



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

MHD PA COMMITTEE JUNE 16, 2022

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NEW DRUGS – CLINICAL EDITS

Common Trade Name	Ingredient Name	Indications
Besremi 500mcg/ml Syringe	Ropeginterferon Alfa-2b-NJFT	Indicated for the treatment of adults with polycythemia vera. Besremi Clinical Edit – To be discussed today
Carvykti 1X10 ⁸ Bag/Cassette	Ciltacabtagene Autoleucel	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. CAR T Cell Therapy Clinical Edit
Enjaymo 1,100mg/22ml Vial	Sutimlimab-jome	Indicated to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Enjaymo Clinical Edit – To be discussed today
Loreev XR 1.5mg Capsule	Lorazepam	Indicated for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets. Benzodiazepines (Select Oral) Clinical Edit Must provide a letter of medical necessity as to why participant cannot use the immediate release tablets.

NEW DRUGS – CLINICAL EDITS

Common Trade Name	Ingredient Name	Indications
Pyrukynd 5mg Tablet Pyrukynd 20mg Tablet Pyrukynd 20-5mg Tablet Pyrukynd 50mg Tablet Pyrukynd 50-20mg Tablet	Mitapivat	Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency. Enzyme Deficiency, Select Agents Clinical Edit – To be discussed today
Ryplazim 68.8mg Vial	Plasminogen, human-tvmh	Indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia). Enzyme Deficiency, Select Agents Clinical Edit – To be discussed today

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Adbry 150mg/ml Syringe	Tralokinumab-ldrm	Indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Respiratory Monoclonal Antibodies (RMA) PDL – Non-Preferred
Cabotegravir 400mg/2ml Vial Cabotegravir 600mg/3ml Vial	Cabotegravir	Indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 with no known or suspected resistance to either cabotegravir or rilpivirine. Antiretroviral Therapy PDL – Non-Preferred
Cibinqo 50mg Tablet Cibinqo 100mg Tablet Cibinqo 200mg Tablet	Abrocitinib	Indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors PDL – Non-Preferred <ul style="list-style-type: none"> • Dose opt of 1 tablet per day • Trial of Dupixent

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Descovy 120-15mg Tablet	Emtricitabine/Tenofovir Alafenamide	<p>Indicated in combination with other antiretroviral agents:</p> <ul style="list-style-type: none"> • For the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg. • Other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighting at least 14kg and less than 35kg. <p>Antiretroviral Therapy PDL – Non-Preferred</p>
Diclofenac Potassium 25mg Tablet	Diclofenac Potassium	<p>Indicated for the:</p> <ul style="list-style-type: none"> • Treatment of primary dysmenorrhea. • Relief of mild to moderate pain. • Relief of the signs and symptoms of osteoarthritis. • Relief of the signs and symptoms of rheumatoid arthritis. <p>NSAIDS PDL – Non Preferred Prior Authorization Required Fiscal Edit</p> <ul style="list-style-type: none"> • Must provide a letter of medical necessity as to why participant cannot use diclofenac sodium.
Fleqsuvy 25mg/5ml Suspension	Baclofen	<p>Indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.</p> <p>Skeletal Muscle Relaxants PDL Edit – Non Preferred</p> <ul style="list-style-type: none"> • Approval for children ≤ 10 years of age without a trial of a preferred agent.
Leqvio 284mg/1.5ml Syringe	Inclisiran	<p>Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).</p> <p>Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors PDL – Non Preferred</p> <ul style="list-style-type: none"> • Trial of Praluent and Reptha required (trial defined as 6 months of both).

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Mayzent 0.25mg Starter Tablet Mayzent 1mg Tablet	Siponimod	Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Multiple Sclerosis, Oral PDL – Non-Preferred
Releuko 300mcg/0.5ml Syringe Releuko 300mcg/ml Vial Releuko 480/0.8ml Syringe Releuko 480mcg/1.6ml Vial	Filgrastim-ayow	Indicated to: <ul style="list-style-type: none"> • Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti- cancer drugs associated with a significant incidence of severe neutropenia with fever. • Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML). • Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT). • Reduce the incidence and duration of sequelae of severe neutropenia, (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. Colony Stimulating Factors PDL – Non-Preferred
Rilpivirine 600mg/2 ml Vial Rilpivirine 900mg/3ml Vial	Rilpivirine	Indicated as a complete regimen for the treatment of HIV-1 infection in adults 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 with no known or suspected resistance to either cabotegravir or rilpivirine. Antiretroviral Therapy PDL – Non-Preferred

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Rinvoq ER 30mg Tablet Rinvoq ER 45mg Tablet	Upadacitinib	Indicated for the treatment of: <ul style="list-style-type: none"> Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Moderately to severely active ulcerative colitis in patient who have had an inadequate response or intolerance to one or more TNF blockers. Targeted Immune Modulators, Janus Kinase (JAK) Inhibitors PDL – Non-Preferred
Seglantis 56mg-44mg Tablet	Celecoxib/Tramadol HCl	Indicated for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Tramadol-Like Agents PDL – Non-Preferred Prior Authorization Required Fiscal Edit <ul style="list-style-type: none"> Must provide a letter of medical necessity as to why participant cannot use the single-ingredient products.
Takyzyro 300mg/2ml Syringe	Lanadelumab-flyo	Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older. Hereditary Angioedema Agents PDL – Preferred
Tezspire 210mg/1.91ml	Tezepelumab-ekko	Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Respiratory Monoclonal Antibodies (RMA) PDL – Non-Preferred
Twyneo 0.1%-3% Cream	Tretinoin/Benzoyl Peroxide	Indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older. Retinoids, Topical PDL – Non-Preferred

NEW DRUGS – PDL EDITS

Common Trade Name	Ingredient Name	Indications
Xarelto 1mg/ml Suspension	Rivaroxaban	<p>Indicated:</p> <ul style="list-style-type: none"> • To reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation. • For treatment of deep vein thrombosis (DVT). • For treatment of pulmonary embolism (PE). • For reduction in the risk of recurrence of DVT or PE. • For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. • For prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients. • To reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD). • To reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD. • For treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years. • For thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure. <p>Anticoagulants, Oral and Subcutaneous PDL – Non-Preferred</p> <ul style="list-style-type: none"> • Approval for children ≤ 10 years of age without a trial of a preferred agent.
Zimhi 5mg/0.5ml Syringe	Naloxone HCl	<p>Indicated in adult and pediatric patients for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.</p> <p>Opioid Emergency Reversal Agents PDL – Preferred</p>

NEW DRUGS – OPEN ACCESS

Common Trade Name	Ingredient Name	Indications
Korsuva 65mcg/1.3ml Vial	Difelikefalin Acetate	Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).
Nuwiq 1,500 Unit Vial	Antihemophilic Factor VIII [Recombinant]	Indicated in adults and children with Hemophilia A for: <ul style="list-style-type: none">• On-demand treatment and control of bleeding episodes.• Perioperative management of bleeding.• Routine prophylaxis to reduce the frequency of bleeding episodes.
Vabysmo 6mg/0.05ml Vial	Faricimab-svoa	Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME).

NEW DRUGS – PA CONTINUED

Common Trade Name	Ingredient Name	Indications
Recorlev 150mg Tablet	Levoketoconazole	<p>Indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing’s syndrome for whom surgery is not an option or has not been curative.</p> <p>Approval Criteria:</p> <ul style="list-style-type: none">• Participant aged 18 years or older AND• Prescribed by or in consultation with an endocrinologist or other appropriate specialist for the treated disease state AND• Documented diagnosis of Cushing’s syndrome AND• Documentation of failed pituitary surgery or reason pituitary surgery is not an option AND• Trial and documented reason why participant is unable to continue ketoconazole• Dose opt of 600mg twice daily

NEW DRUGS – PA CONTINUED

Common Trade Name	Ingredient Name	Indications
Sodium Sulfacetamide 10% Wash	Sulfacetamide Sodium	<p>Indicated for:</p> <ul style="list-style-type: none"> • Seborrheic dermatitis. • Seborrhea sicca (dandruff). • Treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides. <p>Approval Criteria:</p> <ul style="list-style-type: none"> • Trial and documented reason why participant is unable to use a more cost effective sodium sulfacetamide product.
Tarpeyo DR 4mg Capsule	Budesonide	<p>Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.</p> <p>Approval Criteria:</p> <ul style="list-style-type: none"> • Documented diagnosis of IgAN AND • Trial and failure of generic budesonide (Entocort) at 15-18mg daily dose (trial defined as 90 days) AND • Participants are currently receiving stable dose of an RAS inhibitor (ACE Inhibitor or ARB) at a maximum tolerated dose • Initial approval period: 9 months

NEW DRUGS – STEP THERAPY

Common Trade Name	Ingredient Name	Indications
Citalopram 30mg Capsule	Citalopram HBR	Indicated for treatment of major depressive disorder (MDD) in adults. Selective Serotonin Reuptake Inhibitor (SSRI) Step Therapy Edit – Non Reference Prior Authorization Required Fiscal Edit <ul style="list-style-type: none">• Must provide a letter of medical necessity as to why participant cannot use the tablets.

CLINICAL & FISCAL EDITS WITH NO ANNUAL CHANGES

- ▶ Ampyra
- ▶ Botulinum Toxin
- ▶ Crysvida
- ▶ Duchenne Muscular Dystrophy (DMD)
- ▶ Emsam
- ▶ Gamifant
- ▶ Immunoglobulin
- ▶ Koselugo
- ▶ Luxturna
- ▶ Narcolepsy Inhibitors
- ▶ Neuromyelitis Optica Spectrum Disorder (NMOSD)
- ▶ Nuedexta
- ▶ Oxandrin
- ▶ Palforzia
- ▶ Palynziq
- ▶ Ranexa
- ▶ Reblozyl
- ▶ Selective Serotonin Reuptake Inhibitors (SSRI)
- ▶ Synagis
- ▶ Tepezza
- ▶ Tolvaptan
- ▶ Transthyretin-Mediated Amyloidosis (ATTR)
- ▶ Xcopri
- ▶ Zometa