AGENDA

Uniform Formulary Beneficiary Advisory Panel (BAP) For the November 2022 DoD Pharmacy and Therapeutics Committee Meetings January 4, 2023 at 10:00 AM Eastern Daylight Saving Time

Virtual Meeting

- ➤ Administrative Meeting: 9:00 AM 9:45 AM Eastern Daylight Saving Time (General session starts at 10:00 AM Eastern Daylight Saving 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 November 2022 meeting:

Drug Class Reviews

- Atopy Agents
 - Oral Janus Kinase Inhibitor (JAK-1) subclass
- Hematological Agents
 - Red Blood Cell (RBC) Stimulants Erythropoietins subclass

➤ Newly Approved Drugs per 32 CFR 199.21(g)(5) and New Medical Devices

- clindamycin 2% vaginal gel (Xaciato) Antibiotic; vaginal formulation for treating bacterial vaginosis
- deucravacitinib (Sotyktu) Targeted Immunomodulatory Biologics (TIBs); an oral tyrosine kinase 2 (TYK2) inhibitor used for systemic treatment of moderate to severe plaque psoriasis
- fingolimod orally dissolving tablets (Tascenso ODT) Oral Miscellaneous Multiple Sclerosis Agents; new oral disintegrating formulation of fingolimod for patients 10 years of age or older who weigh less than 40 kg
- FreeStyle Libre 3 Therapeutic Continuous Glucose Monitoring System (CGMS); new version of a CGMS for monitoring diabetes
- finasteride/tadalafil (Entadfi) Benign Prostatic Hyperplasia (BPH) Agents; combination product of two products already available as generics, a PDE-5 inhibitor and a 5-alpha reductase inhibitors

- olopatadine/mometasone nasal spray (Ryaltris) Nasal Allergy Agents –
 Corticosteroids; combination product of two products available as generics, a
 nasal steroids and a nasal antihistamine
- Omnipod 5 Miscellaneous insulin device; new version of an External Insulin Infusion Pump for administering insulin
- oteseconazole (Vivjoa) Antifungal; for treatment of recurrent vulvovaginal candidiasis (RVVC) in females who are not of reproductive potential
- ranolazine ER granule (Aspruzyo Sprinkles) Miscellaneous Cardiovascular Agent; a new sprinkle formulation for treating chronic angina
- roflumilast 0.3% cream (Zoryve) Psoriasis Agents; topical phosphodiesterase 4 (PDE-4) for treatment of plaque psoriasis
- sirolimus 0.2% topical gel (Hyftor) Immunosuppressives; a topical treatment for facial angiofibromas associated with tuberous sclerosis complex (TSC)
- tadalafil oral suspension (Tadliq) Pulmonary Arterial Hypertension (PAH) drugs PDE-5 inhibitor; an alternative dosage form for PAH
- zonisamide oral suspension (Zonisade) Anticonvulsant-Antimania Agents; new liquid formulation of Zonisamide

Utilization Management Issues

- Prior Authorization Criteria—New Manual PA Criteria
 - Glaucoma Agents: Cholinergics/Cholinesterase Inhibitors—echothiophate ophthalmic solution (Phospholine Iodide)
- New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)
 - Narcotic Analgesics and Combinations—oxycodone 2.5-, 5-, 7.5- and 10 mg/acetaminophen 300 mg tablets and oxycodone 10 mg/acetaminophen 300 mg/5 mL oral solution
 - Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)—venlafaxine besylate 112.5 mg tablets
- Prior Authorization Criteria—Updated PA Criteria for New FDA-Approved Indications
 - Cystic Fibrosis Agents—lumacaftor/ivacaftor oral granules (Orkambi)
 - Leukemia and Lymphoma Agents: Bryton Tyrosine Kinase (BTK) Inhibitors Subclass—ibrutinib (Imbruvica)
 - Luteinizing Hormone-Releasing Hormone LHRH) Agonists-Antagonists relugolix/estradiol/norethindrone (Myfembree) and elagolix (Orilissa)

- Oncological Agents
 - Lung Cancer subclass—crizotinib (Xalkori)
 - o 2nd Generation Antiandrogens subclass—darolutamide (Nubega)
 - Acute Myelogenous Leukemia (AML) subclass—ivosidenib (Tibsovo)
 - o pemigatinib (Pemazyre)
 - o trametinib (Mekinist)
- Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors Subclass
 - o risankizumab On-Body Injector (Skyrizi OBI)
 - ustekinumab (Stelara)
- Prior Authorization Criteria—Updated PA Criteria for reasons other than New FDA-Approved Indications
 - Androgens-Anabolic Steroids: Testosterone Replacement Therapies testosterone cypionate and testosterone enanthate injection
- Prior Authorization Criteria—Removal of Indication
 - Oncologic Agents: Ovarian Cancer subclass—olaparib (Lynparza)
 - Oncologic Agents: Multiple Myeloma subclass—ixazomib (Ninlaro)
- Change in Copay: Tier 1 Copay
 - Narcotic Antagonists—naloxone injection 5 mg/0.5 mL (Zimhi)
 - Emergency Contraceptives—ulipristal acetate (Ella)

> Re-Evaluation of Nonformulary Generics

- Alzheimer's Agents: Cholinesterase Inhibitors—donepezil 23 mg (Aricept 23 mg, generics)
- 2nd Generation Antihistamines—levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)
- Proton Pump Inhibitors (Tabs/Caps subclass)—lansoprazole (Prevacid, generics)
- > Tier 4/Not-Covered Review: Rapid Acting Insulins—Insulin aspart/niacinamide (Fiasp)

> 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 concur or non-concur on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. The Panel will provide comments on their vote as directed by the Panel Chairman. Comments to the Director, DHA, or their designee will be considered before making a final UF decision.