P&T Committee Changes
Effective 10/1/2023

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 Specialty Medication and Standard Clinical Review List

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

BEYFORTUS (nirsevimab)

- A respiratory syncytial virus (RSV) F protein-directed fusion inhibitor.
- Indicated for the prevention of RSV lower respiratory tract disease in:
    - Neonates and infants born during or entering their first RSV season.
    - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

BRIXADI (buprenorphine)

- A partial opioid agonist.
- Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.
- There is a black box warning for risk of serious harm or death with intravenous administration; Brixadi risk evaluation, and mitigation strategy.

COLUMVI (glofitamab)

- A bispecific CD20-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.
- There is a black box for cytokine release syndrome.

ELEVIDYS (delandistrogene moxeparvovec-rokl)

- An adeno-associated virus vector-based gene therapy.
- Indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.
- There are warnings for acute serious liver injury, immune-mediated myositis, myocarditis, and pre-existing immunity against AAVrh74.

ELFABRIO (pegunigalsidase alfa)
- A hydrolytic lysosomal neutral glycosphingolipid-specific enzyme.
- Indicated for the treatment of adults with confirmed Fabry disease.
- There is a black box warning for hypersensitivity reactions including anaphylaxis.

EPKINLY (epcoritamab-bysp)
- A bispecific CD20-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.
- There is a black box warning for cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome.

IZERVAY (avacincaptad pegol)
- A complement inhibitor.
- Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

LANTIDRA (donislecel-jujn)
- An allogeneic pancreatic islet.
- Indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use in conjunction with concomitant immunosuppression.
- There are warnings for procedural complications, increased risk of islet graft rejection, transmission of donor-derived infections, and panel reactive Antibodies (PRA).

LITFULO (ritlecitinib)
- A kinase inhibitor.
- Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
- It is taken 50 mg orally once daily with or without food.
- There is a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.

NGENLA (somatrogon-ghla)
- A human growth hormone analog.
- Indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.
- There are warnings for severe hypersensitivity, increased risk of neoplasms, glucose intolerance and diabetes mellitus, intracranial hypertension, fluid retention, hypoadrenalism, hypothyroidism, slipped capital femoral epiphysis, progression of preexisting scoliosis, pancreatitis, lipoatrophy, and laboratory tests.

ROCTAVIAN (valoctocogene roxaparvovec-rvox)
- An adeno-associated virus (AAV) vector-based gene therapy product.
- Indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

- There are warnings for infusion-related reactions, hepatotoxicity, thromboembolic events, monitoring laboratory tests, and malignancy.

RYSTIGGO (rozanolixizumab-noli)
- A neonatal Fc receptor blocker.
- Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive.
- There are warnings for infections, aseptic meningitis, and hypersensitivity reactions.

VANFLYTA (quizartinib)
- A kinase inhibitor.
- Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.
- There are black box warnings for QT prolongation, Torsades de Points, and cardiac arrest.

VYJUVEK (beremagene geperpavec-svdt)
- A suspension of a HSV-1 vector-based gene therapy.
- Indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the *collagen type VII alpha 1 chain* (*COL7A1*) gene.
- There is a warning for accidental exposure to VYJUVEK.
- Women who are pregnant should not prepare, administer, or receive VYJUVEK. Women of childbearing potential should use an effective method of contraception during treatment.

VYVGART HYTRULO (efgartigimod alfa and hyaluronidase)
- A combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase.
- Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- There are warnings for infections and hypersensitivity reactions.

XACDURO (sulbactam and durlobactam)
- A co-packaged product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, a beta lactamase inhibitor.
- Indicated in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
    - It is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
- There are warnings for hypersensitivity reactions, *Clostridioides difficile*-associated diarrhea (CDAD), and development of drug-resistant bacteria.

YCANTH (cantharidin)

- A topical solution containing 7 mg of active ingredient cantharidin (0.7%), a lipophilic compound.
- Indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.
- There are warnings for infections and hypersensitivity reactions.

Additions to the Standard Clinical Review List

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

LODOCO (colchicine)

- An alkaloid.
- Indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease.
- There are warnings for blood dyscrasias and neuromuscular toxicity.

MIEBO (perfluorohexyloctane)

- A semifluorinated alkane.
- Indicated for treatment of the signs and symptoms of dry eye disease.
- There is a warning for use with contact lenses.

SKINVIVE (hyaluronic acid with lidocaine)

- A sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colorless, homogeneous gel implant consisting of hyaluronic acid (HA) produced by *Streptococcus* species of bacteria crosslinked with 1,4-butanediol diglycidyl ether (BDDE) formulated to a concentration of 12 mg/mL with 0.3% w/w lidocaine in a physiologic buffer.
- Indicated for intradermal injection to improve skin smoothness of the cheeks in adults over the age of 21.
- There are warnings for injecting into the vasculature, injecting into sites with an active inflammatory process, and use only by health care professionals who have appropriate training and experience.

VEOZAH (fezolinetant)

- A neurokinin 3 (NK3) receptor antagonist.
- Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.
- There is a warning for hepatic transaminase elevation.

VEVYE (cyclosporine)

- A calcineurin inhibitor immunosuppressant.
- Indicated for the treatment of the signs and symptoms of dry eye disease.
- It is instilled by one drop of VEVYE twice a day in each eye approximately 12 hours apart. If used with other eye drops, a 15-minute interval between products should occur.
- There are warnings for potential eye injury and contamination and use with contact lenses.

XDEMVY (lotilaner)

- An ectoparasiticide (anti-parasitic).
- Indicated for the treatment of Demodex blepharitis.
- There are warnings for the risk of contamination and use with contact lenses.

ZURZUVAE (zuranolone)

- A neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator.
- Indicated for the treatment of postpartum depression (PPD) in adults.
- There are warnings for CNS depressant effects, suicidal thoughts and behavior, and embryo fetal toxicity.

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:

ATORVALIQ (Atorvastatin Calcium Susp)

- 600 per 30 days

FILSPARI (Sparsentan Tab)

- 30 per 30 days

INPEFA (Sotagliflozin Tab)

- 30 per 30 days

LODOCO (Colchicine Tab)

- 30 per 30 days

MIEBO (Perfluorohexyloctane Ophth Soln)

- 3 per 30 days

OPVEE (Nalmefene Nasal Spray)

- 4 per 30 days

TEZSPIRE AUTO-INJECTOR (Tezepelumab-ekko Subcutaneous Soln Auto-Inj)

- 1.91 per 28 days

VEOZAH (Fezolinetant Tab)

- 30 per 30 days

VEVYE (Cyclosporine Ophth Soln)

- 60 per 30 days

ZURZUVAE (Zuranolone Cap)

- 14 per 365 days

Step Therapy Changes

Updates to Current Standard Algorithms:

ANTI-INFLAMMATORY (Inflammation)

- Diclofenac 25mg tablets moved from a 1st to a 2nd line medication.

ANTI-INFLAMMATORY - CELEBREX (Inflammation)

- Deleted algorithm and added Celebrex to the Anti-Inflammatory algorithm. It remains a 2nd line medication; however, it now requires trial and failure of two step 1 medications instead of one.

TOPICAL CLINDAMYCIN (Acne)

- Aczone removed from the algorithm. It remains a 2nd line medication on the Dapsone algorithm.

BOWEL PREP (Colonoscopy)

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

ANTICOAGULANTS (Anticoagulant)

- Updated the instructions on the algorithm to state that the Pradaxa **pellets** should be directed to Xarelto only.

MULTIVITAMIN/FOLIC ACID COMBINATION (Vitamin Deficiency)

- Keyfolic, Folamax, Profola, and Dayavite added as 2nd line medications.

Updates to Current Specialty Algorithms:

KUVAN (Hyperphenylalaninemia)

- Sapropterin tablets and packets are 1st line medications.
- Kuvan and Javygtor are 2nd line medications.

Updates to Current Specialty Algorithms:

HIV (HIV)

- Sunlenca added as a 2nd line medication.

MULTIPLE SCLEROSIS - INJ IMMUNOMODULATORS (Multiple Sclerosis)

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

INFERTILITY - CHORIONIC GONADATROPIN (Infertility)

- Novarel moved from a 1st to a 2nd line medication.
- Pregnyl moved from a 2nd to a 1st line medication.

BEVACIZUMAB (VEGF Inhibitors)

- Vegzelma added as a 2nd line medication.

IMMUNOLOGICALS - ANTI-INTERLEUKIN (IL)-5 AGENTS (Asthma)

- Updated disease state on algorithm from “Asthma” to “Asthma Immunotherapies”.
- Tezspire added as a 2nd line medication.

NARCOLEPSY (Narcolepsy)

- Renamed algorithm from “Narcolepsy” to “Narcolepsy – Sodium Oxybate”.
- Xywav added as a 1st line medication.

HUMIRA (Adalimumab)

- Hadlima and adalimumab-fkjp (unlabeled Hulio) added as 1st line medications.
- Cyltezo, Hyrimoz, Hulio (label), Idacio, Yuflyma, and Yusimry added as 2nd line medications.

AUTOIMMUNE INFLAMMATION (Inflammatory Conditions)

- Added the following statement to the "Rules" column of this algorithm:
    - Humira and its biosimilars Hadlima and adalimumab-fkjp (unlabeled Hulio) are all Step 1 agents. ALL other Humira biosimilars are non-preferred.