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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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Pharmacy Benefit Management
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Table of Contents

NEWS……

Drug Issue	Date	News/Event
Elimination of the REMS for Truvada™ and its four approved generics	07/01/2019	The FDA initially approved Truvada™ (emtricitabine/tenofovir disoproxil fumarate) for the treatment of HIV-1 infection in combination with other antiretroviral drugs. Later, the FDA approved the use of Truvada™ for HIV pre-exposure prophylaxis (PrEP), in combination with safe sex practices, to reduce the risk of sexually-acquired HIV-1 infection. As part of this last approval, the FDA established a Risk Evaluation and Mitigation Strategy (REMS), which among other things, required manufacturers to make available training materials for health care professionals and educational information for consumers, due to the risk of developing a resistant HIV-1 variants when starting PrEP or continuing its use in a patient who has undiagnosed HIV-1 infection. Recently, the FDA announced the elimination of this REMS for Truvada™ and its four approved generics, after having evidence showing that the vast majority of health care professionals and at-risk individuals are aware of these risks and prevention methods, and educational materials and treatment guidelines are readily available from the CDC. Although the manufacturers are no longer required to provide educational materials, the approved labeling and Medication Guide explaining the risks and benefits of the product will continue to convey the important safety information and be widely available. Recommendations for healthcare professionals: • Continue to follow the labeled directions for the initiation and proper use of Truvada™ for the PrEP indication to minimize the risk of developing resistant HIV-1 variants when HIV-1 infection is present. • Encourage at-risk individuals to have an ongoing dialogue with their healthcare professional about the benefits and risks of PrEP and other HIV prevention strategies when taking PrEP. • Access educational materials and treatment guidelines readily available from sources like the CDC as well as local health departments.

NEWS……

Drug Issue	Date	News/Event
Boxed warning for Xeljanz™, Xeljanz XR™	07/26/2019	The FDA has approved a boxed warning about an increased risk of blood clots and death with the 10 mg twice daily dose of tofacitinib (Xeljanz™, Xeljanz XR™), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. Recommendations for healthcare professionals: • Discontinue tofacitinib and promptly evaluate patients with symptoms of thrombosis. • Counsel patients about the risks and advise them to seek medical attention immediately if they experience any unusual symptoms, including: sudden shortness of breath, chest pain that worsens with breathing, swelling of a leg or arm, leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm. • Reserve tofacitinib to treat ulcerative colitis for patients who have failed or do not tolerate tumor necrosis factor (TNF) blockers. • Avoid tofacitinib in patients who may have a higher risk of thrombosis. • When treating ulcerative colitis, use tofacitinib at the lowest effective dose and limit the use of the 10 mg twice daily dosage to the shortest duration needed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xpovio™ (selinexor), for oral use / Karyopharm Therapeutics Inc.	Antineoplastic agent; Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist	In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody	07/03/2019	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 80 mg in combination with dexamethasone taken orally on Days 1 and 3 of each week. Adverse reactions must be managed using dosage modification and supportive care. **DOSAGE FORMS AND STRENGTHS** Tablets: 20mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Thrombocytopenia: Monitor platelet counts at baseline, during treatment, and as clinically indicated. Manage with dose interruption, reduction, and supportive care **ADVERSE REACTIONS** Most common adverse reactions: (incidence ≥20%) are thrombocytopenia, fatigue, nausea, anemia, decreased appetite, decreased weight, diarrhea, vomiting, hyponatremia, neutropenia, leukopenia, constipation, dyspnea, and upper respiratory tract infection. **DRUG INTERACTIONS** • No dedicated drug interaction studies have been performed. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Advise females to contact their healthcare provider. • **Lactation:** Advise not to breastfeed • **Pediatric use:** have not been established in pediatric patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Recarbrio™ (imipenem, cilastatin, and relebactam) for Injection, for intravenous use / Merck	Anti-infective agent; Antibacterial; Combination of a penem antibacterial, a renal dehydropeptidase inhibitor, and a betalactamase inhibitor	In patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria: • Complicated urinary tract infections, including pyelonephritis (cUTI) • Complicated intra-abdominal infections (cIAI) Approval of these indications is based on limited clinical safety and efficacy data. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Recarbrio™ and other antibacterial drugs, Recarbrio™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	07/16/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is to administer Recarbrio™ 1.25 grams (imipenem 500 mg, cilastatin 500 mg, relebactam 250 mg) by intravenous (IV) infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CrCl) 90 mL/min or greater. Dosage adjustment is recommended in patients with renal impairment: • For CrCl 60 to 89 mL/min: 1 gram administered by IV infusion over 30 minutes every 6 hours • For CrCl 30 to 59 mL/min: 0.75 grams administered by IV infusion over 30 minutes every 6 hours • For CrCl 15 to 29 mL/min: 0.5 grams administered by IV infusion over 30 minutes every 6 hours • For End Stage Renal Disease on Hemodialysis: 0.5 grams administered by IV infusion over 30 minutes every 6 hours Patients with CrCl less than 15 mL/min should not receive Recarbrio™ unless hemodialysis is instituted within 48 hours. **DOSAGE FORMS AND STRENGTHS** Recarbrio™ 1.25 grams for injection is supplied as sterile powder for constitution in a single-dose vial containing imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg. **CONTRAINDICATIONS** • History of known severe hypersensitivity to any component of Recarbrio™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Recarbrio™ (imipenem, cilastatin, and relebactam) for Injection, for intravenous use / Merck (continuation)	Anti-infective agent; Antibacterial; Combination of a penem antibacterial, a renal dehydropeptidase inhibitor, and a betalactamase inhibitor	In patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria: • Complicated urinary tract infections, including pyelonephritis (cUTI) • Complicated intra-abdominal infections (cIAI) Approval of these indications is based on limited clinical safety and efficacy data. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Recarbrio™ and other antibacterial drugs, Recarbrio™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	07/16/2019	**WARNINGS AND PRECAUTIONS** • **Hypersensitivity reactions:** Hypersensitivity reactions have been reported in patients receiving beta lactam drugs. Discontinue immediately if a hypersensitivity reaction occurs. • **Seizures and central nervous system adverse reactions:** CNS adverse reactions such as seizures have been reported with imipenem/cilastatin, components of Recarbrio™. If focal tremors, myoclonus, or seizures occur, evaluate patients, to determine whether Recarbrio™ should be discontinued. • **Increased seizure potential due to interaction with valproic acid:** Concomitant use of Recarbrio™ with valproic acid or divalproex sodium may reduce the serum concentration of valproic acid which may increase the risk of breakthrough seizures. Avoid concomitant use or consider alternative antibacterial drugs other than carbapenems. • **Clostridium difficile-associated diarrhea (CDAD):** Has been reported with imipenem/cilastatin plus relebactam. Evaluate if diarrhea occurs. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea, nausea, headache, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, phlebitis/infusion site reactions, pyrexia, and hypertension. **DRUG INTERACTIONS** • **Ganciclovir:** Avoid concomitant use. • **Valproic Acid or Divalproex Sodium:** Avoid concomitant use.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Recarbrio™ (imipenem, cilastatin, and relebactam) for Injection, for intravenous use / Merck (continuation)	Anti-infective agent; Antibacterial; Combination of a penem antibacterial, a renal dehydropeptidase inhibitor, and a betalactamase inhibitor	In patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of the following infections caused by susceptible gram-negative bacteria: • Complicated urinary tract infections, including pyelonephritis (cUTI) • Complicated intra-abdominal infections (cIAI) Approval of these indications is based on limited clinical safety and efficacy data. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Recarbrio™ and other antibacterial drugs, Recarbrio™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	07/16/2019	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy have not been established. • **Geriatric use:** Recarbrio™ is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. No dosage adjustment is required based on age. Dosage adjustment for elderly patients should be based on renal function. • **Renal impairment:** Reduce dosage in patients with a CrCl less than 90 mL/min.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ruxience™ (rituximab-pvvr) Injection, for intravenous use / Pfizer Inc.	Antineoplastic agent; CD20-directed cytolytic antibody Note: Biosimilar to Rituxan™	Treatment of adult patients with non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), and granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA)	07/23/2019	**DOSAGE AND ADMINISTRATION** The recommended dose for NHL is 375 mg/m2. The recommended dose for CLL is 375 mg/m2 in the first cycle and 500 mg/m2 in Cycles 2-6, in combination with FC, administered every 28 days. The induction dose for patients with active GPA and MPA in combination with glucocorticoids is 375 mg/m2 once weekly for 4 weeks. The follow up dose for patients with GPA and MPA who have achieved disease control with induction treatment, in combination with glucocorticoids is two 500 mg intravenous infusions separated by two weeks, followed by a 500 mg intravenous infusion every 6 months thereafter based on clinical evaluation. Ruxience™ should only be administered by a healthcare professional with appropriate medical support to manage severe infusion-related reactions that can be fatal if they occur. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL) solution in single-dose vials. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Tumor lysis syndrome:** Administer aggressive intravenous hydration, anti-hyperuricemic agents, monitor renal function. • **Infections:** Withhold and institute appropriate anti-infective therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ruxience™ (rituximab-pvvr) Injection, for intravenous use / Pfizer Inc. (continuation)	Antineoplastic agent; CD20-directed cytolytic antibody Note: Biosimilar to Rituxan™	Treatment of adult patients with non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), and granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA)	07/23/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Cardiac adverse reactions:** Discontinue infusions in case of serious or life-threatening events. • **Renal toxicity:** Discontinue in patients with rising serum creatinine or oliguria. • **Bowel obstruction and perforation:** Consider and evaluate for abdominal pain, vomiting, or related symptoms. • **Immunizations:** Live virus vaccinations prior to or during treatment not recommended. • **Embryo-Fetal toxicity:** Can cause neonatal harm. Advise of potential risk to neonates and use of effective contraception **ADVERSE REACTIONS** Most common adverse reactions: infusion-related reactions, fever, lymphopenia, neutropenia, chills, infections, asthenia, nausea diarrhea, headache, muscle spasms, anemia, peripheral edema. **DRUG INTERACTIONS** • **Cisplatin:** Renal toxicity when used in combination with cisplatin. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm and adverse outcomes in pregnancy. • **Females of reproductive potential:** Females of childbearing potential should use effective contraception during treatment and for 12 months following treatment. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness of rituximab products in pediatric patients have not been established. • **Geriatric use:** : In CLL patients older than 70 years of age, exploratory analyses suggest no benefit with the addition of rituximab to FC.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Hadlima™ (adalimumab-bwwd) injection, for subcutaneous use / Samsung Bioepis Co Ltd	Anti-rheumatic; Monoclonal antibody; Tumor necrosis factor (TNF) blocker Note: Biosimilar to Humira™	• Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Adult Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)	07/23/2019	**DOSAGE AND ADMINISTRATION** For RA, PsA, and AS: • 40 mg every other week. • Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week. For JIA in patient weighing ≥ 30 kg (66 lbs): 40 mg every other week. For adult CD and UC: • Initial dose (Day 1): 160 mg. • Second dose two weeks later (Day 15): 80 mg. • Two weeks later (Day 29): Begin a maintenance dose of 40 mg every other week. • For patients with UC only: Only continue treatment in patients who have shown evidence of clinical remission by eight weeks (Day 57) of therapy. For Ps: 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose. **DOSAGE FORMS AND STRENGTHS** • Injection: 40 mg/0.8 mL in a single-dose prefilled auto-injector (Hadlima PushTouch). • Injection: 40 mg/0.8 mL in a single-dose prefilled glass syringe. **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Hadlima™ (adalimumab-bwwd) injection, for subcutaneous use / Samsung Bioepis Co Ltd (continuation)	Anti-rheumatic; Monoclonal antibody; Tumor necrosis factor (TNF) blocker Note: Biosimilar to Humira™	• Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) • Adult Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)	07/23/2019	**WARNINGS AND PRECAUTIONS** • Serious infections: Do not start Hadlima™ during an active infection. If an infection develops, monitor carefully, and stop Hadlima™ if infection becomes serious. • Invasive fungal infections: For patients who develop a systemic illness on Hadlima™, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. • Malignancies: Incidence of malignancies was greater in adalimumab-treated patients than in controls. • Anaphylaxis or serious allergic reactions: May occur. • Hepatitis B virus reactivation: Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop Hadlima™ and begin anti- viral therapy. • Demyelinating disease: Exacerbation or new onset, may occur. • Cytopenias, pancytopenia: Advise patients to seek immediate medical attention if symptoms develop, and consider stopping Hadlima™. • Heart failure: Worsening or new onset, may occur. • Lupus-like syndrome: Stop Hadlima™ if syndrome develops. **ADVERSE REACTIONS** Most common adverse reactions: infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash. **DRUG INTERACTIONS** • Abatacept: Increased risk of serious infection. • Anakinra: Increased risk of serious infection. • Live vaccines: Avoid use with Hadlima™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Accrufer™ (ferric maltol) Capsules, for oral use / Shield Therapeutics plc	Iron replacement	Treatment of iron deficiency in adults	07/25/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 30 mg twice daily on an empty stomach. Accrufer™ is to be continued as long as necessary to replenish body iron stores. **DOSAGE FORMS AND STRENGTHS** Capsules: 30 mg. **CONTRAINDICATIONS** • Hypersensitivity to the active substance or any excipient. • Hemochromatosis and other iron overload syndromes. • Patients receiving repeated blood transfusions. **WARNINGS AND PRECAUTIONS** • Inflammatory Bowel Disease (IBD) flare: Avoid use in patients with IBD flare. • Iron overload: Accidental overdose of iron products is a leading cause of fatal poisoning in children under 6. Keep out of reach of children. **ADVERSE REACTIONS** Most common adverse reactions: flatulence, diarrhea, constipation, feces discolored, abdominal pain, nausea, vomiting and abdominal discomfort/distension. **DRUG INTERACTIONS** • Dimercaprol: Avoid concomitant use. • Oral Medications: Separate administration of ACCRUFER from certain oral medications. Monitor clinical responses as appropriate.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nubeqa™ (darolutamide) Tablets, for oral use / Bayer HealthCare Pharmaceuticals Inc.	Antineoplastic agent; Androgen receptor inhibitor	Treatment of patients with non-metastatic castration-resistant prostate cancer	07/30/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 600 mg, (two 300 mg tablets) administered orally twice daily. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. **DOSAGE FORMS AND STRENGTHS** Tablets: 300 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Embryo-fetal toxicity: Can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, pain in extremity, and Rash. **DRUG INTERACTIONS** • Combined P-gp and Strong or Moderate CYP3A Inducers: Avoid concomitant use. • Combined P-gp and Strong CYP3A Inhibitors: Monitor patients more frequently for NUBEQA adverse reactions. • BCRP Substrates: Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nubeqa™ (darolutamide) Tablets, for oral use / Bayer HealthCare Pharmaceuticals Inc. (continuation)	Antineoplastic agent; Androgen receptor inhibitor	Treatment of patients with non-metastatic castration-resistant prostate cancer	07/30/2019	**USE IN SPECIFIC POPULATIONS** • **Males of reproductive potential:** Based on the mechanism of action, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose. • **Severe renal impairment (not on hemodialysis):** Patients with severe renal impairment (eGFR 15–29 mL/min/1.73 m2) who are not receiving hemodialysis have a higher exposure to Nubeqa™ and reduction of the dose is recommended. Recommended dose is 300 mg twice daily. No dose reduction is needed for patients with mild or moderate renal impairment (eGFR 30-89 mL/min/1.73 m2). The effect of end stage renal disease (eGFR ≤15 mL/min/1.73 m2) on darolutamide pharmacokinetics is unknown. • **Moderate hepatic impairment:** Patients with moderate hepatic impairment (Child-Pugh Class B) have a higher exposure to Nubeqa™ and reduction of the dose is recommended. Recommended dose is 300 mg twice daily. No dose reduction is needed for patients with mild hepatic impairment. The effect of severe hepatic impairment (Child-Pugh C) on darolutamide pharmacokinetics is unknown.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Otezla™ (apremilast) Tablets / Celgene Corporation	Phosphodiesterase 4 (PDE4) inhibitor	**Previous indication(s):** Treatment of psoriatic arthritis, and plaque psoriasis. **New indication(s):** Treatment of oral ulcers associated with Behçet's Disease.	07/19/2019	With this approval, Otezla™ comes to be the first approved treatment option for oral ulcers associated with Behçet's Disease, a rare, chronic, multisystem inflammatory disease that is difficult to treat. This approval was based results from a study evaluating Otezla™ in 207 adult patients with Behçet's Disease with active oral ulcers who were previously treated with at least one non-biologic medication and were candidates for systemic therapy. Results showed Otezla™ 30 mg twice a day resulted in a 42.7 point reduction from baseline in the pain of oral ulcers as measured by the visual analog scale at week 12, compared with an 18.7 point reduction with placebo. The proportion of patients achieving an oral ulcer complete response (oral ulcer-free) at week 12 was 52.9% in the Otezla™ arm and 22.3% in the placebo arm. The proportion of patients achieving oral ulcer complete response by week 6 and who remained oral ulcer-free for at least six additional weeks during the 12-week treatment phase was 29.8% in the Otezla™ arm and 4.9% in the placebo arm. The daily average number of oral ulcers during the 12-week treatment phase was 1.5 in the Otezla™ arm and 2.6 in the placebo arm.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; Human PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, and renal cell carcinoma **New indication:** As monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy	07/30/2019	This approval was based on data from a studies in patients with recurrent locally advanced or metastatic esophageal cancer who progressed on or after one prior line of systemic treatment for advanced disease. In patients whose ESCC tumors expressed PD-L1, an improvement in OS was observed among patients randomized to Keytruda™ as compared with chemotherapy.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Slynd™ (drospirenone) tablets / Exeltis USA Inc.	Contraceptive; Progestin	For use by females of reproductive potential to prevent pregnancy	05/23/2019	Slynd™ is a progestin-only oral contraceptive.
Xembify™ (immune globulin subcutaneous, human - klhw) Injection / Grifols	Immune globulin	Treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older	07/03/2019	Xembify™ is a new subcutaneous immunoglobulin 20%. Subcutaneous immune globulin 20% is also available under the brand names Cuvitru™ and Hizentra™. Both Cuvitru™ and Hizentra™ carry the same indication as Xembify™. In addition, Hizentra™ is also indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment.
Katerzia™ (amlodipine benzoate) Oral Suspension / Azurity Pharmaceuticals	Cardopvascular agent; Calcium channel blocker	Treatment of hypertension in adults and pediatric patients 6 years of age and older, and coronary artery disease in adults	07/08/2019	Katerzia™ is a new formulation of amlodipine benzoate in oral solution. Amlodipine benzoate was already available in the market as oral tablet, under the brand name Norvasc™ and also as generic. The tablet formulation carries the same indications as Katerzia™.
AirDuo Digihaler™ (fluticasone propionate and salmeterol) Inhalation Powder / Teva Pharmaceuticals USA, Inc.	Respiratory agent; Antiasthma; Corticosteroid and a long-acting $beta_2$-adrenergic agonist (LABA) combination	For used to control symptoms of asthma and to prevent symptoms such as wheezing in people 12 years of age and older.	07/15/2019	AirDuo Digihaler™ is a combination therapy digital inhaler containing built-in sensors that connects to a companion mobile application to provide information on inhaler use to patients with asthma. AirDuo Digihaler™ contains the same active ingredients as AirDuo Respiclick™, Advair Diskus™, and Advair HFA™. AirDuo Digihaler™ will be available in low, medium and high doses: 100/50 mcg, 250/50 mcg and 500/50 mcg.

New FDA Approved Formulations, Dosage Forms, Combination Products and Other Differences

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Drizalma Sprinkle™ (duloxetine) Delayed-release capsules / Sun Pharma Global	Central nervous system agent; Serotonin and norepinephrine reuptake inhibitor (SNRI)	• Major Depressive Disorder (MDD) in adults • Generalized Anxiety Disorder (GAD) in adults and pediatric patients ages 7 years to 17 years old • Diabetic Peripheral Neuropathic Pain (DPNP) in adults • Chronic Musculoskeletal Pain in adult	07/19/2019	Drizalma Sprinkle™ is a new formulation of duloxetine in delayed-release capsules that can be opened and the contents sprinkled over applesauce or opened and the contents administered via a nasogastric tube. Duloxetine was already available in the market as delayed-release capsules under the brand name Cymbalta™ and also as generic. However, this previously available formulation should not be opened; the capsule should be swallowed whole. The new formulation carries the same indications as Cymbalta™.
Baqsimi™ (glucagon) Nasal Powder / Eli Lilly and Company	Endocrine and metabolic agent; Anti-hypoglicemic agent	Treatment of severe hypoglycemia in patients with diabetes ages 4 years and above	07/24/2019	Baqsimi™ comes to be the first formulation of glucagon for nasal administration, design for severe hypoglycemia rescue.
Angiomax RTU™ (bivalirudin) Injection / Maia Pharms Inc.	Blood modifier agent; Anticoagulant; Direct thrombin inhibitor	As an anticoagulant in patients undergoing percutaneous coronary intervention (PCI), including patients with heparin induced thrombocytopenia and heparin-induced thrombocytopenia and thrombosis syndrome	07/25/2019	Angiomax RTU™ is a ready-to-use formulation of bivalirudin. Bivalidurin was already available in the market as lyophilized powder in single-dose vial for reconstitution under the brand name Angiomax™ and also as generic.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Febuxostat Tablets 40 mg and 80 mg / Mylan Pharmaceuticals Inc.; Alembic Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Inc.	Antigout	07/01/2019	Generic for: Uloric
Ketorolac Tromethamine and Phenylephrine Hydrochloride Irrigation Solution 0.3% (base)/1% (base) / Lupin Pharmaceuticals, Inc.	Analgesic	07/01/2019	Generic for: Omidria
Carboprost Tromethamine Injection 0.25mg (base)/mL / Dr. Reddy's Laboratories Limited	Endocrine and metabolic agent	07/02/2019	Generic for: Hemabate
Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg / Alembic Pharmaceuticals Inc.; Alkem Laboratories Ltd.; Amneal Pharmaceuticals LLC; Dr. Reddy's Laboratories Limited; InvaGen Pharmaceuticals, Inc.; MSN Laboratories Private Ltd.; Rising Pharmaceuticals, Inc.; Sciegen Pharmaceuticals Inc.; Teva Pharmaceuticals USA, Inc.	Anticonvulsant	07/19/2019	Generic for: Lyrica Capsules
Pregabalin Oral Solution 20 mg/mL / Alkem Laboratories Ltd.	Anticonvulsant	07/19/2019	Generic for: Lyrica Oral Solution

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Talicia (amoxicillin, omeprazole and rifabutin) Capsules / RedHill Biopharma Ltd.	07/03/2019	Treatment for: Helicobacter pylori Infection	Talicia is a fixed-dose oral combination of rifabutin and amoxicillin (both antibiotics), and omeprazole (a proton pump inhibitor (PPI)), in development for the treatment of Helicobacter pylori infection. RedHill Biopharma announced FDA acceptance of NDA for Talicia.	Moderate
Opicapone / Neurocrine Biosciences, Inc.	07/10/2019	Treatment for: Parkinson's Disease; Adjunctive	Opicapone is a novel, once-daily, oral, selective catechol-O-methyltransferase (COMT) inhibitor, in development for the adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes. Neurocrine Biosciences, Inc. announced FDA acceptance of NDA for opicapone.	High
Enfortumab Vendotin / Astellas and Seattle Genetics	07/16/2019	Treatment for: Urothelial Carcinoma	Enfortumab vedotin is a Nectin-4 targeted antibody-drug conjugate (ADC) in development for the treatment of patients with locally advanced or metastatic urothelial cancer. Astellas and Seattle Genetics submitted a BLA for enfortumab vedotin.	High
Elexacaftor, ivacaftor and tezacaftor / Vertex Pharmaceuticals Incorporated	07/22/2019	Treatment for: Cystic Fibrosis	Elexacaftor, tezacaftor and ivacaftor is a triple combination regimen in development for the treatment of cystic fibrosis. Vertex submitted and NDA for elexacaftor, ivacaftor and tezacaftor.	High

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

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- IBM Micromedex® (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)