

**NEW DRUG REVIEWS FOR 3/21/2019 PRIOR AUTHORIZATION MEETING**

COMMON TRADE NAME	GENERIC NAME	INDICATIONS
<b>CLINICAL EDITS FOR IMPLEMENTATION</b>		
Epidiolex 100mg/ml Solution	Cannabidiol (CBD) Extract	Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
Nocdurna 25mcg Sublingual Tablet Nocdurna 50mcg Sublingual Tablet	Desmopressin Acetate	a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
Sympazan 5mg Film Sympazan 10mg Film Sympazan 20mg Film	Clobazam	A benzodiazepine indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.
Tegsedi 284mg/1.5ml Syringe	Inotersen Sodium	A transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.
Tolsura 65mg Capsule	Itraconazole	An azole antifungal indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients: <ul style="list-style-type: none"> <li>• Blastomycosis, pulmonary and extra pulmonary</li> <li>• Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and</li> <li>• Aspergillosis, pulmonary and extra pulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.</li> </ul>
Xolair 75mg/0.5ml Syringe Xolair 150mg/ml Syringe	Omalizumab	An anti-IgE antibody indicated for: <ul style="list-style-type: none"> <li>• Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.</li> <li>• Chronic idiopathic urticarial in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.</li> </ul>
<b>OPEN ACCESS</b>		
Albuminex 5% Vial Albuminex 25% Vial	Albumin Human-Kjda	A albumin solution indicated for adults and children: <ul style="list-style-type: none"> <li>• Hypovolemia</li> <li>• Ascites</li> <li>• Hypoalbuminemia including from burns</li> <li>• Acute Nephrosis</li> <li>• Acute Respiratory Distress Syndrome (ARDS)</li> <li>• Cardiopulmonary Bypass</li> </ul>
Arsenic Trioxide 10mg/10ml Vial	Arsenic Trioxide	indicated: <ul style="list-style-type: none"> <li>• In combination with tretinoin for treatment of adults with newly-diagnosed low-risk acute promyelocytic leukemia (APL) whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.</li> <li>• For induction of remission and consolidation in patients with APL who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.</li> </ul>

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Cequa 0.09% Droperette	Cyclosporine	A calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).
Dexmedetomidine-D5W 200mcg/50ml Plast Bag Dexmedetomidine-D5W400mcg/100ml Plast Bag	Dexmedetomidine in Dextrose 5%	Indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Also indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.
Granix 300mcg/ml Vial Granix 480mcg/1.6ml Vial	Tbo-Filgrastim	A leukocyte growth factor indicated for the reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
Libtayo 350mg/7ml Vial	Cemiplimab-Rwlc	A programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.
Lumoxiti 1mg Vial Lumoxiti IV Solution Stabilizer Vial	Moxetumomab Pasudotox-Tdfk	A CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).
Panzyga 10% Vial	Immune Glob G(IgG)-Ifas/Glycine	An immune globulin intravenous (human) - ifas 10% liquid preparation indicated for the treatment of: <ul style="list-style-type: none"> <li>• Primary humoral immunodeficiency (PI) in patients 2 years of age and older.</li> <li>• Chronic immune thrombocytopenia (ITP) in adults.</li> </ul>
Vancomycin HCL 1.5G Vial	Vancomycin HCL	A glycopeptide antibacterial indicated in adult and pediatric patients (neonates and older) for the treatment of : <ul style="list-style-type: none"> <li>• Septicemia</li> <li>• Infective Endocarditis</li> <li>• Skin and Skin Structure Infections</li> <li>• Bone Infections</li> <li>• Lower Respiratory Tract Infections</li> </ul>
Xospata 40mg Tablet	Gilteritinib Fumarate	A kinase inhibitor indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test.
Zortress 1mg Tablet	Everolimus	An mTOR inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in adult patients: <ul style="list-style-type: none"> <li>• Kidney Transplant: at low-moderate immunologic risk. Use in combination with basiliximab, cyclosporine (reduced doses) and corticosteroids.</li> <li>• Liver Transplant: Administer no earlier than 30 days post transplant. Use in combination with tacrolimus (reduced doses) and corticosteroids.</li> </ul>

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<b>PDL EDITS FOR IMPLEMENTATION</b>		
Actemra Actpen 162mg/0.9ml Pen	Tocilizumab	<p>An interleukin-6 (IL-6) receptor antagonist indicated for treatment of:</p> <ul style="list-style-type: none"> <li>• Rheumatoid Arthritis (RA) - Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).</li> <li>• Giant Cell Arteritis (GCA) - Adult patients with giant cell arteritis.</li> <li>• Polyarticular Juvenile Idiopathic Arthritis (PJIA) - Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.</li> <li>• Systemic Juvenile Idiopathic Arthritis (SJIA) - Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.</li> <li>• Cytokine Release Syndrome (CRS) - Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.</li> </ul> <p><b>Targeted Immune Modulators PDL - Non Preferred</b></p>
Altreno 0.05% Lotion	Tretinoin	<p>A retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.</p> <p><b>Topical Retinoids PDL</b></p>
Arikayce 590 mg/8.4ml Vial	Amikacin Liposomal/Neb Accessr	<p>An aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.</p> <p><b>Antibiotic Agents – Inhaled PDL</b></p>
Bryhali 0.01% Lotion	Halobetasol Propionate	<p>Indicated for the topical treatment of plaque psoriasis in adult patients.</p> <p><b>Corticosteroids – Topical PDL - Non Preferred</b></p>
Dupixent 200mg/1.14ml Syringe	Dupilumab	<p>An interleukin-4 receptor alpha antagonist indicated:</p> <ul style="list-style-type: none"> <li>• for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.</li> <li>• as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.</li> </ul> <p><b>Atopic Dermatitis Agents (Immunomodulators) PDL</b></p>
Emgality 120mg/ml Pen	Galcanezumab-Gnlm	<p>A calcitonin-gene related peptide antagonist indicated for the preventive treatment of migraine in adults.</p> <p><b>Calcitonin Gene-Related Peptide (CGRP) PDL</b></p>
Lexette 0.05% Foam	Halobetasol Propionate	<p>Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.</p> <p><b>Corticosteroids – Topical PDL - Non Preferred</b></p>
Tresiba 100u/ml Vial	Insulin Degludec	<p>A long-acting human insulin analog indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.</p> <p><b>Insulins - Long Acting PDL - Non Preferred</b></p>

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Xarelto 2.5mg Tablet	Rivaroxaban	<p>A factor Xa inhibitor indicated:</p> <ul style="list-style-type: none"> <li>• to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation</li> <li>• for the treatment of deep vein thrombosis (DVT)</li> <li>• for the treatment of pulmonary embolism (PE)</li> <li>• for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months</li> <li>• for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery</li> <li>• in combination with aspirin, to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).</li> </ul> <p><b>Anticoagulant Agents – Oral and Subcutaneous PDL - Preferred</b></p>
Xelpros 0.005% Ophthalmic Drop	Latanoprost	<p>A prostaglandin F2<math>\alpha</math> analog indicated for reduction of elevated intraocular pressure in patients with open-angle glaucoma, or ocular hypertension.</p> <p><b>Prostaglandin Agonists Ophthalmic Agents PDL - Non Preferred</b></p>
Xerava 50mg Vial	Eravacycline Di-Hydrochloride	<p>A tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older.</p> <p><b>Tetracyclines PDL</b></p>
Xyosted 50mg/0.5ml Auto-Inj Xyosted 75mg/0.5ml Auto-Inj Xyosted 100mg/0.5ml Auto-Inj	Testosterone Enanthate	<p>An androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.</p> <p><b>Testosterone Replacement Therapy PDL - Non Preferred</b></p>
Yupelri 175mcg/3ml Vial-Neb	Revefenacin	<p>An anticholinergic indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).</p> <p><b>COPD Anticholinergic Agents PDL</b></p>
<b>PRIOR AUTHORIZATION</b>		
Khapzory 175mg Vial Khapzory 300mg Vial	Levoleucovorin	<p>A folate analog indicated for:</p> <ul style="list-style-type: none"> <li>• Rescue after high-dose methotrexate therapy in patients with osteosarcoma.</li> <li>• Diminishing the toxicity associated with over dosage of folic acid antagonists or impaired methotrexate elimination.</li> <li>• Treatment of patients with metastatic colorectal cancer in combination with fluorouracil.</li> </ul> <p><b>Clinical Review - Physician must provide documentation as to why generic Fusilev (Levoleucovorin Calcium) cannot be used.</b></p>
Omegaven 10gm/100ml Emulsion	Fatty Acid6/Fish Oil/Gly/P-Lip	<p>Indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC).</p>
Qbrexza 2.4% Towelette	Glycopyrronium Tosylate	<p>An anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.</p>

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Revcovi 2.4mg/1.5ml Vial	Elapegedemase-Lvlr	A recombinant adenosine deaminase indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.
Siklos 1000mg Tablet	Hydroxyurea	An antimetabolite, indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises. <b>Trial of generic Hydroxyurea required.</b>
Tiglutik 50mg/10ml Suspension	Riluzole	Indicated for the treatment of amyotrophic lateral sclerosis.
Tirosint 175mcg Capsule Tirosint 200mcg Capsule	Levothyroxine Sodium	indicated for adults and pediatric patients 6 years and older with: <ul style="list-style-type: none"> <li>• Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism</li> <li>• Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.</li> </ul> <b>Trial of Synthroid or generic Synthroid of 90 out of 120 days, or documented evidence of adverse drug reaction to Synthroid or generic Synthroid.</b>
Ultomiris 300mg/30ml Vial	Ravulizumab-Cwvz	A complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). <b>Trial of Soliris</b>
Xofluza 20mg Tablet Xofluza 40mg Tablet	Baloxavir Marboxil	A polymerase acidic (PA) endonuclease inhibitor indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours.