

AGENDA

Uniform Formulary Beneficiary Advisory Panel (UF BAP) For the February 2021 and May 2021 DoD Pharmacy and Therapeutics Committee Meetings January 25, 2022 at 10:00 AM Eastern Daylight Time

Virtual Meeting

Note that the UF BAP meeting occurring on January 25th and 26th will include information presented at the February 2021, May 2021, August 2021 and November 2021 DoD Pharmacy and Therapeutics (P&T) Committee meetings. The information presented on January 25th will include the recommendations from the February 2021 (presented in the morning) and May 2021 (presented in the afternoon) P&T meetings. The information presented on January 26th will include the recommendations from the August 2021 (presented in the morning) and November 2021 (presented in the afternoon) P&T meetings.

Information from the February 2021 DoD P&T Committee Meeting

- **Administrative Meeting: 7:30 – 9:30 AM Eastern Daylight Time (General session starts at 10:00 AM Eastern Daylight Time)**
- **Roll Call**
- **Welcome and Opening Remarks**
- **Therapeutic Class Reviews**

Members of the DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the DoD Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended Tier 4/Not Covered candidates.

The P&T Committee made recommendations for the following drugs/drug classes during the February 2021 meeting:

- **Drug Class Reviews**
 - *Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors Subclass*
 - *Pulmonary 3 Agents: Combinations Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
 - *berotralstat (Orladeyo) – Corticosteroids-Immune-modulators; for hereditary angioedema (HAE)*
 - *calcipotriene/betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora) - Topical Psoriasis agent*
 - *clascoterone 1% cream (Winlevi) – Acne Agents: Topical acne and rosacea agents*

- *clobetasol propionate 0.05% lotion metered dose pump (Impeklo) – High Potency Topical Corticosteroid for steroid-responsive dermatoses.*
- *hydrocortisone oral sprinkle capsules (Alkindi) – Adrenocortical insufficiency in children*
- *lonafarnib (Zokinvy) – Miscellaneous metabolic agent for Hutchinson-Gilford Progeria Syndrome or processing-deficient Progeroid Laminopathies*
- *loteprednol 0.25% ophthalmic solution (Eysuvis) - Ophthalmic: Corticosteroid for short term use in dry eye disease*
- *pegfilgrastim-apgf syringe (Nyvepria) – White Blood Cell Stimulants*
- *relugolix (Orgovyx) – Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists for advanced prostate cancer*
- *setmelanotide injection (Imcivree) – Weight loss agent for obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency*
- *sodium sulfate/magnesium sulfate/potassium chloride (Sutab) – Laxatives-Cathartics-Stool Softeners: Bowel Preparation for colonoscopy*
- *tramadol oral solution (Qdolo) – Narcotic analgesics and combinations*

➤ **Utilization Management Issues**

➤ **Prior Authorization Criteria—New Manual PA Criteria**

- *Skeletal Muscle Relaxants and Combinations – orphenadrine 50 mg-aspirin 770 mg-caffeine 60 mg tablets (Norgesic, Orphengesic Forte)*
- *Narcotic Analgesics and Combinations-levorphanol tartrate tablets*

➤ **Prior Authorization Criteria—Updated PA Criteria**

- *Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors*
 - *empagliflozin (Jardiance)*
 - *dapagliflozin (Farxiga)*
 - *canagliflozin (Invokana)*

- *Nasal Allergy Agents: Corticosteroids – fluticasone propionate 93 mcg nasal spray (Xhance)*
 - *Pulmonary-1 Agents: Combinations: budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera)*
 - *Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis:*
 - *plasma-derived human CI Esterase Inhibitor IV (Cinryze)*
 - *plasma-derived human CI Esterase Inhibitor SC (Haegarda)*
 - *lanadelumab (Takhzyro) injection*
 - *Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA): risdiplam (Evrysdi) oral solution*
- ***Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications, National Comprehensive Cancer Network Guideline Updates, or Age Ranges***
- *Targeted Immunomodulatory Biologics (TIBs) - anakinra (Kineret)*
 - *Immunosuppressives - belimumab (Benlysta)*
 - *Cystic Fibrosis Agents:*
 - *ivacaftor (Kalydeco)*
 - *elexacaftor/tezacaftor/ivacaftor (Trikafta)*
 - *tezacaftor/ivacaftor (Symdeko)*
 - *Weight Loss Agents - liraglutide (Saxenda)*
 - *Oncological Agents:*
 - *Breast Cancer - neratinib (Nerlynx)*
 - *Multiple Myeloma - selinexor (Xpovio)*
 - *Multiple Myeloma - ixazomib (Ninlaro)*
 - *Sleep Disorders:*
 - *Wakefulness Promoting Agents - pitolisant (Wakix)*
 - *Sleep Disorders: Insomnia Agents-tasimelteon capsule and liquid (Hetlioz, Hetlioz LQ)*

➤ **Panel Discussions**

The Beneficiary Advisory Panel members will have the opportunity to ask questions to each of the presenters. Upon completion of the presentation and any questions, the Panel will discuss the recommendations and vote to accept or reject them. The Panel will provide comments on their vote as directed by the Panel Chairman.

(Break for lunch)

Information from the May 2021 DoD P&T Committee Meeting

➤ **Roll Call**

➤ **Therapeutic Class Reviews**

Members of the DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) will present relative clinical and cost-effective analyses along with the DoD Pharmacy & Therapeutics Committee (P&T) recommendations for the Uniform Formulary (UF) and any recommended Tier 4/Not Covered candidates.

The P&T Committee made recommendations for the following drugs/drug classes during the May 2021 meeting:

➤ **Drug Class Reviews**

- *Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents Subclasses*
- *Sleep Disorders: Insomnia Agents Subclass*

➤ **Newly Approved Drugs per 32 CFR 199.21(g)(5)**

- *cabotegravir (Vocabria) – Integrase strand transfer inhibitor antiretroviral for HIV*
- *ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablet (Tyblume) – Monophasic combination oral contraceptive with 20 mcg estrogen*
- *levetiracetam 1,000 mg and 1,500 mg extended-release tablets (Elepsia XR) – Anticonvulsant Agent*
- *levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) –Thyroid Agent*
- *mannitol inhalation powder (Bronchitol) – Miscellaneous Respiratory Agent for Cystic Fibrosis*
- *methotrexate injection (Reditrex) – Antirheumatic*
- *ponesimod (Ponvory) – Oral miscellaneous multiple sclerosis (MS) agent for relapsing forms of MS*

- *solifenacin oral suspension (Vesicare LS) – Antimuscarinic Overactive Bladder Agent for pediatric neurogenic detrusor overactivity (NDO)*
- *tepotinib (Tepmetko) – Oral oncologic agent for non-small cell lung cancer (NSCLC)*
- *tirbanibulin 1% ointment (Klisyri) – Antineoplastic for actinic keratosis*
- *tivozanib (Fotivda) – Oral oncologic agent for renal cell carcinoma (RCC)*
- *umbralisib (Ukoniq) – Oral oncologic agent for marginal zone lymphoma (MZL) and follicular lymphoma (FL)*
- *vericiguat (Verquvo) – Miscellaneous cardiovascular agent for reducing risk of cardiovascular death in adults with chronic heart failure*
- *vibegron (Gemtesa) – Overactive Bladder (OAB) drug*
- *voclosporin (Lupkynis) – Calcineurin inhibitor immunosuppressive for active lupus nephritis (LN)*

➤ **Utilization Management Issues**

➤ ***Prior Authorization Criteria—New Manual PA Criteria***

- *Attention Deficit/Hyperactivity Disorder (ADHD) Stimulants – Methylphenidate Extended Release 72 mg tablets (Relexxii, generics)*
- *Targeted Immunomodulatory Biologics(TIBs) – Rilonacept injection (Arcalyst)*

➤ ***Prior Authorization Criteria—Updated PA and Step Therapy Criteria***

- *Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Irritable Bowel Syndrome Constipation Predominant (CIC/IBS-C) — lubiprostone (Amitiza)*
- *Antirheumatics: Injectable methotrexate—Otrexup and Rasuvo*
- *OAB Drugs – mirabegron (Myrbetriq)*
- *Renin-Angiotensin Antihypertensives: Combinations – sacubitril/valsartan (Entresto)*

➤ ***Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications, National Comprehensive Cancer Network Guideline Updates, or Age Ranges***

- *Oncological Agents:*
 - *Lung Cancer – crizotinib (Xalkori)*
 - *Lung Cancer – lorlatinib (Lorbrena)*
- *Targeted Immunomodulatory Biologics*
 - *adalimumab (Humira)*
 - *tocilizumab subcutaneous (Actemra SQ)*
- *Parkinson’s Disease Agents – amantadine (Gocovri)*
- *Pulmonary Arterial Hypertensions: prostacyclin nebulized – treprostinil (Tyvaso)*

➤ ***Re-evaluation of Generic Nonformulary Medications***

- *Calcium Channel Blockers: verapamil capsule 24 hour (generic Verelan PM): UF status*

➤ ***Panel Discussions***

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