P&T Committee Changes
Effective 1/1/2023

EmpiRx Health is committed to providing the highest quality service, innovative clinical solutions, and valuable trend management strategies. The EmpiRx Health Pharmacy and Therapeutics (P&T) Committee continually reviews the latest information available to keep our clinical rules and programs up to date to improve care and reduce costs.

As a result of detailed discussions regarding each medication, its indications, FDA guidelines, and potential member safety issues, the following changes have been approved.

Additions to the Clinical Review List

For your reference, we have included the Therapeutic Category as well as the medication use.

KONVOMEP (omeprazole and sodium bicarbonate)

- A combination of a proton pump inhibitor (PPI) and sodium bicarbonate.
- Indicated in adults for treatment of active benign gastric ulcer, and for reduction of risk of upper gastrointestinal bleeding in critically ill patients.
- It is administered orally once daily.
- It is contraindicated in patients receiving rilpivirine-containing products.
- There are warnings for gastric malignancy, acute tubulointerstitial nephritis, sodium content, clostridium difficile- associated diarrhea, bone fracture, severe cutaneous adverse reactions, cutaneous and systemic lupus erythematosus, interaction with clopidogrel, cyanocobalamin deficiency, hypomagnesemia and mineral metabolism, interactions with St. John's Wort or rifampin, interactions with diagnostic investigations for neuroendocrine tumors, interaction with methotrexate, and fundic gland polyps.

Additions to the Specialty Medication and Standard Clinical Review Lists

For your reference, we have included the Therapeutic Category as well as the medication use.

DAXXIFY (botulinum toxin type a)

- An acetylcholine release inhibitor and neuromuscular blocking agent.
- Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.
- It is administered via intramuscular injection only.
- It is contraindicated in patients with hypersensitivity, and infection at injection site.
- There is a black box warning for distant spread of toxin effect.
- There are additional warnings for serious adverse reactions with unapproved use, hypersensitivity reactions, cardiovascular system, pre- existing neuromuscular disorders, dysphagia and breathing difficulties, pre- existing conditions at the injection site, and ophthalmic adverse reactions.

LYTGOBI (futibatinib)

- A kinase inhibitor.
- Indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

- It is administered orally once daily.
- There are warnings for ocular toxicity, hyperphosphatemia, and embryo-fetal toxicity.

RELYVRIO (sodium phenylbutyrate and taurursodiol)

- A combination histone deacetylase inhibitor and hydrophilic bile acid.
- Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.
- It is administered twice daily orally or via feeding tube.
- There are warnings in patients with enterohepatic circulation disorders, pancreatic disorders, or intestinal disorders and use in patients sensitive to high sodium intake.

ROLVEDON (eflapegrastim-xnst)

- A granulocyte colony-stimulating factor (G-CSF).
- Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
- It is administered as a single subcutaneous injection once per chemotherapy cycle.
- There are warnings for splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell crisis in patients with sickle cell disorders, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, myelodysplastic syndrome and acute myeloid leukemia in patients with breast and lung cancer, aortitis, and nuclear imaging.

SKYSONA (elivaldogene autotemcel)

- An autologous HSC-based gene therapy.
- Indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD).
- It is administered as a single dose for intravenous use only.
- There is a black box warning for hematologic malignancy.
- There are additional warnings for serious infections, prolonged cytopenias, delayed platelet engraftment, risk of neutrophil engraftment failure, hypersensitivity reactions, anti-retroviral use, and laboratory test interference.

SOTYKTU (deucravacitinib)

- A tyrosine kinase 2 (TYK2) inhibitor.
- Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- It is administered orally once daily, with or without food.
- There are warnings for infections, tuberculosis, malignancy including lymphomas, rhabdomyolysis and elevated CPK, laboratory abnormalities, immunizations, and potential risks related to JAK inhibition.

SPEVIGO (spesolimab-sbzo)

- An interleukin-36 receptor antagonist.
- Indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults.
- It is administered as a single 900 mg dose by intravenous infusion over 90 minutes.
- There are warnings for infections, risk of tuberculosis, hypersensitivity and infusion-related reactions, and vaccinations.

TERLIVAZ (terlipressin)
- A vasopressin receptor agonist.
- Indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.
- It is administered via intravenous bolus injection.
- It is contraindicated in patients experiencing hypoxia or worsening respiratory symptoms, and in patients with ongoing coronary, peripheral, or mesenteric ischemia.
- There is a black box warning for serious or fatal respiratory failure.
- There are additional warnings for ineligibility for liver transplant, ischemic events, and embryo-fetal toxicity.

XENPOZYME (olipudase alfa-rpcp)
- A hydrolytic lysosomal sphingomyelin-specific enzyme.
- Indicated for the treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.
- It is administered via intravenous infusion every 2 weeks.
- There is a black box warning for severe hypersensitivity reactions.
- There are additional warnings for hypersensitivity reactions including anaphylaxis, infusion-associated reactions, elevated transaminases levels, and risk of fetal malformations during dosage initiation or escalation in pregnancy.

ZYNTEGLO (betibeglogene autotemcel)
- A βA-T87Q-globin gene therapy.
- Indicated for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions.
- It is administered as a single dose intravenous infusion for autologous use only.
- There are warnings for delayed platelet engraftment, risk of neutrophil engraftment failure, risk of insertional oncogenesis, hypersensitivity reactions, anti- retroviral and hydroxyurea use, and interference with serology testing.

Additions to the Quantity Limit List

For your reference, we have included the generic name and dosage along with the appropriate quantity.

New Quantity Limits:

ASPRUZYO SPRINKLE (Ranolazine ER Granules Packet)
- 60 per 30 days

AUVELITY (Dextromethorphan HBr-Bupropion HCl Tab ER 45-105 MG)
- 60 per 30 days

GLEEVEC 100 MG (Imatinib Mesylate Tab 100 MG)
- 90 per 30 days

GLEEVEC 400 MG (Imatinib Mesylate Tab 400 MG)
- 30 per 30 days

NORLIQVA (Amlodipine Besylate Oral Soln 1 MG/ML)

- 300 per 30 days

PROAIR DIGIHALER (Albuterol Sulfate Aer Pow BA 108 MCG/ACT with sensor)
- 1 per 30 days

RADICAVA ORS (Edaravone Oral Susp 105 MG/5ML)
- 50 per 28 days

RADICAVA ORS STARTER KIT (Edaravone Oral Susp 105 MG/5ML)
- 70 per 28 days

RYALTRIS (Olopatadine HCl-Mometasone Furoate Nasal Susp 665-25 MCG/ACT)
- 29 per 30 days

SKYRIZI CARTRIDGE (Risankizumab-rzaa Subcutaneous Soln Cartridge 360 MG/2.4ML)
- 2.4 per 56 days

SKYRIZI IV SOLUTION (Risankizumab-rzaa IV Soln 600 MG/10ML (60 MG/ML))
- 30 per 84 days

TASCENSO ODT (Fingolimod Lauryl Sulfate Tablet Disintegrating 0.25 MG)
- 30 per 30 days

VOQUEZNA DUAL PAK (Amoxicillin Cap 500 MG & Vonoprazan Tab 20 MG Therapy Pack)
- 112 per 14 days

VOQUEZNA TRIPLE PAK (Amoxicillin Cap & Clarithromycin Tab & Vonoprazan Tab Pack)
- 112 per 14 days

Changes to the Quantity Limit List:

REVLIMID 2.5 MG (Lenalidomide Caps 2.5 MG)
- Increased from 21 per 28 days to 28 per 28 days

Additions to the Step Therapy List

New Standard Algorithms:

NITRATES (Angina Pectoris)
- Isosorbide dinitrate (excluding the 40mg strength) is a 1st line medication.
- Isosorbide dinitrate 40mg is a 2nd line medication.

Updates to Current Standard Algorithms:

GLP-1 AGONISTS (Diabetes)
- Rybelsus added as a 1st line medication.
- Mounjaro added as a 3rd line medication.
    - It is directed to Ozempic or Rybelsus AND Trulicity.

ULCER THERAPY COMBINATIONS (Ulcer/GERD)
- Voquezna added as a 2nd line medication.

SLEEP AIDS (Insomnia)
- Dayvigo and Belsomra added as 1st line medications.
- Quviviq added as a 2nd line medication.

CACHEXIA (Cachexia)
- Megestrol suspension 625mg/5mL moved from a 1st to a 2nd line medication.

RANEXA (Chronic Angina)
- Aspruzyo added as a 2nd line medication.

BILE ACID SEQUESTRANTS (Cholesterol)
- Cholestyramine powder packets and light powder packets, Questran, and Prevalite added as 2nd line medications.

SHORT ACTING ANALGESICS (Pain)
- Roxybond added as a 2nd line medication.

TRIPTANS (Migraines)
- Zolmitriptan ODT moved from a 1st to a 2nd line medication.

TOPICAL ANTI-INFLAMMATORY (Inflammation)
- Diclofenac 2% solution added as a 2nd line medication.

TOPICAL PLAQUE PSORIASIS (Plaque Psoriasis)
- Vtama and Zoryve added as 2nd line medications.

NSAID OPHTHALMICS (Ocular Inflammation)
- Bromfenac moved from a 1st to a 2nd line medication.

ROSACEA (Rosacea)
- Epsolay added as a 2nd line medication.

GLUCOCORTICOSTEROIDS (Inflammation)
- Prednisone solution 5mg/mL added as a 1st line medication.
- Prednisone intensol 5mg/mL added as a 2nd line medication.

New Specialty Algorithms:

CYCLIN-DEPENDENT KINASE (CDK) INHIBITORS (Advanced or metastatic breast cancer)
- Ibrance and Verzenio are 1st line medications.
- Kisqali and Kisqali Femara Co-Pack are 2nd line medications.

LEFLUNOMIDE (Rheumatoid Arthritis)
- Leflunomide is a 1st line medication.
- Arava is a 2nd line medication.

LEUCOVORIN (Leucovorin)

- Leucovorin solution and leucovorin tablets (excluding the 10mg strength) are 1st line medications.
- Leucovorin 10mg tablet is a 2nd line medication.

PENICILLAMINE (Chelating Agent)

- Penicillamine tablet 250mg is a 1st line medication.
- Penicillamine capsule 250mg is a 2nd line medication.

RANIBIZUMAB (VEGF Inhibitors)

- Byooviz is a 1st line medication.
- Lucentis is a 2nd line medication.

Updates to Current Specialty Algorithms:

COLONY STIMULATING FACTOR (PEGFILGRASTIM) (Hematopoietic Agents)

- Fulphila moved from a 2nd to a 1st line medication.
- Nyvepria moved from a 1st to a 2nd line medication.

PULMONARY ARTERIAL HYPERTENSION - INHALED PROSTACYCLIN (PAH)

- Tyvaso DPI moved from a 1st to a 2nd line medication.