



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

**MHD DPAC COMMITTEE DECEMBER 15, 2022
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NEW DRUGS – CLINICAL EDITS

Common Trade Name	Ingredient Name	Indications
Aspruzo Sprinkle ER 500mg Packet Aspruzo Sprinkle ER 1000mg Packet	Ranolazine	Indicated for the treatment of chronic angina. Ranolazine Clinical Edit Prior Authorization Required Fiscal Edit <ul style="list-style-type: none"> • Must provide medical necessity as to why the participant cannot utilize generic ranolazine tablets.
Orkambi 75-94mg Granule Packet	Lumacaftor/Ivacaftor	Indicated for the treatment of cystic fibrosis (CF) in patients aged 1 year and older who are homozygous for the F508del mutation in the CFTR gene. Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators Clinical Edit – To be discussed today
Pheburane 483mg/g Pellet	Sodium Phenylbutyrate	Indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS). Enzyme Deficiency, Select Agents Clinical Edit PA Required Fiscal Edit <ul style="list-style-type: none"> • Must provide medical necessity as to why the participant cannot utilize Buphenyl or Ravicti.

NEW DRUGS – CLINICAL EDITS

Common Trade Name	Ingredient Name	Indications
Skysona Infusion Bag-Cassette	Elivaldogene Autotemcel	Indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Skysona Clinical Edit – To be discussed today
Venlafaxine Besylate ER 112.5mg Tablet	Venlafaxine Besylate	Indicated in adults for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD). SNRI Clinical Edit Prior Authorization Required Fiscal Edit <ul style="list-style-type: none"> • Must provide medical necessity as to why the participant cannot utilize generic Effexor XR capsules. • Dose opt of 1 tablet per day
Xenpozyme 20mg Vial	Olipudase Alfa-RPCP	Indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. Xenpozyme Clinical Edit – To be discussed today
Ztalmy 50mg/mL Suspension	Ganaxolone	Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. Ztalmy Clinical Edit – To be discussed today
Zyntegol Infusion Bag-Cassette	Betibeglogene Autotemcel	Indicated for the treatment of adult and pediatric patients with β -thalassemia who require regular red blood cell (RBC) transfusions. Zynteglo Clinical Edit – To be discussed today

NEW DRUGS – FISCAL EDITS

Common Trade Name	Ingredient Name	Indications
Hyftor 0.2% Gel	Sirolimus	<p>Indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.</p> <p>Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Clinical consultant review required
Igalmi 120mcg Sublingual Film Igalmi 180mcg Sublingual Film	Dexmedetomidine HCl	<p>Indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults.</p> <p>Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Clinical consultant review required
Pegasys 180mcg/0.5mL Syringe Pegasys 180mcg/0.5mL Vial	Peginterferon Alfa-2A	<p>Indicated for the treatment of:</p> <p>Chronic Hepatitis C (CHC)</p> <ul style="list-style-type: none"> • Adult Patients: In combination therapy with other hepatitis C virus drugs for adults with compensated liver disease. PEGASYS monotherapy is indicated only if patient has contraindication or significant intolerance to other HCV drugs. • Pediatric Patients: In combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease. <p>Chronic Hepatitis B (CHB)</p> <ul style="list-style-type: none"> • Adult Patients: Treatment of adults with HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation. • Pediatric Patients: Treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT). <p>Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Clinical consultant review required

NEW DRUGS – FISCAL EDITS

Common Trade Name	Ingredient Name	Indications
Pirfenidone 534mg Tablet	Pirfenidone	<p>Indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Must provide medical necessity as to why the participant cannot utilize two of the 267mg pirfenidone tablets.
Vivjoa 150mg Capsule	Oteseconazole	<p>Indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. Prior Authorization Required Fiscal Edit</p> <p>Approval Criteria:</p> <ul style="list-style-type: none"> • Documented diagnosis of RVVC defined as at least 3 VVC episodes within previous 12 months AND • Participant is not of reproductive potential defined as: <ul style="list-style-type: none"> • Participant is postmenopausal OR • Participant is aged at least 12 years and postmenarchal, but not of reproductive potential (i.e., history of tubal ligation, salpingo-oophorectomy, or hysterectomy) AND • Documented therapeutic six-month trial of oral fluconazole maintenance treatment <p>Dose opt of 18 tablets per year</p>
Zonisade 100mg/5ml Oral Suspension	Zonisamide	<p>Indicated as adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older. Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Must provide medical necessity as to why the participant cannot utilize generic zonisamide capsules.

NEW DRUGS – RESOURCE LIST EDITS

Common Trade Name	Ingredient Name	Indications
<p>Caplyta 10.5mg Capsule Caplyta 21mg Capsule</p>	<p>Lumateperone Tosylate</p>	<p>Indicated for the treatment of schizophrenia in adults or for the treatment of depressive episodes associated with bipolar I or II disorder in adults, as monotherapy and as adjunctive therapy with lithium or valproate. Antipsychotics – 2nd Generation (Atypicals) Oral and Transdermal Agents Resource List – Resource List B – To be discussed today</p> <ul style="list-style-type: none"> • Dose opt of 1 capsule per day
<p>Quetiapine 150mg Tablet</p>	<p>Quetiapine Fumarate</p>	<p>Indicated for the treatment of Schizophrenia, bipolar I disorder manic episodes, and bipolar disorder, depressive episodes. Antipsychotics – 2nd Generation (Atypicals) Oral and Transdermal Agents Resource List – Non-Resource – To be discussed today Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Must provide a letter of medical necessity as to why the participant cannot use the other strengths of quetiapine tablets.

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Aemcolo DR 194mg Tablet	Rifamycin Sodium	Indicated for the treatment of travelers' diarrhea caused by non-invasive strains of E.coli in adults. Antibiotics, Gastrointestinal (GI) Oral PDL Edit – Non-Preferred
Doryx MPC DR 60mg Tablet	Doxycycline Hyclate	Indicated for the treatment of rickettsial infections, sexually transmitted infections, respiratory tract infections, specific bacterial infections, ophthalmic infections, anthrax, malaria prophylaxis, adjunctive therapy for acute intestinal amebiasis and severe acne. Tetracyclines PDL Edit – Non-Preferred
Dyanavel XR 5mg Tablet Dyanavel XR 10mg Tablet Dyanavel XR 15mg Tablet Dyanavel XR 20mg Tablet	Amphetamine	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older. ADHD, Amphetamines Long Acting PDL Edit – Non-Preferred
Ibsrela 50mg Tablet	Tenapanor HCl	Indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults. GI Motility Agents, Chronic PDL Edit – Non-Preferred – To be discussed today • Requires therapeutic trial of 2 preferred agents AND 1 non-preferred agent in the PDL

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Quviviq 25mg Tablet Quviviq 50mg Tablet	Daridorexant HCl	Indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Sedative Hypnotics PDL Edit – Non-Preferred – To be discussed today • Requires therapeutic trial of 3 preferred agents AND Belsomra AND Dayvigo 15 Day Supply Fiscal Edit
Ryaltris 665-25mcg Spray	Olopatadine HCl/Mometasone	Indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. Corticosteroids and Rhinitis Agents, Intranasal PDL Edit – Non-Preferred
Sotyktu 6mg Tablet	Deucravacitinib	Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Targeted Immune Modulators, Select Agents PDL Edit – Non-Preferred
Spevigo 450mg/7.5mL Vial	Spesolimab-SBZO	Indicated for the treatment of generalized pustular psoriasis flares in adults. Targeted Immune Modulators, Select Agents PDL Edit – Non-Preferred
Tadliq 20mg/5mL Suspension	Tadalafil	Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. PAH Agents, PDE5 and SGC Stimulators PDL Edit – Non-Preferred

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Tascenso ODT 0.25mg Tablet	Fingolimod Lauryl Sulfate	Indicated for the treatment of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Multiple Sclerosis Agents, Oral PDL Edit – Non-Preferred
Vtama 1% Cream	Tapinarof	Indicated for the treatment of plaque psoriasis in adults. Psoriasis Agents, Topical PDL Edit – Non-Preferred • Requires therapeutic trial of 2 preferred agents AND Zoryve
Xaciato 2% Vaginal Gel	Clindamycin Phosphate	Indicated for the treatment of bacterial vaginosis in females 12 years and older. Antibiotics, Vaginal PDL Edit – Non-Preferred
Zoryve 0.3% Cream	Roflumilast	Indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. Psoriasis Agents, Topical PDL Edit – Non-Preferred • Dose opt of 1 tube per month

NEW DRUGS – STEP THERAPY

Common Trade Name	Ingredient Name	Indications
Injectafer 100mg/2mL Vial	Ferric Carboxymaltose	Indicated for the treatment of iron deficiency anemia (IDA) in: <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Dose opt of 28mL / 25 days

NEW DRUGS – OPEN ACCESS

Common Trade Name	Ingredient Name	Indications
Cimerli 0.3mg/0.05mL Vial Cimerli 0.5mg/0.05mL Vial	Ranibizumab-EQRN	Indicated for the treatment of: <ul style="list-style-type: none"> • Neovascular (Wet) Age-related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV)
Susvimo 10mg/0.1mL Kit	Ranibizumab/Initial Fill Needle	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 vascular endothelial growth factor (VEGF) inhibitor.
Xipere 40mg/mL Vial	Triamcinolone Acetonide/PF	Indicated for the treatment of macular edema associated with uveitis.

CLINICAL & FISCAL EDITS WITH NO ANNUAL CHANGES

- ▶ Aduhelm Clinical Edit
- ▶ Antipsychotics, 1st Generation (Typical) Clinical Edit
- ▶ Benzodiazepine, Select Oral Clinical Edit
- ▶ Butalbital Combinations without Codeine Clinical Edit
- ▶ Corlanor Clinical Edit
- ▶ Empaveli Clinical Edit
- ▶ HBV Nucleotide Analog Reverse Transcriptase Inhibitors Fiscal Edit
- ▶ High Risk Therapies Clinical Edit
- ▶ Kerendia Clinical Edit
- ▶ Morphine Milligram Equivalent (MME) Accumulation Clinical Edit
- ▶ Non-Oral Contraceptives Fiscal Edit
- ▶ Oxazolidinone Fiscal Edit
- ▶ Pompe Disease Clinical Edit
- ▶ Selzentry Clinical Edit
- ▶ Transmucosal Immediate Release Fentanyl (TIRF) Clinical Edit
- ▶ Verquvo Clinical Edit

PDL EDITS WITH NO ANNUAL CHANGES

- ▶ Alzheimer's Agents, AChEIs and NMDA Receptor Antagonists & Combinations PDL Edit
- ▶ Antiemetics, 5-HT₃ and NK₁ Injectables PDL Edit
- ▶ Antiemetics, 5-HT₃, NK₁ and Other Select Non-Injectables PDL Edit
- ▶ Anti-Migraine, Serotonin (5-HT₁) Receptor Agonists PDL Edit
- ▶ Anti-Parkinsonism, MAO-B Inhibitors PDL Edit
- ▶ Anti-Parkinsonism, Non-Ergot Dopamine Agonists PDL Edit
- ▶ Cyclin-Dependent Kinase (CDK) 4/6 Inhibitors PDL Edit
- ▶ Glucagon Agents PDL Edit
- ▶ Hereditary Angioedema Agents PDL Edit
- ▶ NSAIDs PDL Edit
- ▶ Opioid Emergency Reversal Agents PDL Edit
- ▶ Opioids, Long Acting PDL Edit
- ▶ Somatostatin Analogs PDL Edit
- ▶ Vesicular Monoamine Transporter 2 (VMAT₂) Inhibitors PDL Edit