

AGENDA

**Uniform Formulary Beneficiary Advisory Panel (BAP)
For the August 2021 and November 2021 DoD Pharmacy and Therapeutics Committee
Meetings
January 26, 2022 at 9:00 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 August 2021 DoD P&T Committee Meeting

- **Administrative Meeting: 8:00 AM – 9:00 AM Eastern Daylight Time (General session starts at 9:00 AM Eastern Daylight Time)**
- **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 August 2021 meeting:

- **Drug Class Reviews**
 - *Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass*
 - *Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass*
- **Newly Approved Drugs per 32 CFR 199.21(g)(5)**
 - *dasiglucagon injection (Zegalogue) Binders-Chelators-Antidotes Overdose Agents: Hypoglycemia Agents for severe hypoglycemia*
 - *drospirenone/estetrol (Nextstellis) Contraceptive agents: Monophasics with 20 mcg estrogen*

- *ferric maltol (Accrufer) Electrolyte Mineral Trace Element Replacement for iron deficiency*
- *infigratinib (Truseltiq)-Oncological agent for cholangiocarcinoma*
- *omalizumab syringe (Xolair) Respiratory Interleukin for asthma, nasal polyps and chronic idiopathic urticaria (CIU)*
- *pegcetacoplan injection (Empaveli) Hematological agent for paroxysmal nocturnal hemoglobinuria (PNH)*
- *relugolix/estradiol/norethindrone (Myfembree) Luteinizing Hormone Releasing Hormone (LHRH) Agonists Antagonists*
- *riluzole oral film (Exservan) Miscellaneous neurological agent for amyotrophic lateral sclerosis (ALS)*
- *rosuvastatin/ezetimibe (Roszet) Antilipidemic I*
- *semaglutide injection (Wegovy) Weight loss agent and a GLP-1 receptor antagonist for the treatment of obesity*
- *sotorasib (Lumakras) Oncological agent for non-small cell lung cancer (NSCLC)*
- *viloxazine extended release (Qelbree) Non-Stimulant for Attention Deficient Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17 years of age*

➤ **Utilization Management Issues**

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

- *Miscellaneous Insulin Devices – Omnipod and Omnipod DASH*
- *Laxatives-Cathartics-Stool Softeners – Lactulose Packets (Kristalose, generics)*
- *Vitamins: Prenatal – Prenatal Multivitamins (Neonatal-DHA, Neonatal FE)*

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

- *Multiple Sclerosis Agents: ozanimod (Zeposia)*

- *Migraine Agents: rimegepant (Nurtec ODT), ubrogepant (Ubrelvy), lasmiditan (Reyvow)*
- ***Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications, National Comprehensive Cancer Network Guideline Updates, or Age Ranges***
 - *Oncological Agents: avapritinib (Ayvakit)*
 - *Targeted Immunomodulatory Biologics (TIBs): secukinumab (Cosentyx)*
 - *Overactive Bladder Agents*
 - *mirabegron (Myrbetriq)*
 - *fesoterodine (Toviaz)*
 - *Hepatitis C Agents: Direct Acting Agents*
 - *sofosbuvir/velpatasvir (Epclusa) and authorized generic*
 - *glecaprevir/pibrentasvir (Mavyret)*
 - *ADHD Agents: Stimulants*
 - *amphetamine sulfate ODT (Evekeo ODT)*
 - *Gastrointestinal 2 Agents: obeticholic (Ocaliva)*
- ***Copayment Change: Tier 1 (Generic)***
 - *Pulmonary 3 Agents: Combinations Subclass-budesonide/glycopyrrolate/formoterol inhaler (Breztri)*
- ***Brand Over Generic Authorization and Tier 1 (Generic) Copayment***
 - *Pulmonary Arterial Hypertension (PAH) Drugs: ambrisentan (Letairis)*
- ***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 November 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 November 2021 meeting:

➤ Drug Class Reviews

- *Continuous Glucose Monitoring Systems (CGMs)*
- *Subcutaneous Immunoglobulins (SCIG)*

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

- *belumosudil (Rezurock) – Immunosuppressive for chronic graft-vs-host disease*
- *belzutifan (Welireg) – Oncological agent for von Hippel Lindau disease*
- *dihydroergotamine mesylate nasal spray (Trudhesa) – Another DHE nasal spray for acute treatment of migraine in adults with or without aura*
- *finerenone (Kerendia) – Miscellaneous cardiovascular agent for kidney failure associated with diabetes*
- *ibrexafungerp (Brexafemme) – Antifungal for vulvovaginal candidiasis*
- *lorazepam extended-release capsules (Loreev XR) – Extended release lorazepam capsules for anxiety in adults already stabilized*
- *mirabegron extended release granules for oral suspension (Myrbetriq Granules) – Overactive bladder agent for neurogenic detrusor overactivity (NDO)*
- *mobocertinib (Exkivity) – Oncological agent for non-small cell lung cancer (NSCLC)*
- *naloxone nasal 8 mg (Kloxxado) – Narcotic antagonist for opioid overdose*

- *odevixibat (Bylvay) – Miscellaneous metabolic agent for progressive familial intrahepatic cholestasis (PFIC)*
- *olanzapine/samidorphan (Lybalvi) – Combination atypical antipsychotic for schizophrenia and bipolar I disorder*
- *ruxolitinib 1.5% cream (Opzelura) – Topical corticosteroid immune modulator for atopic dermatitis*
- *serdexmethylphenidate/dexmethylphenidate (Azstarys) – Stimulant ADHD agent*

➤ **Utilization Management Issues**

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

- *Antihistamine-1s: First Generation and Combinations—clemastine 0.5 mg/mL oral syrup*
- *Pain Agents: NSAID – diclofenac potassium 25 mg tablet (Lofena)*
- *Anti-Emetic/Anti-Vertigo Agents – meclizine 50 mg tablet (Antivert)*
- *Antilipidemics-1 – niacin 500 mg tablet*
- *Vitamins: Prenatal – Prenatal Multivitamin (Neonatal Complete)*
- *Antidepressant and Non-Opioid Pain Syndrome Agents: Selective serotonin reuptake inhibitors (SSRIs) – sertraline 150 mg and 200 mg capsules*
- *Skeletal Muscle Relaxants and Combinations—tizanidine capsules (Zanaflex, generics)*

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

- *Antilipidemics-1: PCSK9-inhibitors: evolocumab (Repatha)*
- *Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors—zanubrutinib (Brukinsa)*
- *Oncological Agents: Acute Myelogenous Leukemia—ivosidenib (Tibsovo)*
- *Respiratory Interleukins—mepolizumab injection (Nucala)*

- *Sleep Disorders: Wakefulness Promoting Agents—sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)*
- *Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors—adalimumab (Humira)*
- *Targeted Immunomodulatory Biologics (TIBs): Janus Kinase (JAK) inhibitors: baricitinib (Olmiant) and upadacitinib (Rinvoq)*

➤ **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.