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## THERAPEUTIC DRUG GUIDELINES FOR AIR TRAFFIC CONTROL SPECIALISTS

Revision #12 Date: 06-02-2008

REVISION HISTORY		
Rev	Description of Change	Effective Date
1	Posted changes to Accutane and Byetta; clarified nitrates and anticoagulation; deleted Zelnorm; added entacapone and Chantix	08-15-2007
2	Added title page and Revision History page	08-16-2007
3	On page 3: updated Collective Bargaining Agreement reference and clarified that this document may be given to ATCSs	08-29-2007
4	Clarified use of Optivar – do not instill in the eyes while on duty	08-31-2007
5	Corrected policy on mefloquine [Lariam]; added atovaquone/proguanil [Malarone]	10-05-2007
6	Added Januvia	10-10-2007
7	Added Cialis	12-04-2007
8	Added aliskiren (Tekturna)	03-03-2008
9	Added mesalamine, including the various brand names	03-05-2008
10	Clarified that insulin pump is acceptable method of insulin delivery	05-19-2008
11	Updated policy on Chantix – it is not aeromedically acceptable	05-21-2008
12	Added levocetirizine (Xyzal)	06-02-2008

## THERAPEUTIC DRUG GUIDELINES FOR AIR TRAFFIC CONTROL SPECIALISTS

<u>Applicability</u>: These guidelines are for the use of Federal Aviation Administration (FAA) headquarters and field medical elements in determining the eligibility of air traffic control specialists (ATCS) for medical clearance. The guidelines may also be given to and used by ATCSs to determine the likely impact of medications on their safety-related assignments and to assist their personal treating physicians in their choice of medications. Formal medical clearance decisions, however, are based on the relevant medical standards of FAA Order 3930.3, on other applicable agency guidelines, and the clinical opinion of agency physicians. Often, the medical condition or the drug itself, if acceptable, will require clearance under special consideration procedures.

This document is offered in fulfillment of Section 14, Article 66, Medical Qualifications, of the Collective Bargaining Agreement between the National Air Traffic Controllers Association (NATCA) AFL/CIO and the Federal Aviation Administration, Department of Transportation, June 5, 2006.

The Federal Air Surgeon may change medical policies described here, as medically necessary with appropriate notice.

This document shall not be used by any ATCS as authority or permission for use of any medication while performing ATCS duties. Air Traffic management shall not use this document as tacit approval or authority to allow use of medications by ATCSs while performing safety-related duties.

The words "medication" and "drug" are used interchangeably in this document. Throughout, generic or chemical names of drugs are used with examples of available trade names in parentheses or brackets. The same drug may be sold under several different trade names. Use of a trade name does not serve as an endorsement of a proprietary product.

This document does not include comments on all drugs of possible significance in air traffic control. This document does not represent an FAA "approved list" of medications acceptable for use by ATCS personnel while performing their duties; no such list exists. There are too many medications available and changes occur too rapidly to allow the development and maintenance of such a list. Further, under many circumstances, the acceptability of a medication is specific to the individual ATCS and his or her medical condition.

Though medications mentioned in this document may be described as "acceptable" or "not acceptable" for ATCS duties, no inference may be made about any medication not mentioned in this document unless it is of the same type or category, chemically similar to the one mentioned, and used for the same purpose.

## References:

FAA Order 3930.3A
FAA Order 7210.3P
USP DL Drug Information for the

USP DI, Drug Information for the Health Care Provider

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Physicians' Desk Reference (PDR)
PDR Electronic Library
FDA Approved Drug Package Inserts
Mosby's GenRx 1998
Food and Drug Administration web site <a href="http://www.fda.gov">http://www.fda.gov</a>>
The Medical Letter

<u>General</u>: The medical condition for which an ATCS uses a medication is of prime importance. The condition's impact on aviation system safety must be determined and accepted before any decision regarding permission to use the medication is made. When a medication is considered "acceptable" for use by ATCSs, it is assumed the manufacturer's recommended dose is not exceeded.

Drugs classified as "investigational" by the United States Food and Drug Administration (FDA) are normally **not** acceptable for use by ATCSs.

Periodically new drugs are released for treatment of conditions. Sometimes these newer drugs are more powerful drugs and have significant adverse effects. In general, newly approved drugs will not be considered acceptable until the drug has been marketed for at least one year. Upon review of the post-marketing experience with the drug, careful individual evaluation of both the medical condition and the treatment will still be required.

There are medications or classes of medications, which, in any conceivable circumstance, would be considered inappropriate or hazardous for use by ATCSs while performing their duties. Such medications include narcotic analgesics, sedatives, "tranquilizers" or other psychopharmacologic drugs, antihistamines that produce drowsiness or other central nervous system effects, anticonvulsants, and experimental or investigational drugs.

Some of these drugs, used intermittently for self-limited or otherwise minor conditions, may be acceptable for an ATCS who performs his or her duties only after an appropriate time period has passed for clearance of the drug from the body and for resolution of significant symptoms or effects (for example, the short-term use of an antihistamine for acute allergic symptoms). Because of individual variations in the underlying disease, the potential for drug interactions, etc, consultation with the RFS office is necessary regarding these time periods. Other drugs, because of the conditions for which they are used, their specific effects, or their duration of action, would normally preclude medical clearance. Examples of this include the use of barbiturate preparations for chronic gastrointestinal conditions and of antipsychotic drugs by psychiatric patients. For agency employees, the responsible agency physician decides the acceptability of a medication or its use, considering the known characteristics of the medication, the underlying condition, information provided by the subject's attending physician, and Federal Air Surgeon policy. Questions may be referred to the Regional Flight Surgeon or regional medical staff; Manager, Aeromedical Certification Division, AAM-300; Manager, Occupational Health Division, AAM-700; or to the Manager, Medical Specialties Division, AAM-200.

<u>Drugs used for relief of pain and inflammation</u>: ATCSs may not use opiates or other narcotics (e.g., morphine, codeine, hydrocodone [Hydrocet], meperidine [Demerol], pentazocine [Talwin],

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tramadol [Ultracet]) while performing their duties. Normally, at least 24 hours from the last dose should elapse before return to safety or security related duties. The clinical condition of the individual should be considered. Aspirin, acetaminophen (e.g., Tylenol), ibuprofen (e.g., Advil, Motrin), naproxen (e.g., Naprosyn, Aleve), rofecoxib (Vioxx) and most other nonsteroidal anti-inflammatory agents may be used in standard, manufacturer's recommended doses while performing duties in the absence of demonstrated adverse effects or of contraindications from the medical condition being treated. Individuals using these drugs over an extended period should be evaluated periodically regarding the underlying medical conditions as well as the effects of the drugs.

The use of monoamine oxidase inhibitor for **pain syndromes** is **not** acceptable, regardless of dose. Antidepressants such as phenelzine (Nardil) and amitriptyline (Elavil), carbamazepine (Tegretol), or venlafaxine (Effexor) are sometimes used to treat conditions other than depression such as **pain syndromes or hot flashes**. **The use of antidepressants in these circumstances** is **not** acceptable, regardless of dose. In some cases the pain syndrome itself may not be acceptable.

Osteoarthritis and Rheumatoid arthritis may be treated with the acceptable pain relievers and anti-inflammatory agents noted above. Etanercept (Enbrel) and leflunomide (Arava) are normally acceptable for treatment of rheumatoid arthritis. Non-steroidal anti-inflammatory agents (e.g., etodolac [Lodine], piroxicam [Feldene], sulindac [Clinoril], meloxicam [Mobic], and others noted above) generally are acceptable in the absence of adverse effects. Agents such as gold (Myochrysine), methotrexate, azathioprine (Imuran), and other immunosuppressive agents are very potent drugs and require careful monitoring by experienced physicians. Acceptability for ATCS duties would depend on the circumstances of the specific case but may be possible. Infliximab (Remicade), in combination with methotrexate, is a drug approved for use in moderateto-severely active rheumatoid arthritis. It is given intravenously in three doses during drug initiation (infusions on day-0, day-14 and day-42) then followed by infusions every 4-8 weeks. Medical restriction is required during the initial three-dose drug initiation plus two weeks (total restriction is 8 weeks). Two weeks after dose-three of the drug initiation series, if there are no adverse side effects and the disease is under control, special consideration may be possible. When continuing treatment every 4-8 weeks is required, then the ATCS is medically restricted for 24-hours after each dose. The ATCS should promptly report any symptoms of headaches, dizziness, chest pain, swelling of mouth or throat, hives, itching, fever, rash, muscle or joint aches to the RFS. Because it is intended for severe, complicated forms of rheumatoid arthritis, the condition itself is likely to determine if the ATCS could receive medical clearance.

Probenecid (Benemid) and allopurinol (Zyloprim), for **gout**, are acceptable provided there are no adverse effects during a short trial. Acute, symptomatic gouty arthritis medically restricted until symptoms have subsided. If the condition is under control, these medications could be acceptable if a period of trial use demonstrates the absence of adverse effects.

Humira (Adalimumab) is acceptable provided there is close monitoring by the treating physician an prompt notification to the Flight Surgeon of adverse side effects.

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**Headaches.** A history of migraine may serve as a basis for denial of medical clearance or preclude safety-related duties. However, when it is determined that the specific case can be waivered the following medications can be considered. Ergot preparations (Wigraine, D.H.E. 45), without sedatives, are generally acceptable when used for **migraine**. Methysergide (Sansert), for prevention of attacks, is less often used now but could be acceptable if the ATCS remains under careful follow-up for adverse effects. Unfortunately, the use of methysergide suggests a degree of symptomatology and difficulty of control that could be incompatible with ATCS duties. The use of beta-blocking agents for migraine is acceptable. Newer drugs for treatment of acute attacks such as sumatriptan (Imitrex), naratriptan (Amerge), and zolmitriptan (Zomig), are generally acceptable in the absence of adverse effects, but a period of restriction from safety-related duties for some hours after use of the drug and relief of symptoms normally is required. Unacceptable medications include fiorinal and topiramate. Fiorinal contains aspirin, caffeine, and a barbiturate (a class of sedative) and is **not** acceptable. Topiramate (Topamax), an anti-seizure medication that is sometimes used for migraine or cluster headaches, has significant side effects and is **not** acceptable.

Mild **headaches** may safely and acceptably be treated with over-the-counter aspirin, acetaminophen, ibuprofen, naproxen, or similar preparation of various trade names (Tylenol, Advil, Naprosyn, Excedrin, Ecotrin, Motrin, Orudis, etc...) as long as the preparation does not contain an additional ingredient with sedative effects such as an antihistamine or codeine.

None of the medications used for central pain syndromes such as **trigeminal neuralgia** are acceptable and the condition itself often would preclude ATCS duties. Examples of these medications are carbamazepine (Tegretol) and phenytoin (Dilantin).

Psychotropic drugs: This class of medications includes all those with the ability to exert an effect on the mind or mental state of an individual. They are used for various purposes; the most common uses are listed below. Medications used for sleep disorders and anxiety and phobic disorders are not acceptable. The condition itself may be disqualifying. Included among these unacceptable medications are the benzodiazepines (Librium, Valium, Serax, Xanax, Ativan, etc...) amphetamines (Dexedrine), hypnotics (Ambien, Halcion, Dalmane), hydroxyzine (Atarax, Vistaril), meprobamate (Miltown), and miscellaneous ones such as quetiapine (Seroquel), doxepin (Sinequan), buspirone (BuSpar) and the smoking cessation drug, bupropion (Wellbutrin, Zyban). Beta-blocking agents (e.g., Inderal) are acceptable if the condition is well-controlled and no other symptoms or issues related to the condition exist (see also, Cardiovascular Drugs, below).

Nicotine-containing patches, nasal spray, or gum (Nicotrol, Nicorette, Habitrol, Prostep), used as **smoking cessation** aids **are** acceptable if used according to the manufacturer's recommended dosage and there are no adverse side effects. CigArrest gum and tablets, however, contain lobelia, a substance with potential adverse effects. The Office of Aerospace Medicine advises that ATCSs not use products containing lobelia. As noted above, bupropion (Zyban) is **not** acceptable.\_Varenicline [Chantix] is a completely new drug for smoking cessation and is **not** acceptable based on FDA finding that "it is increasingly likely that ... severe changes in mood and behavior may be related to Chantix." The neuropsychiatric side-effects of Chantix could adversely affect performance of safety-related duties.

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Stimulants, sometimes used for **narcolepsy** and **attention deficit hyperactivity disorder**, are **not** acceptable. Included are amphetamines (Adderall), pemoline (Cylert), methylphenidate (Ritalin), dextroamphetamine (Dexedrine), and modafinil (Provigil). The medical condition itself may be unacceptable.

Medications used for **anxiety**, **depression**, and for **psychotic disorders** are **not** acceptable. The condition is considered disqualifying. Among these medications considered **not** acceptable are tricyclic **antidepressants** (e.g., imipramine [Tofranil], doxepin [Sinequan], nortriptyline [Pamelor], amytriptyline [Elavil]), all phenothiazines (e.g., chlorpromazine [Thorazine], trifluoperazine [Stelazine]) and others such as haloperidol [Haldol], clozapine [Clozaril], and risperidone [Risperdal]. Currently, the selective serotonin reuptake inhibitors such as fluoxetine (Prozac), sertraline (Zoloft), nefazodone (Sertone), paroxetine (Paxil), and the related drug venalafaxine (Effexor) are not acceptable for use by ATCSs.

Lithium (Eskalith, Lithobid) normally is **not** permitted. In very rare cases, it may be approved with careful follow-up and where ideal control of the condition being treated permits. Each case must be individually evaluated to determine if special consideration is warranted.

Disulfiram (Antabuse) may **not** be used by ATCSs. The underlying **alcoholism or alcohol abuse** is reason for withdrawal of medical clearance until successful treatment and follow-up are implemented and achieved.

<u>Neurologic Drugs</u>: Medications used as **anticonvulsants**, e.g., phenytoin [Dilantin], divalproex [Depakote], gabapentin [Neurontin], and clonazepam [Klonopin]), are **not** acceptable.

For **Parkinsonism** treatment, levodopa (Larodopa), carbidopa/levodopa combined (Sinemet, Atamet), and amantadine (Symmetrel), may be acceptable if the disease is mild, under good control, and the medication is tolerated without adverse effects. Pergolide (Permax), pramipexole (Mirapex) and ropinirole (Requip) are **not** acceptable because of unacceptable side effects including inducing sleep. Sedating antihistamines, such as diphenhydramine (Benadryl) are **not** acceptable nor are the anticholinergic agents such as biperiden (Akineton) and trihexyphenidyl HCL (Artane), sometimes prescribed for Parkinsonism. Benztropine (Cogentin; an antihistamine-anticholinergic combination), as well as tolcapone (Tasmar) are unacceptable. Other drug combinations may **not** be acceptable as well as liver disease. Comtan (entacapone) as an adjunct to levodopa in the treatment of Parkinson's Disease, it is **not** acceptable; medications containing entacapone in combination with other drugs are also unacceptable. Apokyn (Apomorphine hydrochloride) is **not** acceptable.

For treatment of relapsing-remitting multiple sclerosis glatiramer acetate (Copaxone), may be acceptable if the disease is well controlled and the medication is tolerated without adverse effects. Multiple sclerosis requires individual medical evaluation and clearance determination by the RFS. In mild cases in which the disease is controlled clearance may be possible; careful evaluation of the effects of the medication and of the disease itself is required. The ATCS may not perform ATCS duties for two hours after each glatiramer acetate injection.

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Lidoderm is acceptable for the relief of pain associated with post-herpetic neuralgia. Parcopa (carbidopa + levodopa) for restless leg syndrome is acceptable.

"Muscle relaxants," such as cyclobenzaprine (Flexeril) and carisoprodol (Soma) are not acceptable because of their central nervous system effects.

**Myasthenia gravis** requires individual medical evaluation and clearance determination by the RFS. The use of pyridostigmine (Mestinon) is **not** acceptable. In mild cases of the disease, where control is achieved with immunosuppressive therapy (e.g., azathioprine [Imuran], methotrexate [Immunex, Rheumatrex], steroids, and/or plasmapheresis, clearance may be possible. Normally, **steroids** should not exceed 20 milligrams of prednisone (e.g., Deltasone), or equivalent, per day. Careful evaluation of the effects of the medications and of the disease itself would be required.

<u>Ophthalmic Drugs (eye)</u>: Most topically applied medications are acceptable if they do not interfere with visual function including night vision and the condition for which they are being used is controlled. Included are drugs for chronic open-angle **glaucoma** (e.g., timolol [Timoptic], epinephrine [Epifrin], dipivefrin [Propine]). Histamine antagonists such as ketotifen (Zaditor) may be acceptable if the condition treated is well controlled and the medication is well tolerated. Special testing for compatibility with ATCS duties may be required.

Optivar (azelastine) is acceptable provided it is not used the first time within 48 hours of duties, not instilled in the eyes while on duty, or used with contact lenses.

Otologic Drugs (hearing or balance): Drugs used for the treatment or prevention of motion sickness or vertigo (e.g., dimenhydrinate [Dramamine], meclizine [Antivert]) are not acceptable. Included among those not acceptable are skin patch preparations of scopolamine (Transderm Scop). Antibiotic or steroid topical ear preparations are acceptable if the condition does not interfere with hearing or any required use or function of earphones and equipment.

<u>Nasal Preparations</u>: Decongestant **nose drops** (e.g., phenylephrine [Neo-Synephrine, Vicks Sinex] oxymetazoline [Afrin], xylometazoline [Otrivin]), **are** acceptable in the absence of adverse effects. Steroid **sprays** (e.g., fluticasone [Flonase], triamcinolone [Nasacort], budesonide [Rhinocort]) for **allergic rhinitis** (hay fever) also **are** acceptable.

<u>Cold Remedies</u>: There are too many OTC preparations to list individually. An ATCS should carefully read the ingredients list to determine if the remedy contains drugs that are inappropriate for safety-related duties. These may include barbiturates (e.g., phenobarbital or other substance with "barb" in its name), antihistamines (e.g., diphenhydramine, chlorpheniramine, doxylamine, promethazine, dexbrompheniramine, triprolidine), or an opiate, e.g., codeine, or hydrocodone. These drugs are **not** acceptable for ATCS duties. If the label includes, "Warning. May be habit-forming," or if mentions drowsiness or caution in operating a vehicle, the ATCS should **not** use it. Many liquid preparations contain alcohol and may not be used while on duty: use off duty only with caution. Dextromethorphan, guaifenesin, phenylephrine, pseudoephedrine, and ephedrine **are** acceptable ingredients.

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<u>Antihistamines:</u> Older, sedating type antihistamines (e.g., chlorpheniramine [Chlor-Trimeton, Teldrin], diphenhydramine [Benadryl]) and the newer, but still sedating drugs like cetirizine (Zyrtec) and levocetirizine (Xyzal), are **not** acceptable. The newer, non-sedating antihistamines (e.g., fexofenadine [Allegra], loratadine [Claritin], desloratadine [Clarinex]) including **decongestant** combinations, **are** acceptable for use by working ATCSs after review by RFS confirming the absence of adverse side effects during a brief trial of the drug. The condition must not adversely affect the ability of the ATCS to perform safely.

Respiratory Drugs: Most beta-adrenergic agonists (e.g., metaproteronol [Alupent], terbutaline [Brethine], albuterol [Proventil, Ventolin]), xanthine medications (e.g., theophylline) and cromolyn (Crolom, Intal) used for asthma or other bronchorestrictive pulmonary problems are acceptable in the usual doses and route of administration after evaluation and a trial period of use by the individual. Inhaled anti-inflammatory steroids (e.g., triamcinolone [Azmacort], beclomethasone [Beclovent, Vanceril], fluticasone [Flovent], fluticasone [Advair]) are usually acceptable if the asthma is controlled. Similarly, the newer leukotriene antagonists (e.g., montelukast [Singulair], zileuton [Zyflo], zafirlukast [Acculate]) are acceptable. Over-the-counter preparations (e.g., Primatene Mist) are also acceptable if the manufacturer's instructions are followed.

<u>Steroids</u>: Systemic corticosteroids (e.g., prednisone [Deltasone] tablets) may be used for short periods with caution for acute problems such as **asthma** and **allergic reactions**. Long-term use for other medical conditions requires individual medical evaluation. Normally, the dose must not exceed 20 milligrams per day of prednisone or equivalent.

<u>Cardiovascular Drugs</u>: Like all other medical conditions, it is the cardiovascular disease or condition itself that demands evaluation. This evaluation is fundamental to the eligibility determination of the individual for medical qualification or clearance.

In a few cases, notably cardiac arrhythmias, qualification or clearance may be predicated on successful control with acceptable medication. Drugs that MAY be found acceptable include digitalis preparations (e.g., digitoxin [Crystodigin], digoxin [Lanoxin]), calcium channel blocking agents (e.g., verapamil [Calan, Isoptin, Verelan], nifedipine [Adalat, Procardia], diltiazem [Cardizem]), beta-adrenergic blocking agents (e.g., timolol [Blocadren], propranolol [Inderal], metoprolol [Lopressor], atenolol [Tenormin]), disopyramide (Norpace), procainamide (Procanbid), and quinidine (Quinaglute). In carefully selected cases of supraventricular arrhythmias amiodarone (Cordarone) may be acceptable. Usually, flecainide (Tambocor), mexilitine (Mexitil), and tocainide (Tonocard), are **not** permitted. Additionally, some arrhythmias may require the use of **anticoagulant drugs**.

Medications used specifically for the prevention or treatment of **angina pectoris** are **not** permitted, and this condition itself may lead to withdrawal of medical clearance. Any use of nitrate preparations (e.g., nitroglycerin [Nitrostat], isosorbide [Isordil, Sorbitrate, Imdur]) is presumed to be for treatment of angina. Beta-adrenergic blocking agents and calcium channel blocking agents (see above) are acceptable for treatment of **hypertension** in working ATCSs but **not** for prevention of angina pectoris or treatment of **myocardial ischemia**.

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The following drugs currently used for reduction of elevated blood **lipids** (e.g., niacin [Niaspan] colestipol [Colestid], atorvastatin [Lipitor], fluvastatin [Lescol], simvastatin [Zocor], pravastatin [Pravachol], lovastatin [Mevacor], cholestyramine [Questran], gemfibrizol[Lopid], fenofibrate [Tricor]) **are** acceptable in the absence of significant adverse effects.

**Aspirin**, and dipyridamole (Persantine), are acceptable for their anti-platelet aggregation effect if there are no significant adverse effects. They are not considered anti-coagulants. Newer "anti-platelet" agents such as abciximab (ReoPro), eptifibatide (Integrilin), tirofiban (Aggrastat), clopidrogel (Plavix), and ticlopidine (Ticlid) may be used if the underlying medical condition (usually cardiac) is acceptable.

For treatment of hypertension, most medications are acceptable if well-tolerated and effective. If an antihypertensive is a completely new class of drug then at least one year of post-marketing experience after initial FDA approval is required before the FAA will consider its use in ATCSs. Usually **NOT** acceptable are reserpine and reserpine-diuretic combinations (Hydropres, Diupres), guanfacine (Tenex), guanethidine (Ismelin), guanadrel (Hylorel), guanabenz (Wytensin), clonidine (Catapres), and methyldopa (Aldomet). Medications that usually are acceptable include all FDA approved diuretics (e.g., chlorothiazide [Diuril], triamterene [Dyrenium], hydrochlorthiazide [Hydrodiuril], amiloride [Moduretic], chlorthalidone [Hygroton], spironolactone [Aldactone], metolazone [Zaroxolyn], and combinations [e.g., Dyazide]); all beta-adrenergic blocking agents (see above); calcium channel blocking agents (see above) except bepridil (Vascor); all angiotensin-converting enzyme (ACE) inhibitors (e.g., quinapril [Accupril], ramipril [Altase], captopril [Capoten], lisinopril [Prinivil, Zestril], enalapril [Vasotec], benazepril [Lotensin]); labetalol (Normodyne), doxazosin (Cardura), terazosin (Hytrin), perindopril (Aceon), and prazosin (Minipress). Angiotensin II receptor antagonists also are acceptable in the absence of adverse effects. These include irbesartan (Avapro), losartan (Cozaar), and valsartan (Diovan). The direct renin inhibitor, aliskiren (Tekturna), is also acceptable in the absence of adverse effects.

The use of **anticoagulant** drugs may be permitted after evaluation by the agency. In some cardiac conditions, e.g. **artificial heart valve** implantation or certain arrhythmias, **anticoagulation** (e.g., heparin, warfarin [Coumadin]) may be required. Monitoring of coagulation status is necessary for use of this drug.

Endocrine (hormone) Agents: The use of replacement hormones or other natural or synthetic glandular substances normally is permitted if the medical condition is controlled and otherwise considered acceptable. A period of observation to document stability of control and the absence of adverse effects may be required. Included are pituitary, adrenal, thyroid (e.g., liothyronine [Cytomel]), gastric, and pancreatic substances and, in limited circumstances, insulin. Female hormone replacement therapy with estrogens (e.g., Premarin) or estrogen/progesterone combinations (e.g., Prempro) is acceptable. The use of tamoxifen (Nolvadex) or letrozole (Femara) by women at increased risk for breast cancer or raloxifene (Evista) to prevent osteoporosis and, possibly, lessen the risk of breast cancer is acceptable in the absence of significant adverse side effects. Alendronate (Fosamax) to prevent osteoporosis is acceptable. Hormones used for birth control are normally acceptable in the absence of adverse effects. Where hormones are used in a sex change process, a detailed medical evaluation will be required for medical certification or clearance.

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Clomid (Clomiphene) is approved provided: For continuous administration- No duties for 30 days, or 72 hrs after last dose, whichever is shorter. Pulse administration- No duties until completion of the second cycle (72hrs each pulse). Must be free of clinical side effects as recorded by treating PMD. Must not exceed 100mg/day. Wait times must be repeated if change in dose is increased from prior cycles.

Drugs and/or radioactive iodine for treatment of **hyperthyroidism** (e.g., methimazole [Tapazole]) **are** acceptable after a period of observation to ensure successful **thyroid** control and the absence of adverse effects.

Oral hypoglycemic drugs for diabetes control may be acceptable after an evaluation of the individual's disease, its control, and the presence or absence of adverse reactions. Examples are acetohexamide (Dymelor), chlorpropamide (Diabinese), tolbutamide (Orinase), glimepiride (Amaryl), glipizide (Glucotrol), glyburide (DiaBeta, Micronase, Glynase), acarbose (Precose), metformin (Glucophage), troglitazone (Rezulin), pioglitazone (Actos), rosiglitazone (Avandia), nateglinide (Starlix), and repaglinide (Prandin). Combinations of two of these drugs may be acceptable, but none are acceptable in combination with insulin. The concurrent use of beta-adrenergic blocking agents, however, usually will not be permitted because of their ability to mask the symptoms of hypoglycemia (low blood glucose). Users of these drugs must remain under close medical supervision both to ensure diabetes control and to monitor potential adverse effects. Byetta: may be acceptable under Special Consideration with certain restrictions: an observation period of at least 14 days if the ATCS is not also taking a sulfonylurea and at least 30 days if also taking a sulfonylurea; and, no use of Byetta within two hours of performing or while performing safety related duties. Januvia: may be acceptable under Special Consideration with an observation period of at least 14 days if the ATCS is not also taking a thiazolidinedione or metformin and at least 60 days if also taking a thiazolidinedione or metformin (if the ATCS has already been taking a thiazolidinedione or metformin for over 60 days and the Januvia is added in as a combined therapy then the 14-day waiting period applies). Januvia is not allowed with any other anti-diabetes medications.

<u>Insulin</u>: With strict selection and monitoring, ATCSs who use insulin (either via injection or insulin pump) to control their **diabetes mellitus** may be medically cleared for safety-related duties. Initial and periodic specialized medical evaluations are required and must demonstrate excellent control of the disease and the absence of complications. Monitoring of blood glucose levels prior to and during work shifts are required, and insulin-using ATCSs may not work alone in a facility. Medical Guideline Letter B-86 provides details about medical clearance and monitoring procedures.

<u>Gastrointestinal Agents</u>: Antacids (e.g., Maalox, Mylanta, Tums, Rolaids, Amphojel, Gaviscon) sucralfate (Carafate), and all current histamine H2-receptor antagonists including cimetidine (Tagamet), famotidine (Pepcid), nizatidine (Azid), and ranitidine (Zantac) gastric proton pump inhibitors such as rabeprazole (Aciphex) are acceptable if the medical condition is controlled and there are no adverse effects. Preparations containing sedatives and/or anticholinergic agents preclude ATCS duties until the effects cease, usually 12-24 hours after the last dose of the medication. Methantheline (Banthine) and propantheline (Pro-Banthine), however, have

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occasionally been cleared for use by selected individuals after evaluation of the medical condition and the patient's responses. The antispasmodic agent, dicylomine (Bentyl) is **not** acceptable.

Diphenoxylate with atropine (Lomotil) may be acceptable treatment for diarrhea in individuals who have been observed for adverse effects. Loperamide (Imodium) would be a better choice if there is a strong requirement that the ATCS continue his or her duties. Paregoric is not acceptable and will give a positive drug test for opiates. Tegaserod (Zelnorm or Zelmac) used to treat women with irritable bowel syndrome whose primary symptom is constipation, was withdrawn from the market by the FDA and is not acceptable. Sulfasalazine (Azulfidine) and mesalamine (Asacol, Lialda, Pentasa) have been permitted in ATCSs whose inflammatory bowel disease remains under control without adverse effects. Infliximab (Remicade) is a drug approved for use in moderate to severely active inflammatory bowel disease. It is administered intravenously as a three-dose drug initiation (infusions on day-0, day-14 and day-42) then followed by infusions every 4-8 weeks. Medical restriction is required during the initial three-dose drug initiation plus two weeks (total restriction is 8 weeks). Two weeks after dose-three of the drug initiation series, if there are no adverse side effects and the disease is under control, special consideration may be possible. If retreatment is required after a drug-free period of one-year or more then the same restrictions apply. Infliximab is not currently approved for continuous treatment of inflammatory bowel disease. Any symptoms of headaches, dizziness, chest pain, swelling of mouth or throat, hives, itching, fever, rash, muscle or joint aches should be promptly reported to the RFS. Because it is intended for severe, complicated forms of inflammatory bowel disease (e.g., complicated ulcerative colitis, Crohn's disease), the condition itself is likely to determine if the ATCS could receive medical clearance.

Prescription anorexiant (**weight loss**) drugs, usually stimulants (e.g., methamphetamine [Desoxyn], phentermine [Ionamin]) are **not** acceptable for use by ATCSs; those available overthe-counter, e.g., Dexatrim, are discouraged. Use of fenfluramine (Pondimin) or dexfenfluramine (Redux) alone or in any combination with phentermine is **not** acceptable because of reported significant adverse effects. A new drug, sibutramine (Meridia), structurally is related to amphetamine and acts similar to serotonin reuptake inhibitor drugs. This drug is **not** acceptable. Orlistat (Xenical) a lipase inhibitor for obesity management may be acceptable after medical evaluation and clearance determination by the RFS.

<u>Urogenital Agents</u>: Finasteride (Proscar), tamsulosin (Flomax), doxazosin (Cardura), and terazosin (Hytrin) **are** acceptable, in the absence of adverse side effects, for use by ATCSs for treatment of benign **prostatic hypertrophy**. A short trial use period is appropriate to observe for cardiovascular side effects. Tolterodine (Detrol) and Oxybutynin (Ditropan) for treatment of an overactive bladder are acceptable after a thirty-day observation period with no side effects. DitropanXL, the long-acting form of Ditropan, is **not** acceptable because it can cause sedation similar to Benadryl.

Vardenafil (Levitra), sildenafil (Viagra), and tadalafil (Cialis) used for **erectile dysfunction** therapy, **are** acceptable for use by ATCSs. The manufacturer's recommended dose should not be exceeded. These medications may cause changes in color perception thus careful monitoring and review for this side effect is warranted. The FAA recommends that at least 6 hours elapse from use of either vardenafil or sildenafil prior to beginning of safety-related duties; the

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recommended waiting time for tadalafil is 36 hours prior to beginning safety-related duties due to its longer duration of effect. Users of these medications must ensure that precautions about the concomitant use of certain cardiac medications are followed.

<u>Dermatologic (Skin) Agents</u>: Topical agents without significant absorption or systemic effects are acceptable. The oral antifungal drugs griseofulvin (Fulvicin), terbinafine (Lamisil), and itraconazole (Sporanox) also are acceptable after a short period of observation for adverse effects. However, if used for systemic **fungal disease**, the condition itself could affect medical clearance.

Soriatane (Acitretin) used to treat severe psoriasis may be acceptable after medical evaluation and clearance determination by the RFS. Isotretinoin (Accutane), used for the treatment of severe **acne**, can have vision and psychiatric side-effects. An ATCS is disqualified and may not perform safety related duties as soon as Accutane treatment is started. The ATCS will be disqualified for the duration of Accutane use unless found qualified with Special Consideration. After an initial period of observation, Accutane may be acceptable with Special Consideration and a duty restriction for "no tower duties at night." If the ATCS requests Special Consideration, the following apply:

- Must have been on Accutane at least 2 weeks prior to initial consideration
- Provide a statement/status report from the treating physician or examining AME that includes the dosage used, any side effects and detailed specific comment on the presence of vision or psychiatric side-effects.
- An annual status report addressing the above from the treating physician or examining AME is required.

If found qualified with Special Consideration for Accutane, the ATCS must cease safety-related duties and promptly notify the agency Flight Surgeon if any psychiatric or vision side-effects are noted.

The restriction may be removed after Accutane has been permanently discontinued for at least two weeks. At that time, the following information is required:

- Confirmation of the discontinuation date from the treating physician
- An eye evaluation, FAA Form 8500-7
- A statement from the ATCS confirming the absence of any visual disturbance or psychiatric symptoms after discontinuation

For those who hold a pilot certificate, the airman medical certificate will carry the restriction "Not Valid for Night Flying."

Both soriatane and isotretinoin are in the retinoid class of medications. The use of retinoids has been associated with psychiatric symptoms including depression, irritability, trouble concentrating, suicidal thoughts and suicide. The use of retinoids requires awareness of and close monitoring for these potential side effects. If any occur, promptly report them to your RFS and your treating physician.

Finasteride (Propecia, Proscar) is acceptable for use by ATCSs for treatment of hair loss.

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Antimicrobial, Antifungal, Antiprotozoal, and Antimycobacterial Agents: Generally, any FDA approved antibiotic is acceptable provided the condition for which it is used is under control and there are no adverse effects. The use of high-dose quinolones (e.g., ciprofloxacin [Cipro], moxifloxacin [Avelox], ofloxacin [Floxin], levofloxacin [Levaquin], norfloxacin [Noroxin], gatifloxacin [tequin], trovafloxacin [Trovan]) has been associated with neurologic and or psychologic side effects in some sensitive individuals thus their use warrants awareness and careful review for these potential side-effects. All currently approved medications for the treatment of **tuberculosis** or for skin test conversion (e.g., isoniazid [INH], rifampin [Rifadin], pyrazinamide [Rifater], Rifamate, rifapentine [Priftin], rifabutin [Mycobutin]) are acceptable after an appropriate period of observation for adverse effects.

All currently used oral drugs for **malaria** prevention, **except mefloquine** (Lariam), are acceptable after a period of observation for adverse effects (e.g., sulfadoxine/pyrimethamine [Fansidar], chloroquine [Aralen], atovaquone/proguanil [Malarone]).

Mefloquine (Lariam) is associated with psychiatric symptoms ranging from anxiety, restlessness, confusion, paranoia and depression to hallucinations, psychotic behavior, suicidal thoughts and suicide. These symptoms have been reported even long after mefloquine has been stopped. If any of these symptoms occur, promptly report them to your RFS and your treating physician. An ATCS who elects to use mefloquine for malaria prophylaxis or who contracts malaria and is treated with mefloquine will be incapacitated for the duration of use of mefloquine and for 4 weeks after the last dose. The ATCS must notify the medical office directly or via ATO supervisor no latter than first assigned work day after starting the medication. At that time the ATCS will be incapacitated. Four weeks after taking the last dose of mefloquine, the ATCS must contact the agency flight surgeon for clearance determination prior to resuming safety sensitive duties.

Antiviral medications (other than for treatment of Human Immunodeficiency Virus (HIV) Disease/Acquired Immunodeficiency Syndrome (AIDS): Generally, FDA approved antivirals used for treatment of influenza or for herpes are acceptable provided the condition for which it is used is under control and there are no adverse effects of the medication. It can be expected that there will be an observation period before resuming safety related duties while taking these medications. Antivirals are also used for other conditions – some of which may be disqualifying or require special consideration.

Human Immunodeficiency Virus (HIV) Disease/Acquired Immunodeficiency Syndrome (AIDS): Because of the need for rapid approval and use of new drugs for the treatment of HIV disease, the drugs are brought to market under abbreviated FDA procedures and often exhibit significant toxicity. Accordingly, the Office of Aerospace Medicine maintains a conservative policy towards their use by ATCSs. The emphasis will continue to be on public safety. All drugs used for the treatment of HIV disease must be considered individually by the FAA for a determination of acceptability. The FDA must have approved the drugs, their use must be in conformity with FDA directives or guidelines, and treatment must be under the supervision of a knowledgeable, experienced physician. Those drugs found generally acceptable then must be evaluated in the specific patient contemplating their use. The Federal Air Surgeon must defer clearance until an appropriate period of observed use is completed and the individual is found otherwise acceptable

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for medical clearance. Where a drug is determined to be unacceptable, medical clearance for ATCS duties will be withheld. A diagnosis of **AIDS**, using the Centers for Disease Control and Prevention (CDC) criteria, currently is disqualifying regardless of treatment.

<u>Chemotherapy</u>: Chemotherapeutic materials are almost universally toxic and ATCSs normally will not perform safety-sensitive duties during such treatment and for some period thereafter. Medical clearance decisions will be made on an individual basis by agency medical authority based, in part, on information received from the treating physician and the determinations of the Federal Air Surgeon. The condition requiring treatment will normally be a significant factor. In some cases, where treatment is intermittent, medical clearance during "rest" periods may be possible. Zometa is not approved. Gleevec may be acceptable after at least 3 months of use under Special Consideration for certain conditions. Initial and annual status reports from the treating physician will be required.

Interferon: Various so-called alfa- and beta-interferons (e.g., Roferon-A, Intron A, Infergen, Avonex, Peg-Intron, Rebetron - a combination of interferon-A and the antiviral agent ribavirin, and Betaseron) are used in the treatment of malignancies, chronic viral liver infections, multiple sclerosis, etc.... These substances have frequent and significant adverse side effects that are not compatible with the safety-related duties of an ATCS. While the medical condition often is the determining factor regarding medical clearance, interferons, particularly the alfa type, normally are considered unacceptable. Rare individuals have received medical clearance while receiving beta interferon treatment, but this determination must be through careful individual medical evaluation and review by the Federal Air Surgeon. After an appropriate period following cessation of treatment, the medical clearance issue may be revisited if the medical condition permits.

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