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RX BENEFIT MANAGEMENT

PharmNOTES

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

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urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2019

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NEWS……

Drug Issue	Date	News/Event
Kayexalate™ (sodium polystyrene sulfonate): FDA is recommending that patients avoid taking Kayexalate at the same time as other medicines taken by mouth	09/06/2017	Sodium polystyrene sulfonate is used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. It works by binding with potassium in the intestines so it can be removed from the body. Potassium is a mineral that helps the body function properly. Too much potassium in the blood can cause problems with heart rhythm, which in rare cases can be fatal. Sodium polystyrene sulfonate is available as the brand name Kayexalate™, as generic brands, and also as non-branded generics. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, FDA is recommending separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours . This time should be increased to 6 hours for patients with gastroparesis or other conditions resulting in delayed emptying of food from the stomach into the small intestine. Sodium polystyrene sulfonate drug labels are going to be updated to include information about this dosing separation.
Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Careful Medication Management Can Reduce Risks	09/20/2017	Many patients with opioid dependence may also use benzodiazepines (BZDs) or other central nervous system (CNS) depressants, either under a health care professional's direction or illicitly. Although there are serious risks with combining these medicines, excluding patients from medication-assisted treatment (MAT) or discharging patients from treatment because of use of BZDs or CNS depressants is not likely to stop them from using these drugs together. Instead, the combined use may continue outside the treatment setting, which could result in more severe outcomes. FDA is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking BZDs or other drugs that depress the CNS. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks. Health care professionals should take actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with BZDs or other CNS depressants. Some recommendations: (1) Educating patients about the serious risks of combined use, including overdose and death, that can occur with CNS depressants even when used as prescribed, as well as when used illicitly. (2) Developing strategies to manage the use of prescribed or illicit BZDs or other CNS depressants when starting MAT. (3) Tapering the BZD or CNS depressant to discontinuation if possible. (4) Verifying the diagnosis if a patient is receiving prescribed BZDs or other CNS depressants for anxiety or insomnia, and considering other treatment options for these conditions. (5) Recognizing that patients may require MAT medications indefinitely and their use should continue for as long as patients are benefiting and their use contributes to the intended treatment goals. (6) Coordinating care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment. (7) Monitoring for illicit drug use, including urine or blood screening.

NEWS……

Drug Issue	Date	News/Event
Ocaliva™ (obeticholic acid): Increased Risk of Serious Liver Injury	09/21/2017	Ocaliva™ is used to treat a chronic liver disease known as primary biliary cholangitis (PBC). PBC causes the bile ducts in the liver to become inflamed, damaged and destroyed. This causes bile, a fluid that helps in digestion, to build up in the liver. This build-up damages the liver over time, eventually causing it to lose its ability to function. Ocaliva™ has been shown to improve a certain blood test that measures liver problems. FDA is warning that Ocaliva™ is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. Ocaliva™ may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. The recommended dosing and monitoring for patients on Ocaliva™ are described in the current drug label. FDA is working with the drug manufacturer, Intercept Pharmaceuticals, to address these safety concerns.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mylotarg™ (gemtuzumab ozogamicin) Injection, for intravenous use / Pfizer Inc.	Antineoplastic agent D33-directed antibody-drug conjugate	Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults Treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older **Black Box Warning** Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of gemtuzumab ozogamicin as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with gemtuzumab ozogamicin.	09/01/2017	**DOSAGE AND ADMINISTRATION** For newly-diagnosed, de novo AML (combination regimen): • Induction: 3 mg/m2 (up to one 4.5 mg vial) on Days 1, 4, and 7 in combination with daunorubicin and cytarabine. • Consolidation: 3 mg/m2 on Day 1 (up to one 4.5 mg vial) in combination with daunorubicin and cytarabine. For newly-diagnosed AML (single-agent regimen): • Induction: 6 mg/m2 on Day 1 and 3 mg/m2 on Day 8. • Continuation: For patients without evidence of disease progression following induction, up to 8 continuation courses of MYLOTARG 2 mg/m2 on Day 1 every 4 weeks. For relapsed or refractory AML (single-agent regimen): • 3 mg/m2 on Days 1, 4, and 7. **DOSAGE FORMS AND STRENGTHS** For Injection: 4.5 mg as a lyophilized cake or powder in a single-dose vial for reconstitution and dilution. **CONTRAINDICATIONS** • Hypersensitivity to gemtuzumab ozogamicin or any excipients or components of the product. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Hepatotoxicity, including severe, life-threatening, and potentially fatal hepatic veno-occlusive disease (VOD) has been reported. Increased risk with hematopoietic stem cell transplant (HSCT) following treatment, HSCT prior to treatment, higher monotherapy doses, and moderate or severe hepatic impairment; monitoring recommended and dose interruption, reduction, or discontinuation may be required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mylotarg™ (gemtuzumab ozogamicin) Injection, for intravenous use / Pfizer Inc. (continuation)	Antineoplastic agent D33-directed antibody-drug conjugate	Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults Treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older **Black Box Warning** Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of gemtuzumab ozogamicin as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with gemtuzumab ozogamicin.	09/01/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Administration:** Infusion-related reactions, including life-threatening and fatal cases, have been reported; premedication and monitoring recommended. Interrupt infusion if reaction occurs. Permanent discontinuation required for severe or life-threatening reactions. • **Cardiovascular:** QT interval prolongation has been reported, particularly with concomitant use of calicheamicin. Increased risk with history or predisposition for QTc prolongation, electrolyte disturbances, or concomitant use of QT prolonging agents; monitoring recommended. • **Hematologic:** Fatal or life-threatening hemorrhage due to prolonged thrombocytopenia may occur; monitoring recommended and dose delays or discontinuation of treatment may be required. • **Reproductive:** Drug may cause fetal harm; adequate contraception required during treatment and for at least 6 months after discontinuation in females of reproductive potential and 3 months in female partners of male patients. • **Special populations:** Treatment did not improve event free-survival in patients having adverse-risk cytogenetics; weigh risk vs benefits. **ADVERSE REACTIONS** Most common adverse reactions: e hemorrhage, infection, fever, nausea, vomiting, constipation, headache, increased AST, increased ALT, rash, and mucositis. **DRUG INTERACTIONS** No clinical drug interaction studies have been performed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mylotarg™ (gemtuzumab ozogamicin) Injection, for intravenous use / Pfizer Inc. (continuation)	Antineoplastic agent D33-directed antibody-drug conjugate	Treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults Treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older **Black Box Warning** Hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), has been reported in association with the use of gemtuzumab ozogamicin as a single agent, and as part of a combination chemotherapy regimen. Monitor frequently for signs and symptoms of VOD after treatment with gemtuzumab ozogamicin.	09/01/2017	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause embryo-fetal harm. Verify the pregnancy status of females of reproductive potential prior to initiating. Advise females of reproductive potential to avoid becoming pregnant and to use effective contraception during treatment and for at least 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose. If used during pregnancy, or if the patient becomes pregnant while using it, advise the patient of the potential risk to a fetus. • **Lactation:** Advise not to breastfeed during treatment and for at least 1 month after the final dose. • **Pediatric use:** The safety and efficacy e have not been established in the pediatric patients with newly-diagnosed de novo AML. • **Geriatric use:** No overall differences in effectiveness between these patients and younger patients

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Aliqopa™ (copanlisib) Injection for intravenous use / Bayer Healthcare Pharmaceuticals, Inc.	Antineoplastic agent Phosphatidylinositol-3-kinase (PI3K) inhibitor	Treatment of adult patients with relapsed follicular lymphoma (FL)	09/14/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 60 mg administered as a 1-hour intravenous infusion on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off). Continue until disease progresses or unacceptable toxicity occurs. **DOSAGE FORMS AND STRENGTHS** For injection: 60 mg as a lyophilized solid in single-dose vial for reconstitution. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** Hypertension, including serious hypertensive events, has occurred; monitoring recommended. Dose reduction and interruption or discontinuation of treatment may be required. • **Dermatologic:** Severe cutaneous reactions have been reported; dose reduction and interruption or discontinuation of treatment may be required. • **Endocrine and metabolic:** Hyperglycemia has been reported, including serious hyperglycemic events; monitoring recommended, particularly in patients with diabetes mellitus. Dose reduction and interruption or discontinuation of treatment may be required. • **Hematologic:** Neutropenia has occurred; monitoring recommended. Dose reduction and interruption or discontinuation of treatment may be required. • **Immunologic:** Infections, including serious and fatal cases, have been reported; monitoring recommended and interruption of treatment may be required.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Aliqopa™ (copanlisib) Injection for intravenous use / Bayer Healthcare Pharmaceuticals, Inc. (continuation)	Antineoplastic agent Phosphatidylinositol-3-kinase (PI3K) inhibitor	Treatment of adult patients with relapsed follicular lymphoma (FL)	09/14/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Respiratory:** (1) Pneumonia, including pneumocystis jiroveci pneumonia, has been reported. Consider prophylaxis in high-risk patients. Withhold treatment if suspected. If confirmed, treat until resolved and resume treatment at previous dose. (2) Non-infectious pneumonitis has been reported; interrupt treatment and conduct diagnostic examination. Dose reduction and interruption or discontinuation of treatment may be required if confirmed. • **Reproductive:** May cause fetal harm; contraception required during treatment and for at least 1 month after last dose. **ADVERSE REACTIONS** Most common adverse reactions: hyperglycemia, diarrhea, decreased general strength and energy, hypertension, leukopenia, neutropenia, nausea, lower respiratory tract infections, thrombocytopenia. **DRUG INTERACTIONS** • **CYP3A Inducers:** Avoid concomitant use with strong CYP3A inducers. • **CYP3A Inhibitors:** Reduce Aliqopa™ dose to 45 mg when concomitantly administered with strong CYP3A inhibitors. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Conduct pregnancy testing prior to initiation. Advise female patients of reproductive potential, and male patients with female partners of reproductive potential, to use highly effective contraception during treatment and for at least 1 month after the last dose. • **Lactation:** Advise women not to breastfeed during treatment and for at least 1 month after the last dose. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No dose adjustment is necessary in patients ≥65 years of age.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mvasi™ (bevacizumab-awwb) Injection for intravenous use / Amgen Inc.	Antineoplastic agent Anti-vascular endothelial growth factor A (anti-VEGF) monoclonal antibody Biosimilar to Avastin (bevacizumab)	Treatment of multiple types of cancer : • Metastatic colorectal cancer • Non-small cell lung cancer • Glioblastoma multiforme • Metastatic renal cell carcinoma (mRCC) • Cervical cancer **Black Box Warning** Gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.	09/14/2017	**DOSAGE AND ADMINISTRATION** For metastatic colorectal cancer: (1) 5 mg/kg IV every 2 weeks with bolus-IFL. (2) 10 mg/kg IV every 2 weeks with FOLFOX4. (3) 5 mg/kg IV every 2 weeks or 7.5 mg/kg IV every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first-line bevacizumab product containing regimen. For non-squamous non-small cell lung cancer: 15 mg/kg IV every 3 weeks with carboplatin/paclitaxel. For glioblastoma multiforme: 10 mg/kg IV every 2 weeks . For mRCC: 10 mg/kg IV every 2 weeks with interferon alfa. For persistent, recurrent, or metastatic carcinoma of the cervix: 15 mg/kg IV every 3 weeks with paclitaxel/cisplatin or paclitaxel/topotecan. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/4 mL (25 mg/ mL) in single dose vial and 400 mg/16 mL (25 mg/mL) in single dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Black Box Warning:** (1) Gastrointestinal perforation (may be serious and/or fatal) has been reported; discontinue use if suspected. (2) Increased risk of impaired wound healing and/or wound dehiscence; discontinue use if suspected. (3) Discontinue at least 28 days prior to elective surgery and do not reinitiate for at least 28 days post surgery and until surgical wound is fully healed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mvasi™ (bevacizumab-awwb) Injection for intravenous use / Amgen Inc. (continuation)	Antineoplastic agent Anti-vascular endothelial growth factor A (anti-VEGF) monoclonal antibody Biosimilar to Avastin (bevacizumab)	Treatment of multiple types of cancer : • Metastatic colorectal cancer • Non-small cell lung cancer • Glioblastoma multiforme • Metastatic renal cell carcinoma (mRCC) • Cervical cancer **Black Box Warning** Gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.	09/14/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Black Box Warning:** (4) Hemorrhage, which may be severe or fatal, including hemoptysis, gastrointestinal bleeding, CNS hemorrhage, epistaxis, and vaginal bleeding, has been reported, with an increased risk of gastrointestinal hemorrhage in elderly patients; discontinuation required. (5) Avoid use in patients with serious hemorrhage or recent hemoptysis (0.5 teaspoon or more of red blood). • **Cardiovascular:** Increased risk for severe (Grade 3 or 4) hypertension; monitoring required and interruption or discontinuation may be necessary. • **Fistulae:** Non-gastrointestinal fistulae (ie, tracheoesophageal, bronchopleural, biliary, vaginal, renal, bladder) which may be serious and/or fatal, have been reported. Discontinue use if fistula formation involving internal organs is suspected, permanent discontinuation is required for tracheoesophageal fistula or any Grade 4 fistula. • **Gastrointestinal:** Gastrointestinal fistulae, including gastrointestinal-vaginal fistula, have been reported and may be accompanied by bowel obstruction requiring surgical interventions. • **Hematologic:** (1) sMicroangiopathic hemolytic anemia has been reported when used in combination with sunitinib for treatment of renal cell carcinoma (unapproved use). (2) Thrombotic microangiopathy has been reported; monitoring recommended and discontinuation may be needed. (3) Serious and sometimes fatal arterial thrombotic events (ie, cerebral infarction, angina, transient ischemic attack, myocardial infarction) have been reported, with an increased risk in patients with a history of arterial thromboembolism, diabetes, or age greater than 65 years; discontinue use if severe event is suspected. (4) Venous thromboembolic events have been reported, with an increased risk in patients with persistent, recurrent, or metastatic cervical cancer; permanent discontinuation required if life-threatening (Grade 4) thromboembolism or pulmonary embolism occur.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mvasi™ (bevacizumab-awwb) Injection for intravenous use / Amgen Inc. (continuation)	Antineoplastic agent Anti-vascular endothelial growth factor A (anti-VEGF) monoclonal antibody Biosimilar to Avastin (bevacizumab)	Treatment of multiple types of cancer : • Metastatic colorectal cancer • Non-small cell lung cancer • Glioblastoma multiforme • Metastatic renal cell carcinoma (mRCC) • Cervical cancer **Black Box Warning** Gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.	09/14/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Infusion reactions** (ie, hypertension, hypertensive crisis, wheezing, oxygen desaturation, hypersensitivity reaction (Grade 3), chest pain, headache, rigors, and diaphoresis) have been reported; if severe reaction occurs, stop infusion and institute appropriate therapy. • **Necrotizing fascitis**, sometimes fatal, has been reported, and is typically secondary to wound healing complications, gastrointestinal perforation, or fistula formation; discontinue use if suspected. • **Neurologic:** (1) Posterior reversible encephalopathy syndrome (PRES) has been reported, occurring from 16 hours up to 1 year after treatment initiation; MRI required to confirm diagnosis; discontinue use in patients developing PRES. (2) Intracranial hemorrhage has been reported; discontinue use if suspected. • **Renal:** (1) Nephrotic syndrome, sometimes fatal, has been reported; monitoring recommended; discontinue use if suspected. (2) Proteinuria has been reported, with an increased risk in elderly patients; monitoring recommended and interrupt treatment for greater than or equal to 2 g of proteinuria per 24 hours. • **Reproductive:** (1) Increased risk of ovarian failure has been reported and fertility may be impaired. (2) Ovarian failure has been reported with concomitant modified fluorouracil/leucovorin/oxaliplatin (mFOLFOX) chemotherapy use in premenopausal women with colorectal cancer (unapproved use). • **Respiratory:** Serious and/or fatal pulmonary hemorrhage has been reported; discontinue use if suspected **ADVERSE REACTIONS** Most common adverse reactions: epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Mvasi™ (bevacizumab-awwb) Injection for intravenous use / Amgen Inc. (continuation)	Antineoplastic agent Anti-vascular endothelial growth factor A (anti-VEGF) monoclonal antibody Biosimilar to Avastin (bevacizumab)	Treatment of multiple types of cancer : • Metastatic colorectal cancer • Non-small cell lung cancer • Glioblastoma multiforme • Metastatic renal cell carcinoma (mRCC) • Cervical cancer **Black Box Warning** Gastrointestinal perforations, surgery and wound healing complications, and hemorrhage.	09/14/2017	**DRUG INTERACTIONS** No major drug-drug interactions identifyed. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Advise female patients of reproductive potential to use effective contraception during treatment and for 6 months following the last dose. • **Lactation:** Not recommended. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Adzenys ER™ (amphetamine) Extended-Release Liquid Suspension, for oral use / Neos Therapeutics, Inc.	Central nervous system (CNS) stimulant	Treatment of ADHD in patients 6 years and older **Black Box Warning** Abuse and dependence	09/15/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for pediatric patients (ages 6 to 17 years) is: • Starting dose: 6.3 mg (5 mL) once daily in the morning. • Maximum dose: 18.8 mg (15 mL) for patients 6 to 12 years, and 12.5 mg (10 mL) once daily for patients 13 to 17 years. The recommended dose for adults is 12.5 mg (10 mL) once daily in the morning. **DOSAGE FORMS AND STRENGTHS** Extended-release oral suspension containing 1.25 mg amphetamine per mL. **CONTRAINDICATIONS** • Known hypersensitivity to amphetamine products or other ingredients in Adzenys ER™. • Use of monoamine oxidase inhibitor (MAOI) or within 14 days of the last MAOI dose. **WARNINGS AND PRECAUTIONS** • **Serious Cardiovascular Reactions:** Sudden death has been reported in association with CNS stimulant treatment at recommended doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, or coronary artery disease. • **Blood Pressure and Heart Rate Increases:** Monitor blood pressure and pulse. Consider benefits and risks before use in patients for whom blood pressure increases may be problematic.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Adzenys ER™ (amphetamine) Extended-Release Liquid Suspension, for oral use / Neos Therapeutics, Inc. (continuation)	Central nervous system (CNS) stimulant	Treatment of ADHD in patients 6 years and older **Black Box Warning** Abuse and dependence	09/15/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Psychiatric Adverse Reactions:** May cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychosis. Evaluate for bipolar disorder prior to stimulant use. • **Long-Term Suppression of Growth:** Monitor height and weight in pediatric patients during treatment. • **Peripheral Vasculopathy, including Raynaud's phenomenon:** Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants. • **Serotonin Syndrome:** Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), but also during overdosage situations. If it occurs, discontinue ADZENYS ER and initiate supportive treatment. **ADVERSE REACTIONS** Most common adverse reactions: loss of appetite, insomnia, abdominal pain, weight loss, emotional lability, vomiting, nervousness, nausea, and fever. **DRUG INTERACTIONS** • **Acidifying and Alkalinizing Agents:** Agents that alter urinary pH can alter blood levels of amphetamine. Acidifying agents can decrease amphetamine blood levels, while alkalinizing agents can increase amphetamine blood levels. Adjust Adzenys ER™ dosage accordingly. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Lactation:**. Breastfeeding not recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Solosec™ (secnidazole) Granules, for oral use / Symbiomix Therapeutics, LLC	Nitroimidazole antimicrobial	Treatment of bacterial vaginosis (BV)	09/15/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is a single 2-gram packet of granules once orally. • Sprinkle entire contents of packet onto applesauce, yogurt or pudding and consume all of the mixture within 30 minutes without chewing or crunching the granules. A glass of water may be taken after the administration to aid in swallowing. **DOSAGE FORMS AND STRENGTHS** Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet. **CONTRAINDICATIONS** • History of hypersensitivity to secnidazole, other ingredients of the formulation, or other nitroimidazole derivatives. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Drug-resistant bacteria may develop when prescribed in the absence of bacterial infection. • **Reproductive:** Vulvo-vaginal candidiasis has been reported. **ADVERSE REACTIONS** Most common adverse reactions: vulvo-vaginal candidiasis, headache, nausea, dysgeusia, vomiting, diarrhea, abdominal pain, and vulvovaginal pruritus. **DRUG INTERACTIONS** No major drug-drug interactions identifyed. **USE IN SPECIFIC POPULATIONS** • **Lactation:** Not recommended. Discontinue breastfeeding for 96 hours after administration. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients <18 years. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects ≥ 65 years.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trelegy Ellipta™ (fluticasone furoate, umeclidinium and vilanterol) Inhalation Powder, for oral use / GlaxoSmithKline	Inhaled corticosteroid, long-acting muscarinic antagonist (LAMA) and long-acting beta$_2$-adrenergic agonist (LABA) combination	Treatment of patients with chronic obstructive pulmonary disease (COPD) **Black Box Warning** Asthma-related death	09/18/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 1 inhalation once daily. **DOSAGE FORMS AND STRENGTHS** Inhalation Powder: Inhaler containing 2 foil blister strips of powder formulation for oral inhalation. One strip contains fluticasone furoate 100 mcg per blister and the other contains umeclidinium/vilanterol 62.5 mcg/25 mcg per blister. **CONTRAINDICATIONS** • Hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any excipients of the product. • Severe hypersensitivity to milk proteins. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Risk of asthma-related death is increased with long-acting beta(2)-adrenergic agonists (unapproved use with fluticasone furoate/umeclidinium/vilanterol). • **Cardiovascular:** (1) Clinically significant cardiovascular effects can occur (eg, increased pulse rate, blood pressure increase, cardiac arrhythmia, supraventricular tachycardia, extrasystoles); discontinuation may be necessary. (2) ECG changes (ie, flattening of T-wave, QT prolongation, ST segment depression) have been reported. (3) Exercise caution in patients with cardiovascular disorders, particularly coronary insufficiency, cardiac arrhythmias, and hypertension. • **Concomitant use:** Medications containing other long-acting beta(2)-adrenergic agonists should not be used during therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trelegy Ellipta™ (fluticasone furoate, umeclidinium and vilanterol) Inhalation Powder, for oral use / GlaxoSmithKline (continuation)	Inhaled corticosteroid, long-acting muscarinic antagonist (LAMA) and long-acting beta$_2$-adrenergic agonist (LABA) combination	Treatment of patients with chronic obstructive pulmonary disease (COPD) **Black Box Warning** Asthma-related death	09/18/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Endocrine and metabolic:** (1) Upon switching from systemic to inhaled corticosteroid; deaths due to adrenal insufficiency have been reported in patients with asthma. Wean oral therapy slowly while transferring to inhaled therapy; monitoring recommended. (2) Inadequate adrenal response; especially in postoperative patients or during times of stress; monitoring recommended. (3) Corticosteroid systemic effects; increased risk with higher than recommended doses or coadministration of a strong CYP3A4 inhibitor; monitoring recommended. (4) Hypokalemia, possibly through intracellular shunting, may occur and can produce adverse cardiovascular effects. (5) Aggravation of preexisting diabetes mellitus or ketoacidosis or transient hyperglycemia may occur. • **Immunologic:** (1) Localized Candida albicans infections of the mouth and pharynx have been reported; treatment interruption may be required. (2) Hypersensitivity reactions, including anaphylaxis, may occur; discontinue use. (3) Immunosuppression; increased risk of infections, including chicken pox and measles; avoid exposure. Prophylaxis with immune globulin may be indicated. • **Musculoskeletal:** Decreases in bone mineral density have been reported with long term use. Increased risk with prolonged immobilization, family history of osteoporosis, postmenopausal status, tobacco use, elderly, poor nutrition, or chronic use of bone bass reducing agents (ie, anticonvulsants, oral corticosteroids); monitoring recommended. • **Ophthalmic:** Glaucoma, increased intraocular pressure, and cataracts have been reported with long term use; monitoring recommended. • **Renal:** Exercise caution in patients with urinary retention. Increased risk with prostatic hyperplasia or bladder neck obstruction; monitoring recommended.

New FDA Approved Products

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Trelegy Ellipta™ (fluticasone furoate, umeclidinium and vilanterol) Inhalation Powder, for oral use / GlaxoSmithKline (continuation)	Inhaled corticosteroid, long-acting muscarinic antagonist (LAMA) and long-acting beta$_2$-adrenergic agonist (LABA) combination	Treatment of patients with chronic obstructive pulmonary disease (COPD) **Black Box Warning** Asthma-related death	09/18/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Respiratory:** (1) Use not recommended in rapidly or acutely deteriorating COPD. (2) Use not recommended for the relief of acute symptoms, such as rescue therapy for acute episodes of bronchospasm. (3) Lower respiratory tract infections, including pneumonia, may occur. (4) Paradoxical bronchospasm may occur and can be life-threatening; discontinue use immediately and institute alternative therapy. **ADVERSE REACTIONS** Most common adverse reactions: headache, back pain, dysgeusia, diarrhea, cough, oropharyngeal pain, and gastroenteritis. **DRUG INTERACTIONS** • **Strong CYP450 3A4 inhibitors:** Use with caution. May cause systemic corticosteroid and cardiovascular effects. • **Monoamine oxidase inhibitors and tricyclic antidepressants:** Use with extreme caution. May potentiate effect of vilanterol on vascular system. • **Beta-blockers:** Use with caution. May block bronchodilatory effects of beta-agonists and produce severe bronchospasm. • **Diuretics:** Use with caution. Electrocardiographic changes and/or hypokalemia associated with non–potassium-sparing diuretics may worsen with concomitant beta-agonists. • **Anticholinergics:** May interact additively with concomitantly used anticholinergic medications. Avoid administration of with other anticholinergic-containing drugs. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Not indicated for use in children. The safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No adjustment of the dosage is necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Trelegy Ellipta™ (fluticasone furoate, umeclidinium and vilanterol) Inhalation Powder, for oral use / GlaxoSmithKline
 	
(continuation)
	Inhaled corticosteroid, long-acting muscarinic antagonist (LAMA) and long-acting beta$_2$-adrenergic agonist (LABA) combination	Treatment of patients with chronic obstructive pulmonary disease (COPD)
		
		Black Box Warning
		Asthma-related death
			09/18/2017	**USE IN SPECIFIC POPULATIONS** (continuation)
				• **Pediatric use:** Not indicated for use in children. The safety and efficacy in pediatric patients have not been established.
				• **Geriatric use:** No adjustment of the dosage is necessary.
				• **Hepatic impairment:** Fluticasone furoate systemic exposure may increase in patients with moderate or severe impairment. Monitor for systemic corticosteroid effects.
				• Exercise caution in:
				  • Patients with active or quiescent TB, untreated systemic fungal, bacterial, parasitic, or viral infections, and ocular herpes simplex.
				  • Patients with convulsive disorders or thyrotoxicosis and those who are unusually responsive to sympathomimetic amines.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xhance™ (fluticasone propionate) Nasal Spray / OptiNose US Inc.	Topical nasal corticosteroid	Treatment of nasal polyps	09/18/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 1 spray (93 mcg) in each nostril twice daily at regular intervals (total daily dose 372 mcg). • Two sprays (186 mcg) in each nostril twice daily may by used in some patients (total daily dose 744 mcg). • MAX 2 sprays in each nostril twice daily (total daily dose 744 mcg). **DOSAGE FORMS AND STRENGTHS** Nasal spray: 93 mcg of fluticasone propionate in each 106-mg spray. **CONTRAINDICATIONS** • Hypersensitivity to any ingredient in Xhance™. **WARNINGS AND PRECAUTIONS** • **Local Nasal Effects:** epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing. Monitor patients periodically for signs of possible changes on the nasal mucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma. • **Glaucoma and cataracts:** Close monitoring for glaucoma and cataracts is warranted. • **Hypersensitivity reactions** (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue Xhance™ if such reactions occur. • **Immunosuppression:** potential increased susceptibility to or worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xhance™ (fluticasone propionate) Nasal Spray / OptiNose US Inc. (continuation)	Topical nasal corticosteroid	Treatment of nasal polyps in patients 18 years of age or older	09/18/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hypercorticism and adrenal suppression** may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Xhance™ slowly. Assess for decrease in bone mineral density initially and periodically thereafter. **ADVERSE REACTIONS** Most common adverse reactions: epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis. **DRUG INTERACTIONS** • **Strong CYP450 3A4 inhibitors:** Use not recommended. May increase risk of systemic corticosteroid effects. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and efficacy in pediatric patients have not been established. • **Hepatic impairment:** Monitor patients for signs of increased drug exposure.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Verzenio™ (abemaciclib) for oral use / Eli Lilly and Company	Antineoplastic agent Selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6	Treatment of metastatic breast cancer	09/28/2017	**DOSAGE AND ADMINISTRATION** The recommended starting dose in combination with fulvestrant is 150 mg orally twice daily in combination with fulvestrant 500 mg IM on day 1, 15, and 29 and once monthly thereafter until disease progression or unacceptable toxicity. The recommended starting dose as monotherapy is 200 mg twice daily until disease progression or unacceptable toxicity. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg, 100 mg, 150 mg, and 200 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Gastrointestinal:** Diarrhea has been reported and may be associated with dehydration or infection. Consider antidiarrheal therapy and discontinue use for severe diarrhea or diarrhea resulting in hospitalization. • **Hematologic:** (1) Fatal neutropenic sepsis has been reported. (2) Neutropenia, including febrile neutropenia, has occurred; monitoring recommended and interruption, reduction, or delay of treatment may be required. (3) Venous thromboembolic events, including deep vein thrombosis, pulmonary embolism, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis, have been reported; monitoring recommended. • **Hepatic:** Hepatotoxicity and increases in ALT have been reported; monitoring recommended and interruption, reduction, discontinuation, or delay of treatment may be required. • **Reproductive:** Drug may cause fetal harm; use of adequate contraception is required during treatment and for at least 3 weeks after final dose

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Verzenio™ (abemaciclib) for oral use / Eli Lilly and Company (continuation)	Antineoplastic agent Selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6	Treatment of metastatic breast cancer	09/28/2017	**ADVERSE REACTIONS** Most common adverse reactions: diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, and thrombocytopenia. **DRUG INTERACTIONS** • **CYP3A Inhibitors:** Avoid concomitant use of ketoconazole. Reduce the Verzenio™ dose with concomitant use of other strong CYP3A inhibitors. • **CYP3A Inducers:** Avoid concomitant use of strong CYP3A inducers. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 weeks after the last dose • **Lactation:** Advise not to breastfeed during treatment and for at least 3 weeks after the last dose. • **Pediatric use:** The safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or effectiveness were observed between these patients and younger patient.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Fiasp™ (insulin aspart) Injection, for subcutaneous or intravenous use / Novo Nordisk	Rapid-acting human insulin analog	To improve glycemic control in adults with diabetes mellitus type 1 and type 2	09/29/2017	**DOSAGE AND ADMINISTRATION** Individualize and adjust the dosage of FIASP based on route of administration, individual's metabolic needs, blood glucose monitoring results and glycemic control goal. Dosage adjustments may be needed when switching from another insulin, with changes in physical activity, changes in concomitant medications, changes in meal patterns, changes in renal or hepatic function or during acute illness. **DOSAGE FORMS AND STRENGTHS** Injection: 100 units/mL (U-100): • 10 mL multiple-dose vial • 3 mL single-patient-use FIASP FlexTouch™ pen **CONTRAINDICATIONS** • During episodes of hypoglycemia. • Hypersensitivity to insulin aspart or one of the excipients in Fiasp™. **WARNINGS AND PRECAUTIONS** • **Hyper- or hypoglycemia with changes in insulin regimen:** Carry out under close medical supervision and increase frequency of blood glucose monitoring. • **Hypoglycemia:** May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness. • **Hypoglycemia due to medication errors:** Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection. • **Hypokalemia:** May be life-threatening. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Fiasp™ (insulin aspart) Injection, for subcutaneous or intravenous use / Novo Nordisk (continuation)	Rapid-acting human insulin analog	To improve glycemic control in adults with diabetes mellitus type 1 and type 2	09/29/2017	**WARNINGS AND PRECAUTIONS** (continuation) • **Hypersensitivity reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue FIASP, monitor and treat if indicate. • **Fluid retention and heart failure with concomitant use of thiazolidinediones (TZDs):** Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs. **ADVERSE REACTIONS** Most common adverse reactions: hypoglycemia, allergic reactions, hypersensitivity, injection site reactions, lipodystrophy, and weight gain. **DRUG INTERACTIONS** • **Drugs that Increase Hypoglycemia Risk or Increase or Decrease Blood Glucose Lowering Effect:** Adjustment of dosage may be needed; closely monitor blood glucose. • **Drugs that Blunt Hypoglycemia Signs and Symptoms** (e.g., beta-blockers, clonidine, guanethidine, and reserpine): Increased frequency of glucose monitoring may be required. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between elderly and younger adult patients. • **Renal Impairment:** Patients with renal impairment may be at increased risk of hypoglycemia and may require more frequent FIASP dose adjustment and more frequent blood glucose monitoring. • **Hepatic Impairment:** Patients with hepatic impairment may be at increased risk of hypoglycemia and may require more frequent FIASP dose adjustment and more frequent blood glucose monitoring.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Aptiom™ (eslicarbazepine acetate) Tablets / Sunovion Pharmaceuticals Inc.	Voltage-gated sodium channel blocker	Treatment of partial-onset seizures (POS) in patients with epilepsy **Patient population altered:** Indication expanded to include treatment of POS in children and adolescents 4 to 17 years of age	09/13/2017	Aptiom™ is also approved in the U.S. for the treatment of POS in adults. Aptiom™ is a once-daily, immediate release AED that can be taken whole or crushed, with or without food. The safety and efficacy of Aptiom™ as monotherapy and adjunctive therapy for the treatment of POS in adults was established in five multicenter, randomized, controlled clinical trials. Data from three clinical trials conducted by Sunovion's partner BIAL also supported the safety and tolerability of Aptiom™ for the treatment of POS in pediatric patients. Pharmacokinetic analyses of adult and pediatric data supported the proposed dosing regimen in the pediatric population.
Privigen™ (immune globulin intravenous (human)) / CSL Behring	Immune globulin	Treatment of primary humoral immunodeficiency (PI), chronic immune thrombocytopenic purpura (ITP), and chronic inflammatory demyelinating polyneuropathy (CIDP) **New Indication:** Treatment of adults with CIDP to improve neuromuscular disability	09/14/2017	CIDP is a rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage. The FDA approval was based on results from two Phase III clinical studies that focused on the use of immunoglobulin (Ig) therapy for treating CIDP – the Polyneuropathy And Treatment with Hizentra (PATH) study, the largest controlled clinical study in CIDP patients to date, and the Privigen Impact on Mobility and Autonomy (PRIMA) study. In PATH, 207 patients receiving Privigen were studied for up to 13 weeks, and 73% responded to Privigen over the course of treatment, as measured by their adjusted score on the Inflammatory Neuropathy Cause and Treatment (INCAT) scale, which measures the ability to walk and perform tasks. In PRIMA (n=28), 61% of patients responded to Privigen over 25 weeks, as measured by their adjusted INCAT score.
Briviact™ (brivaracetam) Tablets / UCB	Synaptic vesicle protein 2A ligand and analog of levetiracetam	Treatment of partial-onset seizures in patients with epilepsy **New Indication:** Monotherapy for partial-onset (focal) seizures (POS) in patients 16 years and older with epilepsy	09/14/2017	Briviact™ was already approved as adjunctive treatment for POS in patients in this age group. As a result, adults and adolescents aged 16 years and older with POS in the U.S. can now be initiated on Briviact™ as monotherapy or adjunctive therapy.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Somatuline Depot™ (lanreotide acetate) Injection / Ipsen	Long acting somatostatin analogue	Treatment of acromegaly, gastroenteropancreatic neuroendocrine tumors, and carcinoid syndrome **New Indication:** Treatment of carcinoid syndrome	09/15/2017	The additional Somatuline Depot approval for carcinoid syndrome was based on "Evaluation of Lanreotide Depot/Autogel Efficacy and Safety as a Carcinoid Syndrome Treatment (ELECT): A Randomized, Double-Blind, Placebo-Controlled Trial," published in Endocrine Practice.
Rapivab™ (peramivir) Injection / BioCryst Pharmaceuticals	Influenza virus neuraminidase inhibitor	Treatment of acute uncomplicated influenza **Patient population altered:** Treatment of acute uncomplicated influenza to pediatric patients 2 years and older who have been symptomatic for no more than two days.	09/20/2017	The pediatric approval was based on the interim analysis of an ongoing pediatric clinical study.
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma (HCC) **New Indication:** Treatment of patients with HCC who have been previously treated with sorafenib	09/22/2017	Approval for this indication has been granted under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. In the CheckMate -040 trial, 14.3%* (95% CI: 9.2-20.8; 22/154) of patients responded to treatment with Opdivo™. The percentage of patients with a complete response was 1.9% (3/154) and the percentage of patients with a partial response was 12.3% (19/154).1 Among responders (n=22), responses ranged from 3.2 to 38.2+ months; 91% of those patients had responses of six months or longer and 55% had responses of 12 months or longer.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Human PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, and gastric cancer **New Indication:** Treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy	09/22/2017	This indication is approved under the FDA's accelerated approval regulations based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tracleer™ Film-Coated Tablets and Tablets for Oral Suspension (bosentan) / Actelion Pharmaceuticals US, Inc.	Endothelin receptor antagonist	Treatment of pulmonary arterial hypertension	09/05/2017	FDA has approved a new 32 mg tablet for oral suspension for Tracleer™ for use in pediatric patients aged 3 years and older with idiopathic or congenital pulmonary arterial hypertension (PAH), to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability. With this approval, Tracleer becomes the first FDA-approved medicine for pediatric PAH patients in the United States. PAH is a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs of an affected person.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Oseltamivir Phosphate for Oral Suspension 6 mg (base)/mL / Nesher Pharmaceuticals (USA) LLC	Antiviral	09/14/2017	Generic for: Tamiflu for Oral Suspension

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Elagolix / AbbVie, Inc.	09/06/2017	Management of endometriosis with associated pain	Elagolix is an investigational, orally administered gonadotropin-releasing hormone (GnRH) antagonist in development for the management of endometriosis with associated pain.	Moderate

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

References:

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