MO HEALTHNET PHARMACY PROGRAM NEW DRUGS AND EDITS WITH NO ANNUAL CHANGES

MHD DUR BOARD APRIL 20, 2022
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NEW DRUGS – CLINICAL EDITS

Common Trade Name	Ingredient Name	Indications
Oxbryta 300mg Tablet	Voxelotor	Indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older. **Sickle Cell Disease Clinical Edit – To be discussed today**
Scenesse 16mg Implant	Afamelanotide Acetate	Indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP). **Scenesse Clinical Edit – To be discussed today**
Sertraline 150mg Capsule Sertraline 200mg Capsule	Sertraline HCl	Indicated for the treatment of: • Major depressive disorder (MDD) in adults. • Obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years and older. **SSRI Clinical Edit** **Must provide a letter of medical necessity as to why participant cannot use the tablets.**
Tavneos 10mg Capsule	Avacopan	Indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. **Tavneos Clinical Edit – To be discussed today**
Tecartus 1X10^{8} Infusion Bag Tecartus 1X10^{8} Cassette	Brexucabtagene Autoleucel	Indicated for the treatment of: • Adult patients with relapsed or refractory mantle cell lymphoma (MCL). • Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). **CAR T Cell Therapy Clinical Edit**
Voxzogo 0.4mg Vial Voxzogo 0.56mg Vial Voxzogo 1.2mg Vial	Vosoritide	Indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. **Voxzogo Clinical Edit – To be discussed today**

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Apretude ER 600mg/3ml Vial	Cabotegravir	Indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. **Antiretroviral Therapy (ART) PDL – Non-Preferred** **Approval Criteria:** **1. Trial of generic Truvada, participant must be unable to tolerate generic Truvada OR participant has significant renal impairment.** **2. Only approved for use as PrEP.** **3. Compliance is important and non-compliance increases the risk for drug resistance, therefore if a participant misses one of the first three doses of initiation no additional PA to continue will be granted. In addition, missing two doses in the first year no PA to continue will be granted.** **4. Participant cannot test positive for HIV before initiating Apretude and a positive test for HIV during PrEP treatment will result in termination of PA for Apretude.** **5. Participant must be tested for HIV within one month before initiating Apretude and before requesting PA to continue on Apretude.**
Dupixent 100mg/0.67ml Syringe	Dupilumab	Indicated for: • The treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. • As an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. • As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). **Respiratory Monoclonal Antibodies (RMA) PDL - Non-Preferred – To be discussed today**

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Biktarvy 30-120-15mg Tablet	Bictegravir/Emtricitabine/Tenofovir Alafenamide	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY. **Antiretroviral Therapy (ART) PDL – Preferred**
Elyxyb 120mg/4.8ml Solution	Celecoxib	Indicated for the acute treatment of migraine with or without aura in adults. **NSAID Agents PDL - Non-Preferred** **Must provide a letter of medical necessity as to why participant cannot use the capsules.**
Epclusa 150-37.5mg Pellet Packet Epclusa 200-50mg Pellet Packet	Sofosbuvir/Velpatasvir	Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: • Without cirrhosis or with compensated cirrhosis. • With decompensated cirrhosis for use in combination with ribavirin. **Hepatitis C Agents PDL - Non-Preferred – To be discussed today**
Gvoke 1mg/0.2ml Kit	Glucagon	Indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and older. **Glucagon Agents PDL - Non-Preferred**

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Livmarli 9.5mg/ml Solution	Maralixibat Chloride	Indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. **Bile Salt Agents PDL – Non-Preferred**
Mavyret 50-20mg Pellet Packet	Glecaprevir/Pibrentasvir	Indicated for the treatment of: • Adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). • Adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. **Hepatitis C Agents PDL - Preferred – To be discussed today**

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Qulipta 10mg Tablet Qulipta 30mg Tablet Qulipta 60mg Tablet	Atogepant	Indicated for the preventive treatment of episodic migraine in adults. **CGRP Agents PDL - Non-Preferred**
Semglee 100unit/ml Vial Semglee 100unit/ml Pen	Insulin Glargine-yfgn	Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. **Long-Acting Insulins PDL - Non-Preferred**
Skytrofa 3mg Cartridge Skytrofa 3.6mg Cartridge Skytrofa 4.3mg Cartridge Skytrofa 5.2mg Cartridge Skytrofa 6.3mg Cartridge Skytrofa 7.6mg Cartridge Skytrofa 9.1mg Cartridge Skytrofa 11mg Cartridge Skytrofa 13.3mg Cartridge	Lonapegsomatropin	Indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone. **Growth Hormone Agents, Somatropin PDL - Non-Preferred**
Tyrvaya 0.03mg Nasal Spray	Varenicline Tartrate	Indicated for the treatment of the signs and symptoms of dry eye disease. **Dry Eye Disease Agents PDL - Non-Preferred**

NEW DRUGS – OPEN ACCESS

Common Trade Name	Ingredient Name	Indications
Casirivimab-Imdevimab (EUA) 300-300mg Vial	Casirivimab/Imdevimab	Authorized for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
Susvimo 10mg/0.1ml Vial	Ranibizumab	Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

NEW DRUGS – PA CONTINUED

Common Trade Name	Ingredient Name	Indications
Eprontia 25mg/ml Solution	Topiramate	Indicated for: • Epilepsy: Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with LennoxGastaut syndrome in patients 2 years of age and older. • Preventive treatment of migraine in patients 12 years of age and older. **Approval Criteria:** **Must provide a letter of medical necessity as to why participant cannot use the tablets.**
Livtencity 200mg Tablet	Maribavir	Indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. **Approval Criteria:** **1. Must be used post-transplant for treatment that is refractory to treatment with ganciclovir, valganciclovir, cidofovir or foscarnet.** **2. For treatment of adults and pediatric patients that are 12 years of age or older and weigh greater than or equal to 35 kg.** **3. Participants who could become pregnant require a negative pregnancy test prior to treatment and must use effective contraception during therapy.**

NEW DRUGS – PA CONTINUED

Common Trade Name	Ingredient Name	Indications
Trudhesa 0.725mg Nasal Spray	Dihydroergotamine Mesylate	Indicated for the acute treatment of migraine with or without aura in adults. **Approval Criteria:** **1. Trial and failure of 2 triptans, NSAIDs, Migranal nasal spray (trial defined as 6 months per agent) AND** **2. Be on a preventative agent AND** **3. Dose opt of 1 pack per month**
Vuity 1.25% Drops	Pilocarpine HCl	Indicated for the treatment of presbyopia in adults. **Approval Criteria:** **1. Prescribed by or in consultation with an optometrist, ophthalmologist, or other specialist in the treated disease state AND** **2. Participant aged 40 years or older AND** **3. Participant has documented contraindication to the use of corrective lenses AND** **4. Dose opt of 2.5mL (one bottle) every month**

NEW DRUGS – PA CONTINUED

Common Trade Name	Ingredient Name	Indications
Vyvgart 400mg/20ml Vial	Efgartigimod Alfa-Fcab	Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. **Approval Criteria:** **1. Participant has documented diagnosis of generalized myasthenia gravis AND** **2. Documented positive anti-acetylcholine receptor antibody test AND** **3. Myasthenia Gravis Foundation of America Class II, III or IV AND** **4. Documented baseline Myasthenia Gravis Activities of Daily Living score of greater than or equal to 5 AND** **5. Prescribed by or in consultation with neurologist, rheumatologist, or other specialist in the treated disease state AND** **6. Participant aged 18 years or older AND** **7. Participant is not currently pregnant AND** **8. Adequate therapeutic trial of 2 immunosuppressant agents (90/120 days) AND** **9. Dose does not exceed 1200 mg per infusion AND** **10. No more than 24 infusions per year AND** **11. Initial approval period: 3 months** **Continuation of Therapy:** **1. Subsequent cycles to be administered if the MG-ADL score is greater than or equal to 5 OR** **2. If the patient was an MG-ADL responder initially, but no longer has a clinically meaningful improvement (defined as less than 2 point improvement in total MG-ADL score AND** **3. Treatment has a sustained effect for at least 4 weeks after the end of the previous treatment cycle AND** **4. Participant has continued non-pregnant status AND** **5. Minimum time between treatment cycles should be no less than 50 days from the start of previous treatment cycle and the start of the next treatment cycle AND** **6. Continuation approval period: 6 months**

NEW DRUGS – STEP THERAPY

Common Trade Name	Ingredient Name	Indications
Injectafer 1,000mg/20ml Vial	Ferric Carboxymaltose	Indicated for the treatment of iron deficiency anemia (IDA) in: • Adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron. • Adult patients who have non-dialysis dependent chronic kidney disease **Iron – Injectable Step Therapy Edit** **Dose opt of 20ml/25 days**

CLINICAL & FISCAL EDITS WITH NO ANNUAL CHANGES

- Imcivree Clinical Edit
- Megestrol Acetate Clinical Edit
- Nulibry Clinical Edit
- Oxervate Clinical Edit
- Oxlumo Clinical Edit
- Spravato Clinical Edit
- Zokinvy Clinical Edit
- Zulresso Clinical Edit

PREFERRED DRUG LIST EDITS WITH NO ANNUAL CHANGES

- Actinic Keratosis Agents, Topical
- Androgenic Agents
- Antibiotics, Inhaled
- Antifungals, Oral
- Antifungals, Topical
- Antihistamines & Antihistamines/Decongestant Combinations, 2nd Generation
- Antihistamines, Intranasal
- Antivirals, Herpes Oral
- Antivirals, Topical
- Benzoyl Peroxide/Antibiotic Combinations
- Corticosteroids, Oral Inhaled
- Corticosteroids, Topical
- Corticosteroids and Rhinitis Agents, Intranasal
- Cough/Cold Preparations
- Epinephrine Agents, Self-Injectable
- Fluoroquinolones, Ophthalmic
- Fluoroquinolones, Otic
- Glaucoma Agents
- Mast Cell Stabilizers, Ophthalmic
- NSAIDs, Ophthalmic
- Psoriasis Agents, Oral
- Psoriasis Agents, Topical
- Retinoids, Topical
- Ulcerative Colitis Agents, Oral
- Ulcerative Colitis Agents, Rectal