pharmpiX

RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.
From: OCTOBER 2017

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Pharmacy
Benefit
Management
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NEWS……

- No security warning published during October 2017.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ascor™ (ascorbic acid) Injection, for intravenous use / McGuff Pharmaceuticals, Inc.	Vitamin C	Short term treatment (up to 1 week) of scurvy in adult and pediatric patients age 5 months and older for whom oral administration is not possible, insufficient or contraindicated.	10/02/2017	**DOSAGE AND ADMINISTRATION** • For pediatric patients age 5 months to less than 12 months: 50 mg once daily. • For pediatric patients age 1 year to less than 11 years: 100 mg once daily. • For adults and pediatric patients age 11 years and older: 200 mg once daily. Administer as a slow intravenous infusion. Maximum recommended duration is one week. **DOSAGE FORMS AND STRENGTHS** Injection: 25,000 mg/50 mL (500 mg/mL) – Pharmacy Bulk Package. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Administration**: Not intended for long-term use. • **Hematologic:** Hemolysis has been reported in patients with glucose-6-phosphate dehydrogenase deficiency. Reduced dosage and monitoring recommended; discontinuation may be necessary. • **Laboratory:** Interference in laboratory testing, including blood and urine glucose testing, nitrite and bilirubin levels, and leucocyte count testing, may occur; delay tests based on oxidation-reduction reaction until 24 hours after infusion. • **Renal:** (1) Acute and chronic oxalate nephropathy have been reported with long-term administration of high doses; increased risk in patients with renal disease including renal impairment, history of oxalate kidney stones, geriatric patients, and pediatric patients less than 2 years of age. Monitoring recommended and discontinuation may be necessary. (2) Acidification of urine may occur and lead to precipitation of cysteine, urate, or oxalate stones

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ascor™ (ascorbic acid) Injection, for intravenous use / McGuff Pharmaceuticals, Inc. (continuation)	Vitamin C	Short term treatment (up to 1 week) of scurvy in adult and pediatric patients age 5 months and older for whom oral administration is not possible, insufficient or contraindicated.	10/02/2017	**ADVERSE REACTIONS** Most common adverse reactions: pain and swelling at the site of infusion. **DRUG INTERACTIONS** • **Antibiotics:** Ascorbic acid may decrease the activities of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin. Bleomycin is inactivated in vitro by ascorbic acid. • **Amphetamine and Other Drugs Affected by Urine Acidification:** Ascorbic acid may cause acidification of the urine and result in decreased amphetamine serum levels and affect excretion and plasma concentrations of other drugs sensitive to urine pH. • **Warfarin:** Continue standard monitoring. **USE IN SPECIFIC POPULATIONS** • **Pregnancy and Lactation:** Should not exceed the U.S. Recommended Dietary Allowance (RDA) or daily Adequate Intake (AI) level for ascorbic acid for their age group and condition. • **Pediatric use:** The safety profile of ascorbic acid in pediatric patients is similar to adults; however, pediatric patients less than 2 years of age may be at higher risk of oxalate nephropathy following ascorbic acid administration due to age-related decreased glomerular filtration [see Warnings and Precautions. Ascor is not indicated for use in pediatric patients less than 5 months of age. • **Geriatric use:** Glomerular filtration rate is known to decrease with age and as such may increase risk for oxalate nephropathy following ascorbic acid administration in elderly population. • **Renal Impairment:** Use with caution in patients with history of or risk of renal oxalate stones or evidence of renal impairment or other issues (e.g., patients on dialysis, patients with diabetic nephropathy, and renal transplant recipients).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zilretta™ (triamcinolone acetonide) Sustained-Release Intra-Articular Injection / Flexion Therapeutics, Inc.	Corticosteroid	Management of osteoarthritis pain of the knee. **Limitation of Use** Not intended for repeat administration.	10/06/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 32 mg administered as a single intra-articular injection in the knee. **DOSAGE FORMS AND STRENGTHS** Injectable suspension: Delivers 32 mg of triamcinolone acetonide. Supplied as a single-dose kit containing one vial of Zilretta™ microsphere powder, one vial of 5 mL diluent, and one sterile vial adapter. **CONTRAINDICATIONS** • Concomitant administration of live or live, attenuated vaccines. • Hypersensitivity to triamcinolone acetonide or any other component of the product. • IM injection for idiopathic thrombocytopenic purpura. • Primary treatment for status asthmaticus or acute asthma. **WARNINGS AND PRECAUTIONS** • **Intra-articular Use Only:** Do not administer by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. • **Serious Neurologic Adverse Reactions with Epidural and Intrathecal Administration:** Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use. • **Hypersensitivity Reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care upon occurrence of an anaphylactic reaction. • **Joint Infection and Damage:** May cause joint pain accompanied by joint swelling. If this occurs, conduct appropriate evaluation to exclude septic arthritis and institute appropriate antimicrobial therapy if septic arthritis is confirmed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zilretta™ (triamcinolone acetonide) Sustained-Release Intra-Articular Injection / Flexion Therapeutics, Inc. (continuation)	Corticosteroid	Management of osteoarthritis pain of the knee. **Limitation of Use** Not intended for repeat administration.	10/06/2017	**ADVERSE REACTIONS** Most common adverse reactions: sinusitis, cough and contusions. **DRUG INTERACTIONS** No drug-drug interaction studies have been conducted with Zilretta™. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** In clinical studies, no overall differences in safety or effectiveness were observed between elderly and younger subjects. However, greater sensitivity of some older individuals cannot be ruled out.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yescarta™ (axicabtagene ciloleucel) Suspension, for Intravenous Infusion / Kite Pharma, Inc.	Antineoplastic agent Chimeric antigen receptor T cell (CAR T) therapy	Treatment of adults patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. **Limitation of Use** Not indicated for the treatment of patients with primary central nervous system lymphoma. **Black Box Warning** Cytokine release syndrome (CRS) and neurologic toxicities: (1) CRS, including fatal or life-threatening reactions occurred. Do not administer to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids (2) Neurologic toxicities, including fatal or life-threatening reactions occurred, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment. Provide supportive care and/or corticosteroids, as needed. Yescarta™ is available only through YESCARTA REMS.	10/18/2017	**DOSAGE AND ADMINISTRATION** Dosing is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. The target dose is 2 × 10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10^8 CAR-positive viable T cells. • For autologous use only. For intravenous use only. • Administer a lymphodepleting regimen of cyclophosphamide and fludarabine before infusion of Yescarta™. • Pre-medicate with acetaminophen and an H1-antihistamine. **DOSAGE FORMS AND STRENGTHS** Available as a cell suspension for infusion. Comprises a suspension of 2 × 10^6 CAR-positive viable T cells per kg of body weight, with a maximum of 2 × 10^8 CAR-positive viable T cells in approximately 68 mL. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Hypersensitivity Reactions:** Monitor for hypersensitivity reactions during infusion. • **Serious Infections:** Monitor patients for signs and symptoms of infection; treat appropriately. • **Prolonged Cytopenias:** Patients may exhibit Grade 3 or higher cytopenias for several weeks following infusion. Monitor complete blood counts. • **Hypogammaglobulinemia:** Monitor and provide replacement therapy. • **Malignancies:** Secondary malignancies may occur; monitoring recommended. • **Effects on Ability to Drive and Use Machines:** Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, for at least 8 weeks after infusion.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yescarta™ (axicabtagene ciloleucel) Suspension, for Intravenous Infusion / Kite Pharma, Inc. (continuation)	Antineoplastic agent Chimeric antigen receptor T cell (CAR T) therapy	Treatment of adults patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. **Limitation of Use** Not indicated for the treatment of patients with primary central nervous system lymphoma. **Black Box Warning** Cytokine release syndrome (CRS) and neurologic toxicities: (1) CRS, including fatal or life-threatening reactions occurred. Do not administer to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids (2) Neurologic toxicities, including fatal or life-threatening reactions occurred, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment. Provide supportive care and/or corticosteroids, as needed. Yescarta™ is available only through YESCARTA REMS.	10/18/2017	**ADVERSE REACTIONS** Most common adverse reactions: cytokine release syndrome, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, infections-pathogen unspecified, nausea, hypoxia, tremor, cough, vomiting, dizziness, constipation, and cardiac arrhythmias. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Not recommended for women who are pregnant, and pregnancy after infusion should be discussed with the treating physician. • **Females and Males of Reproductive Potential:** Pregnancy status of females with reproductive potential should be verified. Sexually-active females of reproductive potential should have a pregnancy test prior to starting treatment. • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** Clinical trials did not include sufficient numbers of patients aged 65 years and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Shingrix (herpes zoster subunit vaccine), for intramuscular use / GlaxoSmithKline	Non-live, recombinant subunit vaccine	Prevention of herpes zoster (shingles) in adults aged 50 years and older. **Limitations of Use** Not indicated for prevention of primary varicella infection (chickenpox).	10/20/2017	**DOSAGE AND ADMINISTRATION** The recommended schedule is to administer 2 doses (0.5 mL each) at 0 and 2 to 6 months. **DOSAGE FORMS AND STRENGTHS** Suspension for injection supplied as a single-dose vial of lyophilized varicella zoster virus glycoprotein E (gE) antigen component to be reconstituted with the accompanying vial of AS01B adjuvant suspension component. After reconstitution, a single dose of SHINGRIX is 0.5 mL. **CONTRAINDICATIONS** • History of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine or after a previous dose. **WARNINGS AND PRECAUTIONS** • Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration. **ADVERSE REACTIONS** Most common adverse reactions: Local – pain, redness, and swelling. Systemic – myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms. **DRUG INTERACTIONS** • Immunosuppresive therapies: May reduce the effectiveness.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Calquence™ (acalabrutinib) Capsules, for oral use / AstraZeneca	Bruton tyrosine kinase (BTK) inhibitor	Treatment of mantle cell lymphoma (MCL).	10/31/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg orally approximately every 12 hours. **DOSAGE FORMS AND STRENGTHS** Capsules: 100 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Hemorrhage: Monitor for bleeding and manage appropriately. • **Infections:** Monitor patients for signs and symptoms of infection and treat as needed. • **Cytopenias:** Monitor complete blood counts monthly during treatment. • **Second Primary Malignancies:** Other malignancies have occurred in patients, including skin cancers and other carcinomas. Advise patients to use sun protection. • **Atrial Fibrillation and Flutter:** Monitor for atrial fibrillation and atrial flutter and manage as appropriate. **ADVERSE REACTIONS** Most common adverse reactions: anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising. **DRUG INTERACTIONS** • **CYP3A Inhibitors:** Avoid co-administration with strong CYP3A inhibitors. Dose adjustments may be recommended. • **CYP3A Inducers:** Avoid co-administration with strong CYP3A inducers. Dose adjustments may be recommended. • **Gastric Acid Reducing Agents:** Avoid co-administration with proton pump inhibitors (PPIs). Stagger dosing with H2-receptor antagonists and antacids.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Calquence™ (acalabrutinib) Capsules, for oral use / AstraZeneca (continuation)	Bruton tyrosine kinase (BTK) inhibitor	Treatment of mantle cell lymphoma (MCL).	10/31/2017	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Advise pregnant women of the potential risk to a fetus. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** The safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No clinically relevant differences in safety or efficacy were observed between patients ≥ 65 years and younger.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Botox Cosmetic™ (onabotulin umtoxinA) for Injection / Allergan	Acetylcholine release inhibitor and neuro-muscular blocking agent	Approved for temporary improvement in the appearance of glabellar lines and lateral canthal lines (crow's feet). **New indication:** Temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity in adults.	10/02/2017	In clinical trials, Botox Cosmetic™ demonstrated efficacy compared with placebo in the reduction of the severity of forehead lines: 61% of subjects in study one and 46% of subjects in study two met the primary endpoint compared with placebo (0% in Study one and 1% in Study two). Similar response rates were seen across three treatments cycles with Botox Cosmetic™.
Stelara™ (ustekinumab) Injection / Janssen Biotech, Inc.	Human monoclonal antibody	Treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, and moderately to severely active Crohn's disease. **Patient Population Altered:** Treatment of adolescents (12 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	10/13/2017	FDA has approved an expanded indication for Stelara™ for the treatment of adolescents (12 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Approval is based on data from a study that evaluated the efficacy and safety of Stelara™ in patients aged 12 years or older. At least two-thirds of patients receiving Stelara™ were responders at the week 12 primary endpoint after just two doses at weeks 0 and 4, defined by achieving a Physician's Global Assessment score of 0 or 1 (cleared or minimal psoriasis). Safety findings for adolescent patients treated with Stelara™ were consistent with those seen in studies in adults with plaque psoriasis.
Soliris™ (eculizumab) Injection / Alexion Pharmaceuticals, Inc.	Monoclonal antibody	Treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis, and for the treatment of patients with atypical hemolytic uremic syndrome. **New indication:** Treatment for adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor antibody-positive.	10/23/2017	In the Phase 3 REGAIN study and its ongoing open-label extension study, Soliris™ demonstrated treatment benefits for patients with anti-AchR antibody-positive gMG who had previously failed immunosuppressive treatment and continued to suffer from significant unresolved disease symptoms, which can include difficulties seeing, walking, talking, swallowing and breathing. These patients are at an increased risk of disease exacerbations and crises that may require hospitalization and intensive care and may be life-threatening.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Lyrica™ (pregabalin) / Pfizer Inc.	Central nervous system agent Antiepileptic	Management of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia and spinal cord injury; as an adjunctive therapy for partial onset seizures and for the treatment of fibromyalgia	10/12/2017	FDA has approved Lyrica CR (pregabalin) extended-release tablets CV as once-daily therapy for the management of neuropathic pain associated with diabetic peripheral neuropathy (pDPN) and the management of postherpetic neuralgia (PHN). Lyrica CR did not receive approval for the management of fibromyalgia.
Bydureon™ (exenatide) / AstraZeneca	Glucagon-like peptide-1 (GLP-1) receptor agonist	To improve glycemic control in patients with type 2 diabetes.	10/20/2017	FDA has approved Bydureon BCise™ (exenatide extended-release) injectable suspension. This formulation is an improved once-weekly, single-dose autoinjector device for adults with type-2 diabetes whose blood sugar remains uncontrolled on one or more oral medicines in addition to diet and exercise, to improve glycemic control. Unlike other GLP-1 receptor agonists, Bydureon BCise™ has a unique, continuous-release microsphere delivery system designed to provide consistent therapeutic levels of the active ingredient, to help patients reach and maintain steady state.
Varubi (rolapitant) / Tesaro, Inc.	Substance P/neurokinin 1 (NK1) receptor antagonist	Prevention of delayed nausea and vomiting associated with emetogenic chemotherapy.	10/25/2017	FDA has approved Varubi™ (rolapitant) IV in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Glatiramer Acetate Injection 40 mg/mL / Mylan Pharmaceuticals Inc.	Central nervous system agent; Antirheumatic	10/03/2017	Generic for: Copaxone 40 mg/mL
Dextromethorphan Hydrobromide and Quinidine Sulfate Capsules 20mg/10mg / Actavis Pharma, Inc.	Central nervous system agent	0/10/2017	Generic for: Nuedexta
Dapsone Gel 5% / Taro Pharmaceuticals USA	Anti-infective agents; Anti-acne	10/16/2017	Generic for: Aczone

Source: https://www.drugs.com/generic-approvals.html

PIPELINE……

Drug/Manufacturer	Date	Indications	Comments	Impact
Apalutamide / Janssen Biotech, Inc.	10/11/2017	Treatment of men with non-metastatic castration-resistant prostate cancer (CRPC)	Apalutamide is a next generation oral androgen receptor inhibitor. This NDA submission was based on Phase 3 data from the SPARTAN clinical trial, which assessed the safety and efficacy of apalutamide versus placebo, in men with non-metastatic CRPC who have a rapidly rising prostate specific antigen (PSA) despite receiving continuous androgen deprivation therapy. The SPARTAN clinical trial results will be presented at a future medical meeting.	High
Fremanezumab / Teva Pharmaceutical Industries Ltd.	10/17/2017	Preventive treatment of migraine	Fremanezumab is a fully-humanized monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) ligand. This BLA includes data from the HALO clinical trial program, which enrolled more than 2,000 patients with episodic migraine (EM) and chronic migraine (CM), evaluating both monthly and quarterly dose regimens of fremanezumab. Results from these trials will be published in future peer-reviewed publications.	High
Inveltys (loteprednol etabonate) / Kala Pharmaceuticals, Inc.	10/25/2017	Treatment of post-operative ocular inflammation and pain	Inveltys (loteprednol etabonate) is a topical twice-a-day product.	Low
Plazomicin / Achaogen, Inc	10/26/2017S	Treatment of complicated urinary tract infections	Plazomicin is a next generation aminoglycoside.	Moderate

Soruce: https://www.drugs.com/new-drug-applications.html

References:

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- Pharmacist Letter (www.pharmacistletter.com)
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