www.sciencedirect.com/science/article/pii/S0196070905002176?via%3Dihub

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4. Rudic M, Keogh I, Wagner R, et al. The pathophysiology of otosclerosis: Review of current research. Hear Res. 2015 Dec; 330(Pt A): 51-6. <u>https://www.sciencedirect.com/science/article/pii/S0378595515001549?via%3Dihub</u>

### Vertiginous Disorders, Peripheral (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

# Significant Changes:

Updated Table 1 and References

## I. Waiver Consideration

Air Force aviators with vertigo of any etiology are disqualified for all flying classes, and need to be carefully evaluated before waiver consideration. For waiver consideration, all symptoms must have resolved, with sufficiently normal remaining vestibular function that would not cause clinical disability. Vestibular neuronitis is the only major form of peripheral vertigo to have a minimal risk of recurrence, and is the only form of peripheral vertigo for which FC I and unrestricted FC II waivers may be recommended. The likelihood of recurrence of benign paroxysmal positional vertigo is unacceptably high and precludes aeromedical waiver consideration except in cases with prolonged remission. Ménière's disease has unpredictable and recurrent symptoms with potential for sudden incapacitation, which also precludes aeromedical waiver consideration except in cases with prolonged remission. Superior semicircular canal dehiscence cases, if confirmed by temporal bone CT imaging and resolved with definitive treatment, may then be considered for aeromedical waiver. Aviators with unexplained vertigo, dizziness or disequilibrium symptoms without a definitive diagnosis are generally not recommended for aeromedical waiver due to inability to assess or predict future recurrence risk.

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	Yes ¹	AETC	No
FC II/III/SWA	Yes ²	MAJCOM/AFMRA	Yes
ATC/GBO	Yes	MAJCOM	At discretion of waiver authority

Table 1: Waiver	potential for	peripheral	vertiginous	disorders
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1. IFC I/IA waiver recommended only for cases of resolved vestibular neuronitis

2. Multi-place aircraft waiver generally recommended in cases of Ménière's disease with prolonged remission.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

## A. Initial Waiver Request:

1. Careful history describing: frequency, duration, severity and character of vertiginous attacks; type of maneuvers that provoke symptoms; presence or absence of associated symptoms such as hearing loss, aural fullness, tinnitus, headaches, or focal neurologic symptoms. Also note any past history of syphilis, mumps or other serious infections, inflammation of the eye, autoimmune disorder or allergy, and ear surgery.

- 2. Otolaryngology consultation notes. For complex or undiagnosed cases, strongly consider obtaining formal Neuro-Otology consultation through SAMMC or an academic medical center.
- 3. Audiogram results, to include speech discrimination, tympanometry and acoustic reflexes.
- 4. Vestibular function testing results, which may include electronystagmography (ENG, VNG and calorics), vestibular evoked myogenic potentials (VEMP), computerized dynamic posturography (CDP), and rotary chair testing.
- 5. Laboratory testing results, which may include CBC, ESR, TFTs, lipids, glucose and syphilis serology.
- 6. Pre/post-contrast MRI of the brain and internal auditory canal (IAC) to rule out retrocochlear pathology such as cerebello-pontine angle (CPA) tumors, multiple sclerosis, anatomical variants, etc. Send report and images for review and reference. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without requiring administrative privileges.
- 7. Current physical, ENT and neurologic examination findings. Include assessment for nystagmus, balance, and results of Dix-Hallpike testing.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

### B. Renewal Waiver Request:

- 1. Interval history and level of symptom resolution.
- 2. Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without requiring administrative privileges.
- 3. Current physical, ENT and neurologic examination findings. Include assessment for nystagmus, balance, and results of Dix-Hallpike testing.
- 4. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include the effects of any residual symptoms on operational safety and mission effectiveness, future risk of new symptom development, and future risk of recurrence. The threat posed by ongoing vertigo in the flying environment is self-evident. Since all vertigo is potentially incapacitating (albeit to varying degrees), whether a syndrome is likely to recur or not following apparent resolution of symptoms is the key to whether an aeromedical waiver may be considered. Vestibular neuronitis is the only major form of peripheral vertigo to have a minimal risk of recurrence. The likelihood of recurrence of Benign Paroxysmal Positional Vertigo (15-18% in the first year, with a cumulative recurrence rate of 50% in five years) precludes aeromedical waiver consideration unless prolonged remission occurs. Even in cases with prolonged remission, categorical multi-place aircraft waiver is recommended. Ménière's disease has unpredictable and recurrent symptoms with potential for sudden incapacitation, and few reliable, aeromedically-compatible treatment options. Aeromedical waiver would therefore be recommended only under exceptional circumstances, such as cases with prolonged remission. Superior semicircular canal dehiscence produces symptoms evoked by loud noises or pressure-changing maneuvers such as

coughing, straining or sneezing. If confirmed by temporal bone CT imaging, definitive treatment is possible by surgical resurfacing or plugging the superior semicircular canal. Migrainous vertigo may respond to migraine medications and be potentially waiverable. Cases of unexplained vertigo, dizziness or disequilibrium with no definitive diagnosis are generally not recommended for aeromedical waiver due to inability to accurately assess future recurrence risk.

AIMWITS search in Jan 2019 revealed a total of 250 aviators with the diagnosis of vertigo. A total of 96 were disqualified. Breakdown of the cases revealed: 9 FC I/IA cases (5 disqualified), 135 FC II cases (36 disqualified), 5 RPA pilot cases (2 disqualified), 71 FC III cases (38 disqualified), 25 ATC/GBC cases (12 disqualified), and 5 MOD cases (3 disqualified). The diagnosis of vertigo was a factor is all 96 disqualified cases.

ICD-9 codes f	ICD-9 codes for peripheral vertiginous disorders				
386.0	Ménière's Disease				
386.10	Peripheral vertigo, unspecified				
386.11	Benign paroxysmal positional vertigo				
386.12	Vestibular neuronitis				
386.19	Other peripheral vertigo				
386.30	Labyrinthitis				
386.8	Superior Semicircular Canal Dehiscence				

ICD-10 cod	es for peripheral vertiginous disorders
H81.4	Vertigo of central origin
1, 2, 3, 9	
H81.0	Ménière's Disease
1, 2, 3, 9	
H81.39	Other peripheral vertigo
1, 2, 3, 9	
H81.13	Benign paroxysmal positional vertigo
1, 2, 3, 9	
H81.2	Vestibular neuronitis
1, 2, 3, 9	
H81.31	Aural vertigo, unspecified ear
1, 2, 3, 9	
H83.0	Labyrinthitis
1, 2, 3, 9	
H83.1	Labyrinthine fistula
1, 2, 3, 9	
H83.8X9	Superior Semicircular Canal Dehiscence

### **IV. Suggested Readings**

- 1. Moskowitz HS and Dinces EA. Ménière's disease. UpToDate, Oct 2, 2019.
- 2. Robertson CE and Eggers SDZ. Vestibular migraine. UpToDate, Dec 12, 2018.

3. Fife TD. Dizziness in the outpatient care setting. Continuum (Minneap Minn) 2017; 23(2):359-395.

4. Furman JM. Causes of vertigo. UpToDate, Aug 24, 2018.

5. Barton JSS. Benign paroxysmal positional vertigo. UpToDate, Dec 17, 2018.

6. Furman JM and Barton JSS. Evaluation of the patient with vertigo. UpToDate, Feb 11, 2020.

7. Ropper AH, Samuels MA, Klein JP (Ed). Dizziness, deafness and disorders of equilibrium. *Adams and Victor's Principles of Neurology*, Tenth Edition, McGraw-Hill Education, 2014:290-316.

8. Branch WT and Barton JJS. Approach to the patient with dizziness. UpToDate, Feb 11, 2020.

9. Furman JM. Vestibular neuronitis and labyrinthitis. UpToDate, Jul 18, 2018.

10. Packer MD and Welling DB. Surgery of the Endolymphatic Sac. Ch. 34 in *Otologic Surgery*, 3rd edition. Elsevier Inc., Editors Derald Brackmann, Clough Shelton, Moises Arriaga, 2010.





# Sinusitis (Rhinosinusitis), Hypertrophic Sinus Tissue, and Nasal Polyps

Revised: Oct 2022

Reviewed: Col David Gregory (RAM), Dr. Max Lee (ACS Waiver Guide Coordinator), Lt Col Brent Feldt (AF/SG Otolaryngology Consultant), and Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

**Significant Changes:** Clarification of altitude chamber assessment, updated references, Table 1 clarified for initial training vs trained servicemembers, new format for previous waiver dispositions, for waiver submittal documentation either sinus ostia visualization or CT showing sinus ostia patency is acceptable

# I. Waiver Consideration

Episodes of acute viral or bacterial rhinosinusitis requires no waiver but is grounding for flyers until symptom resolution. However, chronic sinusitis resulting in chronic and/or recurrent clinical symptoms or need for surgical intervention is disqualifying for FC I/IA, II, III, and OSF duties. Nasal polyps that result in symptoms which are incompatible with flight or altitude chamber duties are disqualifying for FC I/IA, FC II, FC III, OSF, and SWA duties. In addition, any surgical procedure for sinusitis, polyposis, or hyperplastic tissue is disqualifying for FC I/IA duties. For ATC and GBO, rhinosinusitis and nasal polyps warrant retention consideration if they interfere with daily work duties/military activities or require ongoing otolaryngology follow-up more than annually.

Flying Class (FC)	Condition	Waiver Potential	ACS Review/
I/IA and II/III/SWA	Nasal polyps controlled with nasal steroids and/or approved	Waiver Authority Yes ¹ AFRS/CMO	Evaluation ⁴ No
(untrained)	oral antihistamines.		
	Chronic sinusitis controlled with nasal steroids and/or approved oral antihistamines.	Maybe ¹ AFRS/CMO	No
	Chronic sinusitis, nasal polyps	Maybe ^{2, 3} AFRS/CMO	No
II/III/SWA (trained)	Nasal polyps controlled with or without nasal steroids and/or approved oral antihistamines.	Yes MAJCOM	No
	Chronic sinusitis controlled with nasal steroids and/or approved oral antihistamines.	Yes ³ MAJCOM	No
	Chronic sinusitis, nasal polyps	Yes ³ MAJCOM	No
ATC/GBO	N/A	N/A	N/A

Table 1: Waiver potential for chronic sinusitis, nasal polyps and/or surgery for same

1. Waiver in any untrained candidate should have at least 12 months of symptoms controlled on medication before waiver consideration.

2. Waiver may be considered if at least 12 months after surgery and symptoms entirely resolved.

3. Altitude chamber evaluation at 8,000 -10,000 ft with rapid decompression is strongly recommended for aircrew in high-performance aircraft. If treated with surgery, altitude chamber ride no earlier than 6 weeks after surgery or when cleared by otolaryngology physician (whichever is later). See Section III.

4. ACS review not required, but can be requested on a case-by-case basis.

## **II. Information Required for Waiver Submittal**

Submit the aeromedical summary (AMS) after the clinical disposition is finalized and the servicemember is stable on appropriate treatments following the best current clinical guidelines and recommendations.

### A. Initial Waiver Request:

- 1. Information to include in history:
  - a. Complete history of symptoms, to include flying and on the ground, with duration, frequency, exacerbating factors, and treatment.
- 2. Otolaryngology consultation and operative reports from all treating providers.
- 3. Current physical examination findings, specifically HEENT documentation of sinus ostia <u>or</u> CT scan of the sinuses with documentation reflecting status of sinus ostia patency.

Sinusitis (Rhinosinusitis), Hypertrophic Sinus Tissue, and Nasal Polyps

- 4. Altitude chamber assessment for aircrews in high performance aircraft. (For aircrew in non-high performance aircraft, report functional assessment in a non-high performance or commercial pressurized aircraft.)
- 5. Form FL4 with return to duty and ALC status, if applicable.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

- B. Renewal Waiver Request:
  - 1. Updated AMS with interval history.
  - 2. Current physical examination findings, specifically HEENT.
  - 3. Otolaryngology and/or allergy consultation (if symptoms have recurred).

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Inflammation of the nose and paranasal sinuses mucosal tissue is called rhinosinusitis. Symptoms lasting longer than three months are classified as chronic rhinosinusitis (CRS). The four significant signs/symptoms of CRS include anterior and/or posterior nasal mucopurulent drainage, nasal obstruction/congestion, facial pain/pressure/fullness, and reduction/loss of sense of smell. Although not all four symptoms may be present, higher number of classic symptoms increases the likelihood of CSR diagnosis. Acute and chronic sinusitis and nasal polyps may only be minimally symptomatic at ground level. However, changes in atmospheric pressure, as seen in the flying and diving operations, may cause barotraumatic sinusitis, sinus "block" or "squeeze," resulting in sudden, incapacitating pain. These symptoms in aviators normally occur on descent, but may also occur less frequently on ascent. According to Boyle's law, when there is an increase in pressure (descent), there is a decrease in volume of gas in a closed space such as the sinus cavity. When negative pressure occurs in an enclosed space such as an obstructed sinus-nasal cavity, there is an expansion of mucosal vasculature, with subsequent edema and hemorrhage as the mucosa is torn from the bony structure of the sinus. Should that event occur immediately prior to or during landing procedures, it could lead to sudden painful distraction and potential incapacitation leading to an aircraft mishap.

As temperature, humidity, particulate matter, and barometric pressures can significantly influence sinus mucosal tissue, the aviator should not fly until sinus symptoms have resolved. There is no quick test to ensure the osteomeatal complex is patent; being able to Valsalva does not ensure aeration of the sinus cavities. One method of ensuring patency after treatment is to expose the aviator to an altitude chamber profile of 8,000 -10,000 feet. Another option in operating locations without an altitude chamber would be visualizing the patent ostia of the affected sinuses or computed tomography (CT) imaging demonstrating patency. The Air Force SG Otolaryngology consultant recommends functional assessments with the altitude chamber evaluation for aircrew in high performance aircraft. For flyers and operators in non-high performance aircraft, a commercial or military pressurized flight without symptoms along with anatomical assessment (visualization or CT) is appropriate. A referral to a rhinologist may be indicated for complex or recalcitrant cases.

Medications used for management of chronic sinus disease must be carefully assessed for compatibility with aviation duties. Oral steroids can be used in the peri-operative period in setting of sinonasal polyposis while nasal steroids are acceptable for flying duties without waiver only for mild allergic rhinitis. Biologic agents/monoclonal antibodies (e.g. dupilumab), may be considered on a case-by-case basis for refractive disease when other therapies have failed. Intranasal and sinus saline rinses can be used for prevention and treatment without grounding, but the underlying need for their use must be considered before clearing the aviator to fly.

AIMWTS search from Jun 2018 to Jun 2022 revealed 311 cases with the diagnosis of nasal polyps, chronic sinusitis, and/or sinus surgeries. Breakdown of the number of waivers and number of total cases are tabulated below.

ICD 10 Codes for Sinusitis,		(# of waivers / total # of cases)				
Nasal Pol	yps, and Surgery	IFC I/IA	FC II	FC III	GBO	ATC
J32.9	Chronic sinusitis, unspecified					
J33.9	Nasal polyp, unspecified	36/40	162/166	82/93	7/8	4/4
09CP4ZZ	Extirpation of Matter from Accessory Sinus, Percutaneous Endoscopic Approach					

## **IV. Suggested Readings**

- Patel, Z., Acute sinusitis and rhinosinusitis in adults: Clinical Manifestations and diagnosis. UpToDate. July 2021. Accessed Aug 4, 2022. <u>https://www.uptodate.com/contents/acute-sinusitis-and-rhinosinusitis-in-adults-clinical-manifestations-and-diagnosis</u>
- Hamilos, D., Chronic rhinosinusitis: Clinical manifestations, pathophysiology, and diagnosis. UpToDate. May 2022. Accessed Aug 4, 2022. <u>https://www.uptodate.com/contents/chronic-rhinosinusitis-clinical-manifestations-pathophysiology-and-diagnosis</u>
- 3. Rosenfeld, R., Clinical Practice Guideline: Adult Sinusitis. Entnet.org. April 2015. https://journals.sagepub.com/doi/full/10.1177/0194599815572097
- Andrew G Boston, MC USAF, K Christopher McMains, MC FS USAR, Philip G Chen, MD, Erik K Weitzel, MC USAF, Algorithm for Management of the Refractive Aerosinusitis Patient, *Military Medicine*, Volume 183, Issue 7-8, July-August 2018, Pages e246–e250, <u>https://doi.org/10.1093/milmed/usx222</u>
- Weitzel, E. K., McMains, K. C., Rajapaksa, S., & Wormald, P. J. (2008). Aerosinusitis: pathophysiology, prophylaxis, and management in passengers and aircrew. *Aviation, space, and environmental medicine*, 79(1), 50–53. <u>https://doi.org/10.3357/asem.2203.2008</u>





# Salivary Gland Disorders

Revised: Sep 2022 Reviewed: Dr. Max Lee (ACS Waiver Guide Coordinator), Lt Col Brent Feldt (AF/SG Otolaryngology Consultant)

Significant Changes: Content and references updates, new format for previous waiver dispositions

# I. Waiver Consideration

Recurrent obstructive calculi of the salivary glands or ducts and salivary fistulae are disqualifying for flying classes I/IA, II, and III duties. Other disorders of the head and neck should prompt line-item review of the latest MSD, as several conditions are also disqualifying for ATC, GBO, and SWA duty. Malignancies in the head and neck of any kind, except basal cell and squamous cell carcinomas without sequelae, are disqualifying for flying and special operational duties and for retention. Generally, benign tumors are considered disqualifying only if they interfere with the function or ability to wear required life support equipment or if they are likely to enlarge or be subjected to trauma during routine military service or have high malignant transformation potential. Benign tumors may require I-RILO if the condition is not remediable or ongoing specialty care is required more than annually.

Chronic systemic conditions, which may involve salivary gland structures or function, are addressed under the specific condition identified (e.g., Sjögren's Syndrome, Diabetes Mellitus, and Sarcoidosis Waiver Guides). If applicable, I-RILO should be processed with FL-4 reflecting return-to-duty status uploaded to AIMWTS prior to AMS submission. Due to the relative infrequency of salivary gland disorders in the flying population and wide variability, a case-by-case approach to waiver consideration is recommended.

Flying Class (FC)	Disqualifying Condition	Waiver Potential Waiver Authority	ACS Review/Eval
	Recurrent salivary stones	Maybe ¹ AFRS/CMO	No
	Salivary fistula	Maybe ¹ AFRS/CMO	No
FC I/IA, and Initial II/III	Impaired speech, mastication, or condition which precludes wear of life support equipment	Unlikely AFRS/CMO	No
	Benign tumor	Maybe ¹ AFRS/CMO	Yes
	Malignant tumor	Maybe ² AFRS/CMO	At the discretion of the waiver authority
	Recurrent salivary stones	Yes MAJCOM	No
	Salivary fistula	Yes MAJCOM	No
FC II/III	Impaired speech, mastication, or condition which precludes wear of life support equipment	Unlikely MAJCOM	No
	Benign tumor	Yes ¹ MAJCOM	Yes
	Malignant tumor	Maybe ³ AFMRA	Yes
	Recurrent salivary stones	N/A	N/A
	Salivary fistula	N/A	N/A
GBO/ATC OSF/SWA	Impaired speech, mastication, or condition which precludes wear of life support equipment	Unlikely MAJCOM	No
	Benign tumor	Yes ¹ MAJCOM	Yes
	Malignant tumor	Maybe ³ AFMRA	Yes

Table 1. Waiver Considerations for Salivary Gland Disorders

1. Consideration for waiver is dependent upon severity of presentation, any associated complications, and/or frequency of recurrence.

2. Waiver consideration requires at least 6 months waiting period from completion of treatment (3 months if

excision only required) and is dependent on tumor type, staging, complications, and likelihood of recurrence.

3. May consider waiver for certain tumors that have a good prognosis on a case-by-case basis.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

- A. The AMS for waiver of recurrent salivary stones or fistula should include:
  - 1. History, physical (thorough head and neck examination), medical evaluation, and treatment for all episodes; to include complete description of presenting symptoms.
  - 2. Reports of all laboratory and imaging studies obtained.
  - 3. Otolaryngology/OMF consultation; with specific reference to likelihood of recurrence.
  - 4. Statement regarding ability to speak clearly and to adequately fit aviator oxygen mask and other required life support equipment.
  - 5. All operative and/or procedure notes related to the condition.

### B. The AMS for waiver for **impaired speech or mastication or other condition which precludes wear of life support equipment** should include:

- 1. History, physical (thorough head and neck examination), medical evaluation, and treatment; to include complete description of presenting symptoms.
- 2. Reports of all laboratory and imaging studies obtained.
- 3. Otolaryngology/OMF consultation reports.
- 4. Statement regarding ability to speak clearly and to adequately fit aviator oxygen mask and other required life support equipment.
- 5. All operative and/or procedure notes related to the condition, if applicable.
- C. The AMS for a waiver for a **benign salivary gland tumor** should include:
  - 1. History, physical (thorough head and neck examination), medical evaluation, and treatment; to include complete description of presenting symptoms and any residual symptoms after treatment.
  - 2. Reports of all laboratory and imaging studies obtained.
  - 3. All operative and/or procedure notes related to the condition.
  - 4. Histology report. (For rare cell types, Joint Pathology Center report required).
  - 5. Otolaryngology/OMF consultation; with specific reference to likelihood of recurrence and/or malignant transformation and need for on-going surveillance.
  - 6. Statement regarding ability to speak clearly and to adequately fit aviator oxygen mask and other required life support equipment.
  - 7. MEB results, if applicable.
- D. The AMS for a waiver for a malignant salivary gland tumor should include:
  - 1. History, physical (thorough head and neck examination), medical evaluation and treatment; to include complete description of presenting symptoms any residual symptoms after treatment.
  - 2. Reports of all laboratory and imaging studies obtained.
  - 3. All operative and/or procedure notes related to the condition.
  - 4. Histology report (Joint Pathology Center report required).

- 5. Otolaryngology/OMF and oncology consultation; with specific reference to likelihood of local recurrence or metastasis and detailed description of recommended surveillance regimen.
- 6. Statement regarding ability to speak clearly and to adequately fit aviator oxygen mask and other required life support equipment.
- 7. MEB results.
- 8. Tumor board results.

Note: For any of the above listed conditions, specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package

### **III. Aeromedical Concerns**

Most salivary gland disorders would generally not be considered to pose an immediate risk to flight, at least relative to the risk for sudden incapacitation in flight from a known or yet to be diagnosed condition. Certainly, a salivary stone may cause pain during aviation and operational duties but this does not generally produce incapacitating levels of discomfort such as those associated with other stone migration events such as renal colic. As such, most aeromedical concerns relate to the identification of conditions that might interfere with clear speech, wear of the oxygen mask, or require acute medical intervention such as antibiotic or anti-inflammatory medication use.

A query of AIMWTS through July 2022 revealed a total of 12 aviator waiver requests for salivary gland disorders. All received an aeromedical waiver. The breakdown of the number of waivers and number of total cases are tabulated below.

ICD-10 Code		(# of waivers / total # of cases)			
Salivary Gland Conditions and Neoplasms		IFC I/IA	FC II	FC III	GBO
K11.5	Sialolithiasis				
K11.6	Mucocele of salivary gland				
K11.7	Disturbance of salivary secretion				
K11.8	Other diseases of the salivary glands				
M35.00	Sicca syndrome, unspecified				
Q38.4	Congenital malformations of salivary glands and ducts				
C07	Malignant neoplasm of parotid gland				
C08.0	Malignant neoplasm of submandibular	1/1	9/9	1/1	1/1
	gland			1, 1	
C08.1	Malignant neoplasms of sublingual				
	gland				
C08.9	Malignant neoplasm of major salivary				
	gland, unspecified				
D11.9	Benign neoplasm of major salivary				
	gland, unspecified				
D00.0	Carcinoma in situ of lip, oral cavity, and				
	pharynx				
235.0	Neoplasm of uncertain behavior of				
	major salivary glands, unspecified				

## **IV. Suggested Readings**

1. Wilson DF, Meier JD, and Ward PD. Salivary Gland Disorders. Am Fam Physician, 2014; 89(6): 882-88. https://www.aafp.org/pubs/afp/issues/2014/0601/p882.html

2. Fazio SB and Emerick K. Salivary gland stones. UpToDate. Apr 20, 2021. Accessed Jul 25, 2022. https://www.uptodate.com/contents/salivary-gland-stones

3. Laurie SA. Salivary gland tumors: Epidemiology, diagnosis, evaluation, and staging. UpToDate. Apr 14, 2022. Accessed Jul 25, 2022. <u>https://www.uptodate.com/contents/salivary-gland-tumors-epidemiology-diagnosis-evaluation-and-staging</u>

4. American Academy of Otolaryngology-Head and Neck Surgery. Clinical Practice Guideline: Evaluation of the Neck Mass in Adults. Sept 10, 2017. Accessed Jul 25 2022. <u>https://www.entnet.org/quality-practice/quality-products/clinical-practice-guidelines/evaluation-of-the-neck-mass-in-adults/</u>

### Vestibular Schwannoma (Acoustic Neuroma) (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), Lt Col Wesley Abadie (AF/SG Otolaryngology Consultant) and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## Significant Changes:

Updated Table 1 and References

## I. Waiver Consideration

Vestibular Schwannoma (VS) is addressed in the USAF Medical Standards Directory (MSD) as "acoustic neuroma" and as "intracranial, meningeal, or other neurologic benign or malignant neoplasm". Newly-diagnosed VS is disqualifying for FC I/IA, II (as well as initial FC II), III, and for retention. VS are benign, slow-growing neoplasms that produce clinical symptoms primarily from local compression. Symptoms are often gradually progressive but may be insidious, with the potential for sudden development of symptoms. For aeromedical waiver consideration, the tumor must be unilateral, and there must be complete resolution of symptoms post-treatment. For aviators in high performance aircraft, in-flight or centrifuge testing should be strongly considered, to validate vestibular reserve is adequate to maintain awareness during maneuvers without sequelae. Any residual cranial nerve deficits should allow adequate communication, full ocular movements without tracking deficits or strabismus, and permit acceptable protective mask sealing. Confirmation of tumor pathology is needed with surgical cases, and surveillance MRI scanning is needed in cases treated non-invasively, to ensure stability and monitor for any growth. A history of previously-treated VS is not disqualifying for ATC, SWA and GBO personnel (except for initial RPA operators).

Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II/III	Yes ¹	MAJCOM	Yes
GBO/ATC/SWA	Yes ^{1,2}	MAJCOM	Yes ²

Table 1: Waiver potential for vestibular schwannoma

1. If treated surgically or with radiation, minimum 6 month observation following definitive treatment, with no aeromedically-significant symptoms

2. History of VS is not disqualifying for GBO (except initial RPA operators), SWA, and ATC personnel.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable.

### A. Initial Waiver Request:

- 1. History symptoms, hearing exams prior to treatment, treatment course, post-surgical vertigo symptoms, and confirmed resolution of vestibular symptoms.
- 2. Current Otolaryngology evaluation, ocular and neurologic examination findings.
- 3. Current audiogram results.

- 4. Vestibular function testing results, which may include electronystagmography (ENG, VNG and calorics), and computerized dynamic posturography (CDP) testing.
- 5. Reports of consultations, surgical procedures, pathology reports or radiation therapy treatment reports, as applicable. For complex or undiagnosed cases, strongly consider obtaining formal Neuro-Otology consultation through SAMMC, WRNMMC, or an academic medical center.
- 6. Reports and images from any imaging studies, pre- and post-treatment. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 7. Tumor board report as applicable.
- 8. Medical Evaluation Board results as applicable.
- 9. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

### B. Renewal Waiver Request:

- 1. Interval history and level of symptom resolution.
- 2. Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3. Copy of current audiogram.
- 4. Current physical, otolaryngology and neurologic examination findings.
- 5. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

### **III. Aeromedical Concerns**

Aeromedical concerns include the effects of any residual symptoms on operational safety and mission effectiveness, future risk of new symptom development, and future risk of recurrence. Symptoms associated with VS are typically attributed to compression of associated cranial nerves (VIII, VII, IV, IX, X), cerebellar compression, and ultimately restricted CSF flow and hydrocephalus or brainstem compression. Tumors are unilateral in over 90 percent of cases. Bilateral VS is pathognomonic of the autosomal dominant genetic disorder neurofibromatosis type 2 (NF-2). The acoustic portion of VIII is involved in almost all cases, with the vestibular, trigeminal and facial nerves involved less frequently. Any aviator with asymmetric hearing loss, especially if progressive, should be screened for VS, as many VS are discovered after observing changes in annual audiograms. Cochlear and vestibular symptoms are of obvious importance to the aviator. Hearing loss and tinnitus can adversely impact communications, while vertigo and disequilibrium can adversely affect the ability to safely control an aircraft. Observation is a reasonable option with small, intracanicular tumors. Surveillance by follow up MRI scanning at 6 months, and then annually is reasonable. However, due to the wide range of progressive and potentially abrupt symptomatology, conservative observational management may be incompatible with the safe performance of aviation-related duties in some cases. In surgically treated patients, complete tumor removal can be accomplished in most cases, with minimal recurrence risk. Worsening of vestibular symptoms is commonly seen following surgical removal, but typically resolves by neurologic compensation with time and rehabilitation. The risk of cerebrospinal fluid leak is variable depending on type of surgery, but is between 6-11% and may require revision surgery or lumbar drainage to resolve. As opposed to total removal of the tumor with conventional

surgery, stereotactic radiation treatment is intended to stop tumor growth. In such cases, postradiotherapy surveillance is necessary to ensure continued control over time. Delayed and slow responses are typical with stereotactic radiosurgery. Some tumors fail to respond to radiation and continue to grow, or are controlled initially, but resume growth over time. All post-operative or post-radiation vestibular symptoms require sustained documentation of compensation over time (e.g. radiation effects may manifest 18-24 months after irradiation) prior to waiver consideration, and any hearing loss needs to be stabilized and well documented by competent audiology services. An in-flight hearing evaluation may be required prior to clearing an aviator for flying duties. A good online resource is the Acoustic Neuroma Association site at <u>www.anausa.org</u> which provides up-to-date information for patients and clinicians regarding this condition.

A review of AIMWTS through Mar 2019 revealed 35 cases. Breakdown of these cases revealed: 1 FC I/IA cases, 21 FC II cases, 1 RPA pilot case, and 12 FC III cases (4 disqualified)

ICD-9 Codes for Vestibular Schwannoma			
225.1	Benign Neoplasm of Cranial Nerves		
388.5	Disorders of Acoustic Nerve		

ICD-10 Codes for Vestibular Schwannoma			
D33.3	Benign Neoplasm of Cranial Nerves		
1, 2, 3, 9			
H93.3X	Disorders of Acoustic Nerve		
1, 2, 3, 9			

## **IV. Suggested Readings**

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### Adjustment Disorder (Aug 2020)

Reviewed: Capt Max Dickey (RAM 2020), Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Dan Van Syoc (ACS waiver guide coordinator), and Lt Col Ric Speakman (AFMRA Physical Standards Development Chief)

Significant Changes: New Format, New Table 1, some content updates including med management

### I. Waiver Consideration

Adjustment Disorders that interfere with the safety of flight are disqualifying for all flying classes. If there are any functional limitations or the Adjustment Disorder lasts greater than 60 days, a waiver is required. If the DSM-5 diagnostic criteria for Adjustment Disorder are met, then aviators should be placed on DNIF status until the disturbance is resolved. If the disorder resolves within 60 days the aviator is placed back on flying status and no waiver is required. If the disorder persists beyond 60 days, or results in a level of care higher than weekly outpatient treatment (inpatient hospitalization, partial hospitalization (PHP), intensive outpatient program (IOP)), the aviator is disqualified and a waiver is required. An evaluation by a qualified mental health professional is required prior to waiver consideration. There is no mandated recovery period before waiver application, except a one-year period after resolution for FC I/IA applicants and other untrained aircrew applicants. The period of remission for trained aircrew should be of such length that the flight surgeon and mental health provider have confidence the aviator will not suffer a clinically significant recurrence.

Adjustment Disorders do not typically require an antidepressant, but it is becoming more common for these medications to be used in their treatment. In 2013, the USAF began allowing select FC II/III personnel to be considered for waivers on antidepressants. In 2018, after 5 years of observation, the USAF allowed all trained aviators, including single seat and B-2 pilots, to be considered for waivers on the following monotherapies (only one aeromedically-approved medication is allowed at a time):

- 1. Sertraline (Zoloft®) up to 200 mg/day
- 2. Citalopram (Celexa®) up to 40 mg/day
- 3. Escitalopram (Lexapro®) up to 20 mg/day
- 4. Bupropion (Wellbutrin®) SR or XL up to 400 mg/day or 450 mg/day, respectively.

The period of stability needed before requesting a waiver for an Adjustment Disorder is at the discretion of the flight surgeon and/or mental health provider. If the aviator is prescribed an aeromedically-approved antidepressant, careful consideration should be taken to consider other diagnoses, such as Depressive Disorders or Anxiety Disorders, which require the aviator be clinically asymptomatic (at "best baseline") for at least 6 months before waiver consideration. As long as the aviator's symptoms remain stable, the dose of the medication may be adjusted or the antidepressant may be switched to maximize treatment and/or limit side effects without

restarting this 6 month waiting period. If the antidepressant used to treat the aviator is ever adjusted in dose or discontinued, 2 weeks of observation should occur before resuming flight duties to assure no adverse/unexpected side effects or return of symptoms occur. If the antidepressant used to treat the aviator is changed to another aeromedically-approved antidepressant secondary to side effects or lackluster response, 4 weeks of observation should occur before resuming flight duties to assure no adverse/unexpected side effects or return of symptoms occur. If symptoms return at any time during treatment, it is recommended a thorough reassessment be conducted and enhancement of the overall treatment plan be considered, to possibly include psychotherapy, healthy lifestyle interventions, and/or antidepressant medication (multimodal treatment is more effective). If the symptoms are occupationally impairing, "best baseline" will need to be restored and the appropriate observational period will need to be established before returning to full flight duties.

Waivers are not considered for FCI or other untrained personnel on antidepressants and are limited to trained FCII, FCIII, ATC, GBO, and SWA. MOD personnel may be permitted to perform their duty while on certain psychotropic medications listed on the Approved Space and Missile Operator Medications list, but a waiver is typically required.

Finally, certain psychiatric disorders render an individual unsuited for duty, rather than unfit, and are subject to administrative separation (IAW AFI 36-3208, para 5.11). Adjustment disorders may fall under this provision if there is unsatisfactory duty performance.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review
FC I/IA	Yes ^{1,2}	AETC	At discretion of AETC
FC II/III	Yes ^{1,2}	MAJCOM	At discretion of MAJCOM
ATC/GBP/SWA	Yes ^{1,2,3}	MAJCOM	At discretion of MAJCOM

Table 1: Waiver potential for Adjustment Disorder > 60 days

1. It is not recommended to consider a waiver until one-year after resolution for FC I/IA and untrained aircrew.

2. Waiver is likely if the stressors are resolved, the individual has demonstrated good coping skills, is on no disqualifying medications, or is stable on an approved antidepressant, and the Adjustment Disorder has clearly resolved.

3. ATC/GBO/SWA personnel with Adjustment Disorder are evaluated based on how the condition affects their ability to continue performing their assigned duties.

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request:

- 1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2. If the local base is unable to provide all required items, they should explain why to the waiver authority

#### B. Renewal Waiver Request:

- 1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

### Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch

USAFSAM.FE.PsychiatryMailbox@us.af.mil 2510 Fifth Street Bldg 840 C Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

Comm: 937-938-2768 DSN: 798-2768

### **III. Aeromedical Concerns**

Adjustment Disorders are one of the most common psychiatric diagnoses among aviators. These disorders are commonly associated with functional impairment resulting from decreased concentration, depression, anxiety, inattention, decreased working/short-term memory, insomnia, fatigue, temporary changes in social relationships and problems with decision making. These impairments are all incompatible with aviation duties.

Adjustment disorders occur following the development of clinically significant emotional or behavioral symptoms in response to identifiable psychosocial stressors. They are categorized by DSM-5 under Trauma- and Stressor-Related Disorders and likewise are found in the Medical Standards Directory (MSD) grouped with these disqualifying conditions. In Adjustment Disorders, the stressors typically involve financial struggles, medical illness, and/or a relationship difficulties. These symptoms are diagnostically significant (distinguishing them from Occupational Problem, Partner Relational Problem, etc.) if the distress is in excess of what would normally be expected from exposure to the stressor or there is associated impairment in social or occupational functioning. Symptoms associated with bereavement following the death of a loved one are not, however, classified as an Adjustment Disorder unless the symptoms are very severe (socially/occupationally impairing) or last longer than expected.

Adjustment Disorder is used in psychiatry, but is more typically seen in primary care settings often due to aviators avoiding the stigma of mental health care. Delay in adequate treatment can lead to progression of symptoms to a more severe mental health diagnosis. Early interventions with psychotherapy to strengthen coping mechanisms and short-term pharmacotherapy have been shown to promote recovery. Psychotherapeutic treatment of Adjustment Disorder enables reduction of the stressor, enhanced coping with the stressor that cannot be reduced or eliminated, and establishment of a support system to maximize adaptation. The judicious use of medications to treat specific symptoms associated with Adjustment Disorders, typically antidepressants, may be helpful.

AIMWITS search in Jul 2020 of waivers adjudicated in the past five years revealed a total of 684 members with an AMS containing the diagnosis of adjustment disorder. There were 218 cases

resulting in a disqualification disposition. Breakdown of the cases was as follows: 65 FC I/IA cases (18 disqualified), 138 FC II cases (22 disqualified), 312 FC III cases (114 disqualified), 52 ATC cases (25 disqualified), 90 GBO cases (31 disqualified), and 27 SWA cases (8 disqualified).

ICD-9 codes for Diagnosis			
309.0	Adjustment disorder with depressed mood		
309.24	Adjustment disorder with anxiety		
309.28	Adjustment disorder with mixed anxiety and depressed mood		
309.3	Adjustment disorder with disturbance of conduct		
309.4	Adjustment disorder with mixed disturbance of emotions and conduct		
309.9	Adjustment disorder – unspecified.		

ICD-10 codes for Diagnosis			
F43.21	Adjustment disorder with depressed mood		
F43.22	Adjustment disorder with anxiety		
F43.34	Adjustment disorder with mixed anxiety and depressed mood		
F43.24	Adjustment disorder with disturbance of conduct		
F43.25	Adjustment disorder with mixed disturbance of emotions and conduct		
F43.20	Adjustment disorder – unspecified.		

### **IV. Suggested Readings**

1. Katzman JW and Tomori O. Adjustment disorders. Ch. 22 in *Kaplan and Sadock's Comprehensive textbook of Psychiatry*, 8th ed. Lippincott, Williams and Wilkins; Philadelphia, 2005.

2. Adjustment Disorders. In *Diagnostic and Statistical Manual of Mental Disorders*, Fifth edition, (DSM-5). American Psychiatric Association, Washington, DC, 2013; pp. 286-89.

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8. Strain J. Adjustment disorders. In *Psychooncology*, Holland J (ed.). Oxford University Press, New York, 1998: 509-517.





# Alcohol Use Disorders

Revised: May 2022

Reviewed: Dr. Terry Correll (Chief of Aerospace Psychiatric Consultation), Dr. Max Lee (Waiver Guide Coordinator), and Maj Paul Vu (AFMRA Medical Standards Policy Chief)

**Significant Changes:** Updates to aeromedical concerns and potential earlier waiver timelines for flyer/operators successfully engaged in (formerly completed) treatment with associated highly reliable surveillance

# I. Waiver Consideration

Alcohol Use Disorders (AUD), whether mild, moderate, or severe, are disqualifying for all classes of flying and special duty in the Department of the Air Force. Only based on a tally of the established criteria, the severity designation does not necessarily correlate with prognosis or course of illness. Consequently, a "mild" AUD may have a worse prognosis/outcome than a "severe" AUD. These disorders have a very high rate of relapse and aeromedical dispositions should be made with great care. Close surveillance is required secondary to high relapse rates. Because of the significant risk of relapse, AUD waivers should be considered yearly to promote close observation for trained assets. Waiver should not exceed a period greater than three years. An "indefinite waiver" or "waiver retirement" is not recommended. Because of the very high number of cases, the majority of aviator waiver recommendations for alcohol-related diagnoses are managed through base and command level interaction. Aeromedical Consultation Service (ACS) review and in-person evaluation is not required, but is available for consultation for complicated cases at the discretion of the waiver authority.

Table 1. Waiver potential for Action Use Disorders.				
Flying Class (FC)   Waiver Potential ¹   Waiver Au		Waiver Authority ²	<b>ACS Review or Evaluation</b>	
I/IA	Maybe ³	AMWD	Maybe ⁴	
All Other	Maybe ³	DAFMAN 48-123	Marsh 4	
Untrained Assets	Maybe	Attachment 2	Maybe ⁴	
MSD Section W	Yes	MAJCOM	Maybe ⁴	
AFSCs	res	MAJCOW	Maybe	
Non MSD Section	Vaa	MAICOM	Maxha ⁴	
W AFSCs	Yes	MAJCOM	Maybe ⁴	

### Table 1: Waiver potential for Alcohol Use Disorders.

1. All aviators with a history of alcohol use disorders must remain 100% abstinent, provide documentation of successful treatment and after-care follow-up, and must not take any medications for substance misuse.

2. If there are medical complications from substance use disorders (bleeding varices, cirrhosis, hallucinosis, etc.), then an IRILO is required IAW DoDI 6130.03 vol 2

3. There is no formal waiver provision for FC I/IA, initial FC II, and other Untrained Assets. The waiver authority considers waivers on a case-by-case basis.

4. ACS review/consultation is at the discretion of the waiver authority.

In order to be considered for waiver, three conditions must be met:

 the individual must have successfully engaged in (formerly completed) treatment (defined below) as determined and documented by the MTF Alcohol & Drug Abuse Prevention & Treatment (ADAPT) program treatment team

- 2) the individual must be compliant (fully engaged) with post-treatment aftercare program requirements (also defined below), and
- 3) the individual must have a positive attitude and unqualified acknowledgement of his/her AUD.

Flight surgeon participation in both the ADAPT treatment team meetings and aftercare follow up is required.

Treatment Program Requirements: Individuals will have successfully completed treatment when the following conditions are met:

- The flyer/operator meet the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria for early remission of AUD (not meeting any AUD criteria for more than three months but less than 12 months, excluding craving. Sustained remission is defined as not meeting any AUD criteria for more than 12 months, excluding craving), and
- 2) The treatment team determines, based on DSM criteria, that the individual shows progress towards agreed-upon goals and/or issues as stated in the treatment plan, and
- 3) The flyer/operator remain 100% abstinent of alcohol without the need for AUD medication.

Post-treatment Aftercare Program Requirements: The individual must

- 1) Remain 100% abstinent of alcohol without the need for AUD medications, and
- 2) Documented participation in an organized alcohol use aftercare program [e.g., Alcoholics Anonymous (AA), or other program approved by the MTF ADAPT Program Manager], "Birds of a Feather" may be a helpful addition, and
- 3) Meet with the designated following professionals for the following specific timeframes:

Professional/Meetings	First Year	Second/Third Year	Fourth Year
Flight Surgeon ¹	Monthly	Quarterly	Annually
ADAPT	Monthly	Monthly	N/A
Psychiatrist, Psychologist, or Social Worker	Annually	Annually	N/A
Organized Alcohol Aftercare Program	3x weekly	1x weekly	Recommended (not required)

Table 2: Post-treatment Aftercare MINIMUM Requirements:

1. The flight surgeon has primary responsibility for collecting and submitting the required documentation for waiver submission. The ADAPT representative documents alcohol use aftercare program attendance. Temporary modification of aftercare program requirements because of operational demands must be approved of documented by the flight surgeon and ADAPT.

2. Important note: the post-treatment aftercare requirements listed are only the MINIMUM. Most people with AUD would benefit from ADDITIONAL treatments, especially in the organized alcohol aftercare program. For example, optimal Alcoholics Anonymous engagement includes securing and regularly connecting with a sponsor, working through the step handbooks, and attending 90 meetings in 90 days initially. Research has demonstrated ~85% effectiveness rate when all these interventions are committed to. Please specifically document these areas accordingly.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

## An **<u>INITIAL WAIVER</u>** may be requested after:

- 1) Successful ADAPT treatment program initiation
- 2) Ongoing successful compliance in the post-treatment aftercare program (Please note that <u>completion</u> of post-treatment aftercare program is no longer a requirement), and
- 3) The individual must have a positive attitude and unqualified acknowledgement of his/her AUD, and
- 4) All possible risks for relapse are addressed/mitigated, including comorbid psychiatric illness, and
- 5) Unanimous treatment team opinion that the individual has returned to his/her "best baseline" of overall functioning, even if continuing in the post-treatment aftercare program, and
- 6) The service member is deemed to be at an acceptable aeromedical risk
  - a. a unanimous decision to pursue a waiver must be rendered by the treatment team. Minority opinion(s) must be valued, discussed, and satisfactorily resolved before proceeding. Clinical wisdom, impartiality, and judgment are required to effectively manage the significant aeromedical risk of an AUD.

## **UNSATISFACTORY PROGRESS IN AFTERCARE PROGRAM:**

Failure of a member to acknowledge his/her alcohol problem, to 100% abstain from alcohol during aftercare, or to comply with all aftercare requirements is medically disqualifying. The following pertain to any individual who fails to remain abstinent or otherwise not comply with all aftercare program requirements: if a relapse occurs during aftercare pending a first waiver, there must be 12 months sobriety/success in aftercare before waiver re-submission. If the member's condition has been waived previously, ground the member and arrange for re-evaluation by a flight surgeon and ADAPT provider to determine potential for retreatment. If the member is determined to have potential for retreatment, follow the initial waiver and aftercare program processes. A second waiver request for substance use disorder may be considered in accordance with initial waiver requirements, but requested no sooner than 12 months from the last date that noncompliance with the post-treatment aftercare program was documented. Second waiver requests are considered on a case-by-case basis only, and waiver authority for these individuals is AFMRA/SG3P. If the member is determined not to have potential for re-treatment, an AMS must be submitted for permanent disqualification.

As part of the waiver package, the individual states in writing that he/she understands the waiver is valid only if total abstinence from alcohol is maintained, and that a verifiable break in abstinence, once the waiver period has begun, is considered medically disqualifying. This written statement, kept in the medical records, must be accomplished at the initial waiver request, and reaccomplished each time a waiver renewal is requested. The abstinence memo must be dated, personally applicable, thoughtfully written, and signed by the member and commander. ACS evaluation is not routinely requested in cases of AUDs, but such evaluation may be requested through the MAJCOM if an aviator's flight surgeon and/or commander desire it, particularly for a second opinion. In such cases, a summary of all evaluations (ADAPT Program, medical, and Mental Health) done during the initial workup, a report from a mental health evaluation done within three months of waiver package submission documenting the presence or absence of comorbid psychiatric pathology and cognitive impairment, an aeromedical summary containing salient laboratory values, and required aftercare documentation should be submitted. Please refer to the Mental Health Waiver Guide Checklist in the USAF Waiver Guide.

## A. Initial Waiver Request:

- 1. Aeromedical summary containing a physical exam and 2 sets of laboratory values [blood alcohol test, urine drug test, CBC with MCV, GGT, AST, ALT, triglycerides, and carbohydrate-deficient transferrin (CDT). A phosphatidylethanol (PEth) test may be utilized as well, though more definitive research is needed].
- 2. Labs should be collected at treatment initiation and just before waiver submission.
  - a. Unannounced lab tests are best because they provide important/necessary accountability and assurance of compliance.
- 3. The summary should also address work performance, peer relationships, family and marital relationships, psychosocial stressors, attitude toward recovery, abstinence, AA or other approved alcohol recovery program attendance, and mental status examination.
- 4. ADAPT statements/summary documenting aftercare and AA or other approved alcohol recovery program attendance.
- 5. Copy of annual psychiatrist/psychologist examination while in aftercare.
- 6. Letter of recommendation from individual's commanding officer.
- 7. Copy of signed abstinence letter (initial and renewal waiver requests must have a signed abstinence statement included as an AIMWTS attachment).
  - a. In the abstinence letter, the individual states in writing that he or she understands that, if granted, the waiver is valid only if total abstinence from alcohol is maintained. A verifiable break in abstinence once the waiver period has begun is medically disqualifying.
  - b. The abstinence memo must be dated, personally applicable, thoughtfully written, and signed by the member and commander.
- 8. Due to the potential for cognitive changes in those with AUD, cognitive function screening is recommended prior to waiver submission.
  - a. A cognitive screening measure, such as the Montreal Cognitive Assessment (MoCA) or Mini-Mental State Exam (MMSE), can be completed during an evaluation by the Flight Surgeon or other provider.
  - b. Low or abnormal scores on screening measures or any concerns regarding cognitive abilities despite normal scores, should prompt referral for comprehensive evaluation of cognitive functioning by neuropsychology.
- 9. Medical Evaluation Board report, if required.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# B. <u>Renewal Waiver Request:</u>

- 1. Interval history aeromedical summary since the last waiver.
- 2. Flight surgeon summary of any interim alcohol-related treatment to include ADAPT and repeat laboratory results as described above.
  - a. Unannounced laboratory testing provides important accountability and assurance.
- 3. Consultation from any providers evaluating member for alcohol/mental health problems or assessing them for history of same.
- 4. Copy of signed abstinence letter (initial and renewal waiver requests must have a signed abstinence statement included as an AIMWTS attachment).
  - a. In the abstinence letter, the individual states in writing that he or she understands that, if granted, the waiver is valid only if total abstinence from alcohol is maintained.
  - b. A verifiable break in abstinence once the waiver period has begun is medically disqualifying.
  - c. The abstinence memo must be dated, personally applicable, thoughtfully written, and signed by the member and commander.
- 5. Due to the potential for cognitive changes in those with AUD, cognitive function screening is recommended prior to waiver submission.
  - a. A cognitive screening measure, such as the Montreal Cognitive Assessment (MoCA) or Mini-Mental State Exam (MMSE), can be completed during an evaluation by the Flight Surgeon or other provider.
  - b. Low or abnormal score on screening measures or any concerns regarding cognitive abilities despite normal scores, should prompt referral for comprehensive evaluation of cognitive functioning by neuropsychology.

Note: Please specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

# **III. Aeromedical Concerns**

Alcohol use disorders (AUDs) in the U.S. military are well-described public health problems being some of the most commonly seen psychiatric issues in aerospace medicine. Several studies demonstrate that military members are involved in heavy drinking (five or more beverages on occasion within the last two weeks) twice as often as compared to similarly matched civilian populations, and their alcohol use is commonly associated with comorbid psychiatric conditions. Operational effectiveness in the US Air Force can be seriously hampered as a result of AUDs, regardless of the severity (mild, moderate, severe AUD), or simply excessive or poorly timed consumption of alcohol (unhealthy drinking). Most flight surgeons would agree that alcohol problems are the "number one killer" of aviation careers.

A continuum exists ranging from normal social use of alcohol to full-blown AUDs. As an alcohol problem progresses, it often causes problems at home first, then in the social environment, with occupational performance typically being the last area to be affected. Aviators will typically do "anything necessary" to keep flying, including hiding their problematic drinking. One of the more vital roles the flight surgeon can serve is involvement with the squadron aircrew during their off-duty time and, in particular, participation in social and

recreational activities where the use of alcohol often occurs. If an aviator is willing to drink excessively in front of superiors, that should raise serious concerns (i.e., driving home after Friday afternoon squadron gathering with alcohol causes one to wonder about how much they are drinking in other scenarios).

AUDs can be difficult to detect. Secondary to expected minimizing and even frank denial of alcohol use, there is not one objective parameter that can be used to make the diagnosis. Therefore, a flight surgeon must be aware and watchful of circumstances which can signal their presence, [e.g., alcohol on the breath during duty hours, an alcohol-related incident, such as a DUI or domestic incident, an elevated blood alcohol level above 100 mg/dL (0.10%) in a person not appearing drunk, unexplained insomnia or hypertension, vague GI problems, frequent minor injuries, along with "broad spectrum" dysfunction in the member's life]. Laboratory abnormalities such as elevations of MCV, GGT, ALT, AST, uric acid, triglycerides, or increased carbohydrate-deficient transferrin (CDT) may also be present. An elevated CDT (above upper limit per laboratory report) indicates the regular intake of 4-5 standard alcoholic beverages for several weeks prior to the test, and is especially revealing in aviators who have signed 100% abstinence agreements. The CDT specificity is over 95% for excessive alcohol use with false positives found primarily in significant hepatic disease. Once a baseline CDT level is established after several unannounced tests, a 30% change indicates a modification in drinking behavior. A phosphatidylethanol (PEth) test may be utilized as well, though more definitive research is needed. PEth has potential in abstinence monitoring, since PEth could be detected for up to 12 days after a single drinking event.

Chronic depression, irritability, and anxiety may indicate the presence of an AUD, especially when they represent a change from a flyer's normal personality. Alcohol can cause reduced mood (be very "depressogenic") for up to two weeks after normal levels of consumption. Redosing commonly worsens mood symptoms with unawareness of this liability of alcohol. One third of all depressions are secondary to alcohol itself as the instigating agent requiring up to four weeks for depressive symptoms to abate after the last drink. Beyond that, alcohol worsens all other depressions and overwhelms the effect of antidepressants making it wise to abstain while treating depressive symptoms. Self-harm and suicide are much more common in people with alcohol problems. Alcohol often becomes a routine way to cope with stress and anxiety, causing "chemical coping," and allowing worsening anxiety symptoms and reduced overall resilience over time. Even normal alcohol use often causes light, broken sleep with associated daytime fatigue due to sympathetic arousals throughout the sleep cycles.

Screening questionnaires (CAGE, MAST, SASSI, AUDIT, and McAndrew) are available for use by the flight surgeon, ADAPT, or through the Mental Health Clinic. The National Institute of Alcohol Abuse and Alcoholism has developed a single-question test for primary care doctors to replace longer questionnaires. This question asks, "How many times in the past year have you had (for men) 5 or more drinks or (for women) 4 or more drinks in a single day?" Answering "1 or more days" in the past year should prompt further investigation. Screening assessments cannot make or confirm the diagnosis of AUD, but they can help inform the clinician to further evaluate for the presence, extent, and severity of alcohol use problems. Clinical correlation with focused interviews and reaching out to collateral contacts is helpful. Sound clinical judgment is required. It is well-established that excessive and/or chronic use of alcohol can result in changes in cognitive functioning. While some alcohol-induced cognitive deficits are acute and subside with the cessation of alcohol use, others can persist for years into abstinence. Due to the potential for cognitive changes in those with AUD, screening of cognitive functioning is recommended prior to waiver submission. A cognitive screening measure, such as the Montreal Cognitive Assessment (MoCA) or Mini-Mental State Exam (MMSE), can be completed during an evaluation by the Flight Surgeon or other provider. Low or abnormal score on screening measures or any concerns regarding cognitive abilities despite normal scores, should prompt referral for comprehensive evaluation of cognitive functioning by neuropsychology.

Per AFI 44-121, it is the responsibility of the flight surgeon to inform the commander and notify the Alcohol and Drug Abuse Prevention and Treatment (ADAPT) program manager of an individual who has been admitted for alcohol detoxification, receives treatment for an injury or illness that may be the result of substance use, or is suspicious of having an alcohol problem. This is an absolute duty to protect and report in the US Air Force. Referral and enrollment in the ADAPT program is key to starting the member on the correct path. Along with the usual medical evaluation, the workup should include an assessment for other psychiatric disorders such as depressive disorders, anxiety disorders, and personality disorders, for which those with AUDs are at increased risk. After the flight surgeon's assessment, ADAPT evaluates/substantiates alcohol and substance use disorders and mental health evaluates/substantiates comorbid psychiatric conditions.

Potential relapse after problematic drinking is identified and treated is extremely high. One study showed that relapse rates among US Air Force personnel are as high as 35%. More definitive research is needed and hard to come by. Abstinence from alcohol is the preferred modality for preventing relapse in aviators since attempting to return to "controlled drinking" once someone has lost control of drinking has very high relapse rates. Abstinence in those with AUD is exceedingly more successful in preventing relapse as compared to those whose attempt to control their drinking during recovery. The FAA requires abstinence for civilian aircrew with AUD. "Near beers" are not recommended because they often contain a low percentage of alcohol and continue to cultivate the drinking behavior(s) and lifestyle. Definitive studies into the efficacies of abstinence versus controlled drinking (harm reduction) are difficult to find because results are often biased towards the approach which is endorsed by the researchers.

Alcohol misuse presents hazards to aviation because of both acute and chronic effects on cognitive and physical performance. Acute alcohol intoxication and hangover are obviously incompatible with flying. Similarly, alcohol withdrawal is a threat to flight safety due to anxiety, tremor, and the increased risk for dysrhythmia or seizure. The majority of adverse effects produced by alcohol relate to the brain, eyes, and inner ear which are three crucial organs to a flyer. Alcohol decreases the ability of the brain to make use of oxygen. This adverse effect can be magnified as a result of simultaneous exposure to altitude, characterized by a decreased partial pressure of oxygen. Further, subtle cognitive impairment, manifesting as slowed reaction time, inattentiveness, difficulty in monitoring multiple sensory inputs, and difficulty making rapid shifts of attention from one stimulus to another, can occur after low doses of alcohol even if it does not result in intoxication. Brain effects include impaired reaction time, reasoning, judgment, and memory. Visual symptoms include eye muscle imbalance, which leads to double

vision and difficulty focusing. Inner ear effects include dizziness, and decreased hearing perception. If such other variables are added as sleep deprivation, fatigue, medication use, altitude hypoxia, or flying at night or in bad weather, the negative effects are significantly magnified. Additionally, normal alcohol use often causes light, broken sleep due to sympathetic arousals throughout the sleep cycles causing daytime fatigue. After moderate alcohol consumption, impairments can persist for many hours after the blood alcohol level has returned to zero, well beyond the 12-hour "bottle-to-throttle" guidelines. Positional alcohol nystagmus and vertigo, indicating impairment in vestibular function, can occur under G-load up to 48 hours after alcohol consumption. Heavy drinkers are at risk for dysrhythmias such as "holiday heart" for several days after drinking. Even after complete elimination of all of the alcohol in the body, there are hangover effects that can last 48 to 72 hours following the last drink. A hangover effect, produced by alcoholic beverages after the acute intoxication has worn off, may be just as dangerous as the intoxication itself. Symptoms commonly associated with a hangover are headache, dizziness, dry mouth, stuffy nose, fatigue, upset stomach, irritability, impaired judgment, and increased sensitivity to bright light. A flyer with these symptoms would certainly not be fit to safely operate an aircraft.

AIR FORCE MANUAL 11-202 Volume 3 Flight Operations (10 Jan 2022) 2.4.2.2. states that "Aircrew will not fly or assume aircraft control if any alcohol was consumed within 12 hours prior to takeoff **or if impaired by alcohol** or any other intoxicating substance, **to include the effects or after-effects.**" Cold showers, drinking black coffee, or breathing 100% oxygen cannot speed up the elimination of alcohol or its after-effects from the body. Excellent and clear-headed judgment is required to decide when it is safe to fly after alcohol consumption.

### Individuals with personal questions should work with their Flight Medicine Clinic.

# Flight Surgeons and Mental Health Providers with waiver questions, Please feel free to contact the ACS Neuropsychiatry Branch:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913

<u>USAFSAM.FE.PsychiatryMailbox@us.af.mil</u> Phone: (937) 938-2768 DSN: 798-2768 Fax: (937) 904-8753 DSN: 674-8753

AIMWTS search From Jan 2017 – March 2022 revealed 649 aviators with a waiver disposition for an alcohol-related diagnosis. There were 24 FCI/IA cases (13 disqualified), 318 FCII cases (32 disqualified), 21 RPA pilot cases (6 disqualified), 392 FCIII cases (100 disqualified), 14 MOD cases (4 disqualified), and 124 cases for GBC/ATC/GBO (33 disqualified). 272 of the

aviators in the pool of 649 had multiple aeromedical summaries for alcohol-related diagnoses. There were a total of 1015 waiver submissions for this time period. There were some who were disqualified and later waived, some waived and later disqualified, and a few who were disqualified, waived and then disqualified again.

ICD-10 codes for Alcohol Use Disorders (AUDs)	
F10.10	Alcohol Abuse
F10.20	Alcohol Dependence
F10.9	Alcohol Use, Unspecified

# **IV. Suggested Readings**

1. *Substance-Related and Addictive Disorders*, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR). American Psychiatric Association Publishing. 2022. <u>https://www.appi.org/dsm5tr</u>

2. Air Force Instruction 44-121, Alcohol and Drug Abuse Prevention and Treatment (ADAPT) Program, 2018.

3. DAFMAN 48-123, Aerospace Medicine Medical Examination and Standards, 8 Dec 2020.

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14. Dubowski KM. Absorption, distribution and elimination of alcohol: highway safety aspects. J Stud Alcohol. 1985;10:98–108.

15. Alejandro Caro-Nuñez T, Chidester T. Literature Review and Recommendations Concerning Alcohol Tolerance Under Part 67. Washington, DC: Office of Aerospace Medicine; 2018. DOT/FAA/ AM-18/5.

16. AIR FORCE MANUAL 11-202 Volume 3 Flight Operations (10 Jan 2022) <u>https://static.e-publishing.af.mil/production/1/af_a3/publication/afman11-202v3/afman11-202v3.pdf</u>

#### **Anxiety Disorders (Dec 2019)**

Reviewed: Lt Col Kevin F. Heacock (Chief, ACS Neuropsychiatry Branch), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

## **Significant Changes:** Restructuring of Waiver Guide, Anti-depressant management, AIMWTS review

### I. Waiver Consideration

Anxiety disorders are disqualifying for all flying classes to include ATC, GBO and SWA duties, and may be disqualifying for continued service. Untreated or undertreated anxiety disorders may have potentially disastrous consequences. If the diagnostic criteria are met for specific phobia, social anxiety disorder, panic disorder, agoraphobia, generalized anxiety disorder, substance/medication-induced anxiety disorder, anxiety disorder due to another medical condition, other specified anxiety disorder, or unspecified anxiety disorder, the aviator is disqualified. Anxiety disorders tend to have a chronic clinical course with low rates of recovery and high likelihood of recurrence. One notable exception is for patients with specific phobia, who when treated early for a clearly defined fear have shown clinically significant improvement in 70-85% of cases treated with exposure therapy. For these reasons, a waiver is only likely in well-defined identifiable precipitating factors which are unlikely to reoccur.

To be considered for waiver, a mental health evaluation, with accurate diagnosis per the current Diagnostic and Statistical Manual (DSM), is the vital first step. USAF psychologists and/or psychiatrists familiar with aeromedical standards are the preferred choice for evaluation and potential development of the treatment plan. If the diagnosis of an anxiety disorder is established, then grounding the aviator is necessary to allow optimal treatment to be initiated. Psychotherapy, healthy lifestyle interventions, and/or psychotropic medications may be utilized as treatment options until anxiety symptoms are fully resolved (an important goal because partial resolution of symptoms may lead to long-term psychiatric morbidity). Psychotherapy may be continued after symptom resolution to bolster resiliency and coping mechanisms.

Antidepressants are usually the psychotropic agent of choice if healthy lifestyle interventions and psychotherapy have not achieved full resolution of symptoms. Clinical judgment is required for the duration of the antidepressant treatment (maintenance treatment phase), often dictated by the duration of anxious symptoms which prompted the treatment. In treating a first episode of major depressive disorder, antidepressants are typically continued for 6-12 months after full resolution of depressive symptoms in order to prevent abrupt relapse after medication cessation. Since there are no comparable guidelines for length of recommended maintenance treatment of anxiety, clinical judgment is necessary.

In 2013, the USAF began allowing select FC II/III personnel to be considered for waivers on antidepressants. After 5 years of observation, in 2018 the USAF allowed all aviators, including single seat and B-2 pilots, to be considered for waivers on the following monotherapies:

- 1. Sertraline (Zoloft®) up to 200 mg/day
- 2. Citalopram (Celexa®) up to 40 mg/day
- 3. Escitalopram (Lexapro®) up to 20 mg/day
- 4. Bupropion (Wellbutrin®) SR or XL up to 400 mg/day or 450 mg/day, respectively

Of these approved medications, Wellbutrin is known to be less effective in treating anxiety disorders. Also, the dosage of the antidepressant tends to require "higher than usual" amounts when treating anxiety as compared to treatment for depression. This often makes Zoloft an attractive choice in treating anxiety among these approved antidepressants.

The aviator on a maintenance antidepressant (only one aeromedically approved medication allowed) needs to be on the medication and remain clinically asymptomatic for at least 6 months before waiver consideration. The dose of the medication can be adjusted to maximize treatment and/or limit side effects without restarting this 6 month period as long as the aviator's symptoms remain stable. If a psychotropic medication is ever adjusted in dose or discontinued in an aviator, two weeks of observation should occur before considering resuming full flight duties to assure no adverse/unexpected side effects or return of symptoms occur. If symptoms return after discontinuing treatment, a return to, or enhancement of, psychotherapy, healthy lifestyle interventions, and/or antidepressant medication for maintenance treatment should be considered.

Flying Class (FC)	Waiver Potential Waiver Authority	ACS Review/Evaluation
I/IA	Maybe ¹	At the request of the
	AETC	waiver authority
II/III	Maybe ^{1,2}	At the request of the
ATC/GBO/SWA	MAJCOM	waiver authority

#### Table 1: Waiver potential for anxiety disorders

1. For all UNTRAINED individuals in any flying class (FC I/IA, FC II/III, or ATC/GBO/SWA), a waiver is NOT considered if they are currently taking an antidepressant. A waiver for an untrained individual with a history of an anxiety disorder is unlikely, unless there are well-defined identifiable precipitating factors which are unlikely to reoccur. A waiver is considered after the anxiety is completely resolved and medications and/or psychotherapy have been discontinued for a minimum of 2 years.

2. For trained personnel, a waiver is considered after anxiety is completely resolved and stability, on or off medication, has been demonstrated for 6 months. A waiver is only likely in well-defined identifiable precipitating factors which are unlikely to reoccur.

### **II. Information Required for Waiver Submission**

### A. Initial Waiver Request:

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

B. Renewal Waiver Request:

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

#### Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch USAFSAM.FE.PsychiatryMailbox@us.af.mil 2510 Fifth Street Bldg. 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

### **III. Aeromedical Concerns**

Many of the emotional and behavioral manifestations of anxiety disorders can interfere with flying safety and mission completion. Severe anxiety can markedly impair the ability to focus and concentrate on the task at hand. Trembling may diminish the ability to manipulate controls. Palpitations, shortness of breath, chest pain, nausea, and dizziness may be significantly distracting. Some of the more severe symptoms of anxiety, such as those seen in panic disorder (overwhelming anxiety, derealization, and fear of losing control) may be acutely incapacitating. Anxiety is often a factor in depression and psychosomatic complaints as well as being associated with substance misuse, particularly alcohol. Clinical levels of situational or chronic anxiety raise concerns regarding an aviator's emotional stamina and resilience needed to manage the inherent dangers and rigors associated with flying, especially during austere and deployed conditions. It should also be noted that anxiety stemming from a chronically high operational tempo, large workload, and accumulating life stressors may manifest itself as low motivation to fly. The aeromedical disposition of flight personnel diagnosed with an anxiety disorder depends on the specific category of the disorder and phase of the illness.

Anxiety disorders are generally characterized by fear/apprehension, obsessions, fear of loss of control, and physiological symptoms severe enough to interfere with social or occupational functioning. Anxiety is seen in many other psychiatric disorders, but in its benign form, is part of normal emotional experience. Symptomatic anxiety can be constant or nearly so, as in generalized anxiety disorder, or episodic. Episodic spells of anxiety can begin without warning or provocation, as in panic disorder, or predictably in certain situations, as in simple or social phobia. In the latter case, efforts to avoid the anxiety-provoking stimulus can drastically impact the aviator's lifestyle.

#### **Special Considerations**

Three terms that relate specifically to anxiety and flying are often used in aerospace medicine. These are: manifestations of apprehension (MOA), fear of flying (FOF), and phobic fear of flying (specific phobia in DSM-5). MOA and FOF are used to denote a non-phobic fear based on uneasiness, lack of motivation, feelings of inadequacy, rational decision, life circumstance, etc.; MOA is used with student aviators and FOF for rated/trained aviators. Both MOA and FOF are handled administratively by the commander (often in the context of a flying evaluation board or the SUPT/UNT equivalent). A mental health consultation is helpful to clarify the issues in MOA and FOF, and to help rule out a true anxiety disorder. An increasingly recognized problem in the ATC/GBC community is fear of controlling. Similar to fear of flying, these cases are almost always handled administratively.

Phobic fear of flying is a true phobia, often involving only flying, though the symptoms can broaden to other areas of life if not treated. Phobic fear of flying is handled like the other anxiety disorders: by medical disqualification, referral to mental health for evaluation and treatment, and then a return to flying when the disorder is resolved. Persistence of anxiety symptoms, despite adequate treatment or a reluctance to enter treatment, should raise questions about the aviator's motivation to fly.

AIMWTS review in Nov 2019 revealed 341 cases since 1 Jan 2015 with a diagnosis of an anxiety-related disorder. Of these, 168 (49%) were disqualified. Breakdown of the cases revealed: 29 FC I/IA cases (17 disqualified), 51 FC II cases (14 disqualified), 20 RPA pilot cases (12 disqualified), 164 FC III cases (84 disqualified), 66 ATC/GBC cases (37 disqualified), 7 Special Warfare Airmen cases (3 disqualified), and 4 MOD cases (1 disqualified).

ICD 9 codes for anxiety disorders			
291.89	Alcohol-Induced Anxiety Disorder		
292.89	Substance/Medication-Induced Anxiety		
	Disorder (name specific substance)		
293.84	Anxiety Disorder Due to Another General		
	Medical Condition		
300.00	Unspecified Anxiety Disorder		
300.01	Panic Disorder		
300.02	Generalized Anxiety Disorder		
300.09	Other specified Anxiety Disorder		
300.22	Agoraphobia		
300.23	Social Anxiety Disorder (Social Phobia)		
300.29	Specific Phobia (formerly Simple Phobia)		
300.3	Obsessive-Compulsive Disorder		

ICD-10 codes f	ICD-10 codes for anxiety disorders		
F41.9	Anxiety Disorder, Unspecified		
F41.0	Panic Disorder (episodic paroxysmal anxiety)		
	without Agoraphobia		
F41.1	Generalized Anxiety Disorder		
F40.01	Agoraphobia with Panic Disorder		
F40.02	Agoraphobia without Panic Disorder		
F40.10	Social Phobia, Generalized		
F40.11			
F42	Obsessive-compulsive disorder		
F06.4	Anxiety Disorder Due to Known		
	Psychological Condition		

F19.980	Other Psychoactive Substance Use,
	Unspecified with Psychoactive Substance-
	Induced Anxiety Disorder

# **IV. Suggested Readings**

1. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. American Psychiatric Publishing, Arlington, VA, 2013.

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### Attention-Deficit/Hyperactivity Disorder (ADHD) (Jun 2019)

Reviewed: Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

**Significant Changes:** Restructuring of Waiver Guide, Consistent with MSD, AIMWTS review

## I. Waiver Considerations.

Attention-Deficit/Hyperactivity Disorder (ADHD) is disqualifying for all flying duties in the US Air Force. A waiver may be considered for flying if the candidate has established academic and occupational stability off medication for a period of at least 12 months. Any candidate who took medications purely for academic enhancement, without a true diagnosis of ADHD, will still need to show adequate academic or occupational stability off medication for at least 12 months before a waiver is considered. The use of psychostimulants solely to optimize cognitive performance is strictly prohibited (Medical Standard Directory (MSD), Section Q, Note 4). Such unauthorized performance enhancement may be an indication of impaired performance and may prompt unfavorable administrative consequences.

A waiver is NOT required for candidates with a prior diagnosis of ADHD if they have not used medication and have not received special accommodations for occupational or academic performance in the last 4 years (MSD, Q8).

Currently, no stimulant medication is aeromedically approved. Although bupropion is aeromedically approved for smoking cessation and other mental health diagnoses, its use in treating ADHD in the aviation community is unauthorized. To date, no waiver has been granted for ADHD controlled on medication.

Table 1: waiver potential for ADHD			
Flying Class (FC)	Waiver Potential	<b>ACS Review/Evaluation</b>	
	Waiver Authority		
I/IA	Maybe ¹	Yes ²	
	AETC		
II/III	Maybe ¹ MAJCOM ⁴	Yes ²	
RPA Pilot	MAJCOM ⁴		
GBO/ATC	Maybe ¹ MAJCOM ³	Maybe	
SWA	MAJCOM ³	_	

### Table 1: Waiver potential for ADHD

1 Individuals with adequate school and/or work performance with no medication use or special accommodation for 4 years do NOT require a waiver. No waiver has been granted to date for ADHD controlled on medication.

2 ACS review/evaluation if requested by AETC for initial FC I/IA, FC II and FC III applicants.

3 For untrained FC II and III, ATC, and GBO personnel, waiver authority is AETC; otherwise, it is the MAJCOM

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request:

1. Obtain and include all school transcripts from grade school and above.

# 2. See Mental Health Waiver Guide Checklist

3. If the local base is unable to provide all required items, they should explain why to the waiver authority.

B. Renewal Waiver Request:

1. Obtain and include all school transcripts not submitted with the initial waiver request.

2. See Mental Health Waiver Guide Checklist

3. If the local base is unable to provide all required items, they should explain why to the waiver authority.

# Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

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#### **III. Aeromedical Concerns.**

Symptoms of ADHD are incompatible with flying duty. However, psychiatric diagnoses made during childhood or as adults are occasionally found to be unsubstantiated in light of a careful, accurate history. This is particularly true in adults if the service member has had no symptoms since early childhood. The more subtle learning and cognitive inefficiencies that can degrade performance under the demands of military flying may not be detected or recognized in prior non-flying pursuits. As it is unlikely that an initial flying applicant or rated aviator would self-identify as suffering from ADHD, the clinician must have a high index of suspicion for this disorder. Complaints may come to the attention of the flight surgeon through the reports of spouses, supervisors, colleagues or other aircrew. In such cases, it needs to be stressed that the aviator's behavior must be sufficiently age-inappropriate, excessive, long-term, and pervasive. The flight surgeon or other clinician who suspects ADHD must attempt to establish a retrospective childhood diagnosis. Diagnostic skepticism is warranted in the context of a referral for poor performance when there is no prior history of cognitive or behavioral problems. Since the diagnosis of ADHD is a clinical one, a comprehensive interview plus careful neuropsychological testing are important diagnostic procedures.

A confirmed diagnosis of ADHD is disqualifying for flying duties. In fact, ADHD is disqualifying for accession into the Armed Forces of the United States if school or work accommodations continued after age 14, there was a history of comorbid mental health disorders, medication was prescribed in the previous 24 months, or there was documentation of adverse academic or occupational performance (DoDI 6130.03 March 30, 2018). The Air Force will process accession waivers if the individual demonstrates at least 15 months of performance stability, off medication immediately preceding enlistment or enrollment (Sec AF Memo 9 Jan 2017).

Use of medication to control ADHD remains incompatible with flying. Further, ADHD can put both aviation duties and military retention at risk if treatment with medication is required for adequate duty performance. If unable to perform without medication, or if unable to meet AFSC qualifications due to the need for medication, referral to the unit commander for determination of administrative disposition is appropriate and a 469 Mobility Restriction should be created stating the member will need a waiver for deployment consideration. If treatment with medication is not required for adequate duty performance, the member remains suited for continued military service. A waiver is required for all flying classes with a history of ADHD treated or requiring special accommodations within the last 4 years.

Attention-Deficit/Hyperactivity Disorder (ADHD) is a neurodevelopmental disorder, and as such, manifests during the developmental period interfering with the trajectory of normal growth and maturation. The diagnosis of adult ADHD should not be made without a history of symptoms beginning in childhood, usually before the age of twelve. ADHD is characterized by "impairing levels of inattention, disorganization, and/or hyperactivity-impulsivity."

Until the past couple of decades, little thought was given to adult manifestations of ADHD. Clinicians now realize this disorder, once believed to "burn out" in adolescence, can persist into adulthood. In childhood, boys outnumber girls by as much as 10 to 1, but the disorder seems to persist in a higher proportion of girls, and by adulthood the ratio of men to women approximates 1 to 1.

Longitudinal studies have shown that ADHD symptoms persist into adult life. Research has shown that adults with the diagnosis of ADHD have a threefold increase risk of motor vehicle collisions, and an increase of industrial accidents are seen whether treated with medication or not. A very large prospective study from Denmark demonstrated individuals diagnosed with ADHD had higher mortality than the general population.

Treatment of ADHD in adults is similar to that of children, although the results in adults are much less predictable than in children. The mainstay of treatment in both groups is pharmacologic treatment with stimulants, which have demonstrated a clinically and statistically significant effect on reducing ADHD symptoms, although some trials have shown that 30% to 50% of adult subjects either do not respond or have adverse effects. There has been some recent success with non-stimulant medication, particularly atomoxetine and bupropion. Others believe that the issue with many "non-responding" adults is that they are probably under-dosed. Non-pharmacologic treatment of ADHD in adults has not been studied. However, it is accepted that psychological treatment (often in a group setting) can improve patients' lives by teaching them how to structure their environment and improve their organizational skills, how to improve social skills and relationships, and how to manage mood liability.

AIMWITS search from Jan 2014 through May 2019 revealed 149 cases; with 91 of them resulted in a disqualification disposition. There were a total of 6 FC I/IA cases with 5 were disqualifications, 28 FC II cases with 14 disqualifications, 11 RPA pilot cases with 5 disqualifications, 83 FC III cases with 53 disqualifications, 18 ATC/GBC cases with 11 disqualifications, and 3 MOD cases with 3 disqualifications.

ICD-9 codes for ADHD		
314.00	ADHD, predominantly inattentive presentation	
314.01	ADHD, predominantly hyperactive/impulsive presentation	
314.01	ADHD, combined presentation	
314.01	ADHD, unspecified	

ICD-10 codes for ADHD		
F90.0	ADHD, predominantly inattentive presentation	
F90.1	ADHD, predominantly hyperactive/impulsive presentation	
F90.2	ADHD, combined presentation	
F90.9	ADHD, unspecified	

#### V. Suggested Readings

1. Gitlow S. Psychiatry. Ch. 12 in Rayman's *Clinical Aviation Medicine*, 5th Ed., Connolly Graduate Medical Publishing, New York, 2013; pp. 315-16.

2. Fitzgerald D, Navathe P, and Drane A. Aeromedical Decision Making in Attention-Deficit/Hyperactivity Disorder. Aviat Space Environ Med, 2011; 82: 550-54.

3. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders: DSM-5.* 5th ed. American Psychiatric Publishing, Arlington, VA, 2013.

4. Dalsgaard S, Østergaard SD, Leckman JF, et al. Mortality in children, adolescents, and adults with attention deficit hyperactivity disorder: a nationwide cohort study. Lancet, 2015; 385(9983): 2190-96

5. Medical Letter. Drugs for ADHD. Vol. 57 (Issue 1464), Mar 2015.

6. Adler LA, Spencer JT, Stein MA, and Newcorn JH. Best Practices in Adult ADHD: Neurobiology, Pharmacology, and Emerging Treatments. Expert Roundtable Supplement to CNS Spectr, 13:9 (Supp 13), September 2008.

# Eating Disorders (Jun 2020)

Reviewed: Dr. Ryan Peirson (ACS Neuropsychiatry Branch Psychiatrist), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Col Marie-France McIntee (AFMRA Physical Standards Development Chief)

## Significant Changes: Restructuring of Waiver Guide, AIMWTS review

# I. Waiver Consideration

Eating Disorders that occur after age 12 are disqualifying for all flying classes and may be disqualifying for continued service. If a member is diagnosed with any eating disorder, including the diagnosis of Eating Disorder Not Otherwise Specified (former terminology) or Other Specified or Other Unspecified Feeding or Eating Disorder, a waiver is required (MSD Q27 and Q28).

To be considered for a waiver, a mental health evaluation, with accurate diagnosis per the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is the vital first step. USAF psychologists/psychiatrists familiar with aeromedical standards are the preferred choice for evaluation and potential development of the treatment plan.

Due to the persistent nature of eating disorders, their risk for a wide-array of health consequences, and the potential for mental health comorbidities, a long period of demonstrated stability is required for waiver eligibility. For all untrained individuals (FC I/IA, II/III, ATC/GBO/SWA) with a history of an eating disorder after age 12 a minimum of two years remission with successful treatment must be documented. For trained individuals (FC II, FC III, ATC/GBO/SWA) with a history of eating disorder after age 12 a minimum of one year remission with successful treatment must be documented.

Tuble It waiter potential for Diagnosis			
Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Maybe ^{1, 2}	AETC	Yes ³
FC II/III/RPA	Yes ^{1, 2}	MAJCOM	Yes ³
II/III and ATC/GBO/SWA	Yes ^{1, 2}	MAJCOM	Yes ³

### Table 1: Waiver potential for Diagnosis

1. Must clearly demonstrate complete resolution of all symptoms before acceptance into initial flying training and have complete documentation from mental health and other medical providers.

2. Patients with eating disorders must meet minimum aviation weight standards.

3. Must be reviewed by the ACS prior to consideration for a waiver.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

#### A. Initial Waiver Request:

- 3. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 4. If the local base is unable to provide all required items, they should explain why to the waiver authority

#### B. Renewal Waiver Request:

- 3. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 4. If the local base is unable to provide all required items, they should explain why to the waiver authority.

#### Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch USAFSAM.FE.PsychiatryMailbox@us.af.mil

2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296 Comm: 937-938-2768 DSN: 798-2768

### **III. Aeromedical Concerns**

Physical and emotional difficulties can lower a person's stamina for managing the high stress of military flying, especially when they occur in concert. Eating disorders can cause life-threatening metabolic alkalosis, hypokalemia, seizures, dehydration, and hypotension which impact readiness, mission completion, and flying safety. Other mental disorders are frequently co-occurring with eating disorders. Anxiety and depression are of particular concern and providers should be mindful of an increased risk of suicide. Personality disorders are also often co-occurring and can make both diagnosis and treatment especially difficult. Problematic personality characteristics common in eating disorders, such as emotional reactivity and perfectionism, may interfere with crew resource management and other aspects of crew relations essential to successful flying.

Please note that the diagnostic criteria of the various disorders were significantly revised in the most recent edition of the DSM-5. Clinicians have more guidance in using clinical judgment and are encouraged to consider the core features of the disorders: clinically significant distress OR impairment in social, occupational, or other important areas of functioning. A number of significant presentations that merit clinical attention and treatment are listed in the "Other Specified" section and are offered as suggestions for presentations in which symptoms are characteristic of an eating disorder but do not meet full criteria for any of the other disorders

named in the diagnostic class. For example, Atypical Anorexia Nervosa, and Purging Disorder, are possibilities for the "Other Specified" category, and should not be overlooked when considering a person's symptoms when they cause distress or impact an area of functioning.

The course and outcome of eating disorders is highly variable. For many people, recovery is marked by periods of remission interrupted by symptom re-occurrence. The potential for relapse is a principal concern in calculating aeromedical risk.

AIMWTS review in Jun 2020 for the previous five years revealed 14 cases with a listed diagnosis of an eating disorder. There were nine cases resulting in a disposition of disqualified. Breakdown of the cases revealed: 2 FC I/IA cases with 1 disqualification, 3 FC II cases with 2 disqualifications, 7 FC III cases with 5 disqualifications, 1 ATC case, and 1 SWA case with 1 disqualification.

ICD-9 codes for Eating Disorders		
307.1	307.1 Anorexia Nervosa	
307.51	07.51 Bulimia Nervosa	
307.51	Binge Eating Disorder	
307.59Other Specified Feeding or Eating Disorder		

ICD-10 codes for Eating Disorders		
F50.01/.02	F50.01/.02 Anorexia Nervosa	
F50.2	Bulimia Nervosa	
F50.8	Binge Eating Disorder	
F50.8	Other Specified Feeding or Eating Disorder	

#### **IV. Suggested Readings**

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 5th ed. American Psychiatric Publishing, Arlington, VA, 2013.

2. Yager J. Eating disorders: Overview of epidemiology, clinical features, and diagnosis. UpToDate. Nov 2018.

3. Hoek HW, van Hoeken D. Review of the prevalence and incidence of eating disorders. Int J Eat Disord 2003; 34:383.

4. Bergh C, Brodin U, Lindberg G, and Södersten P. Randomized controlled trial of a treatment for anorexia and bulimia nervosa. Proc Natl Acad Sci USA, 2002; 99(14): 9486-91.

#### WAIVER GUIDE

Updated: Jun 2013 Supersedes Waiver Guide of Feb 2009 By: Lt Col Michael Hodges (RAM 13) and Dr. Dan Van Syoc Reviewed by Col Kent McDonald, ACS chief of Neuropsychiatry

### CONDITION: Learning Disabilities (Jun 2013)

#### I. Waiver Considerations.

A history of a learning disability is disqualifying for appointment, enlistment and induction into the US Air Force. It is also disqualifying for retention in the military, from an administrative perspective. The MSD lists learning disabilities as disqualifying for all flying classes to include GBO, ATC, and SWA.

Flying Class (FC)	Waiver Potential Waiver Authority	ACS review/evaluation
I/IA	Maybe AETC	Yes ¹
UNTRAINED – II/III/ATC/GBO/SWA	Maybe MAJCOM ²	Yes ¹
TRAINED – II/III and RPA Pilot	Maybe MAJCOM ²	Yes ¹
ATC/GBO/SWA	Maybe MAJCOM ²	No

#### **Table 1: Waiver potential for Learning Disabilities**

1 ACS review/evaluation if requested by AETC for initial FC I/IA, FC II, and FC III applicants.

2 For untrained FC II, and FC III personnel, as well as ATC/GBO/SWA, waiver authority is AETC, otherwise it is the MAJCOM of assignment.

For FC I/IA applicants to receive a waiver, their academic record must have been achieved without any accommodations and there must be no evidence of current problems. Waiver may be considered for aircrew with a history of LD, providing they are symptom free and have not manifested a degradation of their performance of aircrew duties.

AIMWTS review in Feb 2013 for all variations of learning disabilities revealed a total of 14 cases with six resulting in a disqualification disposition. There were a total of 7 FC I/IA cases, one was disqualified. There were no FC II cases. There were a total of 5 FC III cases with 2 disqualified. One member was applying for loadmaster duties and could not pass the Reading Aloud Test which was felt to be secondary to English not being his native language (member inappropriately labeled as LD), while the other case was a flight nurse applicant with dyslexia. Of the 3 ATC cases, all 3 where disqualified for learning difficulties during their apprenticeship.

# II. Information Required for Waiver Submission.

Submitting a Mental Health Waiver Guide:

AFI 48-123 –Chapter 6 (pg. 55) and the Aeromedical Consultation Service (ACS) Waiver Guide addresses waiver evaluations

Step 1 - Is the aviator ready for waiver submission?

A. Waiver is submitted when 1) the member is asymptomatic and 2) medications/psychotherapy treatment have been completed, as applicable to diagnostic category, for the specified time-frame below (Note: psychotherapy "booster sessions", and sometimes SSRIs, are permissible and often advisable after initial symptom resolution): 1 Year—Psychotic Disorders & Somatoform Disorders  $\square$ 6 Months—Mood Disorders, Anxiety Disorders & Suicidal Behavior Discretion of Flight Surgeon—Adjustment Disorders & V-Codes requiring waiver  $\square$ For Traumatic Brain Injury cases, please refer to TBI Waiver Guide  $\square$ For aviators with any other psychiatric disorders, please refer to AFI 48-123 and ACS Waiver Guide B. To be considered for an aeromedical waiver, any disqualifying condition must meet the following criteria per AFI 48-123 Section 6B, 6.2.1.1 through 6.2.1.6. (pg. 57-58): Not pose a risk of sudden incapacitation Pose minimal potential for subtle performance decrement, particularly with regard to the higher senses Be resolved, or be stable, and be expected to remain so under the stresses of the aviation environment If the possibility of progression or recurrence exists, the first symptoms or signs must be easily detectable and not pose a risk to the individual or the safety of others Cannot require exotic tests, regular invasive procedures, or frequent absences to monitor for stability or progression

Must be compatible with the performance of sustained flying operations

Step 2 - Before beginning the Aeromedical Summary (AMS), Flight Surgeon must obtain Mental Health consultation and ensure it contains items specified below:

Instructions for the Mental Health Provider

The mental health evaluation must include a comprehensive written report addressing:

- Consultation must address each criteria in Step 1B
- Clinical mental health history (description of symptoms, treatment modality, frequency and compliance with treatment, relevant personal and family history, and perceived impact on occupational duties)
  - Medication history (dates of initial prescription and termination, reason for termination, dosage, compliance, response, clinical course since termination)

	Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile) ** for alcohol cases, please comment on Carbohydrate-deficient transferrin (CDT) results**
	Current psychosocial situation (marital and occupational, interview with spouse/supervisor, input from line leadership, if possible, and please address current state of any triggers for the mental
	illness) Current and past aviation related duties and any history of current and past occupational performance difficulties (to include perceived impact of mental health condition on performance of duties)
	Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
	Summary and interpretation of psychological/neuropsychological testing results (recommend MMPI-2, NEO PI-R, or similar personality test). For neuropsychological cases, please contact ACS neuropsychologist (Dr. Gary Ford, DSN: 798-2704) for guidance on recommended neuropsychological tests.
	Current mental status
	Diagnosis
	Motivation to fly or engage in special duty operations (past and current)
	Recommendation for future psychological and medical treatment
	Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)
	Copies of all records (mental health/ADAPT/inpatient) and raw testing data should be on hand for shipment to ACS Neuropsychiatry Branch
Step 3 -	Items for the Flight Surgeon to include in the AMS:
	AMS must clearly address each criteria in Step 1B and the risk to the member, mission, and safety
	Summarize Mental Health history and focus on occupational impact
	** If 2 or more months have passed since the comprehensive evaluation/report was completed, the flight surgeon should address how the member has done since and consult with the mental health provider if the member has been seen at mental health since the evaluation**
	Medication history (dates of initial prescription and termination, reason for termination, dosage,
	compliance, response, clinical course since termination) Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile) ** for alcohol cases, please comment on Carbohydrate-deficient transferrin (CDT) results**
	Current psychosocial situation (marital and occupational, interview with spouse/supervisor, if possible - please address current state of any triggers for the mental illness)
	Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
	Current mental status
	Diagnosis
	Motivation to fly (past and current)
	Recommendation for future psychological and medical treatment
	Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)

Step 4 - Items to complete the waiver package:

- Letter of support from command
- Comprehensive mental health written-report

Confirm mental health has made copies of chart(s) and testing. When requested send to:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

Please feel free to contact the ACS Neuropsychiatry Branch with questions: Mr. John Heaton: 798-2766

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for the <u>initial waiver</u> for learning disorder should include the following:

A. AMS detailing any social, occupational, administrative or legal problems, including an analysis of the aeromedical implications of this particular case history.

B. Mental health evaluation summary, *specifically including* psychological and neuropsychological evaluation reports (with their raw data), and any pertinent past medical or

mental health records.

C. Any pertinent current neurological or other medical consultation reports.

D. For FC I/IA, detailed history of academic achievement and use of any accommodations.

E. For trained FC II or III, a letter from the flyer's aviation supervisor or commander supporting a return to flying status.

The AMS for waiver renewal for learning disorder should include the following:

A. Interval history.

B. All applicable testing results.

C. Consultation from mental health professional.

# III. Overview.

A learning disability is a persistent higher order cognitive deficit that interferes with learning and academic achievement, especially in reading, spelling, writing and/or arithmetic in the context of average or above average intelligence.¹ The term, "learning disability," once associated with reading problems, is often misunderstood, and is a non-specific term for numerous disorders of cognition in various combinations and levels of severity. Such variability leads to a spectrum of aeromedical significance, so that knowledgeable evaluation of the individual and a thorough history on educational achievement, rather than simply identifying the diagnosis, is essential to

making a correct aeromedical decision. Previously unrecognized and otherwise irrelevant mild cognitive inefficiencies can prove to be dangerous and result in safety of flight and mission performance issues in military aviation. Due to problems with overall learning, people identified with learning disabilities as children often suffer from low levels of academic achievement.² Since speech and language delays can be a contributing factor in younger ages for learning difficulties, early recognition and intervention is a must.³ Success in later educational endeavors can be potentially compromised unless the parents and/or school recognize the problem early and provide appropriate remediation.

There are multiple variations of learning disabilities, but there are three widely accepted categories that include reading, mathematics, and written expression. A given individual may have more than one form of learning disability. The first category is reading disorder which is defined as a significant impairment in reading that does not have any demonstrable cause in visual, hearing or physical disorders; is not related to mental retardation, emotional disturbance; nor does it have any environmental, cultural or economic disadvantage.⁴ It is estimated that up to one in five children have a significant problem learning to read. Reading disorder is seen in up to 80 percent of school children labeled with a learning disability, or about four percent of the school-age population.^{4,8} All children with this disorder share three key symptoms: inaccurate reading, slow reading, and poor reading comprehension. Reading is a totally different skill than oral language. It requires the brain to link written markings to spoken language. To break it down further, the act of reading is actually at least two different processes: basic reading which has to be taught and is letter-sound knowledge along with word recognition, storing and decoding; and reading comprehension, which is the ultimate goal.⁴ Dyslexia is the most commonly recognized form of reading disorder. One author defined dyslexia as an unexpected difficulty in reading in children and adults who otherwise possess the intelligence and motivation necessary for accurate and fluent reading.⁵ Although the etiology of dyslexia is not known, there are various theories. One is the "Cerebellar Deficit" theory where non-verbal, sensory-motor impairments are felt to have an effect for bringing about dyslexia.⁶ Another is the "Phonological Deficit" hypothesis where dyslexia individuals suffer from a deficit in phonological skills where they have a problem reading nonwords.⁷ The severity of impairment in individuals with this disorder varies widely. There are numerous models being developed in an effort to identify children at an early age and to intervene in an effective manner.^{7,9} Patients with reading disabilities require lifelong assistance, and for secondary and college students, the emphasis is on accommodations, to include extra time, and help with different study skills and test taking.⁸

The second category of learning disabilities is mathematics disorder which is an impairment of arithmetic or mathematic skills that is sufficiently serious to interfere with academic achievement or daily living. This may affect up to six percent of school age children. The only proven treatment of mathematics disorder is systematic instruction.⁴

The last major category is the disorder of written expression, which some call dysgraphia. It is a significant impairment in written communication that is not attributable to the same issues outlined under reading disorder. It is commonly expressed with spelling, grammatical/syntax or punctuation errors, poor paragraph organization, and excessively poor handwriting. Most studies

to date indicate that individuals with the disorder have persistent problems with written language into late childhood and adolescence.⁴

Until the past couple of decades, little thought was given to adult manifestations of learning disabilities. Clinicians now realize these disorders, once felt to "burn themselves out" in adolescence, can persist into adulthood. Even though it does not disappear, given early intervention and positive educational experiences, many of these people can show a remarkable ability to learn and succeed.¹⁰ Both genetic and environmental factors are undoubtedly important in the etiology of these disorders. Physiological as well as anatomic markers are being sought. Still, current science requires thorough clinical, historical, and, often, psychometric evaluation in order to make these diagnoses. Learning disabilities may be associated with underlying abnormalities in cognitive function, including deficits in attention, memory, or linguistic processes. Impaired vision or hearing may affect learning ability and should be investigated through audiometric or visual screening tests. A learning disability may be diagnosed in the presence of such sensory deficits *only* if the learning difficulties are in excess of those usually associated with these deficits.

# **IV. Aeromedical Concerns.**

Typically, significant problems will become manifest in childhood or adolescence and well before an individual is considered as an applicant for aviation service, and the individual will not be selected for flying duties on the basis of low academic performance and/or screening tests (such as the AFOQT). Additionally, it is unlikely that a person with an identified learning disability for which remedial services were provided will be able to successfully complete rigorous military aviation training. As otherwise intelligent officers will have great difficulty keeping up with the rigors of training and operational flying, a confirmed diagnosis of LD is disqualifying for flying class FC I duties, unless the individual can demonstrate passing academic performance off medication and /or solid job performance off medication for a period of no less than 12 months. A history of a learning disorder will not necessarily disqualify a member. Severity and nature of the disorder should be documented. In addition, LD and other psychiatric diagnoses made during childhood are occasionally found to be unsubstantiated in light of a careful, accurate history, and instead can be the result of over-eager achievement-driven parents. This is particularly true if the service member has had no symptoms since early childhood.

ICD-9 Codes for Learning Disabilities		
315.0	Specific Reading Disorder	
315.02	Developmental Dyslexia	
315.1	Mathematics Disorder	
315.2	Other Specific Learning Difficulties	
315.3	Developmental Speech or Language Disorder	
784.61	Alexia and Dyslexia	

ICD-10 Codes for Learning Disabilities	
F81.0	Specific Reading Disorder

R48.0	Dyslexia and Alexia
F81.2	Mathematics Disorder
F81.89	Other Development Disorders of Scholastic Skills
F81.9	Development Disorders of Scholastic Skills, Unspecified

#### V. References.

1. Handler SM and Fierson WM. Learning Disabilities, Dyslexia, and Vision. Pediatrics, 2011; 127: e818-e856.

2. Grigorenko EL. Learning Disabilities in Juvenile Offenders. Child Adolesc Psychiatric Clin N Am, 2006; 15: 353-71.

3. McLaughlin MR. Speech and Language Delay in Children. Am Fam Physician, 2011; 83(10): 1183-88.

4. Tannock R. Learning Disorders, in *Kaplan & Sadock's Comprehensive Textbook of Psychiatry*, 8th ed., Ch. 35. Lippincott Williams Wilkins, 2005.

5. Shaywitz SE, Gruen JR, and Shaywitz BA. Management of Dyslexia, Its Rationale, and Underlying Neurobiology. Pediatr Clin N Am, 2007; 54: 609-23.

6. Sela I and Karni A. Differences in Learning Volitional (Manual) and Non-Volitional (Posture) Aspects of a Complex Motor Skill in Young Adult Dyslexic and Skilled Readers. *PLoS One*, 2012; 7(9): e43488.

7. Van de Broeck W, Geudens A, and Van den Bos KP. The Nonword-Reading Deficit of Disabled Readers: A Developmental Interpretation. Devel Psychol, 2010; 46(3): 717-34.

8. Hamilton SS and Glascoe FP. Evaluation of Children with Reading Difficulties. Am Fam Physician, 2006; 74: 2079-84.

9. Grizzle KL. Developmental Dyslexia. Pediatr Clin N Am, 2007; 54: 507-23.

10. Pratt HD and Patel DR. Learning Disorders in Children and Adolescents. Prim Care Clin Office Pract, 2007: 34: 361-74.

### Mental Health Waiver Guide Checklist (Jan 2019)

Reviewed: Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col I. David Gregory (AFMSA Physical Standards Development Chief)

#### Significant Changes: New Document

#### **Required Period of Clinical Stability**

A period of clinical stability is required after the aviator's "**Best Baseline**" is achieved. "**Best Baseline**" is reached when the aviator's Mental Health Provider (MHP) determines the symptoms of the diagnosis are no longer causing clinically significant distress or impairment and the aviator demonstrates adequate function in social, occupational, and other important areas for functioning. Once "**Best Baseline**" is reached treatment adjustments can still be made, including medication changes, without restarting the period of clinical stability as long as the aviator's levels of distress, impairment, or functioning have not deteriorated to a point which the MHP determines to be clinically significant. Different diagnoses require different lengths of clinical stability prior to requesting a waiver.

- 1 Year—Psychotic Disorders, Somatic Symptoms and Related Disorders, & Eating Disorders

- 6 Months—Mood Disorders, Anxiety, PTSD, & Suicidal Behavior

- **Discretion of Flight Surgeon**—Adjustment Disorder & Other Conditions that May Be a Focus of Clinical Attention requiring waiver

- For aviators with any other psychiatric disorders, please refer to AFI 48-123, Medical Standards Directory (MSD) Section Q: Psychiatry and Mental Health, and ACS Waiver Guides

### **Required Items for Waiver Package**

- Submit waiver package **30 days BEFORE** the required period of stability is reached to ensure the aviator is evaluated as close to their waiver eligibility as possible.

- Please make every effort to provide **complete documentation**. AHLTA is not reliably accessible at the Aeromedical Consultation Service (ACS) and so the Waiver Package should include a PDF of all Mental Health notes in chronological order.

- If the aviator is **Guard** or **Reserve** and has difficulty accomplishing a required item, please note this in the AeroMedical Summary (AMS).

- A well-written and complete evaluation following the waiver guide's template for mental health evaluations improves the chance for an aeroletter disposition with no need for an expensive week long TDY to ACS for face-to-face evaluation

- All Items are needed for both Initial Waiver Requests and Renewal Waiver Requests.

### 1. Mental Health Evaluation – within 1 month of submission – See Template

- To be accomplished after "Best Baseline" as above.

- The evaluator should be a **doctoral level MHP** with preference for a **Psychiatrist** if the aviator is on **psychotropic medication**.

### 2. Flight Surgeon's AeroMedical Summary (AMS) - See Template

- Utilize the Mental Health Evaluation, and summarize the Flight Surgeon's interview of aviator, Commander Letter, and collateral information (supervisor, spouse, etc.).

# 3. ALL Past Mental Health and Pertinent Medical Records – See Authorization Form

Military AND Civilian records are required (MH records behind "break glass" are needed).
Records to submit include: outpatient, inpatient, partial hospitalization, intensive outpatient, ADAPT, FAP, detox/rehab, Pre-military if relevant (child mental health care).

# 4. Commander's Endorsement Letter

- A memo from the aviator's commander supporting their request for waiver and providing insight into the aviator's ability to function effectively at work is very helpful.

# 5. All Pertinent Labs

- Alcohol Use Disorder cases require at least 2 unannounced Carbohydrate-Deficient Transferrin (CDT) studies to demonstrate abstinence.

6. Copy of Abstinence Letter - for Alcohol Use Disorder cases.

# Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913

<u>USAFSAM.FE.PsychiatryMailbox@us.af.m</u> <u>il</u> Phone: (937) 938-2768 DSN: 798-2768 Fax: (937) 904-8753 DSN: 674-8753

# Mental Health Evaluation for Aeromedical Summary

- 1. Date symptoms started. Why then? Comment on context and etiology.
- 2. Initial symptoms and symptoms at their worst.
- 3. How symptoms impacted military and flight duties.
- 4. Date and circumstances of presentation (self-referral, CDE, spouse threatened divorce, etc.).
- 5. Type and length of treatment:
  - a. Psychotherapy
    - i. Name of Provider (psychologist, social worker)
    - ii. Type of therapy (CBT, PE, EMDR, etc.), focus, and core issues
    - iii. Total number of sessions from when to when

# **b.** Medication treatment

- i. Name of Provider (psychiatrist, PCM, FS, PMHNP, PA)
- ii. Medication(s) prescribed, impact, compliance, side effects, and dates
- iii. Current medications

# c. Healthy lifestyle interventions

- i. Premorbid
- ii. Learned and utilized during treatment
- iii. Current utilization for coping and resilience
- 6. Date aviator returned to **"Best Baseline"** even if still receiving ongoing medication(s) or psychotherapy. Comment on symptom resolution and need for ongoing treatment.
- 7. Changes in screening measures (PHQ-9, GAD-7, PCL-5, etc.) and psychological testing with RAW DATA and interpretation, if administered.
- 8. Review of systems, past medical history, past psychiatric history, family psychiatric history, appropriate developmental history, social history, and substance use (caffeine, smoking, EtOH, etc.).
- 9. Current mental status, level of function at work, in military environment, in family, in personal life, and ability to perform under stress and in operational/aviation setting.
- 10. Comment on aviator's awareness, insight, new skills obtained and used, coping ability, and successes. Comment on how aviator tolerated past and recent stressors (indications of resilience).
- 11. Diagnosis supported by DSM-5 criteria.
- 12. Estimated risk of recurrence, based on DSM-5, patient's history, and evaluator's experience.
- 13. Motivation to return to flying duties.

# Flight Surgeon's AMS Template for Mental Health Waiver

- 1. Summary of presentation, course of illness, and treatment.
- 2. How did symptoms impact military and flight duties?
- 3. Date and circumstances of presentation (self-referral, command-directed, spouse threatened divorce, etc.), and initial mental health treatment.
- 4. Type and length of treatment.
- 5. Date aviator returned to "Best Baseline" even if still receiving ongoing medication(s) or psychotherapy. Comment on symptom resolution and if there is a need for ongoing treatment. Confirm required period of stability has been met for the diagnosis.
- 6. Current mental status, level of function at work, in military environment, in family, in personal life, ability to perform under stress and **capacity to function in stressful aviation/operational settings.**
- 7. Comment on aviator's awareness, insight, new skills obtained and used, coping ability, and successes. Comment on how aviator tolerated past and recent stressors (indications of resilience).
- 8. Diagnosis, supported by DSM-5 criteria.
- 9. Estimated risk of recurrence, based on DSM-5, patient's history, and Flight Surgeon's experience.
- 10. Comment on ability, stability, and motivation to fly (or special duty).
- 11. Discuss Command support.
- 12. Estimated aeromedical risk if aviator is returned to flight status. Address the following:
  - a. Risk of sudden incapacitation
  - b. Risk of subtle performance decrement
  - c. Stability under stress (physiological or emotional)
  - d. Possibility of progression or recurrence
  - e. Need for exotic tests
  - f. Compatibility to perform sustained flight operations in austere environments
- 13. Flight Surgeon's endorsement, consultative question(s), and final recommendations.

AUTHORIZATION FOR DISCLOSURE OF MEDICAL OR DENTAL INFORM	AATION	
<ul> <li>PRIVACY ACT STATEMENT</li> <li>In accordance with the Privacy Act of 1974 (Public Law 93-579), the notice informs yet AUTHORITY: Public Law 104 -191; E.O. 9397 (SSAN); DoD 6025.18 -R.</li> <li>PRINCIPAL PURPOSE(S): This form is to provide the Military Treatment Facility disclosure of an individual's protected health information.</li> <li>ROUTINE USE(S): To any third party or the individual upon authorization for the dilegal; retirement/separation; or other reasons.</li> <li>DISCLOSURE: Voluntary. Failure to sign the authorization form will result in the n This form will not be used for the authorization to disclose alcohol or drug abuse patie records of an alcohol or drug abuse treatment program. In addition, any use as an auth authorization except one to use or disclose psychotherapy notes.</li> </ul>	/Dental Treatment Facility/TRICARE Health l sclosure from the individual for: personal use; on-release of the protected health information. nt information from medical records or for aut	Plan with a means to request the use and/or insurance; continued medical care; school; horization to disclose information from
SECTION I - PATIENT DATA		
1. NAME (Last, First, Middle Initial)	2. DATE OF BIRTH (YYYYMMDD)	<b>3. SOCIAL SECURITY NUMBER</b>
4. PERIOD OF TREATMENT: FROM - TO (YYYYMMDD)	5. TYPE OF TREATMENT (X one)	
ALL	OUTPATIENT INPATIEN	NT BOTH
SECTION II - DISCLOSURE		
	TO RELEASE MY PATIENT INFORMAT	TON TO:
(Name of Facility/TRICARE Health Plan)		
a. NAME OF PHYSICIAN, FACILITY, OR TRICARE HEALTH PLAN Neuropsychiatry Branch - Aeromedical Consultation Service USAF School of Aerospace Medicine	b. ADDRESS (Street, City, State and ZIP of 2510 5th Street, Bldg 840, Area B Wright-J USAFSAM.FE.PsychiatryMailbox@us.af.	Patterson AFB, OH 45433-7913
c. TELEPHONE (Include Area Code) (937) 938-2768	d. FAX (Include Area Code) (937) 904-8'	753
7. REASON FOR REQUEST/USE OF MEDICAL INFORMATION (X as applica		
PERSONAL USE CONTINUED MEDICAL CARE X INSURANCE RETIREMENT/SEPARATION	OTHER <i>(Specify)</i> <b>ACS WAIVER PACK</b> SCHOOL LEGAL	AGE
8. INFORMATION TO BE RELEASED All Mental/Behavioral Health (Sections A-F), ADAPT, FAP, and/or civilian records (v background questionnaires, intake forms, psychological/personality testing (standard, 1 (not AHLTA copies), etc.		
	TON EXPIRATION	
DATE (YYYY)	/MDD)	ACTION COMPLETED
SECTION III - RELEASE AUTHORIZATION		
I understand that: I have the right to revoke this authorization at any time. My revocation must be in wr Officer if this is an authorization for information possessed by the TRICARE Health I person(s) I herein name will have used and/or disclosed my protected information on If I authorize my protected health information to be disclosed to someone who is not n be re-disclosed and would no longer be protected. I have a right to inspect and receive a copy of my own protected health information to regulations found in the Privacy Act and 45 CFR ss 164.524. The Military Health System (which includes the TRICARE Health Plan) may not con	Plan rather than an MTF or DTF. I am aware t the basis of this authorization. required to comply with federal privacy protect be used or disclosed, in accordance with the r dition treatment in MTFs/DTFs, payment by th	hat if I later revoke this authorization, the tion regulations, then such information may equirements of the federal privacy protection ne TRICARE Health Plan, enrolment in the
TRICARE Health Plan or eligibility for TRICARE Health Plan benefits on failure to a facility/TRICARE Health Plan to release the information described above to the name	ed individual/organization indicated.	
11. SIGNATURE OF PATIENT/PARENT/LEGAL REPRESENTATIVE	<b>12. RELATIONSHIP TO PATIENT</b> ( <i>If applicable</i> ) self	13. DATE (YYYYMMDD)
SECTION IV - FOR STAFF USE ONLY (To be completed only upon receipt of wri	tten revocation)	
14. X IF APPLICABLE: 15. REVOCATION COMPLETED BY		16. DATE (YYYYMMDD)
AUTHORIZATION REVOKED		

# Mood Disorders: Depressive, Bipolar and Related Disorders (Sep 2019)

Reviewed: Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

### Significant Changes:

Restructuring of Waiver Guide, Anti-depressant management, AIMWTS review

# I. Waiver Consideration

Mood disorders are disqualifying for all flying classes to include ATC/GBO and SWA duties. Untreated or undertreated mood disorders may have potentially disastrous consequences. To mitigate such outcomes, the FAA, Transport Canada, Australia, and the US Army have policies allowing selected aviators to fly while on SSRI's. The USAF followed suit in 2013 allowing select FC II/III personnel to be considered for waivers on antidepressants. After 5 years of observation, in 2018 the USAF allowed all aviators, including single seat and B-2 pilots, to be considered for waivers on the following monotherapies:

- 1. Sertraline (Zoloft®) up to 200 mg/day
- 2. Citalopram (Celexa®) up to 40 mg/day
- 3. Escitalopram (Lexapro®) up to 20 mg/day
- 4. Bupropion (Wellbutrin®) SR or XL up to 400 mg/day or 450 mg/day, respectively.

The aviator on a maintenance antidepressant (only one aeromedically approved medication allowed) needs to be on the medication and remain clinically asymptomatic for at least 6 months before waiver consideration. The dose of the medication can be adjusted to maximize treatment and/or limit side effects without restarting this 6-month period as long as the aviator's symptoms remain stable. If a psychotropic medication is ever adjusted in dose or discontinued in an aviator, two weeks of observation should occur before considering resuming full flight duties to assure no adverse/unexpected side effects or return of symptoms occur. If symptoms return after discontinuing treatment, a return to, or enhancement of, psychotherapy, healthy lifestyle interventions, and/or antidepressant medication for maintenance treatment should be considered.

Waivers are not considered for FCI personnel on antidepressants and are limited to FCII, FCIII, ATC, GBO, and SWA. All FCII, FCIII, and SWA listed (Boom Operator, Flight Engineer, Loadmaster, Aerial Gunner, Combat Control, Pararescue Jumper, Tactical Air Control Party) require ACS review or evaluation and AFMRA waiver. For all other FCIII AFSCs, ACS review is encouraged, and MAJCOM dispositions the waiver.

MOD personnel may be permitted to perform their duty while on certain psychotropic medications listed on the Approved Space and Missile Operator Medications list, but a waiver is typically required.

To be considered for waiver, a mental health evaluation with accurate diagnosis per the Diagnostic and Statistical Manual (DSM) is the vital first step. USAF psychology and/or psychiatry specialists familiar with aeromedical standards are the preferred choice for evaluation and potential development of the treatment plan.

# **DEPRESSIVE DISORDERS**

If the diagnostic criteria for Major Depressive Disorder (MDD), Persistent Depressive Disorder (Dysthymia), or Unspecified Depressive Disorder are met, the aviator is disqualified. A history of two episodes of MDD increases the probability of recurrence to approximately 70%. Therefore, recurrent episodes of depressive disorders are generally disqualifying and not waiverable because of the likelihood of a continually emerging pattern of depressive symptoms negatively affecting overall performance and reliability.

If the diagnosis of a depressive disorder is established, then grounding the aviator is necessary to allow optimal treatment to be initiated. Psychotherapy, healthy lifestyle interventions, and/or psychotropic medications may be utilized as treatment options until depressive symptoms are fully resolved. This is an important goal because partial resolution of symptoms may lead to long-term psychiatric morbidity. Typically, antidepressants are continued for 6-12 months after full resolution of depressive symptoms in order to prevent abrupt relapse after medication cessation. Psychotherapy may be continued after symptom resolution to bolster resiliency and coping mechanisms. A waiver may be considered after 6 months of demonstrated stability (i.e., aviator is back to best baseline functioning). Therefore, it is important for the mental health professional to designate the date of full resolution of symptoms. It is from that date that 6 months of stability should be measured for potential waiver, regardless of ongoing psychotropic medication and/or psychotherapy in pursuit of optimal therapeutic benefit.

# **BIPOLAR and RELATED DISORDERS**

Any aviator with any of the bipolar disorders is permanently disqualified and not eligible for waiver due to the risk of recurrence, the presenting symptoms of loss of insight, tenuous reality-testing, and the unlikelihood of self-referral, poor judgment and poor treatment compliance. The treatment options for bipolar disorders (mood stabilizers and atypical antipsychotics) are not aeromedically-approved for aviators and are not waiverable. In such cases, a medical evaluation board (MEB) should be held to determine fitness for general duty and retention. There is a 29% risk of developing bipolar disorder if both parents are diagnosed with bipolar disorder. Therefore, a family history of a bipolar disorder in both parents is disqualifying for FCI/IA, but can be considered for a waiver after a very thorough mental health evaluation.

Flying Class (FC)	Condition	Waiver Potential	
		Waiver Authority	
I/IA	Family history of bipolar	Maybe ¹	
	disorder (both parents)	AETC	
	Bipolar disorders	No	
	-	AETC	
	Depressive disorders	Maybe ²	
	1	AETC	
II/III	Bipolar disorders	No	
ATC/GBO SWA		AFMSA	
	Major Depressive Disorder	Maybe ^{2, 3}	
	(MDD), single episode	MAJCOM ⁴	
	MDD, recurrent episodes	No	
		MAJCOM ⁴	
	Persistent Depressive	Maybe ^{2, 3}	
	Disorder (Dysthymia)	MAJCOM ⁴	

1. Waiver may be considered after thorough psych evaluation of the applicant

2. For all UNTRAINED individuals (FC I/IA, FC II/III, and ATC/GBO/SWA), a waiver is NOT considered if they are currently taking an antidepressant. A waiver is considered after depression is completely resolved and medications and psychotherapy have been discontinued for a minimum of 2 years..

3. For all TRAINED personnel (FCII/III and ATC/GBO/SWA), a waiver is considered after depression is completely resolved and stability, on or off medication, has been demonstrated for 6 months.

4. If categorical waiver (FC IIC or FC IIIC) is required due to medication requirements, then AFMRA is the waiver authority. If the aviator does not meet retention standards per the MSD, then AFMRA is the waiver authority.

### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request:

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

B. <u>Renewal Waiver Request:</u>

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

Please feel free to contact the ACS Neuropsychiatry Branch with questions:ACS Aerospace Medicine Branch, USAFSAM/FECAc/o Neuropsychiatry Branch2510 Fifth Street Bldg 840Wright Patterson AFB, OH 45433-7913Fax: (937) 904-6296 DSN: 674-9296

# **III. Aeromedical Concerns**

Mood disorders can be associated with a variety of cognitive, emotional, and behavioral symptoms, including depressed mood, impaired judgement, slowed information processing speed, impaired memory and/or attention and concentration, inflated self-esteem or grandiosity, disturbances in energy and sleep, significant weight loss or gain, psychomotor agitation or retardation, fatigue, distractibility, flight of ideas, inappropriate guilt, indecisiveness, suicidal ideation, and excessive involvement in pleasurable activities that have a high potential for undesirable consequences (e.g., spending sprees, promiscuity, substance abuse). These cognitive, emotional, and behavioral difficulties can lead to observable as well as subtle changes in functioning that negatively affect performance under physically and psychological taxing conditions. As a result, mood disorders, as well as an elevated risk of recurrence for such conditions, are incompatible with aviation safety and flying duties.

Many aviators struggle with depressive disorders. Numerous emotional and behavioral manifestations of depression can impair an aviator's cognitive abilities (e.g. ability to focus, sustain attention and concentration, working and general memory, psychomotor coordination, reasoning, spatial judgement, and reaction time) as well as social functioning (e.g., social isolation and withdrawal, increased irritability/agitation). Some of the more severe symptoms of depression, such as suicidal ideation and impaired reality testing, may be acutely disabling. Furthermore, depression often coexists with anxiety and psychosomatic complaints, as well as substance abuse.

There are aeromedical concerns with the use of psychotropic medications for treatment as well. All psychotropic medications have potentially undesirable or dangerous side effects. Common side effects of antidepressants include nausea, vomiting, diarrhea, insomnia, jitteriness, tremor, agitation, restlessness, perspiration, dizziness, and headaches.

AIMWTS review in Sep 2019 for the diagnoses of major depression and bipolar disease resulted in 241 cases since 1 Jan 2014. Of that total, 130 were disqualified. Breakdown of the review revealed 14 FC I/IA cases (11 disqualified), 38 FC II cases (13 disqualified), 7 RPA pilot cases (6 disqualified), 115 FC III cases (57 disqualified), 43 ATC/GBC cases (30 disqualified), 14 MOD cases (6 disqualified), and 10 SWA cases (7 disqualified).

ICD-9 codes for mood disorders		
296.2	Major depressive disorder, first episode	
296.3	Major depressive disorder, recurrent	
300.4	Persistent depressive disorder (dysthymia)	
311	Unspecified depressive disorder	
296.xx	Bipolar I disorder	
296.89	Bipolar II disorder	
301.13	Cyclothymic disorder	
296.80	Unspecified bipolar and related disorders	

ICD-10 codes for mood disorders		
F32.9	Major depressive disorder, single episode, unspecified	
F33.9	Major depressive disorder, recurrent, unspecified	
F34.1	Dysthymic disorder	
F31.9	Bipolar disorder, unspecified	
F31.81	Bipolar II disorder	
F34.0	Cyclothymic disorder	

# IV. Suggested Readings

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4. Goldman LS, Nielsen NH, and Champion HC. Awareness, Diagnosis, and Treatment of Depression. J Gen Intern Med, 1999; 14: 569-80.

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17. Transport Canada. Handbook for Civil Aviation Examiners: Psychiatry (SSRIs). Guidelines for the Non-psychotic Conditions. <u>www.tc.ca</u>.

18. US Army Aeromedical Policy Letters and Technical Bulletins, Fort Rucker AL: Retrieved November 2010 from <a href="https://aamaweb.usaama.rucker.amedd.army.mil/AAMAWeb/p3.html">https://aamaweb.usaama.rucker.amedd.army.mil/AAMAWeb/p3.html</a>

## Other Conditions That May Be a Focus of Clinical Attention (Jun 2020) (V and Z Codes) and Miscellaneous Disorders

Reviewed: Lt Col Teg McBride (ACS Neuropsychiatry Branch Psychologist), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Col Marie-France McIntee (AFMRA Physical Standards Development Chief)

Significant Changes: Updated and converted to new waiver guide template

## I. Waiver Consideration

In the Medical Standards Directory (MSD) item Q37 reads, "Other Conditions that are the focus of clinical attention (V Code problems) when they result in DOWN, or generate a DLC lasting greater than 60 days." Problems may arise such as worry, anxiety, anger, depression, guilt, somatization, and behavioral acting-out that lead to the need for grounding or disqualification. This waiver guide section covers many such conditions: "Any psychiatric condition, or history thereof, which would interfere with AFSC-specific aviation, controller or special duty performance (such as claustrophobia)." In addition, unsatisfactory Adaptability Rating for Military Aviation (ARMA) and other flying classes (AR-ATC, AR-MOD, AR-RPA, AR-SWA) (MSD item Q35) is disqualifying for all duty positions.

Additionally, there are numerous conditions listed in the MSD Psychiatry and Mental Health section that do not have a corresponding waiver guide topic. If any of those conditions apply to the aviator under consideration for a waiver, the guidance in this chapter applies.

Before submitting the case for waiver consideration, the base-level flight surgeon must first discern whether the condition is. unfitting vs. unsuiting for service. If the Airman requires a fit/unfit determination, the case requires IDES action for a retention decision; if the Airman requires a suited/unsuited determination, the case requires consideration for an administrative separation or discharge via the chain of command.

Flying Class (FC)	Waiver Potential	ACS Evaluation/Review
	Waiver Authority	
I/IA	Yes	At the request of AETC
	AETC	-
II/II/ATC/GBO/SWA	Yes	At the request of MAJCOM
	MAJCOM	_

Table 1: Waiver potential for "Other Conditions" Diagnoses

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

A. Initial Waiver Request:

- 1 See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2 If the local base is unable to provide all required items, they should explain why to the waiver authority

#### B. Renewal Waiver Request:

- 1 See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2 If the local base is unable to provide all required items, they should explain why to the waiver authority.

## Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECAc/o Neuropsychiatry BranchUSAFSAM.FE.PsychiatryMailbox@us.af.mil2510 Fifth Street Bldg 840Comm: 937-938-2768Wright Patterson AFB, OH 45433-7913DSN: 798-2768Fax: (937) 904-6296 DSN: 674-9296Sign 2000 (Sign 2000) (Sign 2000)

## **III. Aeromedical Concerns**

The "Other Conditions" represent a psychiatric gray area in aerospace medicine. Many of the everyday problems faced by flyers - and therefore by flight surgeons - may be described by these conditions. These often involve the kinds of situations discussed in flying safety deliberations by flight surgeons, or in stress management lectures by aerospace psychologists or physiologists, because they may interfere with safe or effective flying. Matters such as adjusting to different cultures, dealing with a recalcitrant child, or trying to save a failing marriage are of obvious aeromedical concern. Whether they are grounds for administrative or medical removal from flying duties, or for establishing a psychiatric diagnosis, are matters of degree. What becomes most relevant to aeromedical decision-making is the response of the aviator rather than the severity of the stressor. Numerous "small" stressors can produce as much fatigue, irritability, early task saturation, distraction, and cognitive inefficiency as a single major stressor.

Aeromedically dangerous responses to stressors include those of worry, anxiety, anger, depression, guilt, somatization, and behavioral acting-out. These responses may occur during stable situations, or during such challenges as unexpected TDYs, deployments, or a PCS. Other aeromedically relevant issues include disruption of sleep, significant weight loss or gain, preoccupation, inability to relax, overall mood, affective changes, duty requirements, and flying performance as assessed by the flyer, peers, and/or supervisors. Because these conditions and their impact can be insidious, the flight surgeon should approach such problems in flyers carefully, using techniques that range from informal discussion, as the least intrusive intervention, all the way to a referral for full mental health workup/treatment. Each type of assessment or intervention should consider whether the aviator should continue to fly. In some cases, the aviator may be able to resolve the troubling issue without being placed in a DNIF status. If placed DNIF, once the flyer has engaged in treatment (medications/psychotherapy) and their symptoms are sufficiently relieved so that return to flying is possible, then decide whether a waiver will be necessary. *Note: A flyer may be recommended for return to flying while "talk therapy" continues as long as symptoms have subsided sufficiently (during marital therapy, for example).* 

If the concerning responses to the stressor persist or are severe, a formal mental health diagnosis may be warranted. The flight surgeon must always be vigilant for more severe pathology. Relationship distress is a good example of a stressor that may precipitate multiple DNIF periods due to loss of sleep and evolve into an "Other Condition" requiring evaluation and treatment. It may be that the relationship issue precipitates a Major Depressive Disorder that requires treatment and a waiver. The relationship problems may even be the result of a Major Depressive Disorder that began affecting the aviator's personal relationships. If a diagnosis seems warranted, establish it in accordance with DSM-5 criteria, and see that the flyer receives proper treatment. The length of demonstrated stability post-treatment prior to submission of a waiver is at the discretion of the flight surgeon. *NOTE: Beware of delaying or withholding proper treatment solely in order to avoid DNIF or to "protect the aviator's career."* 

Many flyers with "Other Conditions and Miscellaneous Psychiatric Diagnoses" typically have other concurrent emotional or behavioral disturbances such as anxiety, depression, or a substance use problem that may be aeromedically significant. Others have personality issues or traits that are problematic. Flyers with these issues should be individually assessed with attention given to rule out a DSM-5 diagnosis.

Some of the diagnoses (such as Other specified disruptive, Impulse-Control, and Conduct Disorder) tie in closely with reliability, integrity, and security concerns. Returning these aviators to flight status may cause subsequent issues in the squadron and morale problems among the flight crew. Many of these individuals also have unstable interpersonal relationships with family which can have a significantly negative impact on flying operations. Administrative, legal, or security clearance action may be required even if the primary problem is not medically disqualifying.

AIMWTS search in Jun 2020 for the previous five years revealed 110 cases with a V or Z-code diagnosis. There were 7 FC I cases (4 disqualified), 24 FC II cases (7 disqualified), 52 FC III cases (25 disqualified), 8 ATC cases (6 disqualified), 13 GBO cases (8 disqualified), and 6 SWA cases (3 disqualified).

ICD-9 codes for Other Conditions and Miscellaneous Psychiatric Diagnoses		
V62.3	Academic or Educational Problem	
V62.4	Acculturation Difficulty	
V71.01	Adult Antisocial Behavior	
V62.82	Bereavement, Uncomplicated	
V61.03	Disruption of family by separation or divorce	
V62.22	Exposure to Disaster, War, or Other Hostilities	
V61.8	High Expressed Emotion Level Within Family	
V65.2	Malingering	
V15.81	Nonadherence to medical treatment	
V62.29	Other problem Related to Employment	
V62	Other Psychosocial Circumstances	
312.89	Other specified disruptive, Impulse-Control, and Conduct Disorder	
278.00	Overweight or Obesity	
V61.20	Parent-Child Relational Problem	
V62.89	Phase of Life Problem	
V62.21	Problem Related to Current Military Deployment Status	
316	Psychological Factors Affecting Medical Conditions	
V61.10	Relationship Distress With Spouse or Intimate Partner	
V62.89	Religious or Spiritual Problem	
302.70	Unspecified Sexual Dysfunctions	

ICD-10 codes for Other Conditions and Miscellaneous Psychiatric Diagnoses		
Z55.9	Academic or Educational Problem	
Z60.3	Acculturation Difficulty	
Z72.811	Adult Antisocial Behavior	
V62.82	Bereavement, Uncomplicated	
Z63.5	Disruption of family by separation or divorce	
Z65.5	Exposure to Disaster, War, or Other Hostilities	
Z63.8	High Expressed Emotion Level Within Family	
Z76.5	Malingering	
Z91.19	Nonadherence to medical treatment	
Z56.9	Other problem Related to Employment	
F91.9	Other specified disruptive, Impulse-Control, and Conduct Disorder	
E66.9	Overweight or Obesity	
Z62.820	Parent-Child Relational Problem	
Z62.812	Personal history (past history) of neglect in childhood	
Z62.810	Personal history (past history) of physical or sexual abuse in childhood	
Z62.811	Personal history (past history) of psychological abuse in childhood	
Z60.0	Phase of Life Problem	
Z56.82	Problem Related to Current Military Deployment Status	
F54	Psychological Factors Affecting Medical Conditions	
Z63.0	Relationship Distress With Spouse or Intimate Partner	
Z65.8	Religious or Spiritual Problem	
F52.9	Unspecified Sexual Dysfunctions	

#### **IV. Suggested Readings**

1. Ahmed SM, Lemkau JP, and Hershberger PJ. Psychosocial Influences on Health. Ch. 3 in *Rakel: Textbook of Family Medicine*, 8th ed., Saunders, 2011.

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#### Personality Disorders (Aug 2020)

Reviewed: Dr. Joe Wood (ACS Neuropsychiatry Branch Psychologist), Dr. Dan Van Syoc (ACS waiver guide coordinator), and Lt Col Ric Speakman (AFMRA Physical Standards Development Chief)

**Significant Changes:** Updated to new template, updated Table 1 with GBO/SWA, emphasized ARMA concerns in section IV

## I. Waiver Consideration

A personality disorder that is severe enough to repeatedly manifest itself by significant interference with safety of flight, crew coordination, or mission completion is disqualifying for all flying classes and special duties positions. In addition, unsatisfactory duty performance due to personality disorder may cause the member to be unsuitable for military service, as opposed to unfit, and subject to administrative separation. If the member has personality traits but does not meet the criteria for personality disorder, they still may be deemed ARMA unsat. It is strongly recommended that all cases being considered for a waiver be reviewed by the ACS.

#### Table 1: Waiver potential for Personality Disorders¹

Table 1: Walver potential for 1 ersonanty Disorders			
Flying Class (FC)	Waiver Potential	Waiver Authority	<b>ACS Review or Evaluation</b>
FC I/IA	No ²	AETC	Only if requested by AETC
FC II/III ATC/GBO/SWA	Yes ³	MAJCOM	Yes

1. Cases considered for waiver must be psychologically stable and manifestations no longer interfering with duty.

2. Waiver not recommended for any initial flying class for individuals with a history of personality disorder.

3. No indefinite waivers.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

## A. Initial Waiver Request:

- 1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2. If the local base is unable to provide all required items, they should explain why to the waiver authority

B. Renewal Waiver Request:

- 1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.
- 2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

#### Please feel free to contact the ACS Neuropsychiatry Branch with questions:

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#### **III. Aeromedical Concerns**

Management of personality disorders is directed primarily toward the more predominant symptom characteristics. Initially, efforts are focused on maintaining and supporting the patient-physician relationship and establishing a working alliance. The treating physician needs to have a good understanding of the personality characteristics of these patients and work to adapt his or her style in order to optimize communication and the ultimate clinical outcome. Psychotropic medications are not a front-line approach to the care of most of patients. If a particular case lends itself to treatment with medications, it should not be attempted by a non-mental health professional.

Adaptability Rating for Military Aviation (ARMA) Unsatisfactory:

For all flying classes the question of suitability is important. Personality disorders and traits may impact performance of military duty and flight safety. However, full-blown personality disorders are rare in aviators. More common are problematic personality traits that will not be labeled as a personality disorder but may be grounds for an ARMA unsatisfactory designation. Characteristics such as immaturity, impulsivity, inflated self-esteem, high neuroticism, or recurrent dishonesty are undesirable in aviators.

The term ARMA was originally used as a selection tool for pilots and can still be used most fruitfully in selecting out any applicant whose emotional disposition and/or behavior meets its definition. For example, any flying applicant whose history includes self-harm, chaotic relationships and suicidality should be carefully assessed for waiver consideration, even if he or she has not been diagnosed with a disqualifying psychiatric condition.

ARMA unsatisfactory may also be applied to trained aviators. Preexisting maladaptive personality traits may have been previously hidden, or can be triggered due to situational stressors or life events. Improvement in functioning can potentially occur in some of these cases, but the course of treatment can be lengthy with significant progress difficult due to the characterologic nature of the traits. Consultation with a mental health provider with aviation experience and/or consultation with the ACS is recommended for potential ARMA cases.

AIMWTS review in Jul 2020 for the previous five years produced 58 cases with the diagnosis of personality disorder; all but two resulted in a disposition of disqualified. Breakdown of the cases revealed: 1 FC I case, 12 FC II cases, 22 FC III cases, 4 ATC cases, 18 GBO cases, and 1 SWA case. One FC II case and 1 FC III case were waived. The vast majority of the cases had at least one other psychiatric diagnosis in addition to the diagnosis of personality disorder.

ICD-9 codes for Personality Disorders		
310.1	Personality Change Due to Another Medical	
	Condition	
301.22	Schizotypal Personality Disorder	
301.0	Paranoid Personality Disorder	
301.20	Schizoid Personality Disorder	
301.7	Antisocial Personality Disorder	
301.83	Borderline Personality Disorder	
301.54	Histrionic Personality Disorder	
301.4	Obsessive-Compulsive Personality Disorder	
301.82	Avoidant Personality Disorder	
301.6	Dependent Personality Disorder	
301.81	Narcissistic Personality Disorder	
301.89	Other Specified Personality Disorder	
301.9	Unspecified Personality Disorder	

ICD-10 codes for Personality Disorders		
F07.0	Personality Change Due to Another Medical	
	Condition	
F21	Schizotypal Personality Disorder	
F60.0	Paranoid Personality Disorder	
F60.1	Schizoid Personality Disorder	
F60.2	Antisocial Personality Disorder	
F60.3	Borderline Personality Disorder	
F60.4	Histrionic Personality Disorder	
F60.5	Obsessive-Compulsive Personality Disorder	
F60.6	Avoidant Personality Disorder	
F60.7	Dependent Personality Disorder	
F60.81	Narcissistic Personality Disorder	
F60.89	Other Specified Personality Disorder	
F60.9	Unspecified Personality Disorder	

#### **IV. Suggested Readings**

1. Personality Disorders in Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, 2013, pp. 645-47.

2. Angstman KB and Rasmusen NH. Personality Disorders: Review and Clinical Application in Daily Practice. Am Fam Physician, 2011; 84(11):1253-60.

3. Skodol A. Personality Disorders. UpToDate. Online version. Feb 18, 2016.

4. Feinstein RE and Connelly JV. Personality Disorders. Ch. 60 in Rakel: Textbook of Family Medicine, 7th ed., 2007.

5. Rayman RB. *Clinical Aviation Medicine*, 4th Ed. New York, NY; Professional Publishing Group, Ltd; 2006, pp. 303-05.

#### Posttraumatic Stress Disorder (PTSD) (Jan 2020)

Reviewed: Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### Significant Changes:

Restructuring of Waiver Guide, Anti-depressant management, AIMWTS review

## I. Waiver Consideration

A diagnosis of Posttraumatic Stress Disorder (PTSD) does NOT require a waiver if the member is able to return to full duty within 60 days of symptom onset (minor residual symptoms are acceptable). However, the condition is disqualifying and a waiver will be required before consideration of return to flight status if any of the following conditions are met: (a) DNIF lasts greater than 60 days; (b) member experiences a recurrence of debilitating symptoms upon return to the operational environment; or (c) original symptom severity was such that in the opinion of the flight surgeon, return to the operational environment would entail high risk to the member, the mission or flight safety should the symptoms recur. Flight surgeons caring for distressed aviators, especially in times of combat, need to be particularly sensitive to these issues and work closely with a psychiatrist or psychologist early in the evaluation, treatment and aeromedical disposition of these aviators whether or not their symptoms are caused by combat/operational stress or other traumatic incidents.

To be considered for waiver, a mental health evaluation, with accurate diagnosis per the DSM-5, is the vital first step. USAF psychologists/psychiatrists familiar with aeromedical standards are the preferred choice for evaluation and potential development of the treatment plan. Most waivers granted to date have been limited to those with six months of sustained remission. Mild, residual symptoms, not thought to be duty impacting, are relatively common and acceptable.

In 2013, the USAF began allowing select FC II/III personnel to be considered for waivers on antidepressants. After 5 years of observation, in 2018 the USAF allowed all aviators, including single seat and B-2 pilots, to be considered for waivers on the following monotherapies:

- 1. Sertraline (Zoloft®) up to 200 mg/day
- 2. Citalopram (Celexa®) up to 40 mg/day
- 3. Escitalopram (Lexapro®) up to 20 mg/day
- 4. Bupropion (Wellbutrin®) SR or XL up to 400 mg/day or 450 mg/day, respectively

Of these approved medications, Wellbutrin is known to be less effective in treating PTSD. Also, the dosage of the antidepressant tends to require "higher than usual" amounts when treating PTSD as compared to treatment for depression. This often makes Zoloft an attractive choice in treating PTSD among these approved antidepressants.

The aviator on a maintenance antidepressant (only one aeromedically approved medication allowed) needs to be on the medication and remain clinically asymptomatic for at least 6 months before

waiver consideration. The dose of the medication can be adjusted to maximize treatment and/or limit side effects without restarting this 6-month period as long as the aviator's symptoms remain stable. If a psychotropic medication is ever adjusted in dose or discontinued in an aviator, two weeks of observation should occur before considering resuming full flight duties to assure no adverse/unexpected side effects or return of symptoms occur. If symptoms return after discontinuing treatment, a return to, or enhancement of, psychotherapy, healthy lifestyle interventions, and/or antidepressant medication for maintenance treatment should be considered.

Flying Class (FC)	Waiver Potential Waiver Authority	ACS Evaluation or Review
I/IA	Maybe ¹ AETC	Yes ²
II/III and ATC/GBO/SWA	Yes MAJCOM	Yes ²

1. Must clearly demonstrate complete resolution of all PTSD symptoms before acceptance into initial flying training and have complete documentation from mental health providers.

2. Must be reviewed by the ACS prior to consideration for a waiver.

#### **II. Information Required for Waiver Submission**

#### A. Initial Waiver Request:

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

#### B. <u>Renewal Waiver Request:</u>

1. See Mental Health Waiver Guide Checklist in Psychiatry Waiver Guide Folder.

2. If the local base is unable to provide all required items, they should explain why to the waiver authority.

#### Please feel free to contact the ACS Neuropsychiatry Branch with questions:

ACS Aerospace Medicine Branch, USAFSAM/FECA

c/o Neuropsychiatry Branch	<u>USAFSAM.FE.PsychiatryMailbox@us.af.mil</u>
2510 Fifth Street Bldg 840	Comm: 937-938-2768
Wright Patterson AFB, OH 45433-7913	DSN: 798-2768
Fax: (937) 904-6296 DSN: 674-9296	

#### **III. Aeromedical Concerns**

The diagnosis of PTSD, especially in the combat environment, is fraught with difficulty. Normal reactions to combat, operational stress, and emotional/stressful events can all be confused with and labeled as PTSD, especially when the member is routinely exposed to the stressful environment. While symptoms are similar, the course of treatment and aeromedical dispositions of the reactions are extremely different. Flight surgeons and mental health providers need to consider the length, severity, and functional impact of PTSD symptoms along with the situationally induced nature and accompanying stressors that triggered the condition. There is a high prevalence of other psychiatric disorders in individuals diagnosed with PTSD, with both men and women reporting other comorbid psychiatric conditions. Major Depressive Disorder is among the most common comorbid conditions for both men and women, affecting nearly 50%. Alcohol Use Disorder is also highly comorbid in men (seen in over half of all cases). Additionally, there is a threefold to sevenfold increased risk for both men and women with PTSD for diagnosis of Anxiety Disorders, including Generalized Anxiety Disorder, Panic Disorder, and Specific Phobias. These diagnoses should be screened for to consider flying status, treatment, and waiver potential for them as well.

Early intervention and treatment may prevent chronic disease. Long-term multifaceted treatment has shown the greatest benefit to those afflicted, given the complex nature of PTSD. Various psychotherapeutic modalities have been shown to be effective in PTSD. Prolonged Exposure, Cognitive Processing Therapy (CPT), and Eye Movement Desensitization and Reprocessing (EMDR) therapy have been found effective in randomized trials. Psychotherapy, along with healthy lifestyle modifications, are the treatment of choice for PTSD. It is advisable for primary care providers and flight surgeons to refer these patients to a therapist or treatment team with experience in such therapies.

The therapeutic goals of psychopharmacologic therapy are to decrease intrusive thoughts and images, phobic avoidance, pathological hyperarousal, hypervigilance, impulsivity, and depression. Selective Serotonin Reuptake Inhibitors (SSRIs) were found to be effective as first-line drug therapy in a systematic review of 35 randomized trials and are recommended in treatment guidelines for PTSD from the American Psychiatric Association. SSRIs have been found to reduce flashbacks, arousal, and avoidance in patients with PTSD.

Prolonged severe operational stress can cause symptoms of PTSD. For operational stress reactions, the individual's symptoms typically clear shortly after removal/restriction from duty. Specific situational anxiety reactions that develop after traumatic incidents (e.g. claustrophobia, flying phobia), when symptoms do not interfere with duty, are best treated with occupational exposure with or without short term DNIF. In situations in which exposure-based therapies would facilitate resolution of symptoms, prolonged restriction from duty may actually delay recovery.

In some instances, a member's symptoms are more generalized, accompanied by a change in social or occupational functioning, and do not clear with time off, adequate sleep and initial treatment attempts. In these cases, consider the diagnosis of PTSD, other associated conditions, and the member's motivation. Many of the symptoms of PTSD can interfere with flying safety and mission completion. Severe anxiety symptoms markedly impair the ability to focus and concentrate on the task at hand. Some of the more severe symptoms, such as flashbacks, may be acutely incapacitating. Associated mental health conditions can also negatively affect the ability of the aviator to successfully complete the mission. DNIF and treat whenever symptoms interfere with safety of flight, the mission, or the member's safety, regardless of diagnosis.

Remotely Piloted Aircraft (RPA) operators and others involved in remote warfare have the potential to develop PTSD through their viewing of work-related video and other electronic media. Recent efforts to investigate the prevalence of PTSD in the remote warfare community suggest rates of

PTSD are similar to other USAF pilots and lower than the general population. To this point, few cases of PTSD as a direct result of RPA operations have been reported.

AIMWTS review in Jan 2020 for the previous five years revealed 246 airmen with a diagnosis of PTSD, with 158 of the cases resulting in a disqualified disposition. Breakdown of the cases revealed: 9 FC I/IA cases (4 disqualified), 40 FC II cases (24 disqualified), 11 RPA cases (8 disqualified), 123 FC III cases (77 disqualified), 31 ATC/GBC cases (25 disqualified), 29 Special Warfare airmen (18 disqualified), and 3 MOD cases (2 disqualified). The major factors resulting in a disqualification were persistent symptoms, chronic disease, other mental health diagnoses, and the need to treat with medications not approved for use in USAF aircrew.

ICD-9 code for PTSD		
309.81	Post-traumatic stress disorder	
IGD 40		

IC	ICD-10 codes for PTSD		
F4	3.10	Post-traumatic stress disorder, unspecified	
F4	3.12	Post-traumatic stress disorder, chronic	

## IV. Suggested Readings

1. Sireen J. Posttraumatic stress disorder in adults: Epidemiology, pathophysiology, clinical manifestations, and diagnosis. UpToDate. Dec 2015.

2. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. American Psychiatric Publishing, Arlington, VA, 2013.

3. Gitlow S. Psychiatry. Ch. 12 in Rayman's *Clinical Aviation Medicine*, 5th ed. New York; Castle Connolly Graduate Medical Publishing, LTD, 2013, pp. 314-15.

4. Watts BV, Schnurr PP, Mayo L, et al. Meta-Analysis of the Efficacy of Treatments of Posttraumatic Stress Disorder. J Clin Psychiatry, 2013; 74(6):e541-50.

5. Ursana RJ, Bell C, Eth S, et al. Practice Guideline for the Treatment of Patients with Acute Stress Disorder and Posttraumatic Stress Disorder. American Psychiatric Association, 2004.

6. Wood JD, Heaton J, Hubner M, and Rhodes N. Formation of the U.S. Air Force Aviator Post-Traumatic Stress Disorder Study Group. U.S. Air Force School of Aerospace Medicine: Wright-Patterson AFB, OH 2016; Technical Report AFRL-SA-WP-TR-2016-0017.

7. Wood J, Heaton JE. (2016 Mar) Aeromedical Consultation Service PTSD Study Group. Paper presented at the NATO Science and Technology Organization Technical Course, Ramstein AFB, Germany.

8. Wood J, Chappelle W, Correll T, et al. Prevalence of Posttraumatic Stress Disorder in Remotely Piloted Aircraft Operators in the United States Air Force. Special Report AFRL-SA-WP-SR-2016-0005.

#### WAIVER GUIDE

Updated: Jul 2014 Supersedes Waiver Guide of Apr 2010 By: Lt Col Niraj Govil (RAM XV) and Dr Dan Van Syoc Reviewed by Col Kent McDonald, psychiatrist and chief of the ACS Neuropsychiatry Branch

#### CONDITION: Psychotic Disorders (Jul 2014)

#### I. Waiver Consideration.

Psychotic disorders, as well as delirium and other cognitive disorders are disqualifying for all flying classes to include ATC/GBO and SWA duties. Waiver may be considered after the patient has been free of psychotic symptoms and off all mental health treatment including psychotropic medications for one year. A psychotic episode caused by alcohol, and occurring during the course of alcohol abuse or alcohol dependence, is considered for waiver in accordance with the waiver requirements for an alcohol use disorder (DSM V). A psychotic episode caused by alcohol, but not in the setting of alcohol abuse or dependence, is considered for waiver according to the guidance in this waiver guide. When the inducing substance is illicit, a return to flying is unlikely. In all other cases of substance-induced psychotic disorders, there must be clear evidence (history, physical examination, and laboratory evaluation) that the substance (e.g. prescribed medication producing an idiosyncratic reaction or an unintentional overuse of an over-the-counter medication) caused the psychosis. In cases of a psychotic disorder due to a general medical condition waiver, may be considered once the psychosis and the medical condition have completely resolved and are unlikely to recur, if the medical condition itself is waiverable.

Schizophrenia, schizoaffective disorder, delusional disorder, brief psychotic disorder without marked stressor(s), and shared psychotic disorder are permanently disqualifying for flying and special operational duties. Antipsychotic medications and close psychiatric monitoring are incompatible with flying duties. An MEB is required for any psychotic episode that is not due to a clearly identifiable and avoidable cause. Any psychotic episode other than those with a brief duration, good prognosis and clearly identifiable and reversible cause must meet MEB.

Before submitting the case for waiver consideration, the base-level flight surgeon must first discern whether the condition is unsuiting vs. unfitting for service. If the Airman requires a fit/unfit determination, the case needs MEB action; if the Airman requires suited/unsuited determination, the case then needs consideration of an administrative separation or discharge via the chain of command.

Flying Class (FC)	Waiver Potential ¹	ACS Evaluation/Review
	Waiver Authority	
I/IA	No	Only if requested by AETC
	AETC	
II/III	Yes ²	Yes
	MAJCOM	
ATC/GBO/SWA	Yes ²	Yes
	MAJCOM	

Table 1: Waiver potential for psychotic disorders

1 No indefinite waivers.

2 For all UNTRAINED individuals (FC I/IA, FC II/III, and ATC/GBO/SWA), a waiver is NOT considered.

AIMWITS search in Jul 2014 revealed a total of 19 members with a submitted aeromedical summary containing a diagnosis of psychosis. Breakdown of the cases revealed: 1 FC I/IA cases (disqualified), 10 FC II cases (8 disqualified), 6 FC III cases (3 disqualified), and 1 ATC/GBC case (disqualified).

## II. Information Required for Waiver Submission.

Submitting a Mental Health Waiver Guide:

## Step 1 - Is the aviator ready for waiver submission?

	Waiver is submitted when 1) the member is asymptomatic and 2) medications/psychotherapy treatment have been completed, as applicable to diagnostic category, for the specified time-frame below (Note: psychotherapy "booster sessions", and sometimes SSRIs, are permissible and often advisable after initial symptom resolution): 1 Year—Psychotic Disorders & Somatoform Disorders
	6 Months—Mood Disorders, Anxiety Disorders & Suicidal Behavior
	Discretion of Flight Surgeon-Adjustment Disorders & V-Codes requiring waiver
	For Traumatic Brain Injury cases, please refer to TBI Waiver Guide
	For aviators with any other psychiatric disorders, please refer to AFI 48-123 and ACS Waiver Guide
B.	To be considered for an aeromedical waiver, any disqualifying condition must meet the following criteria per AFI 48-123 Section 6B, 6.2.1.1 through 6.2.1.6. (pg.31):
	Not pose a risk of sudden incapacitation
	Pose minimal potential for subtle performance decrement, particularly with regard to the higher senses
	Be resolved, or be stable, and be expected to remain so under the stresses of the aviation environment
	If the possibility of progression or recurrence exists, the first symptoms or signs must be easily detectable and not pose a risk to the individual or the safety of others
	Cannot require exotic tests, regular invasive procedures, or frequent absences to monitor for stability or progression
	Must be compatible with the performance of sustained flying operations

#### Step 2 - Before beginning the Aeromedical Summary (AMS), Flight Surgeon must obtain Mental Health consultation and ensure it contains items specified below: Instructions for the Mental Health Provider

The mental health evaluation must include a **<u>comprehensive written report</u>** addressing:

Consultation must address each criteria in Step 1B
Clinical mental health history (description of symptoms, treatment modality, frequency and compliance with treatment, relevant personal and family history, and perceived impact on occupational duties)
Medication history (dates of initial prescription and termination, reason for termination, dosage,
<pre>compliance, response, clinical course since termination) Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile) ** for alcohol cases, please comment on Carbohydrate-deficient transferrin (CDT) results**</pre>
Current psychosocial situation (marital and occupational, interview with spouse/supervisor, input from line leadership, if possible, and please address current state of any triggers for the mental illness)
Current and past aviation related duties and any history of current and past occupational performance difficulties (to include perceived impact of mental health condition on performance of duties)
Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
Summary and interpretation of psychological/neuropsychological testing results (recommend MMPI-2, NEO PI-R, or similar personality test). For neuropsychological cases, please contact ACS neuropsychologist (Dr. Gary Ford, DSN: 798-2704) for guidance on recommended neuropsychological tests.
Current mental status
Diagnosis
Motivation to fly or engage in special duty operations (past and current)
Recommendation for future psychological and medical treatment
Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)
Copies of all records (mental health/ADAPT/inpatient) and raw testing data should be on hand for shipment to ACS Neuropsychiatry Branch
Items for the Flight Surgeon to include in the AMS: AMS must clearly address each criteria in Step 1B and the risk to the member, mission, and safety
Summarize Mental Health history and focus on occupational impact ** If 2 or more months have passed since the comprehensive evaluation/report was completed, the flight surgeon should address how the member has done since and consult with the mental
<i>health provider if the member has been seen at mental health since the evaluation</i> ** Medication history (dates of initial prescription and termination, reason for termination, dosage,
<pre>compliance, response, clinical course since termination) Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile) ** for alcohol cases, please comment on Carbohydrate-deficient transferrin (CDT) results**</pre>

	Current psychosocial situation (marital and occupational, interview with spouse/supervisor, if possible - please address current state of any triggers for the mental illness) Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
	Current mental status
	Diagnosis
	Motivation to fly (past and current)
	Recommendation for future psychological and medical treatment
	Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)
Step 4 -	Items to complete the waiver package: Letter of support from command
	Comprehensive mental health written-report
	Confirm mental health has made copies of chart(s) and testing. When requested send to:
	ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch

2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

Please feel free to contact the ACS Neuropsychiatry Branch with questions: TSgt Tonya Merriweather: DSN 798-2703, SSgt Krista Traut 798-2738, or Mr. John Heaton: 798-2766

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for <u>initial waiver</u> for psychotic disorders should include the following:

A. History – An aeromedical summary detailing history of the disorder and all treatments administered, the current status of any social, occupational, administrative or legal problems associated with the case, and an analysis of the aeromedical implications of this particular case history.

B. Treatment – medications and therapy used for the psychotic disorder and any other psychiatric conditions. Are there any side effects due to the medication? A good laboratory examination to include a toxicology screen and blood alcohol level are vital to the waiver. Psychosis almost always results in an emergency room visit so ensure the records are attached.

C. Psychiatry/psychology consultation: Need all treatment notes from treating mental health professional as well as an MEB-type narrative summary of the mental health record.

D. Report of all psychological testing, if performed.

E. Letter of support from squadron commander.

The AMS for <u>waiver renewal</u> for psychotic disorders should include the following:

A. History – interim history since last waiver.

B. Treatment – current therapy for the condition, if any.

C. Psychiatry/psychology consultation report(s) if accomplished since last waiver request.

### **III. Overview.**

Schizophrenia Spectrum and Other Psychotic Disorders are defined by one or more of the following: delusions, hallucinations, disorganized thinking (will be evident through speech), grossly disorganized behavior or abnormal motor movement (catatonia) and negative symptoms.¹. Psychotic states are periods of high risk for agitation, aggression, impulsivity, and other forms of behavioral dysfunction.² They can occur as standalone psychiatric disorders or psychosis can be seen in conjunction with other psychiatric and medical disorders. Schizophrenia is probably the best-known psychotic disorder, but is extremely rare in aviators. Other recognized psychotic disorders, and brief psychotic disorder. It is difficult to assess the prevalence of psychotic disorders in the population as these people often do not seek medical care. Some recent estimates of the lifetime prevalence of such disorders are as high as 3.0% of the US population.³

Due to the multiple screening processes involved in aircrew selection; it is unlikely that someone with a psychotic disorder would ever be selected for training. It is recognized that most serious psychotic conditions begin in adolescence with initial subtle symptoms that may be very hard to detect. This early period often consists of nonspecific symptoms in otherwise normal functioning people and detection can be very difficult.⁴ As with all mental health conditions, there are various degrees of severity of psychotic disorders with some individuals leading a relatively normal life with rare to occasional symptomatic flares. Such episodes have occurred in military aircrew. The short lived psychotic symptoms that occur in aircrew usually are induced by severe stress and or sleep deprivation. Those that last greater than one day but less than 30 days, are usually classified as a brief psychotic disorder or psychotic disorder not otherwise specified (DSM IV).⁵

A form of psychotic disorder that may impact our aircrew members is that associated with alcohol use, substance abuse, prescribed medications, or as a reaction to a medical condition. Psychotic disorders can occur from intoxication from these commonly abused substances: alcohol, amphetamines, cannabis, cocaine, hallucinogens, inhalants, opioids (such as meperidine), phencyclidine, sedatives, hypnotics, and anxiolytics. Similar disorders can occur from withdrawal from these classes of substances: alcohol, sedatives, hypnotics, and anxiolytics. I Regarding substance abuse (to include alcohol), it may be difficult to separate primary psychotic disorders from those resulting from substance abuse. There are often some slight differences in the demographics of these two populations that may make it easier to discern the cause. Patients with a substance abuse etiology tend to occur at a later age, have greater antisocial personality disorder comorbidity, higher homelessness, and poorer family support.⁶ A flyer's chances of returning to fly after a psychotic episode are far greater if it can be shown that a substance or medication was the cause. For this reason it is of paramount importance to get a good history, a broad laboratory assessment, and a blood alcohol level and a toxicology screen in any aviator who has an episode of psychosis or bizarre behavior.

Treatment for patients with psychotic disorders can be difficult. It may take some time to make a correct diagnosis and these patients are frequently noncompliant with treatment modalities and follow up care. Many of these patients need to be evaluated and treated in a very structured environment with the use of neuroleptic medications. Most of the more serious psychotic disorders

have a significant risk of suicide (and perhaps homicide as well), so this needs to be carefully assessed as well.⁷

## IV. Aeromedical Concerns.

Psychosis is disqualifying for aviation duties. Symptoms of aeromedical concern include poor reality testing, poor insight, eccentric and bizarre behavior, social withdrawal, hallucinations, delusions (sometimes of a persecutory or self-destructive nature), confusion, clouding of consciousness, illogical thought, and a risk of suicide. Because of concern about unpredictable recurrence (with potentially devastating effects upon flying safety, mission completion, and personal health), careful documentation, management, and monitoring are important to aeromedical prognosis. If and when psychosis occurs in an aviator, the flight surgeon must consider waiverable disorders. Potentially waiverable causes of psychosis include toxic (substance-induced psychotic disorder), metabolic, or infectious conditions (psychotic disorder due to a general medical condition), and brief psychotic disorder with marked stressor(s).⁸ Thorough documentation during the illness is vital to maximize the probability of an aviator's return to flying status after psychosis. Acute, stress-related psychoses in aviators often resolve quickly with hospitalization and stress relief and without antipsychotic medication

ICD-9 codes for psychotic disorders		
291.3	Alcohol-induced psychotic disorder	
298.9	Unspecified psychosis	
293.9	Unspecified Transient Organic Mental Disorder	
298.8	Other and unspecified reactive psychosis	
291.8	Other specified alcoholic psychosis	
291.0	Alcohol withdrawal delirium	

ICD-10 codes for psychotic disorders		
F10.951	Alcohol use, unspecified, with alcohol-induced psychotic disorder with	
	hallucinations	
F29	Unspecified psychosis not due to a substance or known physiological	
	condition	
F06.8	Other specified mental disorders due to known physiological condition	
F23	Brief psychotic disorder	
F10.159	Alcohol abuse with alcohol-induced psychotic disorder, unspecified	
F10.231	Alcohol dependence with withdrawal delirium	

## V. References.

1. Schizophrenia Spectrum and Other Psychotic Disorders. In *Diagnostic and Statistical Manual of Mental Disorders*, Fifth edition, (DSM-V). American Psychiatric Association. Washington, DC, 2013; pp 87-122.

2. Jibson MD. Overview of psychosis. UpToDate, 1 Nov 2013.

3. Perälä J, Suvisaari J, Saarni SI, et al. Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population. Arch Gen Psych, 2007; 64: 19-28.

4. Bhangoo RK and Carter CS. Very Early Interventions in Psychotic Disorders. Psychiatr Clin N Am, 2009; 32: 81-94.

5. Ordiway V and Rayman RB. Case Report of an In-Flight Incident Involving an Aircraft Commander with a Psychiatric Illness. Aerospace Med, 1974; 45: 316-17.

6. Caton CLM, Drake RE, Hasin DS, et al. Differences Between Early-Phase Primary Psychotic Disorders With Concurrent Substance Use and Substance-Induced Psychoses. Arch Gen Psych, 2005; 62: 137-45.

7. Merrin EL. Delusional and Other Psychotic Disorders. Ch. 19 in *Review of General Psychiatry*, 5th edition, 2000.

8. Rayman RB, et al. *Rayman's Clinical Aviation Medicine*, 5th ed. New York; Castle Connolly Medical Publishing, Ltd., 2013, pp. 316-17.

WAIVER GUIDE Updated: Jul 2014 Supersedes Waiver Guide of Apr 2010 By: Maj John E. Miles (RAM XV) and Dr. Dan Van Syoc Reviewed by Dr. Terry Correll, ACS staff psychiatrist

## CONDITION: Somatic Symptoms and Related Disorders (Jul 2014)

## I. Waiver Consideration.

Somatic symptom disorders including, but not limited to illness anxiety disorder or conversion disorder are disqualifying for all classes of flying in the US Air Force.¹¹ Consideration for a waiver will only be entertained if the aviator is successfully treated and remains off all psychotropic medication for 12 months. Factitious disorders are disqualifying for all flying classes to include retention on active duty; however, for retention, factitious disorders are handled administratively as unsuiting conditions in accordance with DoDI 1332.38 E5.1.3.9.7.^{12, 13}

Malingering is not considered a mental illness. In DSM-5, malingering receives a V-code as one of several presenting problems that may become a focus of clinical attention or that may exacerbate or otherwise affect the diagnosis, course, prognosis, or treatment of a patient's mental disorder.¹ As such, it too is considered unsuiting rather than unfitting for continued military service and any patient exhibiting such behavior should be referred to the chain of command. As specified in Article 115 of the Uniformed Code of Military Justice (UCMJ), any person who for the purpose of avoiding work, duty, or service feigns illness, physical disablement, mental lapse or derangement; or intentionally inflicts self-injury; shall be punished as a court-martial may direct.¹⁴

Thus, before submitting a case for waiver consideration, the base-level flight surgeon must first discern whether the condition is unsuiting vs. unfitting for service. If the Airman requires a fit/unfit determination, the case needs MEB action; if the airman requires a suited/unsuited determination, the case needs consideration of an administrative separation or discharge via the chain of command.

Flying Class (FC)	Condition	Waiver Potential ¹	
		Waiver Authority	
I/IA	Somatic Symptoms and	No	
	Related Disorders	AETC	
II/III and	Somatic Symptoms and	Yes ²	
ATC/GBO/SWA	Related Disorders	MAJCOM	

Table 1: Waiver potential for Somatic Symptoms and Related Disorders

1 No indefinite waivers.

2 For all UNTRAINED individuals (FC I/IA, FC II/III, and ATC/GBO/SWA), a waiver is NOT considered.

AIMWTS search in Apr 2014 revealed 23 cases; 4 had the diagnosis of conversion disorder, 1 had the diagnosis of pain disorder, 1 had the diagnosis of hypochondriasis, 7 had the diagnosis of somatization disorder, and 10 had the diagnosis of undifferentiated somatoform disorder. Breakdown of the cases revealed: 0 FC I/IA cases, 9 FC II cases (5 disqualified), 8 FC III cases (5 disqualified), 2 MOD cases (2 disqualified), 4 ATC/GBC cases (3 disqualified).

## II. Information Required for Waiver Submission.

#### Submitting a Mental Health Waiver Guide:

AFI 48-123 –MSD, 6 FEB 2014, Q1 and the Aeromedical Consultation Service (ACS) Waiver Guide addresses waiver evaluations

### Step 1 - Is the aviator ready for waiver submission?

- A. Waiver is submitted when 1) the member is asymptomatic and 2) medications/psychotherapy treatment have been completed, as applicable to diagnostic category, for the specified time-frame below (Note: psychotherapy "booster sessions", and sometimes antidepressants, are permissible and often advisable after initial symptom resolution):
- 1 Year—Psychotic Disorders & Somatic Symptom and Related Disorders
- 6 Months—Mood Disorders, Anxiety Disorders & Suicidal Behavior
- Discretion of Flight Surgeon—Adjustment Disorders & "Other Conditions" (V-Codes) requiring waiver
- For Traumatic Brain Injury cases, please refer to TBI Waiver Guide
- For aviators with any other psychiatric disorders, please refer to AFI 48-123 and ACS Waiver Guide
- B. To be considered for an aeromedical waiver, any disqualifying condition must meet the following criteria per AFI 48-123 Section 6B, 6.2.1.1 through 6.2.1.6. (pg.31):

Not pose a risk of sudden incapacitation

- Pose minimal potential for subtle performance decrement, particularly with regard to the higher senses
- Be resolved, or be stable, and be expected to remain so under the stresses of the aviation environment
- If the possibility of progression or recurrence exists, the first symptoms or signs must be easily detectable and not pose a risk to the individual or the safety of others
- Cannot require exotic tests, regular invasive procedures, or frequent absences to monitor for stability or progression
- Must be compatible with the performance of sustained flying operations

#### Step 2 - Before beginning the Aeromedical Summary (AMS), Flight Surgeon must obtain Mental Health consultation and ensure it contains items specified below: Instructions for the Mental Health Provider

The mental health evaluation must include a **<u>comprehensive written report</u>** addressing:



Consultation must address each criteria in Step 1B

Clinical mental health history (description of symptoms, treatment modality, frequency and compliance with treatment, relevant personal and family history, and perceived impact on occupational duties)

Medication history (dates of initial prescription and termination, reason for termination, dosage, compliance, response, clinical course since termination)

	Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile) ** <i>for alcohol cases, please comment on carbohydrate-deficient transferrin (CDT) results</i> **
	Current psychosocial situation (marital and occupational, interview with spouse/supervisor, input from line leadership, if possible, and please address current state of any triggers for the mental illness)
	Current and past aviation related duties and any history of current and past occupational performance difficulties (to include perceived impact of mental health condition on performance
	of duties) Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
	Summary and interpretation of psychological/neuropsychological testing results (recommend MMPI-2, NEO PI-R, or similar personality test). For neuropsychological cases, please contact ACS neuropsychologist (Dr. Gary Ford, DSN: 798-2704) for guidance on recommended neuropsychological tests.
	Current mental status
	Diagnosis Motivation to fly or engage in special duty operations (past and current)
	Recommendation for future psychological and medical treatment
	Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)
	Copies of all records (mental health/ADAPT/inpatient) and raw testing data should be on hand for shipment to ACS Neuropsychiatry Branch
Step 3 -	<b>Items for the Flight Surgeon to include in the AMS:</b> AMS must clearly address each criteria in Step 1B and the risk to the member, mission, and safety
	Summarize Mental Health history and focus on occupational impact
_	** If 2 or more months have passed since the comprehensive evaluation/report was completed, the flight surgeon should address how the member has done since and consult with the mental health provider if the member has been seen at mental health since the evaluation**
	Medication history (dates of initial prescription and termination, reason for termination, dosage, compliance, response, clinical course since termination)
	Laboratory results (i.e., thyroid, liver function tests, drug screen, CDT, CBC, chemical profile)
	** <i>for alcohol cases, please comment on carbohydrate-deficient transferrin (CDT) results</i> ** Current psychosocial situation (marital and occupational, interview with spouse/supervisor, if possible - please address current state of any triggers for the mental illness)
	Habits (exercise, diet, medications, supplements, alcohol, tobacco, caffeine, energy drinks, sleep)
	Current mental status
	Diagnosis
	Motivation to fly (past and current)
	Recommendation for future psychological and medical treatment
	Prognosis (estimate of symptom recurrence, potential impact on future aviation related duties)
Step 4 -	Items to complete the waiver package: Letter of support from command

Comprehensive mental health written-report

Confirm mental health has made copies of chart(s) and testing. When requested send to:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913 Fax: (937) 904-6296 DSN: 674-9296

Please feel free to contact the ACS Neuropsychiatry Branch with questions: SSgt Krista Traut 798-2653, or Mr. John Heaton: 798-2766

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The AMS for the <u>initial waiver</u> for somatic symptom and related disorders should include the following:

A. List and fully discuss <u>all</u> clinical diagnoses requiring a waiver.

B. A complete discussion of the history of the disorder and all treatments administered, the current status of any social, occupational, administrative or legal problems associated with the case, and an analysis of the aeromedical implications of this particular case history.

C. Consultation from a psychiatrist or psychologist. All treatment notes from the treating mental health professional as well as an MEB-type narrative summary of the mental health record are required.

D. Report of all psychological testing, if performed.

E. Letter of support from the aviator's supervisor.

The AMS for waiver renewal should include the following:

A. Interval history

B. Treatment – current therapy for the condition, if any.

C. Consultation from psychiatry/psychology if accomplished since the last waiver request.

## III. Overview.

Five diagnoses are grouped within the category of somatic symptom and related disorders: somatic symptom disorder, illness anxiety disorder, conversion disorder, psychological factors affecting other medical conditions, and factitious disorder.¹ These conditions were previously classified in the Fourth Edition of the Diagnostic and Statistical Manual of Mental Health Disorders (DSM-IV) as either somatoform disorders (somatization disorder, conversion disorder, pain disorder, hypochondriasis, body dysmorphic disorder, undifferentiated somatoform disorder, and somatoform disorders. With the publication of DSM-5 in May 2013, the conditions were reclassified in an effort to simplify diagnosis in the primary care setting by focusing on the conditions' distressing somatic symptoms and the accompanying abnormal thoughts, feelings, and behaviors. The new classification removed the requirement that the somatic symptoms be medically unexplained. Although often similar to these disorders in presentation, malingering is not

considered a mental illness even when it impacts the diagnosis, prognosis, or treatment of a medical condition.

The following discussion will focus on somatic symptom disorder, conversion disorder, and factitious disorder. In general, these conditions are more common among females, ethnic minorities, those with fewer years of education, and those of lower socioeconomic status. The 12-month prevalence rate for any somatic symptom or related disorder is about 6 percent of the general population. In women, these disorders have been associated with childhood sexual abuse and recent exposure to physical or sexual violence. These conditions are also strongly associated with other psychiatric disorders, especially anxiety and depression.²

Somatic symptom disorder is a new diagnosis which includes many conditions previously classified as somatization disorders or hypochondriasis. Diagnosis requires the persistence of one or more somatic symptoms that are very distressing or significantly interfere with normal functioning. The condition is marked by excessive thoughts, feelings, or behaviors regarding the symptoms. The symptoms may or may not be medically explained.¹

Conversion disorders are characterized by neurologic symptoms (e.g. weakness, paralysis, seizures, blindness) that are incompatible with recognized neurologic or medical conditions but still cause distress and/or psychosocial impairment.¹ Diagnosis depends upon clinical findings that reveal a symptom to be incongruent with anatomy, physiology, or known diseases, or inconsistent at different times.² Conversion disorders seldom occur for the first time after the age of 35, and symptoms are markedly more common among women than men. In fact, the disorder was originally known as hysteria, a name derived from the Greek word for uterus ( ) because of the ancients' belief that the symptoms arose from a physical displacement of this organ. Studies have found that over a quarter of normal post-partum and medically ill women report having had conversion symptoms at some point during their lives. Although the prognosis for conversion disorder is initially good with symptoms frequently resolving relatively quickly, up to 25% of patients relapse within one year. Cases with an acute onset, a clearly identifiable provoking stressor, and a short interval between onset and treatment tend to do best. Cases manifesting as blindness, aphonia, or paralysis tend to do better than those involving seizures or tremors.³

In both somatic symptom disorder and conversion disorder, symptoms are not seen as intentional, voluntary, or consciously produced.² In factitious disorders and malingering, on the other hand, an individual intentionally produces or feigns physical or psychological symptoms, presenting himself or herself to others as ill, impaired, or injured. In factitious disorders, the deceptive behavior is evident even in the absence of obvious external rewards. The factitious disorder patient's primary goals are to assume the sick role and to receive medical, surgical, or psychiatric care (i.e., to feel "cared for"). In malingering, symptoms are consciously produced or feigned because of a clear external incentive, e.g., to avoid an undesirable deployment, to be discharged from the military, or to obtain monetary compensation.²

Factitious disorder may be suspected when a patient presents with a dramatic but inconsistent medical history. Symptoms may be unclear and changing and may become more severe after treatment has begun. New symptoms may appear following negative lab results and predictable relapses may follow improvements. The patient may display extensive knowledge of hospitals and medical jargon, as well as a textbook presentation of his or her illness. The patient may display an

unusual willingness or eagerness to undergo medical tests, operations, or other procedures and may have a history of seeking treatment from multiple providers. The patient may be reluctant to allow health care professionals to talk to family members, friends, and previous providers.⁴ A particularly severe and chronic form of factitious disorder is Münchausen syndrome which is marked by the following three components: recurrent hospitalizations, travel from hospital to hospital (peregrination), and pathological lying (pseudologia fantastica). While the majority of cases of factitious disorder involve physical symptoms, some patients primarily feign psychological symptoms. Psychological complaints (like physical ones) encompass a broad spectrum of symptoms, including depression, anxiety, psychosis, bereavement, dissociation, posttraumatic stress, and even homicidal ideation.⁵⁻⁷

There are two significant negative consequences to somatic symptom and related disorders. First is the excess health care cost resulting from frequent medical visits, diagnostic testing, invasive procedures, and hospitalizations. Second is the adverse impact on the doctor-patient relationship that is common in this setting.⁸ Management of these disorders frequently requires that patients spend an extended time away from their duties. Even when present for duty, patients are often preoccupied with their physical symptoms and less devoted to mission-oriented tasks. Their symptoms may lead to medical recommendations for multiple duty limiting restrictions.

Among aviators, somatic symptom and related disorders may represent a difficult manifestation of fear of flying. As detailed in DeHart's Fundamentals of Aerospace Medicine, chronic physical or physiologic symptoms may be presented by a flier (sometimes preceded by the words, "I'd like to fly, but...") as incompatible with continuing to fly. This attitude presents a striking contrast to that of most fliers who insist on flying in spite of their symptoms. A reluctant flier's symptoms can arise from an unconscious conflict between anxiety about flying and a greater anxiety about giving up the role of the aviator. "Involuntary" grounding for physical reasons beyond the flier's conscious control offers an acceptable way out of the conflict. As an example, with an unconscious conflict presenting as a conversion disorder, the aviator has no conscious anxiety about flying, and therefore responds to any question concerning apprehension in flight with denial because the question represents a challenge to their defense that the symptoms offer against the intolerable but unconscious underlying anxiety. The flier may have little concern about any disease the symptoms represent, concentrating instead on being removed from flying duties in order to avoid the distress. The entire presentation of the case differs from that of the usual aviator who does not want to be grounded. Three clinical observations may help identify the unconscious aspect of the conversion symptoms. First, the flier tends to describe the symptoms in terms of their effect on flying. Second, the flier may express no particular anxiety about being significantly ill, and have little interest in specific treatment. Third, if asked, "Will you go back to flying when you are well?" the flier may equivocate or signal reluctance. Identifying the somatoform nature of the problem may allow the physician to avoid unnecessary, expensive, or invasive diagnostic procedures. Even if the psychologic nature of the problem is established, the flier is unlikely to agree with the formulation and to cooperate in necessary psychotherapy. The nature of the symptoms (headaches, various pains, sensory deficits, autonomic disturbances of the gastrointestinal tract) may preclude safe return to flying duties.⁹ All the somatic symptom and related disorders may be a defense against fear of flying so it is important to evaluate for recent stressors surrounding flying duty in any of the somatoform presentations.

There is no specific therapy for somatic symptom and related disorders. Management of these conditions requires a good clinician-patient relationship. Attempts should be made to limit a patient's routine care to a single primary clinician and hospital, although in all aeromedical cases, care should also be closely coordinated with psychiatric consultation. Cognitive Behavioral Therapy (CBT) has been found to be an effective treatment for these disorders in some settings. Any underlying medical illnesses must be fully treated while also protecting patients from self-harm and harmful medical procedures. Excessive, repetitive, and unnecessary diagnostic testing should be avoided, especially invasive medical and surgical workups. The doctor needs to be supportive, yet realistic in his or her treatment course. Once firmly established, somatic presentations of fear of flying may be quite resistant to therapy.^{2, 6, 9, 10}

## **IV. Aeromedical Concerns.**

These disorders have a chronic course with patients making repeated visits to physicians due to multiple physical or somatic complaints. The attendant somatic concerns and behaviors interfere with flying availability and reliability. Because of the chronic and recurrent nature of these disorders, treatment offers only a weak hope of returning to flying status; motivation to fly, or lack thereof, significantly influences the aviator's prognosis. These individuals are frequently not motivated for psychotherapy, and may attempt to change physicians when confronted. Therefore, consider conservative medical management and reassurance after ruling out possible organic causes for complaints.

ICD-9 codes for somatic symptom and related disorders			
300.11	Conversion disorder		
300.7	Hypochondriasis		
300.81	Somatization disorder		
300.82	Undifferentiated somatoform disorder		
300.16	Factitious disorder with predominantly psychological		
	signs and symptoms		
300.19	Other and unspecified factitious illness		
301.51	Chronic factitious illness with physical symptoms		
307.89	Other pain disorders related to psychological factors		
V65.2	Person feigning illness		

ICD-10 codes for somatic symptom and related disorders		
F44.4	Conversion disorder with motor symptoms or deficit	
F44.6	Conversion disorder with sensory symptoms or deficit	
F45.21	Hypochondriasis	
F45.0	Somatization disorder	
F45.1	Undifferentiated somatoform disorder	
F68.11	Factitious disorder with predominantly psychological	
	signs and symptoms	
F68.8	Other specified disorders of adult personality behavior	
F68.12	Factitious disorder with predominantly physical signs and	
	symptoms	
F45.42	Pain disorder with related psychological factors	
Z76.5	Malingerer (conscious simulation)	

#### V. References.

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), American Psychiatric Association, Arlington, VA, 2013.

2. Greenberg DB. Somatization: Epidemiology, pathogenesis, clinical features, medical evaluation, and diagnosis. UpToDate . Dec 2013.

3. Hales RE, Yudofsky SC, and Talbott JA. American Psychiatric Press Textbook of Psychiatry, 2nd ed., 1994.

4. Cleveland Clinic. An Overview of Factitious Disorders. Accessed on 31 Mar 2014 from http://my.clevelandclinic.org/disorders/factitious disorders/hic an overview of factitious disorders.aspx.

5. Eisendrath SF and Guillermo GG. Factitious Disorders. Ch. 27 in Review of General Psychiatry, 5th ed., 2000.

6. Lipsitt DR. Factitious disorder and Munchausen syndrome. UpToDate. Nov 2013.

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8. Kroenke K. Somatoform Disorders and Recent Diagnostic Controversies. Psychiatr Clin N Am, 2007; 30: 593-619.

9. Jones DR. Somatoform Disorders. Ch. 17, Aerospace Psychiatry in *Fundamentals of Aerospace Medicine*, 4th ed., 2008, pp. 418-19.

10. Oyama O, Paltoo C, and Greengold J. Somatoform Disorders. Am Fam Physicians, 2007; 76: 1333-38.

11. AFI 48-123, 5 Nov 2013.

12. DoD Instruction 1332.38, 14 Nov 1996.

13. Medical Standards Directory (MSD), 6 FEB 2014.

14. UCMJ art. 115 (2002).





# Attempted Suicide or Suicidal Behavior

Revised: Apr 2022

Reviewed: Lt Col Kevin F. Heacock (ACS Neuropsychiatry Branch Chief), Dr. Max Lee (Waiver Guide Coordinator), and Maj Paul Vu (AFMRA Medical Standards Policy Chief)

## Significant Changes:

Updated definitions for suicide, suicide attempt, and suicidal ideation; updated suicide rates using DoD Annual Suicide Report CY 2020

## I. Waiver Consideration

A history of Attempted Suicide or Suicidal Behavior is disqualifying for all classes of flyers, to include ATC/GBO and SWA personnel. To be eligible for waiver, it is recommended the member display a period of **clinical stability for 6 months** after reaching "Best Baseline" functioning. "Best Baseline" is reached when the flyer's Mental Health Provider (MHP) determines the symptoms of the diagnosis are no longer causing clinically significant distress or impairment and the flyer demonstrates adequate function in social, occupational, and other important areas for functioning. Once "Best Baseline" is reached, treatment adjustments can still be made, including medication changes, without restarting the period of clinical stability as long as the flyer's levels of distress, impairment, or functioning have not deteriorated to a point which the MHP determines is clinically significant.

Flying Class (FC) Waiver Potential		Waiver Authority ACS Review or Evaluat	
FC I/IA	Maybe ^{1, 3}	AFRS/CMO	Yes ²
FC II/III	Maybe ^{1, 3}	MAJCOM	Yes ²
ATC/GBO/SWA	Maybe ^{1, 3}	MAJCOM	Yes ²

#### Table 1: Waiver potential for flyers with history of Attempted Suicide or Suicidal Behavior

1. Underlying conditions that exacerbated suicidal behavior must be treated successfully and the flyer or flyer candidate must not have a higher risk of suicidal behavior than does the general military population.

2. ACS review/evaluation if requested by Waiver Authority for initial FC I/IA, FC II, FC III, ATC, GBO, and SWA applicants.

3. No indefinite waivers.

## II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. Initial/Renewal Waiver Request:

- 1. See Mental Health Waiver Guide Checklist
- 2. If the local base is unable to provide all required items, they should explain why, explaining reason to waiver authority.

## **III. Aeromedical Concerns**

Suicidal behavior must always be taken seriously in any Airman, especially those who are required to meet enhanced medical standards. Not only is the individual flyer at risk, but the safety of others in the air and on the ground must be considered, as well as the conservation of valuable national assets, and the implications of access to nuclear and other weapons.

Especially concerning is the performance requirements of military flyers for readiness and mission completion. While suicide behavior may be a single act, it often represents a distinct, overt pattern of behavior in a long, debilitating process. By and large, flyers are known to demonstrate emotional composure and may deny, suppress, and/or otherwise defend against emotional turmoil. Because of this, the need for peers and flight surgeons to carefully monitor aircrew for early signs of emotional conflict, despair, and intimate relationship deterioration is essential.

A history of attempted suicide or suicidal behavior is disqualifying (referred to generally as suicidal behavior in the waiver guide). All suicidal ideation (thinking about, considering, or planning suicide), self-destructive actions, or overt suicidal attempts by flyers require immediate DNIF action and mental health evaluation, including voluntary or involuntary hospitalization if psychiatrically indicated. Such decisions are based on many factors besides the specific diagnosis, including the patient's intent to die, the lethality of the method chosen, availability of means, the energy put into the attempt, the role of possible substances, the circumstances of the rescue (i.e., found by accident vs. found after hints, phone call, presentation to the emergency department, etc.), and the emotional support systems available to the flyer. Of great concern in flyers with suicidal ideation is the possibility of suicide by aircraft, which is rare, but has occurred in civilian and military settings. Appropriate action should be taken in regard to the Personnel Reliability Assurance Program, if applicable. If the precipitating event involved acute or chronic alcohol misuse, an additional waiver will be managed IAW DAFMAN48-123 and AFI44-121, Alcohol and Drug Abuse Prevention and Treatment (ADAPT) Program.

Suicide is defined as "death caused by self-directed injurious behavior with any intent to die as a result of the behavior." Suicide often results from extreme emotional pain coupled with the belief that cessation of the mental suffering will only be achieved by no longer living. Suicidal ideation refers to thinking about, considering, or planning suicide; suicide plan refers to the identified method and preparation of ending one's life; and suicide attempt refers to a non-fatal, self-directed, potentially injurious behavior with intent to die as a result of the behavior. Another closely related behavior is non-suicidal self-injury which involves cutting, burning, severe scratching, and hitting. Severe cases of non-suicidal self-injury may involve bone breaking and ocular enucleation. The National Institute of Mental Health (NIMH) states that most suicide attempts are expressions of extreme distress, not attempts to garner attention. The NIMH emphasizes that a person who appears suicidal should not be left alone and requires immediate mental-health treatment.

The overall rate for suicide within the general U.S. population is 13.4 per 100,000 people and is the tenth leading cause for death. Those attempting suicide most often engage in medication overdose, while suicide completers most often die from self-inflicted gunshot wounds or strangulation. Demographic analyses of non-military populations indicate that women are three

times more likely to attempt suicide than men, but men are three times more likely to successfully complete suicide (largely associated with the method of suicide employed).

Suicides committed by members of the military has raised concerns among policymakers, military leaders, and the population at large. Historically, the suicide rates for military populations have been lower than those of the general population, but as suicide rates have risen in the military, the <u>DoD Annual Suicide Report for 2020</u> found that in 2019, the rates were comparable to the U.S. population, after accounting for age and sex. The number of suicides among all active duty members was 145 in 2001 and began a steady increase until more than doubling to 321 in 2012, and rising further to 384 in 2020. The suicide rate among Active Components of the military statistically increased from 2015 to 2020 (i.e., 20.3 to 28.7 per 100,000 service members). The suicide rate among Reserve and Guard members was statistically unchanged over the same period, 21.7 and 27 per 100,000, respectively.

Suicide remains a major public health problem within the AF and the AF has continually tracked suicides of Airmen since the 1980s. From 1990-1994, rates of AF suicides increased from 10.0 to 16.4 per 100,000, accounting for 23% of all deaths among active duty personnel. In response to this observed rise, a population based program aimed at preventing and reducing stigma was implemented within the AF community and a 33% relative risk reduction was found in those exposed to the program. As part of the AF's 2002 initiative, the Air Force Guide for Managing Suicidal Behavior was established for use in outpatient behavioral healthcare settings. The Guide was most recently updated in 2014. Over the past decade, Active Duty AF suicide rates have risen from 15.5 per 100,000 in 2010 to 24.8 per 100,000 in 2019. Suicide rates per 100,000 among the services in 2020 were: Army 36.4, Marines 33.9, Air Force 24.3, and Navy 19.3.

Factors contributing to suicidal ideation include distressing life circumstances combined with feelings of hopelessness or helplessness, a recent significant emotional loss, a history of suicide in a family member or close associate, substance abuse, the presence of a psychiatric disorder, and chronic or terminal illness. Risk factors in the US military population have been found to include being on an SSRI, relationship problems, financial challenges, legal problems and substance misuse. In a study comparing suicide non-completers vs suicide completers in the AF, non-completers were likely to be single, never married, and younger (under 24 years old). Completers tended to be older, married and had relationship problems. Of the 384 Active Component service members to complete suicide in 2020, 359 (93.5%) were enlisted. The overall rate for officers has consistently been lower than that of enlisted members.

From the current known information about flyer suicide, the incidence is small, and probably much less than most other military or civilian occupational groups. Between 2003 and 2012 there were 2,758 fatal aviation accidents. The National Transpiration Safety Board (NTSB) determined that eight were aircraft assisted suicides. All pilots involved were male with a median age of 46 years. Four of the eight pilots were positive for disqualifying substances. Specifically, four pilots tested positive for alcohol, one for benzodiazepines, two positive for unapproved antidepressants, and two were positive for diphenhydramine. Six of the eight had reported thoughts of suicide, attempted suicide before, and/or left a note. Additionally, 88% had experienced domestic problems, 13 % had legal issues, and 25% suffered from depression.

Individuals with personal questions should work with their Flight Medicine Clinic.

Flight Surgeons and Mental Health Providers with waiver questions, Please feel free to contact the ACS Neuropsychiatry Branch:

ACS Aerospace Medicine Branch, USAFSAM/FECA c/o Neuropsychiatry Branch 2510 Fifth Street Bldg 840 Wright Patterson AFB, OH 45433-7913

USAFSAM.FE.PsychiatryMailbox@us.af.mil

Phone: (937) 938-2768 DSN: 798-2768 Fax: (937) 904-8753 DSN: 674-8753

AIMWTS review from Jan 2017 to Mar 2022 revealed 346 cases submitted with a diagnosis of suicide attempt/behavior/ideation. There was a disposition of disqualified in 135 of the cases. Breakdown of the cases revealed: 36 FC I/IA (26 disqualified), 66 FC II (12 disqualified), 14 RPA Pilot (7 disqualified), 147 FC III (49 disqualified), 57 ATC/GBC/GBO (33 disqualified), 1 MOD (1 disqualified), and 13 SWA (1 disqualified).

ICD-10 codes for Attempted Suicide or Suicidal Behavior			
T14.91 Suicide attempt			
R45.851	R45.851 Suicidal ideations		
F48.9	F48.9 Nonpsychotic mental disorder, unspecified		
F99 Mental disorder, not otherwise specified			

## **IV. Suggested Readings**

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7. Kochanek KD, Murphy SL, Su J, et al. Deaths: Final Data for 2014. National Vital Statistics Reports, 65(4), June 30, 2016.

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# Asthma

Revised: Dec 2021

Reviewed: Lt Col Dara Regn (ACS Pulmonologist), Maj Luke Menner (ACS Internal Medicine) Dr. Max Lee (ACS Waiver Guide Coordinator), and Col Micah Schmidt (AFMRA Physical Standards Development Chief)

## Significant Changes:

Updated to reflect waiver potential for aviators and operators using long acting beta agonist.

## I. Waiver Consideration

Active asthma, of any type, is disqualifying for all flying classes, ATC, GBO, and SWA duties, as well as for retention. A history of remitted childhood asthma is also disqualifying for all initial flying classes, ATC, and SWA duties. Untrained applicants with a history of remitted childhood asthma will be considered for waiver on a case-by-case basis. Typically, untrained applicants with active asthma will not be considered for waiver.

For trained aircrew and special duty operators with active asthma, waiver may be considered once the disease is controlled on career-field approved medications with demonstration of negative bronchodilator response on spirometry. Bronchoprovocation testing on therapy is required to assess for disease control. Use of more than three metered-dose short acting beta-2 agonists (SABA) inhalers per year is suspicious for inadequate treatment and indicates need for therapy escalation. Unapproved career-field medications for disease control may be considered on a case-by-case basis.

High-performance pilots requesting waiver may be considered eligible when the aviator is symptomless, lung function tests are normal (FEV1 greater than 80% predicted or peak expiratory force is 80% of personal best), and no airway hyper-responsiveness is demonstrated on bronchoprovocation challenge testing.

 Table 1: Waiver potential for asthma

Flying	<b>Condition/Treatment</b>	Waiver Potential/	ACS evaluation
Class		Waiver Authority	required
I/IA	History of remitted childhood asthma and/or exercise-induced bronchospasm	Maybe ¹ AMWD	Yes
	Active asthma, any type, including exercise-induced bronchospasm treated with pre- exercise SABA	No AMWD	No
II/III ATC/SWA	History of remitted childhood asthma and/or exercise-induced bronchospasm ¹	Yes ^{1,2} AMWD/MAJCOM	No
	Active asthma, any type, including exercise-induced bronchospasm treated with pre- exercise SABA ³	Yes MAJCOM ⁴	Maybe ^{5,6}
	Asthma treated with theophylline or systemic corticosteroids	No AFMRA	No
GBO	History of remitted childhood asthma and/or exercise-induced bronchospasm	N/A	N/A
	Active asthma, any type, including exercise-induced bronchospasm treated with pre- exercise SABA ³	Yes MAJCOM	Maybe ^{5,6}
	Asthma treated with theophylline or systemic corticosteroids	No AFMRA	No

1 History of childhood asthma is only disqualifying for initial qualification.

2 Untrained FC II (flight surgeon), ATC and GBO applicants identified to have active asthma on screening may be considered for waiver on case-by-case basis. Untrained FC III and SWA applicants will not be considered for waiver.

3 Use of more than three metered-dose SABA inhalers per year is suspicious for inadequate treatment.

4 AFMRA is the waiver authority for high-performance pilots.

5 ACS evaluation is required for FC II(except flight surgeons)/III/SWA. Other special duty classes do not require ACS review unless requested by the waiver authority.

6 ACS evaluation will normally include full pulmonary function testing and methacholine challenge test and possibly exercise challenge test to assess efficacy of therapy.

## II. Information Required for Waiver Submission.

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

A. The AMS for exercised induced bronchospasm (EIB) should include:

- 1. Detailed history to include chronology of asthmatic episodes, provocative factors, emergency room visits and treatment.
- 2. Rate of utilization of metered-dose inhalers.
- 3. Results of all spirometry studies (FEV1, FVC, and FEV/FEC).*
- 4. Internal medicine, pulmonary consult or allergy consult.
- 5. Medical evaluation board (MEB) results.
- 6. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

* At least one study should include post-bronchodilator spirometry, regardless of whether baseline spirometry is "within normal limits." If EIB is suspected, exercise challenge test should be performed to establish a diagnosis.

B. The aeromedical summary for asthma to include history of childhood asthma should include:

- 1. Detailed history to include other pertinent past medical history (birth history, allergies, family history), chronology of asthmatic episodes, provocative factors, current Asthma Control Test score,⁺ emergency room visits, and treatment.
- Results of all spirometry reports. Should also include results of spirometry with pre and post bronchodilator before and after initiation of therapy (examples include, ICS[†] +/-LABA, montelukast)^{*}. In cases with history of childhood asthma for FC I applicants, methacholine challenge is needed for final disposition and may be accomplished at USAFA or ACS.
- 3. Internal medicine or pulmonary consult.
- 4. Allergy consult if individual also has allergic rhinitis.
- 5. MEB results, if complete.
- 6. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

⁺ The Asthma Control Test (ACT) is a quick, 5-question assessment tool that is meant to quantify the level of the patient's asthma control. It is scored on a scale of 5-25. The American Thoracic Society considers a score of > 19 to be indicative of well-controlled asthma. The questionnaire can be found at www.asthmacontroltest.com.

[†] Regardless of the ICS used, it is important to use the lowest dose necessary to achieve control.

^{*} In cases of active asthma, ACS may accomplish additional bronchoprovocation testing to include exercise and methacholine challenges during ACS evaluation.

## III. Aeromedical Concerns

Asthma is a chronic inflammatory condition of the airways that typically begins in childhood and though symptoms may resolve or improve during adolescence and adulthood, never goes away. Selection of aircrew for military aviation is complicated because many asthmatics who become free of symptoms in early adolescence will suffer relapse in their twenties or early thirties. Numerous natural history studies have attempted to correlate a variety of factors to the risk of persistence or relapse of asthma, but results have been inconclusive due to heterogeneous nature of asthma. As stated by the Expert Panel 3 of the National Asthma Education and Prevention Program, asthma "is a common chronic disorder of the airways that is characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness, and underlying

inflammation. The interaction of these features determines the clinical manifestations and severity of asthma and the response to treatment." Per the CDC, asthma prevalence in the U.S is currently 9.3% affecting 24 million people annually. There is no cure for asthma, but with regular treatment, it can be controlled, allowing patients to live full and productive lives.

The major symptoms of asthma include wheezing, shortness of breath, chest tightness, and cough which can be distracting and incapacitating in aeromedical environment. Both clinical experience and studies have shown that subjective reporting of symptoms does not correlate well with severity of obstruction hence need for asthma education with asthma action plan to include routine objective measurement with peak flow diaries for clinical monitoring. Patients tend to adapt to chronic airflow obstruction, so that symptoms correlate better with the rate of fall of FEV1 during an attack, rather than with the absolute degree of obstruction. Spirometry utilizing the forced vital capacity maneuver is the standard method for measuring obstruction. Proper technique and adequate effort by the individual are crucial. In the past, a ratio of FEV1/FVC less than 0.75 was used to define the presence of airflow obstruction. However, the normal range of FEV1 can vary significantly, depending on race, age, gender, and anthropomorphic measurements. Population based studies of normal individuals have been used to create algorithms that take these factors into account. By convention, we consider values above the 95th or below the 5th percentile for a given population to be abnormal. However, it should be noted that analyzing pulmonary function data of pilot applicants across NATO, we have found that this cohort's baseline airway function is, unsurprisingly, far superior to that of the general population. Airway obstruction is defined as a FEV1/FVC ratio lower than the predicted range for the individual patient. The FEV1 is used to gauge the severity of the obstruction. Reversible airway obstruction is defined as an increase of at least 12% and 200 mL in FEV1, after administration of an inhaled bronchodilator.

Exercise is a critical element in healthy living, particularly for those with asthma and regular exercise helps improve lung function. However, exacerbation of chronic or intermittent asthma by exercise is an extremely common symptom, reported by 70-90% of asthmatics; since it is well documented that many individuals fail to symptomatically differentiate asthma from normal exertional breathlessness. In addition to exercise exacerbating bronchospasm in established asthma, there is a separate phenomenon of solitary exercise-induced bronchospasm (EIB). In contrast, asthmatic deaths as a result of exercise in those with established asthma are well documented. Solitary EIB occurs in recreational as well as high school and collegiate athletes; the prevalence is significant, typically affecting about 9-12% of children in athletic programs. The phenomenon has been best studied in professional athletes. Endurance sports have a higher risk than intermittent activities. The greatest risk involves winter sports, which is consistent with the likely mechanism of EIB, which is oxidative stress of the airways. Screening of the 1998 Winter Olympic Team using sport-specific challenge showed an overall rate of EIB of 23%, with cross-country skiing showing a prevalence of 50%.

The 2019 Global Initiative for Asthma (GINA) report contained the biggest update in thirty years, stating that for safety reasons, SABA treatment alone is no longer recommended, as it does not protect members from severe exacerbations and that regular or frequent use of SABAs increases risk of exacerbations. GINA now recommends that all adults and adolescents with asthma should receive either daily low dose inhaled corticosteroid (ICS) containing controller treatment or symptom-driven (in cases of mild asthma) ICS-LABA combination therapy to reduce risk of serious exacerbations.

The long-term goals of asthma management are to achieve good symptom control, minimize future risk of asthma related mortality, exacerbations, persistent airflow limitation due to airway remodeling and side-effects of treatment. If asthma remains uncontrolled despite good adherence and inhaler technique, asthma therapy should be stepped up to combination ICS/LABA (with progressively increasing dose of ICS) as risk of exacerbations is reduced. Therapy can be stepped down if good asthma control is achieved and sustained for 3 months. Therefore, as key components to optimization of asthma control and reduced exacerbations with minimal side effects, ICS, LABA, and leukotriene modifiers are now aircrew approved. Since ICS and montelukast both show efficacy for exercise-induced symptoms in established asthma, use of SABA should not be necessary. The sole exception would be an exacerbation associated with a respiratory infection, during which the aviator should be DNIF. If such an exacerbation occurs, the individual should remain DNIF for one week after stopping use of SABA, to allow the inflammatory process to resolve. In patients with asthma or EIB prescribed montelukast, the risks and benefits and alternative therapies should be considered given recent reports of neuropsychiatric side effects. Asthma medications which are NOT aircrew approved due to side effect profile include long acting muscarinic antagonists (LAMAs), which have traditionally been used to treat COPD and are used for asthma COPD overlap (ACO), monoclonal antibody therapies (e.g. anti-IgE, anti-IL5/5R, anti-IL4R), and oral corticosteroids.

The ACS typically performs a methacholine challenge test (MCT) on all members requesting a waiver for asthma and an exercise challenge in those with history of exercise-induced symptoms. This test is done on the member, while they are taking their controller medications to measure their level of residual bronchial hyper-reactivity. In the ACS's experience, asthmatics who require rescue inhaler use, even rarely, typically fail their methacholine challenge tests and are not granted waivers. For this reason, it is of paramount importance for the local flight surgeon to make sure the patient's asthma is under excellent control, prior to submitting a waiver application.

The Air Force is now considering waivers for asthmatic high performance pilots and aircrew requiring routine use of mask with enrollment and monitoring in management group. A waiver is possible with optimal asthma control based on case series data from Jan 1988 to Sept 2005, where 13 high-performance aviators with asthma severity ranging from mild to severe, had NO cases of sudden incapacitation or safety breaches during these flight years using their aviator asthma management algorithm. The case series covered 182 flight years in 18 aviators (high performance and non-high performance included). Only one high-performance aviator had clinical recrudescence that required permanent grounding. In USAF asthmatic fighter pilots, asthma is considered controlled when the aviator is symptomless, lung function tests are normal (FEV1 greater than 80% predicted; or peak expiratory force, 80% of personal best), and no airway hyper-responsiveness is demonstrated on challenge testing with aircrew approved therapy. Each aviator is also provided asthma education, an individualized action plan, and peak flow monitoring if not already accomplished locally. Since inception of this management group in Nov 2018, the ACS has evaluated eight fighter pilots with asthma and recommended they be waivered to return to their normal duties with no adverse events.

AIMWTS review in May 2020 for the previous five years revealed 1,123 aviators with a diagnosis of asthma with 174 cases resulting in a disqualification. Breakdown of the cases

demonstrated: 415 FC I/IA cases (77 disqualified), 138 FC II cases (5 disqualified), 305 FC III cases (62 disqualified), 66 ATC cases (seven disqualified), 167 GBO cases (16 disqualified), and 32 SWA cases (seven disqualified). The vast majority of the approved FC IIA cases listed a diagnosis of childhood asthma.

ICD-9 C	ICD-9 Codes for Asthma		
493.0	Extrinsic asthma		
493.1	Intrinsic asthma		
493.2	Chronic obstructive asthma		
493.3	Other forms of asthma (exercised induced, cough variant)		
493.9	Asthma, unspecified		

ICD-10 Codes for Asthma		
J45.20	Mild intermittent asthma, uncomplicated	
J45.998	Other asthma	
J45.909	Unspecified asthma, uncomplicated	

#### **IV. Suggested Readings**

1. Global Initiative for Asthma. Pocket Guide for Asthma Management and Prevention. 2019 and 2020.

- 2. NHLBI Guidelines for the Diagnosis and Management of Asthma (EPR-3), July 2007.
- 3. Akinbami LJ, Moorman JE, and Lie X. Asthma Prevalence, Health Care Use, and Mortality: United States, 2005–2009. National Health Statistics, N0.r 32; January 12, 2011.
- 4. Rundell KW, Im J, Mayers LB, et al. Self-reported symptoms and exercise-induced asthma in the elite athlete. Med Sci Sports Exerc, 2001; 33: 08-13.
- 5. Thole RT, Sallis RE, Rubin AL, Smith GN. Exercise-induced bronchospasm prevalence in collegiate crosscountry runners. Med Sci Sports Exerc, 2001; 33: 1641-6.
- 6. Becker JM, Rogers J, Rossini G, et al. Asthma deaths during sports: report of a 7-year experience. J Allergy Clin Immunol, 2004; 113: 264-7.
- 7. Storms WW. Asthma associated with exercise. Immunol Allergy Clin North Am, 2005; 25: 31-43.
- 8. Medical Therapy for Asthma: Updates from the NAEPP Guidelines. Am Fam Physician, 2010; 82(10): 1242-51.
- 9. Carter, D, Pokroy R, Azaria B, et al. Asthma in Military Aviators: Safe Flying is Possible. Aviat Space Environ Med, 2006; 77 (8).

#### Pneumothorax (Jun 2020)

Reviewed: Lt Col Dara Regn (ACS Pulmonologist), Dr. Dan Van Syoc (ACS Waiver Guide coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

#### **Significant Changes:** New format and updated policy

# I. Waiver Consideration

As of the July 2016 MSD, Air Force policy regarding spontaneous pneumothoraces has been significantly revised effectively making spontaneous pneumothorax disqualifying for FCI/IA/FCII/FCIII/SWA/OSF aviation duties. This new guidance applies to all initial flying class exams regardless of the date of prior pneumothorax as well as fully trained FCII/FCIII/SWA/OSF aviators experiencing a primary pneumothorax after the date of this publication. A single episode of spontaneous pneumothorax in a fully trained aviator <u>prior</u> to publication of this new MSD guidance would not require a waiver as long as results of PA inspiratory and expiratory chest radiographs and CT chest imaging are clearly documented in the medical record, and show full expansion of the lung with no demonstrable pathology which would predispose to recurrence. If a fully trained FCII/FCIII/SWA/OSF aviator were to experience a recurrent pneumothorax, they would then require a waiver. Pneumothorax is not disqualifying for ATC or GBO personnel.

In summary, aeromedical waiver for spontaneous pneumothoraces may be considered only if PA inspiratory and expiratory chest radiograph and CT chest scan show full expansion of the lung and no demonstrable pathology which would predispose to recurrence, such as blebs or bullae, or after definitive surgery to prevent recurrence if CT demonstrates residual blebs. Any form of definitive surgical pleurodesis is acceptable for waiver, but thoracoscopic abrasive pleurodesis performed by a Thoracic or Cardiothoracic trained surgeon, appears to offer the best combination of efficacy and minimal morbidity. Chemical pleurodesis with talc slurry, tetracycline compounds, or other pleurodesing agents is generally not acceptable for waiver. If chemical pleurodesis has been completed prior to entry into the military service or an aviation career field, a waiver may be considered on a case-by-case basis after review by the ACS.

Flying Class	Condition	Waiver Potential	ACS Review
(FC)		Waiver Authority	
I/IA	Primary pneumothorax	Yes ²	Yes
		AETC	
	Multiple	Yes ^{1, 2}	Yes
	pneumothoraces or	AETC	
	pathology noted on		
	chest CT		
II/III/SWA	Primary pneumothorax	Yes ²	Yes
		MAJCOM	
	Multiple	Yes ^{1, 2}	Yes
	pneumothoraces or	MAJCOM	
	pathology noted on		
	chest CT		

#### Table 1: Waiver potential for Pneumothorax

1. If definitive surgery has been performed with resolution of symptoms.

2. Indefinite waiver possible after ACS verification that CT imaging is without demonstrable pathology which would predispose to recurrence.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

#### A. Initial Waiver Request:

- 1. A complete history of the event to include any possible predisposing factors.
- 2. Documentation of all treatments given.
- 3. Labs/Imaging: Reports of all imaging exams. CT chest imaging required with the actual images forwarded to the ACS for formal review.
- 4. Copies of all operative reports and a statement from treating physician.
- 5. Spirometry results including pre- and post-bronchodilator challenge, lung volume and DLCO studies by plethysmography.
- 6. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

#### B. <u>Renewal Waiver Request:</u>

- 1 Interval history specifically noting any symptoms, changes in disease course and treatments since the last waiver submission.
- 2 Current CT chest imaging with actual images forwarded to the ACS for formal review.
- 3 Statement of patient condition from treating physician.
- 4 Spirometry results including pre- and post-bronchodilator challenge, lung volume and DLCO studies by plethysmography.
- 5 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

#### **III. Aeromedical Concerns**

Spontaneous pneumothorax is best defined as "air in the pleural space of non-traumatic cause." Secondary spontaneous pneumothorax is one that occurs in the presence of known underlying parenchymal or airway disease. Primary spontaneous pneumothorax, by default, is one that occurs in the absence of such underlying disease. However, it would be incorrect in such cases to define the lung as normal, since the vast majority prove to have visceral subpleural blebs at thoracoscopy. Most cases of primary spontaneous pneumothorax occur at rest, and it is actually unusual to see cases in the athletic realm.

Primary spontaneous pneumothorax typically peaks in the 10 to 30 year age group, affecting males about 5 to 10 times more frequently than females. The age-adjusted incidence in males and females varies widely in the clinical literature with reported rates from 7.4 per 100,000 in United States to 37 per 100,000 in United Kingdom. It occurs primarily in tall, thin individuals and is rare in those over the age of 40. Smoking has been shown to increase the risk of primary spontaneous pneumothorax by a factor of 20 in a dose-dependent manner. More than 20,000 new cases of spontaneous pneumothorax occur each year in the United States at a cost of more than \$130 million (2006 costs). Although the incidence in the general population is usually quoted as 9 per 100,000, the real incidence is probably higher. In most large series, 1% to 2% are incidentally found on chest film; since small pneumothorax in this way are slim, arguing that the disease is probably more common than thought. Fortunately, primary spontaneous pneumothorax has low mortality, with death rare in those cases occurring below age 50.

The classic presentation in a symptomatic patient with spontaneous pneumothorax is dyspnea and pleuritic chest pain. The chest pain is almost always ipsilateral and may radiate to the shoulder, neck, and into the back. Physical exam may demonstrate tachycardia, tachypnea, hyperresonance to percussion, diminished breath sounds, and asymmetrical chest wall expansion may be present. There are also a multitude of possible ECG changes that can be seen in the setting of a pneumothorax. The diagnosis is best confirmed with a standard chest film. Expiratory films are no more sensitive than inspiratory films in detecting pneumothoraces and are not recommended unless there is high clinical suspicion of pneumothorax and the inspiratory film is non-diagnostic. If present on the chest film, it will demonstrate a pleural line. A specific subcategory that deserves mention is catamenial pneumothorax. This is a spontaneous pneumothorax occurring in a female within 48 to 72 hours of the onset of menses. Although these are often ascribed to endometriosis, pleural endometrial implants have been identified in only a third of patients. It is important to question any female with a spontaneous pneumothorax about the timing in relationship to menses, since the initial treatment of catamenial pneumothorax is hormonal. Should the patient fail a trial of contraceptive steroids, this disorder responds well to the same prophylactic surgical treatments described below.

The major issue with spontaneous pneumothorax is recurrence. After an initial pneumothorax, the chance of recurrence in the absence of definitive treatment is 20 to 50%, a risk which probably rises after subsequent episodes. (some researchers have shown that after two pneumothoraces, the risk of a third is 62%; of those who have had three episodes, 83% will have a fourth). The clinical standard of care for a number of years has been to perform a definitive surgical procedure after the second

pneumothorax, but with the availability of thoracoscopic pleurodesis, there are many who feel that surgery is indicated after the first episode, particularly in those who are at high risk because of their occupation or because of travel to remote areas.

Depending on the size of the pneumothorax, acute treatment may consist of observation, usually combined with oxygen, which hastens resolution (rate of pleural air absorption in the absence of supplemental oxygen is 1.25%/day; this is increased 3-4X in the presence of supplemental oxygen); simple aspiration of the air, which is successful about 65% of the time; or catheter or tube thoracostomy. There has been discussion for many years as to the emergency management of spontaneous pneumothorax. For many years, the gold standard was insertion of a chest tube (tube thoracostomy). Recent evidence indicates that needle aspiration is at least as safe and effective as tube thoracostomy and also carries the benefit of fewer hospital admissions and shorter length of hospital stay. Some emergency departments have begun to adopt ambulatory care treatment in small uncomplicated cases of pneumothorax. This is accomplished through the use of a one way Heimlich valve. While data for this treatment is limited, it offers the obvious advantage of eliminating an admission, and provides improved patient comfort.

The definitive procedure until relatively recently was chemical pleurodesis which was accomplished via the chest tube by inserting a sclerosing substance into the pleural space causing the pleura to adhere to the chest wall thereby preventing recurrences. The most common substances used were tetracycline derivatives or talc slurry. The recurrence rate with each of these was not totally acceptable and also was potentially fraught with unacceptable side effects. Problems with talc range from pain and fever to respiratory failure and ARDS. The newer and more successful interventions are surgical and include video assisted thorascopic surgery (VATS) or open thoracotomy. These procedures can lead to recurrence prevention by either mechanical abrasion pleurodesis or pleurectomy.

The most likely symptoms are chest pain and dyspnea, either of which could be incapacitating in aircrew. There is also the concern with gas expansion at altitude in untreated pneumothorax in aviators, in accordance with Boyles Law. The level of expansion can be calculated using Boyles equation P1V1=P2V2. For example, assuming a total lung volume of 6 L and a one sided 20% pneumothorax traveling from sea level to 8000 ft: (760 mmHg)(600 mL)=V2(567 mmHg), then V2=804 mL, or approximately a 33% expansion. Given the above calculation, it is possible that the gas expansion may cause significant physiological deficit. In a review of 112 aviators with spontaneous pneumothorax, 37% admitted they could have been incapacitated had the episode occurred during flight. Overall, seventeen percent of the episodes occurred under operational conditions. Eleven percent actually occurred during flight, although it was unclear how many of these resulted in mission aborts. Of note, another 6% occurred in the altitude chamber, and all but one of those occurred after rapid decompression.

AIMWTS review in May 2020 for the previous five years revealed 49 members with a diagnosis of pneumothorax. Of those, six were disqualified. Breakdown of these cases demonstrated: 9 FC I/IA cases (one disqualified), 11 FC II cases, 18 FC III cases (three disqualified), 1 ATC case, 5 GBO cases, and 5 SWA cases (two disqualified).

ICD-9 c	ICD-9 codes for Pneumothorax		
512	Pneumothorax		
512.0	Spontaneous tension pneumothorax		
512.1	Iatrogenic pneumothorax		
512.8	Other spontaneous pneumothorax		
860	Traumatic pneumothorax and hemothorax		
860.0	Traumatic pneumothorax without mention of open wound into thorax		

ICD-10 codes for Pneumothorax		
J93.11	Primary spontaneous pneumothorax	
J93.0	Spontaneous tension pneumothorax	
J95.811	Postprocedural pneumothorax	
J93.12	Secondary spontaneous pneumothorax	
S27.2XXA	Traumatic hemopneumothorax	
S27.0XXA	Traumatic pneumothorax	

#### **IV. Suggested Readings**

1. Light RW and Lee YCG. Pneumothorax, Chylothorax, Hemothorax, and Fibrothorax. Ch. 74 in *Mason: Murray and Nadel's Textbook of Respiratory Medicine*, 5th ed., Saunders, 2010.

2. Voge VM and Anthracite R. Spontaneous Pneumothorax in the USAF Aircrew Population: A Retrospective Study. Aviat Space Environ Med, 1986; 57: 939-49.

3. Baumann MH. Management of Spontaneous Pneumothorax. Clin Chest Med, 2006; 27: 369-81.

4. Sahn SA and Heffner JE. Spontaneous Pneumothorax. N Engl J Med, 2000; 342: 868-74.

5. Szymanski TJ, Jaklitsch MT, Jacobson F, et al. Expansion of Postoperative Pneumothorax and Pneumomediastinum: Determining When it is Safe To Fly. Aviat Space Environ Med, 2010; 81: 423-26.

6. Brims FJH and Maskell NA. Ambulatory treatment in the management of pneumothorax: a systemic review of the literature. Thorax, 2013; 68: 664-69.

7. Zehtabchi S and Rios CL. Management of Emergency Department Patients With Primary Spontaneous Pneumothorax: Needle Aspiration or Tube Thoracostomy? Ann Emerg Med, 2008; 51: 91-100.

8. Pickard JS. Spontaneous Pneumothorax. Ch. 13 (Pulmonary Diseases) in *Rayman's Clinical Aviation Medicine*, 5th ed. Castle Connolly Graduate Medical Publishing, Ltd., New York, 2013.

#### Sarcoidosis (Jun 2020)

Reviewed: Lt Col Dara Regn (ACS Pulmonologist), Dr. Dan Van Syoc (ACS Waiver Guide Coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

# Significant Changes:

New format and new MSD updates

# I. Waiver Consideration

Sarcoidosis is disqualifying for all flying classes (FC I/IA, II, and III), ATC/GBO, and SWA personnel, as well as retention. Therefore, a waiver and MEB are necessary for these personnel.

History of cardiac or CNS involvement is typically not waiverable. Also sarcoidosis causing hypercalcemia is not compatible with a waiver. Please consult Uveitis Waiver Guide if ophthalmologic sarcoidosis is present.

Flying Class (FC)	Condition	Waiver Potential	ACS
		Waiver	review/evaluation
		Authority	
I/IA	History of sarcoidosis	Maybe ^{1.2}	Yes
	(asymptomatic or	AETC	
	symptomatic) with		
	disease resolution.		
Trained	Sarcoidosis that is	Yes ^{1, 3}	Yes, initial waiver
II/III	asymptomatic, stable, no	AFMRA	or if relapse
ATC/GBO	treatment required, and		
	no functional		
	impairment.		
	Sarcoidosis previously	Yes ^{1,4}	Yes, initial waiver
	treated with steroids and	AFMRA	or if relapse
	now asymptomatic,		1
	stable and no functional		
	impairment. ¹		
Untrained	History of sarcoidosis	Maybe ^{1, 2}	Yes
II/III	(asymptomatic or	AFMRA	
ATC/GBO	symptomatic) with		
	disease resolution. ⁴		

#### Table 1: Waiver potential for sarcoidosis

1. History of cardiac or CNS involvement is typically not waiverable.

2. Waiver considered only if asymptomatic, no functional impairment and remission without treatment for at least 3 years duration.

^{3.} Waiver for trained aviators requires three-month follow-up to assure stability of newly diagnosed (histologically proven) disease prior to waiver submission.

^{4.} If systemic corticosteroid therapy results in remission, then waiver may be submitted after six months off medication if asymptomatic, no evidence of recrudescence and pituitary-adrenal axis has returned to normal function (see Systemic Glucocorticoid (Steroid) Treatment Waiver Guide).

# II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

A. AMS for sarcoidosis for <u>initial waiver or waiver for recurrent</u> (relapsed) sarcoidosis should include the following:

1. History – occupational (silicates, beryllium) and environmental (moldy hay, birds, TB, coccidioidomycosis, histoplasmosis) exposures, signs, and symptoms (including negative, covering all organ systems), activity level, medications/treatment (if treated with corticosteroids within the year then Cosyntropin® stimulation test [see Systemic Glucocorticoid (Steroid) Treatment Waiver Guide]).

- 2. Complete physical with emphasis on lung, skin, eye, liver and heart, and *thorough* neurologic examination.
- 3. Internal medicine or pulmonologist consultation.
- 4. Testing CXR, biopsy results, full pulmonary function testing with spirometry pre/post bronchodilator, lung volumes, and DLCO, 12-lead ECG and 24-hour Holter monitor test.
- 5. Laboratories complete blood count (CBC), calcium, liver function tests, creatinine, blood urea nitrogen (BUN), urinalysis, 24-hour urine creatinine, and 24-hour urine calcium.
- 6. TB skin test.
- 7. Ophthalmology/optometry exam, to include slit lamp.
- 8. MRI with gadolinium. Neurology consultation if symptoms or signs indicate possible involvement.
- 9. MEB results.
- 10. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.
- B. AMS for <u>waiver renewal</u> of individuals in continued remission should include the following:
  - 1 History brief summary of previous signs, symptoms, and treatment, current signs or symptoms (include negative), activity level, and medications.
  - 2 Physical complete physical, addressing lung, skin, eye, liver, heart, and CNS.
  - 3 Testing CXR, full pulmonary function testing with spirometry pre/post bronchodilator, lung volumes, and DLCO.
  - 4 Laboratories complete blood count (CBC), calcium, liver function tests, creatinine, blood urea nitrogen (BUN), and urinalysis. 24 hour urine calcium and creatinine should also be submitted if previous symptoms or current findings indicate systemic involvement.
  - 5 Ophthalmology/optometry exam, to include slit lamp.
  - 6 Neurologic or cardiac evaluation if current findings indicate involvement.
  - 7 If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why that could not be provided.

#### **III. Aeromedical Concerns**

The most common aeromedical concerns are typically cardiac and pulmonary, though ophthalmologic and neurologic involvement may prove to be a hindrance to flight crew duties as well. Myocardial involvement may present as arrhythmias, conduction block, and syncope leading to sudden incapacitation during flight. Restrictive pulmonary disease is itself an aeromedical concern, particularly if blood gases are affected or airway hyper-reactivity is present. A crewmember with stage II or III sarcoidosis may have altered oxygen diffusion, thus exacerbating or accelerating symptoms of hypoxia and reduced decision-making abilities at altitude. Reductions in FVC and FEV1 may accompany sarcoidosis even with optimized medical management.³

CNS disease (e.g., cranial nerve palsies, encephalopathy, seizures), depression, ocular complications (e.g., uveitis, iritis, chorioretinitis), and renal calculi all have direct aeromedical implications. Neuromuscular involvement, especially of proximal muscle groups (and the predilection towards quadriceps muscle group involvement), have important implications for rudder control and anti G-straining maneuvers.

No individual should fly while undergoing treatment. Steroid treatment itself has a variety of metabolic, psychiatric, and CNS effects, which may make flying hazardous.

Sarcoidosis is a multisystem disorder characterized by the presence of discrete, compact, noncaseating epithelioid granulomata. The typical sarcoid granuloma is found in the lung, distributed along lymphatic chains, but can be found in virtually any organ. Though the precise etiology is unknown, recent evidence demonstrating T-cell lymphocytes layering around the granuloma suggests an immunological reaction in genetically susceptible individuals who are exposed to specific environmental agents. There is also newer evidence that there may be an infectious etiology to the condition.

Most commonly, sarcoidosis presents in one of three ways: as an asymptomatic finding on CXR; with nonspecific constitutional symptoms; or with organ-specific complaints. In various series, 30% to 60% of clinical presentations are asymptomatic and incidentally found, typically with radiographic findings of bilateral hilar adenopathy (BHA), with or without parenchymal opacities. Nonspecific symptoms may include fever, weight loss, fatigue, or muscle weakness. Organ-specific presentations are protean, and may manifest with dermatologic lesions, dyspnea on exertion, cough, vision changes or eye pain, cranial or peripheral nerve palsies, seizures, arthralgia, cardiac conduction blocks or even sudden cardiac death. Due to the variability of symptoms, delay in diagnosis is not uncommon.

<u>Pulmonary involvement</u>: Pulmonary sarcoidosis is a predominantly interstitial lung disease, with symptoms and radiographic findings similar to other fibrotic lung diseases. Prominent symptoms are dyspnea, dry persistent cough, and chest pain. Significant interstitial disease may lead to abnormal pulmonary function and oxygen diffusion capacity. However, in contrast with other interstitial lung diseases such as idiopathic pulmonary fibrosis, profuse radiographic changes are often associated with minimal physiologic alterations in lung function. The granulomatous inflammation, which favors the upper lung fields, tends toward a peribronchial distribution, which helps explain two additional clinical phenomena that are unusual with other interstitial lung diseases: transbronchial biopsy is usually successful in establishing a histologic diagnosis, and some

patients (roughly 15%) experience bronchospasm as a complication of the disease. Sarcoidosis has rarely presented with tracheal or laryngeal involvement, hemoptysis, unilateral involvement, pleural effusion, pneumothorax, pleural thickening, cavity formation, calcification of lymph nodes, or clubbing.

Even when patients initially present with extrapulmonary manifestations, over 90% have radiographically evident pulmonary involvement. Because pulmonary involvement is nearly ubiquitous, and is the most common cause of sarcoid-related morbidity, staging of sarcoidosis is based on radiological characteristics of the CXR. It is important to note that sarcoidosis normally does not progress though each of the 5 stages in a predictable fashion. Patients with sarcoidosis can present with any stage of disease; and while their disease may go on to progress to another stage, it may also remit or remain stable. The following are the various stages and remission rates:

- Stage 0 disease has a normal CXR (which implies extrapulmonary disease is the presenting manifestation or that the disease has remitted).
- Stage I disease is defined by the presence of BHA, which is often accompanied by right paratracheal node enlargement. 50% of affected patients exhibit BHA as the first expression of sarcoidosis. Regression of hilar nodes within one to three years occurs in 75% of such patients, while 10% develop chronic enlargement that can persist for 10 years or more. When BHA is associated with EN, migratory polyarthralgias, and fever, the diagnosis of Löfgren's syndrome is highly likely. Patients with stage 1 disease are most often asymptomatic.
- Stage II disease consists of BHA and reticular opacities (the latter occurring in the upper more than the lower lung zones). These findings are present at initial diagnosis in 25% of patients. Two-thirds of such patients undergo spontaneous resolution, while the remainder either have progressive disease or display little change over time. Patients with stage II disease usually have mild to moderate symptoms, most commonly cough, dyspnea, fever, and/or fatigue.
- Stage III disease consists of reticular opacities with shrinking or absent hilar nodes. Reticular opacities are predominantly distributed in the upper lung zones. This form typically remits in 10-20% of cases.
- Stage IV disease is characterized by fibrotic, reticular opacities with evidence of volume loss, predominantly distributed in the upper lung zones. Conglomerated masses with marked traction bronchiectasis may also occur. Extensive calcification and cavitation or cyst formation may also be seen. Remission occurs in 0-5% of individuals with this stage.

<u>Cardiac involvement:</u> Approximately 5% develop clinically evident cardiac involvement, though autopsy studies of sarcoid patients have reported granulomatous infiltration of the myocardium in 13 to 30% of patients. (It should be borne in mind that, with the exception of cardiac and severe pulmonary disease, sarcoidosis is rarely fatal, and thus myocardial sarcoidosis is almost certainly over-represented in autopsy series.) The left ventricle and interventricular septum are most often involved. Heart block is most likely due to disease of the AV node or the bundle of HIS. Since healed myocardial granulomata may become foci for abnormal automaticity leading to arrhythmias, patients in remission who have had myocardial involvement remain at risk for sudden death. Before the advent of implantable cardiac defibrillators, several studies of cardiac sarcoid reported a risk of sudden death of 33-67%. Routine ECG, Holter monitoring, and transthoracic

echocardiogram are routinely used to screen for cardiac sarcoidosis. However, if the diagnosis is suspected, cardiac MRI is the most sensitive imaging modality.

<u>Dermatologic involvement:</u> Cutaneous manifestations of sarcoidosis involve approximately onethird of patients, and can be variable. The classic panniculitis of EN is a common presentation of acute sarcoidosis in Caucasian, Puerto Rican, and Mexican patients and is the least beneficial lesion to biopsy. Other dermatologic lesions include small purplish papules, plaques, or subcutaneous nodules. While these are less distinctive on physical examination, biopsy will often yield a histologic diagnosis of noncaseating granulomata. Small, pink, maculopapular eruptions may wax and wane, may present as scarring sarcoidosis, and may cause alopecia. Sarcoid lesions may invade old scars. On blanching with a glass slide, dermal sarcoid lesions often reveal an "apple jelly" yellowish brown color. As a rule, sarcoid lesions do not itch, ulcerate, or cause pain.

<u>Ocular involvement:</u> In most series, ocular involvement occurs in 25-33% of individuals. As with other granulomatous disorders, sarcoidosis can affect any part of the eye and involvement may or may not be symptomatic. Anterior uveitis is the most common manifestation, often presenting with ocular pain, redness or changes in vision. Posterior chronic uveitis may be occult and may, over time, lead to secondary glaucoma, cataracts, or blindness. Other eye lesions include conjunctival follicles, dacryocystitis, and retinal vasculitis.¹

Nervous system involvement: Neurological manifestations can occur in up to 5 to 10% of cases, though one series found neural involvement in 26% of sarcoid patients. Neurosarcoidosis favors the base of the brain, and may present as a cranial nerve palsy (especially facial nerve palsy), panhypopituitarism, fulminant delirium, hydrocephalus or chronic meningitis. Seizures have been reported in 5%-22% of neurosarcoidosis patients, but are rarely the presenting symptom. Granulomatous involvement of the hypothalamus may result in defective release of vasopressin, adrenocorticotropic hormone, and glucagon; in particular the defect in vasopressin may lead to diabetes insipidus. These lesions are typically early findings and respond well to treatment. On the other hand, space occupying lesions, seizures, peripheral nerve lesions, and neuromuscular involvement tend to occur as a late manifestation, and most likely indicate chronic disease.² MRI imaging often reveals the presence of leptomeningeal enhancement. Cerebrospinal fluid (CSF) findings are nonspecific, and may include lymphocytosis, increased protein, and/or elevated angiotensin-converting enzyme (ACE) levels, lysozymes, increased CD4/CD8 ratios and β-2 macroglobulins. The triad of facial nerve palsy, parotiditis, and anterior uveitis is called the Heerfordt syndrome and, unlike most neural involvement, suggests a favorable prognosis.

<u>Musculoskeletal involvement:</u> Joint pains occur in approximately 25-39% of sarcoid patients, although deforming arthritis is rare. Acute polyarthritis (especially in the ankles) usually occurs in the presence of anterior uveitis or EN. Chronic arthritis may mimic rheumatologic disease, even to the extent of causing a false positive test for rheumatoid factor. Muscular involvement may affect up to 10% of sarcoidosis patients. Proximal muscle weakness, muscle wasting, diaphragmatic weakness, and quadriceps weakness have been described in the literature. Respiratory muscle involvement has very rarely led to respiratory failure.

Lymphatic involvement: Extrathoracic lymphadenopathy is commonly found in the cervical, axillary, epitrochlear, and inguinal chains. Such nodes are typically non-tender and patients are usually unaware of them; their importance is primarily as an easy site for diagnostic biopsy. At the

time of autopsy, the spleen is involved in 40-80%, but clinically important manifestations of hypersplenism such as anemia or spontaneous rupture are rare.

<u>Gastrointestinal involvement</u>: Although liver biopsy will show sarcoid granulomata in 70% of cases, altered liver function due to granulomatous hepatitis or portal hypertension is rare. (Due to the lack of specificity of hepatic granulomata, the liver is not recommended as a biopsy site.) Clinically symptomatic gastrointestinal involvement, which may mimic infectious gastroenteritis, inflammatory bowel disease, tuberculosis, fungal infection or pancreatic neoplasm, affects less than 1% of patients.¹

Osseous involvement: Lytic or sclerotic bone lesions are present in 10% of cases and are almost always accompanied by chronic skin findings. Bone resorption secondary to endocrine abnormalities with vitamin D, noted below, is integral to the pathogenesis of hypercalciuria.

<u>Endocrine/renal involvement</u>: Disordered calcium metabolism, due to conversion of vitamin D to the active form within granulomata, often results in hypercalciuria with the attendant risk of nephrolithiasis; hypercalcemia is much less common (2-10%).

<u>Quality of life/Emotional implications</u>: One study of 111 sarcoid individuals revealed up to 66% had experienced depression (worse while on steroid treatment) and 55% had increased stress when compared to the average study population without sarcoidosis. These levels are comparable to patients with symptomatic AIDS, end-stage renal disease, and moderate to severe COPD.

The pulmonary literature has vacillated about the need for histologic confirmation of sarcoidosis in the most typical presentation, that of an individual with asymptomatic BHA found on CXR. Since this is a relatively uncommon presentation for lymphoma, some have argued in favor of clinical follow-up rather than proceeding to biopsy. However, current consensus is that histologic confirmation is advisable to confirm sarcoidosis, and to rule out lymphoma and infections such as tuberculosis. For aviators, "watchful waiting" is even more problematic, since it would require grounding for up to twelve months. And regardless of flight status, most patients are anxious to have confirmation of the diagnosis. If physical examination demonstrates involvement of superficial lymph nodes, skin (except EN), conjunctivae, or salivary glands, then biopsy should be directed toward that site. CT scan may prove to be useful for extent of involvement, particularly to delineate mediastinal adenopathy. Transbronchial biopsy has a high yield in Stage 1 and higher disease; even when the disease process appears to be limited to hilar nodes, biopsy of lung tissue is usually positive for non-caseating granulomata. The use of endobronchial ultrasound allows direct sampling of enlarged hilar and mediastinal lymph nodes, further increasing the diagnostic yield of bronchoscopy. Bronchoalveolar lavage, on the other hand, is of limited prognostic value, other than to exclude alternative diagnoses. When flow cytometry analysis is done on the lavage fluid, an elevated CD4/CD8 ratio can suggest sarcoidosis. However, this finding is non-specific and is insufficient to make a definitive diagnosis. As noted earlier, liver biopsy is not recommended. The Kveim test and blind scalene lymph node or fat pad biopsies are obsolete. The ACE level is elevated in 40-90% of individuals with active sarcoidosis; however, a high ACE level is not specific for sarcoidosis, and the magnitude of an initial elevation has no prognostic significance. As cardiac involvement typically has a patchy distribution, cardiac biopsy has low sensitivity (about 20% in one study) and is not recommended, even when there is a high suspicion for myocardial involvement. In general, disease that is isolated to the heart, brain, or eye is not biopsied. The

diagnosis is normally based on clinical presentation and characteristic radiographic findings. In the first two cases, such involvement is rarely waiverable anyway. Idiopathic granulomatous uveitis must be evaluated at the ACS, and is generally waiverable only when quiescent (see Uveitis Waiver Guide.)

Only a minority of sarcoidosis patients will actually require therapy. When treatment is necessary, the standard regimen is a prolonged course of oral prednisone, but recommended dosages vary widely. Corticosteroids accelerate clearance of symptoms, physiologic disturbances, and x-ray changes, but it is not clear that long-term prognosis is altered by such therapy. Treatment is indicated for patients with progressive pulmonary disease, cardiac involvement, CNS disease, uveitis, or hypercalcemia. For the 10% who fail to respond to corticosteroids, chlorambucil, leflunomide, azathioprine, hydroxychloroquine, TNF-inhibitors and methotrexate are possible alternative medications.

More than 85% of remissions occur within the first two years. Failure to regress spontaneously within 2 years forebodes a chronic or persistent course. Only about 2-8% of those individuals who spontaneously remit or stabilize will relapse at a later date. Corticosteroid-induced remissions, on the other hand, have a high rate of relapse, ranging from 14-74%, although one study showed no relapses if individuals remained asymptomatic for three years after prednisone withdrawal.

A recent British study has developed a prognostic tool that utilizes a composite physiologic index (CPI) along with high-resolution CT (HRCT) staging system. This is an early tool that offers hope for more successful management decision making.

A search of AIMWTS in May 2020 revealed six members with an aeromedical disposition and a diagnosis of sarcoidosis. There were two FC II cases and four FC III cases. One of the FC III cases was disqualified due to multi-organ disease.

ICD-9 code for Sarcoidosis		
135 Sarcoidosis		
ICD-10 co	de for Sarcoidosis	
<b>ICD-10 co</b> D86.9	de for Sarcoidosis Sarcoidosis, unspecified	

# **IV. Suggested Readings**

1. American Thoracic Society. Statement on sarcoidosis. Am J Respir Crit Care Med, 1999; 160: 736-55.

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# **Sleep Disorders (Jun 2020)**

Reviewed: Lt Col Dara Regn (ACS Sleep Medicine); Maj Caelan Ford (Sleep Medicine), Dr. Dan Van Syoc (ACS waiver guide coordinator), and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

#### **Significant Changes:**

RILO no longer required for OSA unless persistent symptoms (see MSD G5)

# I. Waiver Consideration

Narcolepsy, obstructive sleep apnea, and other sleeping disorders are disqualifying for all flying classes (FC I/IA, II, III, ATC, GBO, SWA). Current or history of sleepwalking is disqualifying for all flying classes (primarily an accession issue), and is unsuiting rather than unfitting for continued military service.

The initial sleep diagnostic workup need not be performed at Wilford Hall or the 88th MDG, although this is certainly encouraged where geographically practical. If at all feasible, the initial sleep evaluation and polysomnogram should be performed at an academic or military treatment facility or sleep laboratory. In a recent review of ACS experience with OSA, academic laboratory values were concordant with our reference laboratory in 89% of cases, whereas non-academic laboratories were concordant in only 24% of cases. Any FC II aviator other than flight surgeons, with a documented sleep disorder, will require an ACS evaluation prior to returning to flying status. FC III individuals and flight surgeons will be seen on a case-by-case basis at the ACS at MAJCOM request.

For a waiver to be recommended, the patient must 1) be using a form of therapy that has been documented to be effective on polysomnography testing or CPAP compliance download (RDI of <5 with dental orthotic, positional therapy, weight loss, or CPAP), 2) have resolution of sleep-related symptoms, and 3) demonstrate excellent compliance (CPAP usage on 90% of nights for at least 5 hours per night, on average). Generally speaking, all those utilizing CPAP therapy MUST demonstrate a pattern of excellent compliance for at least 30 consecutive days, prior to being granted initial OSA waiver. In order to reduce the time required to RTFS, FC II individuals who will require ACS evaluation may submit waiver packages before 30 days of compliance has been documented. However, the patients will still be required to demonstrate a pattern of ongoing usage of at least 30 consecutive days at the time of their ACS evaluation (updated usage data will be downloaded during their ACS evaluation). OSA waiver renewal requires demonstration of at least 90 consecutive days of compliance. At the ACS, maintenance of wakefulness testing will be performed on all cases, while neuropsychological testing will be performed only on those with severe sleep apnea or clinical indication (for example significant oxygen desaturation). Neither of these tests need to be performed locally prior to waiver submission.

Flying Class (FC)			
		Waiver Authority	review/evaluation
I/IA	Sleep walking	Maybe ¹ AETC	No
	Narcolepsy	No AFMRA	No
	Obstructive sleep apnea and other sleep disorders	No AETC	No
II (other than FS)	Sleep walking	Maybe ² AFMRA	No
	Narcolepsy	No AFMRA	Yes ³
	Obstructive sleep apnea	Yes ^{2, 5} MAJCOM6	Yes ³
	Other sleep disorders	Maybe MAJCOM ⁶	Yes ³
III and FS (FC II) SWA	Sleep walking	Maybe ¹ AFMRA	No
	Narcolepsy	No AFMRA	Yes, probable review only
	Obstructive sleep apnea	Yes ^{2, 5, 6} MAJCOM6	Maybe
	Other sleep Disorders	Maybe MAJCOM ⁶	Yes, probable review only
ATC/GBO	Sleep walking	Maybe ¹ AFMRA	No
	Narcolepsy	No AFMRA	No
	Obstructive sleep apnea	Yes ⁴ MAJCOM6	No
11-4	Other sleep Disorders	Maybe MAJCOM ⁶	No

Table 1: Waiver potential for various sleep disorders.

1 Last episode of sleepwalking must be at least three years prior to application with normal psych evaluation. I-RILO may be required if not administratively separated for all sleepwalking cases.

2 Mild or moderate OSA documented at ACS with resolved symptoms, good compliance, and normal MWT is waiverable. Severe OSA may also be waiverable, but must also demonstrate normal neuropsych testing. 3 ACS evaluation includes polysomnography, actigraphy and multiple sleep latency testing (for narcolepsy) or maintenance of wakefulness testing (for OSA) at Wright-Patterson Medical Center Sleep Disorders Laboratory, and may include neuropsychologic testing to evaluate cognitive function.

4 The only FC III cases seen routinely at the ACS will be Air Battle Managers for the evaluation of possible obstructive sleep apnea. Other aviators do not require ACS review unless requested by the waiver authority.

5 Indefinite waivers will not be granted for OSA.

6 AFMRA retains waiver authority for any OSA that requires an IRILO and is returned to duty.

# II. Information Required for Waiver Submittal

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

The aeromedical summary <u>for initial waiver</u> for sleep disorders other than sleep walking should include the following:

- History history of weight since reaching adulthood, symptoms (including pertinent negatives), treatment and effectiveness (Epworth score pre and post treatment), and documentation of resolution of symptoms, if applicable. Co-morbidities that exacerbate excessive daytime somnolence in the setting of OSA including depression, elevated BMI, sleep duration (bedtime/wake time) and smoking history should be included in the waiver submission. Family history of sleep apnea is also pertinent. Clinical notes documenting the face-to-face clinical evaluations by the treating sleep physician must also be included.
- 2. Physical height and weight, BMI, blood pressure, neck circumference, and ear, nose and throat, cardiovascular, and pulmonary exam.
- 3. Polysomnography results
  - a. Diagnostic PSG results required (in lab or home sleep study are acceptable).
  - b. In lab CPAP titration is NOT required.
  - c. RDI will be used to determine OSA severity.
  - d. FCII initial waiver evaluations will have repeat in lab split night PSG and MWT performed as part of ACS evaluation.
  - e. FCIII/SWA/FCII FS/ATC/GBO do not require in person evaluation and repeat in lab sleep studies to include MWT at ACS, however this can be accomplished by ACS at MAJCOM or AFMRA request if there are clinical concerns regarding persistent symptoms or elevation in RDI >5 events/hr despite therapy.
  - f. If treated with dental orthotic/appliance, repeat sleep study with device demonstrating RDI <5 events/hr is required.
- 4. If treatment with a PAP device, objective evidence of acceptable adherence to use (usage on  $\geq$ 90% of nights for at least 5 hours per night, on average).
- 5. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS on why it could not be provided.

The aeromedical summary for <u>waiver renewal</u> for sleep disorders other than sleepwalking should include the following:

- 1. History brief summary of initial symptoms, weight and findings at ACS evaluation, current symptoms (including Epworth score), current treatment, and weight history since previous waiver granted. Clinical notes documenting the face-to-face clinical evaluations by the treating sleep physician must also be included.
- 2. Physical height and weight, BMI, blood pressure, neck circumference, and ear, nose and throat, cardiovascular, and pulmonary exam.
- 3. Initial polysomnography results. RDI will be used to determine OSA severity.

- a. FCII renewals will be re-evaluated by the ACS to include repeat split night PSG to reassess OSA severity and adequacy of therapy, and MWT to reassess sleepiness
- b. FCIII/SWA/FCII FS/ATC/GBO do not require repeat in lab sleep study locally, MWT or in person ACS evaluation. However, the ACS at MAJCOM or AFMRA request can evaluate the member if there are clinical concerns regarding persistent symptoms or elevation in RDI >5 events/hr despite therapy.
- 4. If treatment with a PAP device, objective evidence of acceptable adherence to use (usage on  $\geq$ 90% of nights for at least 5 hours per night, on average).
- 5. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why it could not be provided.

The aeromedical summary for waiver for history of sleepwalking should include the following:

- 1. History age on onset, frequency, last episode, activities during sleepwalking, family history.
- 2. Psychology/psychiatric consult.
- 3. If any of the above requested items cannot be provided, please provide an explanation to the waiver authority in the AMS why it could not be provided.

#### **III. Aeromedical Concerns**

In our current high-tempo operational environment, an increase in short-notice alerts and long-range missions has led to a culture in which chronic sleep deprivation has become the norm. This has a significant adverse impact on overall health and flight safety. Although aviation accidents are rare, 80% are due to human error with pilot fatigue accounting for 15-20% of human errors in fatal accidents. Since 2003, the cost of fatigue related accidents in the USAF has been \$2 billion. The common thread running through most sleep disorders is insufficient quantity or quality of sleep, which leads to excessive daytime sleepiness and diurnal impairment of alertness and cognitive function. Sleep disorders increase mortality, morbidity, performance problems, accidents, injuries and health-care utilization. While pathologic sleep disorders command the greatest attention, the commonest causes of excessive sleepiness are actually physiologic; such as poor sleep hygiene also known as behaviorally induced insufficient sleep syndrome, and circadian shifting. Chronic sleep deprivation for physiologic reasons may cause as much debility as a pathologic sleep disorder. While the definition of sufficient sleep varies, one should generally not work up a complaint of hypersomnolence unless the individual is attempting, on a reasonably regular schedule, to get six to eight hours of sleep per twenty-four hour period. Careful attention must also be paid to alcohol and stimulant (including caffeine) use, since heavy use may disrupt sleep patterns, and may induce or worsen sleep disorders.

With the exception of somnambulism, any of the sleep disorders above may result in excessive daytime sleepiness and increased risk of microsleeps resulting in an inability to maintain the alertness necessary for safety while flying. Cognitive function and neuromuscular coordination may both be affected by the sleep disorder and/or the treatment modalities used. Microsleeps are characterized by 10-30 seconds of intrusion of sleep into the waking state, and are associated with sleep deprivation. Microsleeps feel like "lost time," "auto-pilot mode," or lapses of attention, not like falling asleep. After 24h of acute sleep deprivation, one has a certain number of microsleeps per hour, during each of which the member is unable to respond to new stimuli. After 10 days of

sleeping 6 hours a night (chronic mild sleep deprivation, given the average person needs 7-9h per night), the number of microsleeps per hour is the same as after one night of acute total sleep deprivation. This is extremely dangerous during high vigilance activities, as 10-30 seconds of inability to respond to new stimuli can cause motor vehicle, aircraft, and judgement errors.

When called upon to perform in operational situations with less than optimal sleep, those with OSA are already sleep deprived. Furthermore, when faced with sleep deprivation, normal individuals typically respond by adapting sleep architecture, e.g., longer periods of REM sleep. This is likely a physiologic response and serves to increase sleep efficiency in normal individuals. However, OSA tends to be most severe in REM. The result is that individuals with OSA may have more than the usual difficulty in adjusting to sleep deprivation or the circadian rhythm disruption, which occurs with travel across time zones. This would present an additional hazard to a flyer who may deploy several time zones away and would still be expected to perform flying duties.

If an aviator is diagnosed with OSA, they should be made DNIF, and treatment should be initiated as soon as possible. All aviators who are obese or overweight should be treated with weight loss. Most patients will also require treatment with an adjunctive therapy such as an oral appliance, positional therapy, or CPAP. After weight loss is achieved, the adjunctive therapy should only be discontinued if the patient has demonstrated a normal RDI/AHI (less than five events per hour) on PSG and resolution of symptoms off therapy. Surgery may also be considered as an adjunctive therapy, though given the morbidity and variable efficacy, it is difficult to recommend surgery as a first-line therapy. If the aviator does not have symptoms clearly associated with the diagnosis, the ACS recommends that the disorder be confirmed at an academic sleep center such as Wilford Hall Ambulatory Surgical Center, Walter Reed National Military Medical Center or the 88th Medical Group at Wright-Patterson AFB before considering a surgical procedure. The neurocognitive deficits associated with OSA can, for the most part, be mitigated with treatment, such as CPAP therapy. However, it is important to note that in one study of patients with sleep apnea and neurocognitive deficits, nearly all the improvement seen with CPAP use was lost after just one night without therapy. It should also be noted that at the ACS, we have found 41% of OSA waiver referrals also have sleep complaints of at least one other concomitant sleep disorder such as insomnia, restless leg syndrome, or parasomnias.

If narcolepsy is diagnosed by an outside sleep laboratory, the aviator should be referred to the ACS for confirmation of the diagnosis. Although this diagnosis, if confirmed, will result in permanent disqualification, the ACS has seen multiple instances of aviators who were improperly diagnosed as narcoleptic.

Lastly, individuals with history of somnambulism can injure themselves during sleepwalking episodes, as complex and inappropriate behaviors can occur, including driving, going outside, and even walking out of windows. Therefore, those with somnambulism in a combat environment are considered a hazard to themselves and to others.

AIMWTS review for the previous five years revealed 535 aviators with a diagnosis of a sleep disorder. There were 86 disqualifications. Breakdown of the cases was as follows: 8 FC I/A cases (4 disqualified), 195 FC II cases (23 disqualified), 235 FC III cases (43 disqualified), 36 ATC cases (6 disqualified), 38 GBO cases (5 disqualified), and 22 SWA cases (5 disqualified).

ICD 9 codes for sleep disorders		
307.4	Specific disorders of sleep of non-organic origin	
	(including Sleepwalking)	
327.42	Primary insomnia	
347	Narcolepsy (with or without cataplexy)	
780.57	Unspecified sleep apnea	
327.51	Periodic limb movement disorder	
333.94	Restless leg syndrome	

ICD 10 codes for sleep disorders		
F51.9	Sleep disorder not due to a substance or known	
	physiologic condition, unspecified	
G47.52	REM sleep behavior disorder	
G47.411	Narcolepsy (with cataplexy)	
G47.419	Narcolepsy (without cataplexy)	
G47.30	Sleep apnea, unspecified	
G25.8	Restless leg syndrome	

#### **IV. Suggested Readings:**

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- 11. RAND report Sleep in the Military: Promoting Healthy Sleep Among U.S. Servicemembers. 2015
- 12. Walker, Matthew. Why we sleep: Unlocking the power of sleep and dreams. Simon and Schuster, 2015.

# Benign Prostatic Hyperplasia (May 2020)

Reviewed: Lt Col Kevin Alford (RAM 21), Dr. Dan Van Syoc (ACS waiver guide coordinator), Lt Col Necia Pope (AF flight surgeon and urologist) and Lt Col David Gregory (AFMRA Physical Standards Development Chief)

Significant Changes: Updated Aeromedical Concerns, New Format

# I. Waiver Consideration

Symptomatic Benign prostatic hyperplasia (BPH) with urinary retention is disqualifying for FC I/IA, FC II, FC III, and SWA duties. Asymptomatic BPH, and history of invasive surgical therapy such as TURP are not disqualifying, and do not require waiver submission if the obstructive symptoms are relieved, urinary continence is maintained, and healing is complete; in addition, any complications from surgery would be disqualifying. Of note, it is recommended that after invasive surgery, the aviator remain DNIF for a <u>minimum</u> of 3 weeks to heal due to the risk for acute bleeding and post-operative urgency. Furthermore, DNIF is required if the patient's symptoms remain operationally significant, regardless of the treatment course. BPH is not disqualifying for retention or for ATC or GBO personnel, but certain medications used to treat symptomatic BPH may require waiver.

Flying Class (FC)	Waiver Potential	<b>Review/Evaluation at the</b>
	Waiver Authority	ACS
I/IA	Maybe ^{1, 2}	No
	AETC	
II, III	Yes ^{1, 3, 4}	No
SWA	MAJCOM	
ATC and GBO	N/A ⁵	N/A

1 No indefinite waivers

2 This problem is very unlikely in the predominately-young population contemplating flying training. Such a case will need to be worked up very carefully to rule out other sources of GU pathology.

3 No waiver required if symptoms are mild (less than seven on the AUA-SI Scale) without evidence of urinary retention and watchful waiting is the "treatment".

4 If treated with an approved alpha-blocker, waiver should be restricted to non-high performance aircraft. Pilots on alfuzosin and tamsulosin should also be restricted to flying with another qualified pilot, e.g., FC IIC (non-high performance, with another qualified pilot). Pilots on silodosin are eligible for FC IIA waiver (see "Aeromedical Concerns" above).

5 BPH is not disqualifying for ATC or GBO personnel, but certain medications used to treat symptomatic BPH may require waiver.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines & recommendations.

# A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment. Include history of lower urinary tract symptoms and current American Urological Association-Symptom Index (AUA-SI) score. Discuss all attempted treatments/medications to include results and side effects.
- 2. Current Physical Exam. Include a current genitourinary exam to include a digital rectal exam.
- 3. Reports of Pertinent Laboratory Studies: urinalysis, prostate-specific antigen (PSA), serum creatinine, and other relevant studies that were performed.
- 4. Reports of Specific Diagnostic Tests if Performed. May include urine flow rate, post-void residual, cystoscopy, ultrasound studies.
- 5. Consultation reports: Urology evaluation if surgery performed or severe symptoms; surgical report (or surgeon's follow up notes clearly delineating the procedure performed) and pathology if surgery performed.
- 6. FL4 with RTD and ALC status, if member did not meet retention status.
- 7. Any other pertinent information.
- 8. If the local base is unable to provide all required items, they should explain why to the waiver authority.

# B. <u>Renewal Waiver Request:</u>

- 1. Interim history to include change in symptoms, medication usage, and side effects.
- 2. AUA-SI Score with prior year(s) comparison.
- 3. Exam: digital rectal exam and any other pertinent exam findings.
- 4. Serum PSA with prior year(s) comparisons.
- 5. Current treatment doses and documentation of therapeutic benefit.
- 6. Consultation reports if consultation required/obtained.
- 7. If the local base is unable to provide all required items, they should explain why to the waiver authority.

# **III. Aeromedical Concerns**

The aeromedical concerns of BPH/BPO include the risks for acute urinary retention, distracting lower urinary tract symptoms (LUTS), and adverse effects from treatment of the condition. Acute urinary retention can cause severe abdominal discomfort that can be functionally incapacitating. The risk for acute incapacitation secondary to BPH, , in asymptomatic individuals is low; therefore, BPH identified in the absence of symptoms (*eg* secondary to screening prostate specific antigen (PSA) results) is not disqualifying. Those with symptomatic BPH have varying risk of acute urinary retention based on post void residual and, in some cases, medical treatment (anticholinergic medications or Beta-3 adrenergic medication)

Aviators and special duty operators with LUTS, particularly increased urinary frequency and urgency, may be distracted to a sufficient degree to impair operational duties. Similarly, frequent nocturia can disrupt sleep and contribute to aeromedically relevant fatigue. Many individuals with BPH have only mild symptoms and BPH with LUTS is not necessarily disqualifying. In the absence of a history of acute urinary retention, the USAF flight surgeon must judge the severity of symptoms to determine the impact on aviation duties and the need for waiver. Use of tools such as the American Urological Association Symptom Index (AUA-SI) may help determine the severity of symptoms.

Medical therapy for BPH can create aeromedically significant adverse effects. Approved medications for use in aviators and special duty operators with waiver include 5-alpha-reductase inhibitors and three alpha-1-adrenergic antagonists (alfuzosin, silodosin, and tamsulosin). Regarding the 5-alpha-reductase inhibitors, specifically finasteride, a detailed aeromedical medication review in Sep 04 concluded it to be both effective and safe in the aerospace environment. However, it is important to recognize that treatment with 5-alpha-reductase inhibitors improves LUTS by reducing the size of the prostate and may take 6 months to become effective and up to two years to reach maximum efficacy. Therefore, aeromedically relevant symptoms may persist for a substantial period of time after starting the medication. Still, some studies have shown reduced rates of urinary retention in those on 5-alpha-reductase inhibitors. Alpha-1-adrenergic antagonists may cause orthostasis, hypotension, and dizziness. As a result, these medications may impair aviation safety, particularly in aviators exposed to sustained acceleration and increased +G_zs. These risks are more prominent in the less uroselective agents (terazosin and doxazosin) than in the more uroselective, aeromedically approved, agents (alfuzosin, silodosin, and tamsulosin). Of note, the alpha-1-adrenergic antagonists have maximum approved dosing limits.

Other unapproved medications are commonly used for treatment of LUTS associated with BPH. Anticholinergic medications, such as tolteridine and oxybutynin, are used to treat overactive bladder. These medications increase the risk of urinary retention in those with elevated post-void residuals, and, like other anticholinergics, may cause cognitive impairment, visual blurriness, drowsiness, and other aeromedically relevant adverse effects. Beta-3 Adrenoceptor Agonists, such as Mirabegron, represent a newer class of medications for the treatment of irritative LUTS (frequency, urgency, and nocturia). Reported adverse effects of these medications are hypertension and urinary retention. While the cited adverse effects likely have a lower potential for significant deleterious aeromedical effect, there is a dearth of evidence to confirm their safety in the aviation environment. Phosphodiesterase-5 (PDE-5) inhibitors are used for those with BPH and concomitant erectile dysfunction. Tadalafil, a long acting PDE-5 inhibitor, is approved by the FDA for use in BPH. These medications increase the risk for hypotension, visual changes (including impaired color vision), and dizziness. While there are several studies demonstrating efficacy similar to the alpha blockers, long term data on aeromedical safety is lacking; .

Many surgical options exist for the treatment of BPH. Transurethral resection of the prostate (TURP) remains the most common procedure performed but there are newer treatment options which may be performed with increasing frequency in the younger patient population. This includes such procedures as UroLift^R or Aquablation. Surgical treatment for BPH is unlikely to result in long-term adverse effects of aeromedical significance. However, in the near post-operative period, bleeding from the procedural site can occur or a temporary worsening of irritative symptoms. As a result, aviators who undergo TURP or other surgical treatments of BPH should anticipate a DNIF for at least 3-4 weeks and should not return to flying until cleared by the urologist.

AIMWTS review in May 2020 for the previous five years revealed 78 aviators with a disposition containing the diagnosis of BPH. Of that total, six aviators were disqualified. Breakdown of the cases revealed: 36 FC II cases (one disqualified), 32 FC III cases (four disqualified), 3 ATC cases, 4 GBO cases, and 3 SWA cases (one disqualified). Of the six disqualifications, only one was disqualified for the BPH diagnosis, and that due to the use of a non-waiverable medication.

ICD-9 code for	Benign Prostatic Hyperplasia
600	Hyperplasia of prostate

# ICD-10 code for Benign Prostatic HyperplasiaN40, N40.0,Enlarged prostate

N40, N40.0, Enlarged prostate N40.1

# **IV. Suggested Readings**

1. McVary KT, Roehrborn CG, Avins AL, Barry MJ, et al. Management of Benign Prostatic Hyperplasic. American Urological Association, 2010. <u>https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)</u>

2. Foster HE, Barry MJ, Gandhi MC, Kaplan SA et. al. Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms. American Urological Association, 2018. https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline#x8218

3. Gravas S, Cornu JN, Gacci M, Gratzke C et. al. Management of Non-neurogenic Male LUTS. European Association of Urology, 2013. <u>https://uroweb.org/guideline/treatment-of-non-neurogenic-male-luts/</u>

4. Marberger MJ, Andersen JT, Nickel JC, et al. Prostate Volume and Serum Prostate-Specific Antigen as Predictors of Acute Urinary Retention. Combined Experience from Three Large Multinational Placebo-Controlled Trials. Eur Urol. 2000; 38(5): 563-68.

5. Emberton M, Fitzpatrick JM, Garcia-Losa M, et al. Progression of benign hyperplasia: systematic review of the placebo arms of clinical trials. BJU Internat, 2008; 102: 981-86.





# **Congenital Urinary Anomalies**

Revised: Aug 2022

Reviewed: Dr. Max Lee (ACS Waive Guide coordinator), Lt Col Christopher Allam (AF/SG Urology consultant), and Lt Col Paul Vu (AFMSA Physical Standards Development Chief)

# **Significant Changes:**

Updated suggested readings, new format for previous waiver dispositions

# I. Waiver Consideration

In general, any congenital renal or urinary system anomaly that results in impaired renal drainage, systemic hypertension, pain, functional impairment of either kidney, or require specialty care more than annually are disqualifying for all flying and special mission duties. Additionally, congenital disorders of the urinary tract or genitalia of sufficient severity to cause distracting symptoms, frequent infections, or interfere with normal functioning are disqualifying for all flying and operational duties. Polycystic kidney disease (PCKD, even with normal renal function), absence of a kidney, or a horseshoe kidney are disqualifying for IFC I/IA, FC II/III, and SWA duties but are not disqualifying for ATC, GBO, and operational support duties.

With careful evaluation and appropriate treatment, many of the above listed conditions can be considered for aeromedical waiver. However, waiver recommendations will depend on the status of the underlying disease, interventions performed, and functional outcomes.

Flying Class (FC)	Disease/Condition	Waiver Authority Waiver Potential	ACS Review/ Evaluation
IFC I/IA/II/III/SWA (initial)	PCKD ¹ , absence of a kidney, horseshoe kidney, congenital disorders of the urinary tract, hydronephrosis, renal ptosis ²	AFRS/CMO Yes ³	Maybe
FC II/III/SWA (trained)	PCKD ¹ , absence of a kidney, horseshoe kidney, congenital disorders of the urinary tract, hydronephrosis, renal ptosis ²	MAJCOM Yes ³	Maybe
ATC, GBO	Congenital disorders of the urinary tract, hydronephrosis, renal ptosis ²	MAJCOM Yes	No

# Table 1: Waiver potential for Disease/Condition

1. PCKD with normal renal function.

2. Applies to renal ptosis with impaired renal drainage, hypertension, or pain.

3. Waiver for initial certifications must be considered very carefully. Waiver considerations will depend on the probability of stone formation and deterioration of renal function.

# **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

# A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Reports of any pertinent laboratory studies, imaging studies, copies of images (as indicated).
  - a. Laboratory studies at a minimum should include a urinalysis, BUN, and creatinine.
  - b. The AMS should include a careful assessment of renal function and mention of presence or absence of stone disease.
- 3. Urology and/or Nephrology consultation reports, including follow-up notes with examination findings after disease resolution.
- 4. Any specific diagnostic tests performed, before and after treatment (as indicated).
- 5. Documentation of return to full physical activity, including specific comments regarding any activity limitations.
- 6. Current physical examination findings, including a GU exam and any pertinent ancillary studies.
- 7. FL4 with RTD and ALC status, if member did not meet retention status

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. Renewal Waiver Request:

- 1. Interim history and exam to include change in symptoms (particularly renal function), medication usage, and side effects.
- 2. Result of all interim imaging, laboratory, and ancillary studies.
- 3. Current treatment doses and documentation of therapeutic benefit.
- 4. Reports from treating Urology and/or Nephrology consultant.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### **III. Aeromedical Concerns**

Depending on the underlying condition, a number of symptoms may occur which could impair flying performance and mission completion. These include flank pain, renal stones, urinary urgency, urinary frequency, urinary obstruction, and dysuria; all of which have the potential of sudden incapacitation or significant distraction. Recurrent infections and ongoing renal damage may lead to cortical scarring, hypertension, and compromised renal function. With these and other complications, close specialty follow-up may be required. While many or most presentations of congenital urinary anomalies are asymptomatic, some have distinct features that warrant attention. Medullary sponge kidney (MSK) can present with renal colic, urinary tract infections, or hematuria. It is commonly found in patients with kidney stones and approximately 70% of patients with medullary sponge kidney will develop stones at some point. MSK itself is largely a benign process otherwise with little aeromedical impact

Horseshoe kidney is associated with hydronephrosis in approximately 80% of patients, kidney stones in 20%, and other genitourinary anomalies in about one-third. There is also an increased risk of urinary tract infection with horseshoe kidney. This condition itself poses minimal acute risk during flight provided the member does not have obstruction or stones.

Polycystic kidney disease (PCKD) is associated an increased risk of kidney stones, anemia, urinary tract infections, and hypertension. It is typically diagnosed during age 30-50 with presenting symptoms of hematuria in 50%, renal colic, and gastrointestinal symptoms. PCKD may be associated with intracranial aneurisms, especially in those who have PCKD and family history of cerebral aneurisms. Flank pain from enlarged kidneys or ruptured cysts can be significant. PCKD is associated with other abnormalities including liver cysts, pancreatic cysts, and cardiac valvular abnormalities that may be incompatible with safe flying operations. Elevated blood pressure or a decline in renal function indicates disease progression with a significant percentage of PCKD patients progressing to renal failure requiring dialysis. Therefore, close attention should be paid in PCKD patients regarding renal function, blood pressure, and history of flank pain.

Unilateral renal agenesis may be complicated by other genitourinary malformations and is associated with vesicoureteral reflux, increasing the risk of significant urinary tract infections. If the remaining kidney is functioning normally, there is usually little risk to flying. Congenital obstructions of the ureteropelvic junction often present with intermittent flank pain especially when the person is well-hydrated (Dietl's crisis). Obstructions can also present with abdominal pain, nausea, vomiting, worsening renal function, or hematuria. Obstructions are also associated with other anomalies listed above, particularly horseshoe kidney. A review of recently submitted waivers for frank urinary obstruction revealed that all members had the condition surgically or procedurally corrected and were therefore no longer symptomatic demonstrating excellent outcomes after surgical treatment. However, these servicemembers also presented with other significant symptoms apart from their obstruction and warrants careful individual aeromedical risk assessments.

Renal ptosis, also known as floating kidney or nephroptosis, is characterized by a kidney that changes in position by more than 2 vertebral bodies between supine and upright positions. While commonly asymptomatic, the positional movement of the kidney can cause vomiting, abdominal pain from obstruction, or ischemia. Severe flank pain (Dietl's crisis) with sitting up in a thin female member that resolves upon lying down should raise the clinical suspicion for renal ptosis. Many patients will also have fibromuscular dysplasia of the renal artery leading to concurrent problems with hypertension. Nephropexy, or surgical fixation of the kidney, normally resolves symptomatic cases. Given the seated position of most aircrew, symptomatic nephroptosis is not normally compatible with flying duties.

Renal ectopy occurs when one or both kidneys do not ascend to the retroperitoneal fossa, even sometimes failing to ascend out of the pelvis itself. Unilateral renal ectopy is often asymptomatic and would not pose a risk to aviation itself. Symptomatic renal ectopy can present with obstruction and recurrent urinary tract infections, particularly if associated with vesicoureteral reflux. It may also present as urinary incontinence due to pressure from safety restraints on the lower abdomen. These sequelae, along with a potential decline in renal function, may impact operational duties.

Some of these conditions, such as medullary sponge kidney and horseshoe kidney, are associated with nephrolithiasis and therefore the Renal Stone waiver guide should be referenced in patients with renal stones. If renal function is affected or hypertension develops, as can happen particularly with PCKD, reference the Chronic Kidney Disease and Hypertension waiver guides respectively.

AIMWTS search in July 2022 for the prior 5 years revealed a total of 51 cases submitted with a diagnosis of unilateral renal agenesis, polycystic kidney, medullary sponge kidney, obstructive defects of renal pelvis and ureter, and horseshoe kidney. The breakdown of the number of waivers and number of total cases are tabulated below.

Please use only these ICD-10 codes for	(# of waivers / total # of cases)					
AIMWTS coding purposes	IFC I/IA	FC II	FC III	ATC	GBO	SWA
N28.83 (Renal Agenesis, unilateral),	0	7/7	1/1	1/1	1/1	0
Q60.0, Q60.2 (Renal Agenesis, unilateral)						
Q61.2 (Polycystic Kidney, adult type)	0	9/9	1/1	0/0	3/3	0
Q61.5 (Medullary Sponge Kidney)	0	2/2	0	0	0	0
Q61.8 (Other cystic kidney diseases)	0	0	0	0	0	0
Q61.9 (Cystic kidney disease, unspecified)	0	0	0	0	0	0
Q62.39 (Obstructive defects of renal pelvis, ureter)	1/1	2/2	3/3	0	2/2	0
Q60.3, Q60.5 (Renal hypoplasia, unspecified)	0	0	0	0	0	0
Q63.1 (Lobulated, fused, and horseshoe kidney)	1/1	15/15	3/3	1/1	0	0
Q63.2 (Ectopic kidney)	0	0	0	0	0	0

# **IV. Suggested Readings**

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- 2. Simms RJ. Autosomal dominant polycystic kidney disease. BMJ, 2016; 352(8044): 243-47. https://www.bmj.com/content/352/bmj.i679.long
- 3. Goldfarb DS et al. Medullary sponge kidney. UpToDate. Updated Feb 1, 2022. Accessed Jul 28, 2022. <u>https://www.uptodate.com/contents/medullary-sponge-kidney</u>
- 4. Rosenblum ND. Renal ectopic and fusion abnormalities. UpToDate. Updated Dec 8, 2021. Accessed Jul 28, 2022. <u>https://www.uptodate.com/contents/renal-ectopic-and-fusion-anomalies</u>
- Krajewski W, Wojciechowska J, et al. Hydronephrosis in the course of ureteropelvic junction obstruction: An underestimated problem? Current opinions on the pathogenesis, diagnosis and treatment. Adv Clin Exp Med. 2017 Aug;26(5):857-864. doi: 10.17219/acem/59509. PMID: 29068584. https://advances.umw.edu.pl/pdf/2017/26/5/857.pdf

**Congenital Urinary Anomalies** 

#### WAIVER GUIDE

Updated: Jul 2014 Supersedes Waiver Guide of Mar 2011 By: Dr Dan Van Svoc Reviewed by Lt Col Timothy Phillips, AF/SG consultant for Urology and Lt Col Eric Barnes, *AF/SG consultant for Nephrology* 

#### **CONDITION:** Hematuria (Jul 2014)

#### I. Waiver Consideration.

Hematuria by itself is not disqualifying for flying classes I/IA, II, III and SWA duties. It is also not disqualifying for retention purposes, for ATC and GBO duties. While hematuria itself is not disqualifying, the underlying cause (such as calculi) may be disqualifying or require waiver. No waiver required if fully evaluated and final diagnosis is benign or idiopathic with appropriate follow-up.

Flying Class (FC)	Condition	Waiver Potential Waiver Authority
I/IA	"Benign" or idiopathic	N/A
	Calculi†	Maybe AETC
	Other causes*	Maybe AETC
II/III ATC/GBO/SWA	"Benign" or idiopathic	N/A
	Calculi†	Maybe MAJCOM
	Other causes*&	Maybe AETC**

#### Table 1: Waiver notential for hematuria

[†]See Renal Stones waiver guide for details

*IgA nephropathy, glomerulonephritis, cancer, etc.

[&] Untrained personnel will need to be evaluated similarly as for FC I/IA ** AFMRA is waiver authority if retention standards are applicable

AIMWITS search in Jul 2014 revealed a total of 514 members with an AMS for the diagnosis of hematuria. Breakdown of the cases revealed: 47 FC I/IA cases (11 disqualified), 198 FC II cases (8 disgualified), 248 FC III cases (30 disgualified), 13 ATC/GBC cases (1 disgualified), and 8

MOD cases (1 disqualified). Almost all of the disqualifications were due to other medical problems, or if it was due to hematuria, there were other renal issues as well. In the ATC/GBC and MOD cases, the underlying reason for the waiver submission was not hematuria. For future waiver guide updates, the total number of cases will be much less as only a small percentage of cases with hematuria will require a waiver to be submitted.

#### **II. Information Required for Waiver Submission.**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines/recommendations.

For flying classes I/IA, II, IIU, and III, a waiver for the finding of microscopic hematuria only (if proteinuria also seen in urinalysis then initiate steps J through L listed below concurrently) is not necessary. An initial work-up of hematuria, though, should include the following:

A. Thorough history to identify possible sources for hematuria, upper versus lower tract, and identification of risk factors for malignancy.

- B. Examination of external urethra and prostate (male) or pelvis (female).
- C. Urinalysis and urine culture.
- D. Serum BUN and creatinine.

E. Repeat urinalysis 48 hours after cessation of menstruation, analgesic medications, vigorous exercise, or sexual activity. Repeat urinalysis 6 weeks after treatment of a urinary tract infection.

In individuals where the above information supports a "benign" cause (menstruation, analgesic medications, vigorous exercise, sexual activity, and/or the resolution of a urinary tract infection) and the repeat urinalysis is normal, no further workup is required.

If A - F above does not point to a "benign" cause of the hematuria (menstruation, analgesic medications, vigorous exercise, sexual activity, and/or the resolution of a urinary tract infection), the aeromedical summary is required to contain the following additional elements:

G. Radiographic evaluation of upper tract CT, IVP and/or ultrasound (helical CT with and without contrast is now upper tract imaging procedure of choice, if available).

H. Urology consult (to include cystoscopy if indicated) should follow upper tract imaging, particularly if risk factors for malignancy are identified.

I. If no urological etiology is found, consultation with a nephrologist for possible renal biopsy should be obtained.

If proteinuria, dysmorphic red blood cells, red cell casts, or elevated serum creatinine level is present, the following additional work-up is required:

J. Complete blood count (CBC).

- K. 24-hour urine for creatinine and protein, if urinalysis positive for protein.
- L. Nephrology consultation to include consideration of a renal biopsy.

If a cause for the hematuria is determined such as calculi, IgA nephropathy, glomerulonephritis or cancer, then waivers will be also be needed for those diagnoses. Current waiver guides exist

for renal stones, IgA nephropathy, and bladder cancer which need to be adhered to if that diagnosis is applicable.

#### III. Overview.

Gross hematuria is relatively common - one out of every 1000 visits to the emergency room is prompted by a patient's discovery of gross hematuria. Asymptomatic microscopic hematuria (AMH) is even more common, with a prevalence of 1.2% to 5.2% in young adult males, and as high as 16% to 21% in community population-based studies.^{1, 2, 3} Discovering the underlying process, if any, causing the hematuria is the key to a proper aeromedical disposition. Some emergency department estimates are that the underlying cause of hematuria is elusive in as many as 61% of cases.⁴ The risk factors for significant underlying disease include: cigarette smoking, occupational exposure (benzene, aromatic amines), history of gross hematuria, age greater than 35 years, history of urologic disorder or disease, urinary tract infection, analgesic abuse, irritative voiding symptoms, pelvic radiation, and cyclophosphamide use.⁵ Screening for hematuria in patients with no symptoms suggestive of urinary tract disease is not recommended by any medical body.⁶

Hematuria may be transient and common causes of such cases are vigorous physical exercise, sexual intercourse, trauma, digital rectal examination, or menstrual contamination. If a transient etiology is suspected, the clinician should order a follow-up urinalysis 48 hours after the positive test and a negative result will probably confirm the diagnosis of transient hematuria.^{7, 8} The most common <u>non-transient</u> causes of hematuria in adults include urinary tract infections, stone disease, benign prostatic enlargement and a urologic malignancy.⁹

A positive dipstick for blood in urine indicates hematuria, hemoglobinuria or myoglobinuria. Hematuria can be distinguished from hemoglobinuria and myoglobinuria by microscopic examination of the centrifuged urine; the presence of a large number of erythrocytes establishes the diagnosis of hematuria. If erythrocytes are absent, examination of the serum will distinguish hemoglobinuria and myoglobinuria. In hemoglobinuria, the supernatant will be pink and in myoglobinuria, the serum remains clear. Dipsticks for heme detect 1 to 2 RBCs per high powered field (HPF) which is equivalent to the sensitivity of urine sediment examination, but will result in more false positive tests. The American Urologic Association has stated that the most accepted upper limit of normal for urinary RBCs, based on an exam of the urinary sediment, is <3 per HPF.¹⁰ Asymptomatic microscopic hematuria is defined as 3 or greater RBCs per HPF on a single properly collected urinary specimen in the absence of obvious benign cause.¹⁰

Hematuria of nephrologic origin is frequently associated with casts in the urine and almost always associated with significant proteinuria. Protein in the urine greater than 200mg/24 hours is of nephrologic origin; significant hematuria from a urologic origin will not elevate protein that high. Erythrocytes arising from glomerular disease are typically dysmorphic and show a wide range of morphologic alteration. Conversely, erythrocytes arising from tubulointerstitial renal disease and of urologic origin have a uniformly round shape.¹¹

Hematuria may be essentially a normal variant, or it may be a sign of underlying disease, which may possibly even be life-threatening. For the purposes of evaluation and diagnosis, hematuria is divided into two general categories: glomerular and non-glomerular.

Glomerular hematuria (loss of blood into urinary tract from glomeruli) is frequently associated with proteinuria, protein or RBC casts, and dysmorphic RBCs on phase-contrast microscopy. The differential diagnosis of hematuria with proteinuria or casts is extensive, and includes nephron damage and many forms of glomerulonephritis. The most common glomerular sources have been found to be IgA nephropathy (Berger's disease) and thin glomerular basement membrane disease.⁷

Non-glomerular hematuria is blood that enters the urinary tract distal to glomeruli, so that RBCs have normal morphology on phase-contrast microscopy. Proteinuria and casts are not normally associated with non-glomerular hematuria. The most common non-glomerular sources are stones, infection and malignancy. In six major studies of microscopic hematuria, between 1% and 12.5% had a neoplastic etiology and between 3.5% and 16.5% had calculi as the etiology. In one study of 161 aviators with asymptomatic microscopic hematuria, no evident pathology developed over a mean follow-up period of 7.6 years.^{11, 12}

The differential diagnosis of asymptomatic hematuria without proteinuria or casts (e.g. nonglomerular hematuria) includes neoplasm, calculi, infection, trauma (including exercise), analgesic use/abuse and sickle cell nephropathies. Bleeding into the urinary tract from a source between the urethra and the renal pelvis will result in no protein, cells or casts. Hematuria at the beginning or end of the stream usually indicates a urethral or prostatic source.

Once infectious and glomerular etiologies of hematuria have been ruled out, other etiologies will need to be considered. The consensus among urologists is that patients presenting with hematuria less than 35 years of age and no risk factors should at a minimum have upper tract imaging with CT urography or other modalities as directed below. Cystoscopy need only be performed in this group of patients at the discretion of a urologist. For the remainder of cases (≥35 years old or risk factors), a complete urologic evaluation to include imaging and cystoscopy is indicated.¹⁰ Cystoscopy is utilized to directly visualize the lining of the bladder to detect evidence of bladder cancer. The goal of imaging is to detect neoplasms, urinary tract calculi, renal cystic disease, and obstructive lesions that could be responsible for the hematuria.¹² Most clinicians consider multidetector CT urography to be the preferred initial imaging modality in most patients presenting with unexplained hematuria. Other modalities used include intravenous pyelography (IVP), ultrasonography, MR urography, retrograde pyelography with plain films.^{6, 10}

A negative evaluation for a patient with asymptomatic microscopic hematuria is good news for the patient. But each of these folks deserves some sort of follow-up as reports have shown that 1% to 3% of these patients may progress to a urologic malignancy within three years and another small proportion can also develop renal insufficiency.¹³

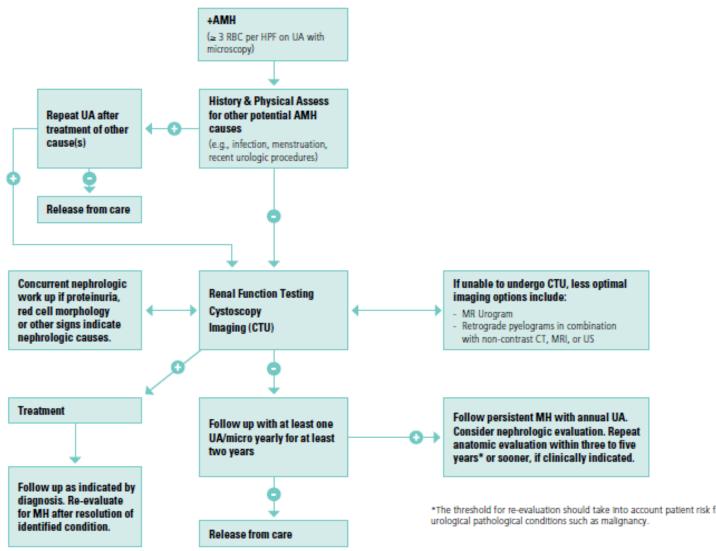
The American Urological Association (AUA) Guideline: Diagnosis, Evaluation and Follow-up of Asymptomatic Microhematuria (AMH) in Adults (Table 1 and Figure 1 below):

# Table 2. Common Risk Factors for Urinary Tract Malignancy in Patients with Microhematuria¹⁰

Table 1: Common Risk Factors for Urinary Tract Malignancy in Patients with Microhematuria
Male gender
Age (> 35 years)
Past or current smoking
Occupational or other exposure to chemicals or dyes (benzenes or aromatic amines)
Analgesic abuse
History of gross hematuria
History of urologic disorder or disease
History of irritative voiding symptoms
History of pelvic irradiation
History of chronic urinary tract infection
History of exposure to known carcinogenic agents or chemotherapy such as alkylating agents
History of chronic indwelling foreign body

#### FIGURE 1. Algorithm for Evaluation and Follow-up of Asymptomatic Microhematuria

#### Diagnosis, Evaluation and Follow-up of AMH



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### **IV. Aeromedical Concerns.**

Persistent or recurrent hematuria is not disqualifying, unless an underlying etiology is identified. Because hematuria can be a sign of significant underlying disease, it must be evaluated fully. Calculi can cause extreme pain, lead to urinary tract infection and obstruction and/or result in sudden incapacitation while in flight. Urinary neoplasms are often slow growing but must be diagnosed and treated early to optimize survival and function. Glomerular disease must be evaluated and renal function assessed to determine proper treatment and to address worldwide deployability (e.g. renal reserve, ability to tolerate dehydration, etc.).

ICD-9 code for	D-9 code for hematuria	
599.7	Hematuria	

ICD-10 codes for hematuria		
R31.9	Hematuria, unspecified	
R31.2	Other microscopic hematuria	

#### V. References.

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# Prostatitis

Revised: Sep 2022 Reviewed: Dr. Max Lee (ACS Waiver Guide coordinator), Lt Col Christopher Allam (AF/SG Urology consultant), and Lt Col Paul Vu (AFMRA Medical Standards Policy Chief)

## Significant Changes:

Minor revision, updated suggested readings, new format for previous waiver dispositions

## I. Waiver Consideration

Acute prostatitis as classified by the National Institute of Health Classification I (NIH I) symptoms is not compatible with flying or special mission duties and require DNIF until symptom resolution. Chronic prostatitis (NIH II – IV) and abscess of the prostate are disqualifying for all flying and special mission duties.

### Table 1: Waiver potential for Prostatitis

Flying Class (FC)	Condition	Waiver Authority Waiver Potential	ACS Review/ Evaluation
(10)	NIH I	N/A	
FC I/IA, II, III, ATC,	NIH II	Unlikely ¹ AFRS/CMO	
GBO, & SWA (initial)	NIH III	Unlikely ² AFRS/CMO	No
()	NIH IV	Unlikely ³ AFRS/CMO	
	NIH I	N/A	
FC II, III, ATC,	NIH II	Yes MAJCOM	
GBO, & SWA (trained)	NIH III	Maybe ² MAJCOM	No
	NIH IV	Maybe ³ MAJCOM	

1. Risk of recurrent and prolonged infections limits waiver potential for untrained.

2. Treatment of chronic pain is usually with alpha-blockers which are incompatible with FC I/IA or II duties and are rarely allowable for FC III duties due to alpha blocker's aeromedically significant side effects include postural hypotension, dizziness, vertigo and syncope.

3. Chronic prostatitis secondary to conditions like prostate cancer that is responsive to treatment may be waived for trained FC II or III after treatment completion and six-months waiting period. See prostate cancer waiver guide.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should be submitted after diagnostic evaluation has been completed and appropriate treatments have been initiated using best current clinical guidelines and recommendations.

### A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
  - a. Document current absence of symptoms and any medication side effects.
  - b. Document return to full physical activity or specify activity limitations.
- 2. Complete exam: general exam with temperature, external urologic exam, and rectal exam.
- 3. Urinalysis, cultures, and labs such as PSA and CBC if required.
- 4. Urologist's consultation, diagnosis, and study results to rule out other abnormalities, including follow-up notes after acute resolution (scanned into AIMWTS).
- 5. In NIH III/CPPS cases, consider the psychological status of the flyer.
- 6. Any other pertinent information.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

#### B. Renewal Waiver Request:

- 1. Summary of recurrence frequency, symptoms, treatment with any side effects, and activity levels.
- 2. External urologic exam and rectal exam.
- 3. All interim urology consultation notes (scanned into AIMWTS).
- 4. Any other pertinent information.

Note: Specify in the aeromedical summary any reasoning/justification for not including items listed above with the submitted waiver package.

### **III. Aeromedical Concerns**

Prostatitis, or increased inflammatory cells within the prostatic parenchyma, is classified into four categories by the National Institutes of Health (NIH) discussed below. Initial diagnosis is made by history, physical, urinalysis, and cultures. Urinalysis and cultures may be obtained before and after prostatic massage in NIH categories II – IV. However, prostatic massage should be avoided in acute prostatitis or during acute illness due to the risk of inducing bacteremia. The recurrent infections or inflammations seen in NIH II – IV require urology consultation, but acute prostatitis is usually treated by the aeromedical provider unless associated with abscess, urinary retention, or other complications. Primary aeromedical concerns of prostatitis involve recurrent distracting symptoms, medication side effects, and vibration/G-load forces that may exacerbate symptoms.

1. <u>Acute bacterial prostatitis (NIH I).</u> Symptoms include fever, genitourinary pain (suprapubic, perineal or rectal), obstructive voiding symptoms, dysuria, urgency, frequency, malaise, nausea and vomiting, and can progress to frank septicemia. Approximately 5% of patients will progress to a type of chronic prostatitis. Distracting symptoms are incompatible with flying duties and require DNIF until asymptomatic.

- 2. <u>Chronic bacterial prostatitis (NIH II).</u> Typically affects men aged 40-70 years with histories of recurrent UTIs, often predisposed by an inadequately treated initial acute infection or functional voiding abnormalities. Members are often asymptomatic between recurrences but bacteriuria persists. Identifiable uropathogens are present in less than 5% of these patients. The likelihood of recurrent rapid onset of distracting symptoms makes this condition incompatible with flying duties unless cured or suppressed with antibiotics.
- 3. <u>Chronic pelvic pain syndrome (CPPS) (NIH III).</u> Most cases of prostatitis in the general population involve this category of chronic genitourinary pain without uropathogenic bacteria. Members have many symptoms of traditional prostatitis but also report pain in the perineum, suprapubic area, penis, groin or lower back, and may report pain during or after ejaculation. Over 50% of patients may experience painful ejaculation. There are two subtypes distinguished by the degree of white blood cells (WBC) in prostatic secretions, urine, or semen but the clinical utility of this academic distinction is questioned between nonbacterial prostatitis (inflammatory) CPPS NIH IIIA and prostatodynia (noninflammatory) CPPS NIH IIIB.
- 4. <u>Asymptomatic inflammatory prostatitis (NIH IV).</u> WBCs are seen in prostatic secretions, post-prostatic massage urine, semen, or histological sections of the prostate but the patient is completely asymptomatic. No infection is present and cultures are negative. These patients may have elevated PSA, benign prostatic hypertrophy, or prostate cancer. Full urological workup is required for waiver consideration in order to better assess the aeromedical risk.

AIMWTS search performed spanning the period of Jul 2017 to Jul 2022 showed waiver submissions for 36 cases of prostatitis. The breakdown of the number of waivers and number of total cases are tabulated below. All received waivers except one FC III case that was disqualified for other aeromedically significant reasons.

	use only these ICD-10 codes for AIMWTS	(# of waivers / total # of cases)		
coding purposes		IFC I/IA	FC II	FC III
N41.0	N41.0 Acute prostatitis			
N41.1	Chronic prostatitis			
N41.3	.3 Prostatocystitis		25/25	9/10
N41.4	1			
N41.8	J			
N41.9 Inflammatory disease of prostate, unspecified				
A54.22	A54.22 Gonococcal prostatitis (acute or chronic)			
A59.02	Trichomonal prostatitis			

### **IV. Suggested Readings**

- 1. Pontari M. Chronic prostatitis and chronic pelvic pain syndrome. *UpToDate*. Feb 9, 2022. Accessed Jul 27, 2022. <u>https://www.uptodate.com/contents/chronic-prostatitis-and-chronic-pelvic-pain-syndrome</u>
- 2. Watson RA. Chronic Pelvic Pain in Men. *Emedicine*, Mar 17, 2020. Accessed Jul 27m, 2022. <u>https://emedicine.medscape.com/article/437745-overview#a6</u>
- 3. Coker TJ and Dierfeldt DM. Acute Bacterial Prostatitis: Diagnosis and Management. Am Fam Physician, 2016; 93(2): 114-20. <u>https://www.aafp.org/pubs/afp/issues/2016/0115/p114.html</u>
- 4. Nickel JC. Prostatitis. Can Urol Assoc J. 2011 Oct;5(5):306-15. doi: 10.5489/cuaj.11211. PMID: 22031609; PMCID: PMC3202001. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202001/</u>





## **Renal and Ureteral Stones (Nephrolithiasis)**

Revised: Jun 2021

Authors/Reviewers: Dr. Christopher Keirns and Maj Luke Menner; Lt Col Christopher Allam (AF/SG Consultant for Urology); Dr. Max Lee (ACS Waiver Guide Coordinator)

**Significant Changes:** Information required for waiver submittal updated to clarify the type of 24-hour urinary studies (i.e., UroRisk® Diagnostic Profile) that are needed for risk stratification.

## I. Waiver Consideration

A history of recurrent renal colic or a single episode of renal colic with retained renal stone(s) is disqualifying for all flying classes, ATC, GBO, and SWA duties. A single episode of renal colic without retained stones is not disqualifying, but all metabolic risk factors for stone formation must be mitigated. Incidentally discovered renal stones without a history of renal colic is disqualifying for FC I/A, FC II, FC III and SWA duties; however, it is not disqualifying for ATC or GBO duties. Symptomatic renal stones that are not amendable to treatment, recurrent in frequency that precludes satisfactory duty performance, or requires specialty care follow-up more than annually is disqualifying for all flying classes, ATC, GBO and SWA duties as well as for retention. Untrained personnel are unlikely to receive waiver for any history of renal colic or presence of retained renal stone(s). In all cases, a thorough metabolic evaluation is required and any metabolic risk factors predisposing to stone formation must be mitigated prior to waiver consideration. Individuals with retained renal stones must have a documented surveillance plan to monitor for stone progression.

A restricted waiver to a multi-place aircraft with another qualified pilot maybe indicated for manned aviation pilots with either retained renal stones or greater than three documented renal colic episodes due to the heightened annual risk of developing renal colic or other stone-related complications. On a case-by-case basis, pilots with retained asymptomatic renal stones may be considered for an unrestricted waiver. In such cases, ACS/SG Urology Consultant review of each case and local imaging studies is highly encouraged (but not required) in order to provide the waiver authority an individualized estimate of the annual risk of stone related events. Individuals with retained stone(s)  $\geq$ 3-mm located in the upper or mid renal pole(s) and individuals with greater than three documented renal colic episodes (regardless of the presence or location of retained renal stones) are felt to be at heightened aeromedical risk.

Flying Class (FC)	Waiver Potential	Waiver Authority ²	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II/III/SWA	Yes ^{3,4}	MAJCOM	Maybe ⁵
ATC/GBO	Yes ³	MAJCOM	No

Table 1: Waiver potential for SINGLE EPISODE of renal colic WITH retained stone(s)¹

1. Single episode of renal colic without retained stone(s) is not disqualifying, but all metabolic risk factors for stone formation must be mitigated.

- 2. Untrained personnel of any class are unlikely to receive aeromedical waiver and waiver authority is AETC.
- 3. All metabolic risk factors for stone formation must be mitigated.
- 4. In general, individuals with retained stone(s) ≥3-mm located in the upper or mid renal pole(s) are felt to be at heightened aeromedical risk.
- ACS/SG Urology consultant review of case and local imaging studies in order to provide individualized risk estimates of future stone related events is encouraged IF an unrestricted waiver is being considered in select pilots with higher risk retained stone(s). ACS/SG Urology consultant review of cases involving FC III/SWA personnel typically not required.

Flying Class (FC)	Waiver Potential	Waiver Authority ⁶	<b>ACS Review or Evaluation</b>
FC I/IA	No	AETC	No
FC II/III/SWA	Yes ^{7,8}	MAJCOM	Maybe ⁹
ATC/GBO	Yes ⁷	MAJCOM	No

6. Untrained personnel of any class are unlikely to receive aeromedical waiver and waiver authority is AETC.

7. All metabolic risk factors for stone formation must be mitigated.

8. In general, individuals with retained stone(s) ≥3-mm located in the upper or mid renal pole(s) and individuals with >3 renal colic episodes (regardless of the presence or location of retained renal stones) are felt to be at heightened aeromedical risk.

 ACS/SG Urology consultant review of case and local imaging studies in order to provide individualized risk estimates of future stone related events is encouraged IF an unrestricted waiver is being considered in select pilots with higher risk retained stone(s). ACS/SG Urology consultant review of cases involving FC III/SWA personnel typically not required.

Table 3: Waiver potential for INCIDENTALLY DISCOVERED retained renal stone(s) (i.e., no history of renal colic)

Flying Class (FC)	Waiver Potential	Waiver Authority ¹⁰	ACS Review or Evaluation
FC I/IA	No	AETC	No
FC II/III/SWA	Yes ^{11,12}	MAJCOM	Maybe ¹³
ATC/GBO	N/A	N/A	N/A

10. Untrained personnel of any class are unlikely to receive aeromedical waiver and waiver authority is AETC.

11. All metabolic risk factors for stone formation must be mitigated.

12. In general, individuals with retained stone(s)  $\geq$ 3-mm located in the upper or mid renal pole(s) are felt to be at heightened aeromedical risk.

13. ACS/SG Urology consultant review of case and local imaging studies in order to provide individualized risk estimates of future stone related events is encouraged IF an unrestricted waiver is being considered in select pilots with higher risk retained stone(s). ACS/SG Urology consultant review of cases involving FC III/SWA personnel typically not required.

## **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after the clinical disposition is complete and the service member is stable on all appropriate treatments, following the best current clinical guidelines and practice recommendations.

## A. Initial Waiver Request:

- 1. Summary of presentation, course, and treatment.
- 2. Consultation reports from all treating providers or specialists, which should include:
  - a. Discussion of presentation, etiology, and treatment
  - b. Discussion of metabolic and dietary risk factors predisposing to stone recurrence
  - c. Plan for mitigating risk of stone recurrence
  - d. Documentation of adherence and tolerance to pharmacologic therapy if indicated
  - e. Plan for monitoring stone progression if retained stones are present
- 3. Laboratory studies required:
  - a. Metabolic evaluation to include 24-hour urinary studies (i.e., UroRisk® Diagnostic Profile), urinalysis, stone analysis, serum uric acid, serum parathyroid hormone, and renal panel including calcium. Repeat the 24-hour urinary studies (i.e., UroRisk® Diagnostic Profile) if initial test was abnormal or treated with pharmacologic therapy.
  - b. All other laboratory and imaging studies ordered by treating provider(s) or consulting specialist(s).
- 4. Imaging studies required:
  - a. Submit all diagnostic and follow-up imaging reports.
  - b. If unrestricted waiver is being considered in select pilots with retained stones, and ACS is being consulted, submit all diagnostic and follow-up imaging reports as well as CD copy of the images to the ACS for review.
- 5. Current physical examination findings.
- 6. FL4 with RTD and ALC status, if applicable.
- 7. Any other pertinent information.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

## B. Renewal Waiver Request:

- 1. Updated AMS with interval history, including:
  - a. Discussion of any recurrence of renal colic or evidence of stone progression
  - b. Current plan to mitigate risk of recurrent renal colic or stone progression
- 2. Consultation reports from all treating provider(s) or specialist(s).
- 3. Updated laboratory and imaging studies:
  - a. Updated 24-hour urinary studies (i.e., UroRisk® Diagnostic Profile) if previously abnormal or on preventive therapy
  - b. KUB to assess kidney stone burden (new stone(s) and/or stone progression). A CT abdomen/pelvis (preferably low dose) may be required if history of radiolucent stone(s) or if KUB previously did not identify retained stone(s).

- c. If unrestricted waiver is again being considered in select pilots with retained stones, and ACS is being consulted, submit all diagnostic and follow-up imaging reports as well as CD copy of the images to the ACS for review.
- 4. Current physical examination findings.
- 5. Any other pertinent information.
- 6. If the local base cannot provide any of the above listed information, they should document why, explaining the reason to the waiver authority.

## **III. Aeromedical Concerns**

The development of renal or ureteral stones is a relatively common condition affecting USAF aviators and special duty operators. Migration of stones through the renal collecting system and ureter may result in aeromedically significant renal colic and/or complications from stone impaction (i.e. hydroureteronephrosis, acute kidney injury, infection, etc.). The presenting symptoms of renal colic range widely from pain resulting in distracting symptoms to overt incapacitation. Treatment may range from conservative management with symptomatic care to potentially invasive urologic procedures depending on the symptoms, stone size, and/or presence of complications. The challenge presented to the flight medicine community is identifying those individuals that have an unacceptably high risk of developing future stone-related events (i.e. renal colic, complications, stone progression, and urologic intervention). Multiple factors influence the risk of developing future stone-related colic with a history of symptomatic stones being the single most important predictor. Retained stone(s) in the kidney collecting system and ureters also increases the risk of future stone-related events and potentially serves as a nidus for further stone formation especially if modifiable risk factors are not corrected. Stone size, location, and number are also factors contributing to an individual's overall future risk.

Metabolic factors increasing risk of future stone events include hyperoxaluria, hypercalciuria, hypocitraturia, elevated urine uric acid levels, persistently acidic urine (pH less than 5), persistently alkaline urine (pH greater than 7), and low 24-hour urinary volume. Dietary factors leading to increased risk of stone formation include diets high in sugar/sweeteners, sodium, oxalate, animal protein, and low in calcium. Environmental factors such as dehydration, hot climates, and sedentary work increase risk of kidney stone formation and are commonly experienced by aircrew members. All USAF aircrew and special duty operators with a history of renal colic or incidentally discovered retained renal stone(s) are required to be evaluated for any underlying modifiable risk factors, which must be corrected to mitigate aeromedical risk of developing renal colic prior to returning them to operational duties or granting them an aeromedical wavier. In addition, studies have shown a significant risk reduction in recurrent renal colic and future stone events when preventative pharmacologic therapy is used in appropriate individuals. It is not recommended to undergo any urologic procedures for the purpose of obtaining a waiver.

The primary aeromedical goal in all individuals with a history of renal or ureteral stones is to limit the flying/operational impact of future stone-related events. Despite historically strict waiver tolerances put in place for aviators with a history of nephrolithiasis and renal colic, in-flight stone events have on occasion been reported in USAF aircrew. It is for this reason that USAF pilots may on occasion be restricted to multi-place aircraft with another qualified pilot in

an effort to mitigate aeromedical risk. Instructor pilots and single seat high-performance pilots do have the potential to be considered for an unrestricted waiver on a case-by-case basis, but each determination is individualized and review by the ACS/SG Urology Consultant is available to provide the waiver authority with the most accurate risk estimate possible.

Review of AIMWTS data in Mar 2020 revealed a total of 589 waiver packages containing the diagnosis of nephrolithiasis since Jan 2010. Of that total, 19 were FC I/IA (13 disqualified), 240 were FC II (13 disqualified), 231 were FC III (40 disqualified), 26 were ATC (2 disqualified), 60 were GBO (10 disqualified) and 13 were SWA (1 disqualified). Rationale for disqualifications included frequency, severity of symptoms, size and location of retained stones. In addition, disqualification decisions were made on the basis of the presence of other serious comorbidities that when taken together with the history of nephrolithiasis, would render the aeromedical risk to be unacceptable.

Common ICD-9 codes used for Nephrolithiasis			
592.0	Calculus of the kidney		
592.1	Calculus of the Ureter		
592.9	Urinary calculus, unspecified		
788.0 Unspecified renal colic			

Common ICD-10 codes used for Nephrolithiasis			
N20.0	Calculus of the kidney		
N20.1	Calculus of the Ureter		
N20.9	Urinary calculus, unspecified		
N23	Unspecified renal colic		

## **IV. Suggested Readings**

1. Assimos D, Krambeck A, et al. Surgical Management of Stones: AUA/Endourology Society Guideline. *Journal of Urology*. 2016; 196(4):1153-1160. Last accessed March 2020: <u>https://www.auanet.org/guidelines/kidney-stones-surgical-management-guideline</u>

2. Pearl MS, Goldfarb DS, et al. Medical Management of Kidney Stones: American Urologic Association Guideline. *Journal of Urology*. 2014; 192(2):316-324. Last accessed March 2020: <u>https://www.auanet.org/guidelines/kidney-stones-medical-mangement-guideline</u>

3. Recurrence of Kidney Stone (ROKS) Calculator 2018. <u>https://qxmd.com/calculate/calculator_438/roks-recurrence-of-kidney-stone-2018</u>

4. Qaseem A, et al. "Dietary and Pharmacologic Management to Prevent Recurrent Nephrolithiasis in Adults: A Clinical Practice Guideline From the American College of Physicians." *Annals of Internal Medicine*. 2014; 161(9):659-667. Last accessed March 2020: <u>https://annals.org/aim/fullarticle/1920506/dietary-pharmacologic-management-prevent-recurrent-nephrolithiasis-adults-clinical-practice-guideline</u>

5. Vaughan LE, Enders FT, et al. Predictors of Symptomatic Kidney Stone Recurrence After First and Second Episodes. *Mayo Clinic Proceedings*. 2019; 94(2):202-210.

6. Zisman AL. Effectiveness of Treatment Modalities on Kidney Stone Recurrent. *Clinical Journal of the American Society of Nephrology*. 2017; 12(10):1699-1708. Last accessed March 2020: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5628726/





## Anthropometrics (Short Stature, Excessive Height, Weight, and Other Body Measurements)

Revised: April 2021 Authors/Reviewers: Capt Caleb James (RAM '22), Col Christopher Borchardt, and Dr. Max Lee (ACS Waiver Guide Coordinator)

Significant Changes: Waiver guide restructured; updated to reflect the most recent MSD.

## I. Waiver Consideration

Individuals who do not meet DAFMAN 48-123 and the Medical Standards Directory anthropometric standards may apply for a categorical waiver to enter flight training. AETC/CC, in coordination with AETC/SG, is the waiver authority for all anthropometric waivers. AETC/CC has delegated this waiver authority to the AETC/A2/3/10 (Director of Intelligence, Operations, and Nuclear Integration). Standing height, sitting height, buttock-to-knee length, and nude body weight are the screening measurements required for all initial Flying Class (FC) I, IA, II, and III physicals to determine the need for further anthropometric clearance. Categorical waivers would be limited to those aircraft in which the candidate meets "functional fit" and "safe-escape" standards. The criteria for "functional fit" is based on Air Force Research Lab (AFRL) cockpit anthropometric surveys of USAF aircraft. The criteria for "safe-escape" would be based on ejection-seat design criteria.

A waiver is required if the applicant does not meet parameters listed on Table 1 during the initial flying class physical. There are no anthropometric standards for ATC or GBO personnel. In addition, there is a minimum functional reach of 76 inches for aeromedical evacuation crewmembers, regardless of height. See MDS Section T, Career Enlisted Aviator Interim Standing Height Standards, for additional details regarding enlisted aircrew height standards.

Condition	FC I	FC IA, initial II, and initial III	SWA	Waiver Potential Waiver Authority
Height	<64 inches or >77 inches	<64 inches or >77 inches*	<60 inches or >80 inches for males, <58 inches or >80 inches for females	Possible‡ AETC/A2/3/10
Sitting height	<34 inches or >40 inches	<33 inches or >40 inches (for initial FC IA and II)	N/A	Possible‡ AETC/A2/3/10
Weight and buttock-knee	If outside values of Table 2.	If outside values of Table 2.†	N/A	No waiver potential for FC- I/IA due to T-6 ejection seat. Waiver authority for non-ejection seat aircraft for all others is AETC/A2/3/10.

#### Table 1: Waiver potential for anthropometric issues

* Career Enlisted Aviator Standing Height Standards have been updated on 10 Feb 2020 and can be found in Section T of the MSD.

† Required for fighter track UNT, flight surgeons, and any aircrew whose primary duties are in ejection seat aircraft.
‡ FC I waiver eligibility depends on functional fit and safe-escape criteria. FC IA, II, and III waiver eligibility depends on safe-escape criteria only.

## STANDING HEIGHT and SITTING HEIGHT:

For initial FC I/IA, II, and III, the standing-height limits are 64-77 inches. Additionally, there are specific requirements for enlisted aircrew found in Section T of the MSD. SWA standing height limits are 60-80 inches for males and 58-80 inches for females. FC I/IA and FCII applicants will be screened for sitting heights less than 34 inches or more than 40 inches. Specific aircraft requirements can be found in Table 2. Initial FC II (FS) sitting height must be between 33-40 inches. For FC I, buttock-to-knee measurements shall be no greater than 27 inches. If outside these ranges, the applicant does not meet anthropometric standards and may be considered for an anthropometric waiver.

For FC I applicants seeking an anthropometric waiver, eight cardinal measurements must be performed at either the USAFA (for USAFA cadets) or Medical Flight Screening (MFS) clinic at USAFSAM (for ROTC, OTS, and AD UFT Board Selectees). These measurements include: standing height, sitting height, buttock-knee length, sitting knee height, arm span, sitting eye height, acromial height, and functional reach. These measurements are forwarded to AETC/SGPA for consideration of waiver potential. AETC/SGPA enters the cardinal

measurements into a web-based Pilot Accommodation Study (PASS) computer program, which derives its data from the above mentioned AFRL study. The PASS program determines "functional fit" for all USAF aircraft as either "safe," "marginal," or "unsafe." Candidates with "safe" and "marginal" functional fits are able to adequately reach and manipulate the aircraft controls for that particular aircraft. It is noteworthy that since the T-38 is the pipeline aircraft to all fighters and bombers, conditional FC I anthropometric waivers that exclude the T-38 also exclude fighters and bombers.

After using the PASS program to assess functional fit, AETC/SGPA will make one of three possible waiver recommendations: unconditionally qualified, conditionally qualified for certain aircraft, or disqualified. This waiver recommendation is coordinated through AETC/A3F before final approval from AETC/A2/3/10.

For non-pilot aircrew whose duties could be in an ejection seat aircraft, (e.g. F-15E weapons system navigator, flight surgeon, aerial photographer, flight test engineer) sitting height, buttknee length, and weight (discussed in WEIGHT section) must meet the minimum safe ejection seat requirements listed in Table 2. If outside these standards, then the conditional waiver will not include ejection-seat aircraft.

(Mi	MAXIMUM VALUES (inches) (Minimum sitting height for all ejection seat aircraft is 33")					
Aircraft	Butt-Knee Length	Sitting Height	Weight Limits			
T-6	27.9	41.5	103-245			
T-38	30.8	40	103-240			
A-10	26.7*	43.6	103-245			
F-15	27.2	44.1	103-245			
F-16	27.1	39.7	103-245			
F-22	27.9	43.4	103-245			
F-35	28.4	42.3	103-245			
B-1	28	44.4	103-245			
B-2	30.6	55.3	103-245			
B-52	28.4	53	103-245			

 Table 2: Ejection Seat Safe Escape Standards

* Based on data obtained after an A-10 mishap.

## WEIGHT:

More restrictive weight criteria exist for safe-escape standards from ejection-seat aircraft. Specifically, nude body weight must be between 103 and 245 lbs (103-240 lbs for the T-38). Trained aircrew in ejection seat aircraft that fall outside these limits are placed on DNIF status and referred to the line commander for administrative action. Trained aircrew flying ejection seat aircraft and not meeting weight standards may be considered for reassignment to a non-

ejection seat aircraft. This process is managed by the operational chain of command and does not require a medical waiver for weight.

An individual who does not meet weight standards should be evaluated for primary medical causes of the weight gain/loss. If the evaluation rules out a pathologic cause, effective weight control may be obtained by an adequate dietary and physical exercise programs.

## **II. Information Required for Waiver Submission**

The aeromedical summary (AMS) should only be submitted after clinical disposition has been completed and all appropriate treatments have been initiated using best current clinical guidelines and recommendations.

- A. AMS for anthropometric waivers should include the following:
  - 1. Required anthropometric measurements for the applicable flying class physical.
  - 2. If weight less than minimum standard, AMS should include weight history, review of systems, physical exam, and appropriate laboratory work up to rule out secondary causes.

## **III. Aeromedical Concerns**

Height and weight extremes are concerns for functional fit and ejection. Functional fit takes into account the aircrew's angle of view over the nose of the aircraft and the ability to reach and actuate all controls. Improper functional fit due to anthropometric limitations can result in the inability to control the aircraft during certain phases of flight. Aircraft ejection sequences poses additional risk to the aviator regardless of anthropometric measurement. Operating anthropometric ranges for ejection seats are set to minimize injuries that include vertebral spine, femur fractures from seat-pan impact, injuries from bodily contact with fixed canopy and canopy rails, and flail injuries related to the ejection sequence. Furthermore, in non-ejection related mishaps, anthropometric standards contribute to improved crash related survivability factors including cockpit volume, restraint position, and energy absorption that is commonly performed as part of the container, restraint, energy absorption, environment, and post-crash factors (CREEP) analysis.

### **IV. Suggested Readings**

- 1. AETC Anthropometric Waiver Policy message, April 2003.
- 2. AETC/DO Anthropometric Waiver Policy Memorandum, 10 Mar 04.
- 3. AETC BBP on Anthropometric Waiver Policy, May 2005.
- 4. Air Force Manual 36-2905 (Air Force Physical Fitness Program). 11 Dec 2020.
- 5. Zehner GF, Hudson JA. Body Size Accommodation in USAF Aircraft. AFRL-HE-WP-TR-2002-0118.

#### Decompression Sickness and Arterial Gas Embolism (Mar 2020)

Reviewed: Dr. Roger Hesselbrock (ACS Neurologist), Col Michael Richards (AF/SG Hyperbaric Medicine Consultant), Dr. Dan Van Syoc (ACS Division Deputy Chief), and Lt Col David Gregory (AFMSA Physical Standards Development Chief)

#### **Significant Changes:**

Updated Waiver Considerations and References

#### I. Waiver Consideration

Decompression sickness (DCS) or air embolism (AGE) with neurologic involvement by history, physical examination or evidence of structural damage on imaging studies is disqualifying for FC I/IA, FC II, FC III and Operational Support Flying Duty. Current literature suggests it is rare for DCS symptoms to begin more than 36 hours following decompression exposure. However, DCS should still be considered in the differential diagnosis for individuals presenting with DCS symptoms beyond this period of time if there is history of a credible exposure to significant change in pressure (i.e. at or above 18,000 ft, scuba diving, or hyperbaric exposure). Hypobaric chamber-induced neurologic DCS/AGE with symptom resolution within 2 weeks does not require waiver. Any altitude-induced DCS/AGE episode that requires recompression therapy and symptoms are not resolved within two weeks requires a waiver. Current medical knowledge does not permit clear delineation of susceptibility to repeat DCS, nor does it allow precise definition of risk of sudden incapacitation or of neurocognitive impairment. As a consequence, the Aeromedical Standards Working Group (ASWG) recommended the following pending acquisition of data that will permit further refinement of risks: a minimum 72-hour DNIF period following clinical symptoms related to hypobaric chamber exposure, a minimum 2-week DNIF following an altitudinal exposure with complete resolution of symptoms within 2 weeks of exposure and with acceptable studies as listed below, and a minimum 6-month DNIF period following altitudinal exposure for symptoms persisting beyond 2 weeks or without acceptable studies as listed below. DCS is not disqualifying for ATC and GBO duties.

Flying Class (FC)	Waiver Potential	Waiver Authority	ACS Review or Evaluation
FC I/IA	Yes ¹	AETC	Yes
FC II/III/OSD	Yes ¹	MAJCOM/ AFMRA	Yes

Table 1: Wai	ver potential	for DCS	and AGE
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1. If symptoms completely resolve after more than 14 days, or any residual symptoms are not functionally-limiting, aeromedical waiver recommendation is likely.

#### **II. Information Required for Waiver Submittal**

The aeromedical summary (AMS) should only be submitted after diagnostic evaluation has been completed, all appropriate treatments have been initiated using best current clinical guidelines and recommendations, and the member is clinically stable. Recompression by hyperbaric oxygen therapy is the definitive treatment for DCS and AGE.

Table 2 lists considerations for aeromedical waiver consideration after DCS or AGE.

	DCS/AGE with <u>no</u> CNS ¹ or	DCS/AGE categorized as severe, including
	pulmonary involvement	CNS ¹ or pulmonary involvement
Hypobaric	No Waiver Required	Waiver Required
chamber or	_	
altitude-	May be RTFS by local flight	Minimum 1-month DNIF following resolution
induced	surgeon after consultation with	of all symptoms if all results below are
DCS, with	base SGP, USAFSAM Hyperbaric	acceptable upon review by the ACS.
all symptoms	Medicine Branch and	Minimum 6-month DNIF if all results below
resolved	MAJCOM/SGP. Requires a	are not acceptable upon review by the ACS.
within 2	minimum 72-hour DNIF following	
weeks	resolution of all symptoms.	
Altitude-	Waiver Required	Waiver Required
induced DCS	-	
with	Symptom-focused evaluation by	Requires a minimum 6-month DNIF with
persistent	appropriate specialty/specialties	evaluation as listed below and review by the
symptoms	and aeromedical disposition per	ACS.
beyond 2	AFI	
weeks		

Table 2: DCS/AGE return to flying status (RTFS) considerations

1. If peripheral neurological complaints are the sole presenting symptoms and if these symptoms completely resolve with recompression treatment, a full 2-week or 1-month DNIF is not warranted.

A. Initial Waiver Request:

- 1. Complete history of event detailing risk factors, exposures, initial symptoms, treatment, any residual symptoms, signs and functional limitations.
- 2. Current physical, mental status and neurologic examinations performed by a Neurologist or Hyperbaric Medicine specialist.
- 3. Copies of relevant clinical notes (particularly consultation reports from Neurology, and Hyperbaric Medicine if obtained), and reports of diagnostic studies.
- 4. Neurocognitive testing at one month, to include the Multidimensional Aptitude Battery (MAB) and MicroCog tests, with results sent to ACS.
- 5. Noncontrast MRI studies (on minimum 1.5T MRI unit) within one month of episode, with report(s) and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 6. Documentation of any consultation with USAF Hyperbaric Medicine physician.
- 7. Chest x-ray (PA/lateral) to rule out lung parenchymal pathology in cases of pulmonary AGE.
- 8. If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

B. Renewal Waiver Request:

1 Interval history, including any residual symptoms, signs, and current functional status.

- 2 Copies of any applicable interim specialty reports, labs, imaging reports and images. If images are sent to ACS on CD, please ensure that the images can be viewed on a standard AF desktop system without needing administrative privileges.
- 3 Current physical, mental status and neurologic exam findings.
- 4 If the local base cannot provide any of the above listed information, they should document why, explaining reasoning to waiver authority.

## **III. Aeromedical Concerns**

Aeromedical concerns include the effects of any residual neurologic or cognitive symptoms on operational safety and mission effectiveness, and future risk of recurrence. The pathophysiology of decompression illness is not entirely understood. The risk of recurrent injury or increased susceptibility to subsequent injury following an initial episode of DCS is unknown, as is the short and long-term risk of permanent neurocognitive impairment following repeated episodes of neurologic DCS. Permanent subcortical dementia following a single episode of neurologic DCS in an aviator has been documented in at least one ACS-assessed case. The risk of seizures from structural brain abnormalities following altitudinal DCS is unknown. An unexpectedly increased amount of subcortical white matter hyperintensities have been noted on brain MRI in some U-2 pilots and hypobaric chamber personnel, even in the absence of a history of neurologic DCS. The clinical significance, both immediate and long term, of these findings is currently unknown. A consensus statement from the 2010 DCS-AGE Workshop noted the risk of seizures is unknown, with currently no medical evidence indicating increased risk of seizure. Large-vessel occlusion from AGE in the aviation environment is rare. If it does occur, the pulmonary rupture that caused the AGE must completely heal before consideration of returning to flying duties. Furthermore, any pulmonary pathologic conditions that could predispose to recurrence should be excluded via radiographic studies.

Review of AIMWTS through Jan 2019 showed 48 cases of decompression sickness; seven received a disqualified disposition. Breakdown of the cases revealed: 2 FC I/IA cases (both disqualified), 27 FC II cases (1 disqualified), and 19 FC III cases (4 disqualified).

ICD-9 codes for Decompression sickness		
993.3	Caisson disease	
958.0	Air embolism	

ICD-10 codes for Decompression sickness			
T70.3 (generic)	Decompression Sickness		
T70.3XXA (initial encounter)	Aeroembolism		
T70.XXD (subsequent encounter)			
T70.3XXS (sequelae)			

### **IV. Suggested Readings**

1. Connolly DM, Lee VM, Hodkinson PD. White matter status of participants in altitude chamber research and training. Aerosp Med Hum Perform 2018; 89(9):777-786.

2. Cooper JS, Hanson KC. Aerospace, Decompression Illness. StatPearls, Mar 21, 2019. Link: https://www.ncbi.nlm.nih.gov/books/NBK537264/

3. Savica R. Environmental neurologic injuries. Continuum (Minneap Minn) 2017; 23(3):862-871.

4. Pollock NW, Buteau D. Updates in decompression illness. Emergency Medicine Clinics 2017; 35(2):301-319.

5. Hossack M, Sladky J, McGuire SA. A proposed mechanism of neuronal injury in pilots and aircrew personnel with hypobaric exposure. Neurology 2017; 88(16, Suppl):S53.005

6. McGuire SA et al. White matter hyperintensities and hypobaric exposure. Ann Neurol 2014; 76(5):719-726.

7. McGuire SA et al. Hyperintense White Matter Lesions in 50 High-Altitude Pilots With Neurologic Decompression Sickness. Aviat Space Environ Med 2012; 83:1117-1122.

8. Webb J, Pilmanis A. Fifty Years of Decompression Sickness Research at Brooks AFB, TX: 1960-2010. Aviat Space Environ Med 2011; 82(5, Suppl.):A1-A25.