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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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NEWS……

Drug Issue	Date	News/Event
Decreased survival associated with the use of Keytruda™ (pembrolizumab) or Tecentriq™ (atezolizumab) as monotherapy	05/18/2018	The FDA is alerting about decreased survival associated with the use of Keytruda™ (pembrolizumab) or Tecentriq™ (atezolizumab) as monotherapy in clinical trials to treat patients with metastatic urothelial cancer who have not received prior therapy and who have low expression of the protein programmed death ligand 1 (PD-L1). Early reviews from two ongoing clinical trials (KEYNOTE-361 and IMVIGOR-130) found patients in the monotherapy arms of both trials with PD-L1 low status had decreased survival compared to patients who received cisplatin- or carboplatin-based chemotherapy. Health care professionals should be aware that the populations enrolled in the ongoing clinical trials were eligible for platinum-containing chemotherapy, and therefore differ from those enrolled in the trials that led to the accelerated approvals of both Keytruda™ and Tecentriq™ in the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy. FDA recommends providers select patients for the treatment of locally advanced or metastatic urothelial cancer using the criteria described in Section 14 of each label. These criteria supported the approvals for Keytruda™ and Tecentriq™ for initial monotherapy in cisplatin-ineligible patients.
Potential risk of neural tube defects with dolutegravir	05/18/2018	Serious cases of neural tube birth defects involving the brain, spine, and spinal cord have been reported in babies born to women with human immunodeficiency virus (HIV) treated with dolutegravir. Preliminary results from an ongoing observational study found that women who received dolutegravir at the time of becoming pregnant or early in the first trimester appear to be at higher risk for these defects. To date, in this observational study there are no reported cases of babies born with neural tube defects to women starting dolutegravir later in pregnancy. This new safety issue is under investigation and updates will be published when more information is available. Dolutegravir is available as a single ingredient product under the brand name Tivicay™ and as a fixed dose combination tablet with other antiretroviral drugs under the brand names Juluca™ and Triumeq™. Healthcare professionals should inform women of childbearing age about the potential risk of neural tube defects when a dolutegravir-containing regimen is used at the time of conception and early in pregnancy. In addition, healthcare professionals should weigh the benefits and the risks of dolutegravir when prescribing antiretroviral medicines to women of childbearing age. Alternative antiretroviral medicines should be considered. If the decision is made to use dolutegravir in women of childbearing age, health care professionals should reinforce the consistent use of effective birth control. Perform pregnancy testing before initiating a dolutegravir-containing regimen in women of childbearing age to exclude pregnancy.

NEWS……

Drug Issue	Date	News/Event
Risk of serious and potentially fatal blood disorder with oral over-the-counter benzocaine products	05/23/2018	The FDA is warning that oral over-the-counter (OTC) benzocaine products pose a serious risk to infants and children younger than 2 years. In addition, the FDA is requesting that companies add new warnings to all other benzocaine oral health products to describe certain serious risks. Benzocaine can cause methemoglobinemia, a condition where the amount of oxygen carried through the blood is greatly reduced and which can be life-threatening and result in death. Due to the significant safety risk of methemoglobinemia, benzocaine products should no longer be marketed for the temporary relief of sore gums due to teething in infants or children younger than 2 years and companies must stop selling these products for such use. Benzocaine products should only be used in adults and children 2 years and older. Manufacturers must make the following changes to the labels: • Adding a warning about methemoglobinemia; • Adding contraindications, directing parents and caregivers not to use the product for teething and not to use in infants and children younger than 2 years; and • Revising the directions to direct parents and caregivers not to use the product in infants and children younger than 2 years. Benzocaine products are marketed as gels, sprays, ointments, solutions, and lozenges under brand names such as Anbesol, Orabase, Orajel, Baby Orajel, Hurricaine, and Topex, as well as store brands and generics. Health care professionals should warn patients of the possibility of methemoglobinemia and advise them of the signs and symptoms when recommending or prescribing local anesthetic products.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Andexxa™ (coagulation factor Xa (recombinant), inactivated-zhzo) / Portola Pharmaceuticals, Inc.	Blood modifier agent Recombinant modified human Factor Xa (FXa) Note: Orphan drug designaton.	For patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding **Limitation of use:** Andexxa™ has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban and rivaroxaban. **Black box warning:** Thromboembolic risks, ischemic risks, cardiac arrest, and sudden deaths	05/03/2018	**DOSAGE AND ADMINISTRATION** It is recommended to dose Andexxa™ based on the specific FXa inhibitor, dose of FXa inhibitor, and time since the patient's last dose of FXa inhibitor. Andexxa™ is administered as an intravenous (IV) bolus, with a target rate of 30 mg/min, followed by continuous infusion for up to 120 minutes. There are two dosing regimens: • Low dose regimen: o Initial IV Bolus: 400 mg at a target rate of 30 mg/min o Follow-on IV Infusion: 4 mg/min for up to 120 minutes • High dose regimen: o Initial IV Bolus: 800 mg at a target rate of 30 mg/min o Follow-on IV Infusion:8 mg/min for up to 120 minutes It is of note that the safety and effectiveness of more than one dose have not been evaluated. **DOSAGE FORMS AND STRENGTHS** Lyophilized powder in single-use vials of 100 mg of coagulation factor Xa (recombinant), inactivated-zhzo. **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Andexxa™ (coagulation factor Xa (recombinant), inactivated-zhzo) / Portola Pharmaceuticals, Inc. (continuation)	Blood modifier agent Recombinant modified human Factor Xa (FXa) Note: Orphan drug designaton.	For patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding **Limitation of use:** Andexxa™ has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban and rivaroxaban. **Black box warning:** Thromboembolic risks, ischemic risks, cardiac arrest, and sudden deaths	05/03/2018	**WARNINGS AND PRECAUTIONS** • **Black box warning:** Arterial and venous thromboembolic events, ischemic events, and cardiac events, including sudden death, have occurred during treatment with Andexxa™. Resume anticoagulant therapy as soon as medically appropriate following treatment with Andexxa™. • **Immunologic:** Re-elevation or incomplete reversal of anti-FXa activity has been reported. **ADVERSE REACTIONS** Most common adverse reactions: urinary tract infections and pneumonia. **DRUG INTERACTIONS** No drug interactions identified at the moment. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in the pediatric population have not been studied. • **Geriatric use:** No overall differences in safety or efficacy were observed between these subjects and younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Plenvu™ (polyethylene glycol 3350 with electrolytes) for Oral Solution / Salix Pharmaceuticals, Inc.	Laxative Lower-volume, polyethylene glycol based osmotic laxative	For cleansing of the colon (bowel preparation) prior to colonoscopy in adults	05/04/2018	**DOSAGE AND ADMINISTRATION** Two doses of Plenvu™ are required for a complete preparation for colonoscopy, using one of the following dosing regimens: • Two-Day: Dose 1 the evening before the colonoscopy (approximately 4 pm to 8 pm) and Dose 2 the next morning (approximately12 hours after the start of Dose 1). • One-Day: Dose 1 the morning of the colonoscopy (approximately 3 am to 7 am) and Dose 2 a minimum of 2 hours after the start of Dose 1. It is of note that Plenvu™ must be reconstituted in water prior to ingestion and additional clear liquids must be consumed after each dose of Plenvu™ in both dosing regimens. **DOSAGE FORMS AND STRENGTHS** For Oral Solution: (1) First dose - one pouch labeled Dose 1; (2) Second dose: two pouches labeled Dose 2 Pouch A and Dose 2 Pouch B. • Dose 1 contains 100 grams of polyethylene glycol (PEG) 3350, NF; 9 grams of sodium sulfate, NF; 2 grams of sodium chloride, USP/NF; and 1 gram of potassium chloride, USP/NF. • Dose 2 Pouch A contains 40 grams of PEG 3350, NF; 3.2 grams of sodium chloride, USP/NF; and 1.2 grams of potassium chloride, USP/NF. • Dose 2 Pouch B contains 48.11 grams of sodium ascorbate, USP/NF; and 7.54 grams of ascorbic acid, USP/NF. **CONTRAINDICATIONS** • Gastrointestinal (GI) obstruction • Bowel perforation • Gastric retention • Ileus • Toxic megacolon • Hypersensitivity to any ingredient in Plenvu™

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Plenvu™ (polyethylene glycol 3350 with electrolytes) for Oral Solution / Salix Pharmaceuticals, Inc. (continuation)	Laxative Lower-volume, polyethylene glycol based osmotic laxative	For cleansing of the colon (bowel preparation) prior to colonoscopy in adults	05/04/2018	**WARNINGS AND PRECAUTIONS** • **Risk of fluid and electrolyte abnormalities:** Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after use. • **Cardiac arrhythmias:** Consider pre-dose and post-colonoscopy ECGs in patients at increased risk. • **Seizures:** Use caution in patients with a history of seizures and patients at increased risk of seizure, including medications that lower the seizure threshold. • **Patients with renal impairment or taking concomitant medications that affect renal function:** Use caution, ensure adequate hydration and consider testing. • **Mucosal ulcerations:** Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. • **Suspected GI obstruction or perforation:** Rule out diagnosis before administration. • **Patients at risk for aspiration:** Observe during administration. • **Glucose-6-phosphate dehydrogenase deficiency (G6PD):** Use with caution. • **Risks in patients with phenylketonuria:** Contains phenylalanine. • **Hypersensitivity reactions, including anaphylaxis:** Inform patients to seek immediate medical care if symptoms occur **ADVERSE REACTIONS** Most common adverse reactions: nausea, vomiting, dehydration and abdominal pain/discomfort.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Plenvu™ (polyethylene glycol 3350 with electrolytes) for Oral Solution / Salix Pharmaceuticals, Inc. (continuation)	Laxative Lower-volume, polyethylene glycol based osmotic laxative	For cleansing of the colon (bowel preparation) prior to colonoscopy in adults	05/04/2018	**DRUG INTERACTIONS** • **Drugs that increase risks due to fluid and electrolyte change:** Use caution when prescribing Plenvu™ for patients with conditions and/or who are using medications that increase the risk of fluid and electrolyte disturbances or may increase the risk of renal impairment, seizures, arrhythmias, or QT prolongation in the setting of fluid and electrolyte abnormalities. • **Stimulant laxatives:** Concurrent use of stimulant laxatives and Plenvu™ may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g. bisacodyl, sodium picosulfate) while taking Plenvu™. • **Co-administered drugs:** Plenvu™ can reduce the absorption of other co-administered drugs. Administer oral medications at least 1 hour before the start of administration of each dose of Plenvu™. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness in pediatric patients has not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between geriatric patients and younger patients. • **Renal impairment:** Use Plenvu™ with caution in patients with renal impairment or patients taking concomitant medications that may affect renal function. These patients may be at risk for renal injury. Advise these patients of the importance of adequate hydration before, during and after the use of Plenvu™, and consider performing baseline and post-colonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Retacrit™ (epoetin alfa-epbx) for Injection, for intravenous or subcutaneous use / Hospira, Inc.	Blood modifier agent Erythropoiesis-stimulating agent (ESA) Note: Biosimilar to Epogen/Procrit (epoetin alfa)	(1) For the treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection, and (2) for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery **Limitations of use:** Has not been shown to improve quality of life, fatigue, or patient well-being. It is not indicated for use: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. • In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. • In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. • In patients scheduled for surgery who are willing to donate autologous blood. • In patients undergoing cardiac or vascular surgery. • As a substitute for RBC transfusions in patients who require immediate correction of anemia. **Black box warning:** ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.	05/15/2018	**DOSAGE AND ADMINISTRATION** For patients with CKD, the recommended initial dose is 50 to 100 Units/kg 3 times weekly (adults) and 50 Units/kg 3 times weekly (pediatric patients). Maintenance dose must be individualized. Intravenous route is recommended for patients on hemodialysis. For patients on zidovudine due to HIV-infection, the recommended dose is 100 Units/kg 3 times weekly. For patients with cancer on chemotherapy, the recommended dose is 40,000 Units weekly or 150 Units/kg 3 times weekly (adults); 600 Units/kg intravenously weekly (pediatric patients > 5 years). For surgery patients, the recommended dose is 300 Units/kg per day daily for 15 days or 600 Units/kg weekly. • Evaluate iron status before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia before initiating treatment. **DOSAGE FORMS AND STRENGTHS** Injection: 2,000 Units/mL, 3,000 Units/mL, 4,000 Units/mL, 10,000 Units/mL, and 40,000 Units/mL in single-dose vials. **CONTRAINDICATIONS** • Uncontrolled hypertension. • Pure red cell aplasia (PRCA) that begins after treatment with Retacrit™ or other erythropoietin protein drugs. • Serious allergic reactions to Retacrit™ or other epoetin alfa products.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Retacrit™ (epoetin alfa-epbx) for Injection, for intravenous or subcutaneous use / Hospira, Inc. (continuation)	Blood modifier agent Erythropoiesis-stimulating agent (ESA) Note: Biosimilar to Epogen/Procrit (epoetin alfa)	(1) For the treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection, and (2) for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery **Limitations of use:** Has not been shown to improve quality of life, fatigue, or patient well-being. It is not indicated for use: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. • In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. • In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. • In patients scheduled for surgery who are willing to donate autologous blood. • In patients undergoing cardiac or vascular surgery. • As a substitute for RBC transfusions in patients who require immediate correction of anemia. **Black box warning:** ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.	05/15/2018	**WARNINGS AND PRECAUTIONS** • **Black box warning - Increased mortality, myocardial infarction, stroke, and thromboembolism:** (1) Using ESAs to target a hemoglobin (Hgb) level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with co-existent cardiovascular disease and stroke. Use the lowest dose sufficient to reduce the need for RBC transfusions. (2) Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended. • **Black box warning - Increased mortality and/or increased risk of tumor progression or recurrence in patients with cancer:** ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy. ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Discontinue following the completion of a chemotherapy course. • **Hypertension:** Control hypertension prior to initiating and during treatment with Retacrit™. Reduce or withhold Retacrit™ if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions. • **Seizures:** Epoetin alfa products increase the risk for seizures in patients with CKD. Increase monitoring of these patients for changes in seizure frequency or premonitory symptoms. • **Lack or loss of hemoglobin response:** For lack or loss of Hgb response to Retacrit™, initiate a search for causative factors. If typical causes are excluded, evaluate for PRCA. In the absence of PRCA, follow dosing recommendations for management of patients with an insufficient Hgb response to Retacrit™ therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Retacrit™ (epoetin alfa-epbx) for Injection, for intravenous or subcutaneous use / Hospira, Inc. (continuation)	Blood modifier agent Erythropoiesis-stimulating agent (ESA) Note: Biosimilar to Epogen/Procrit (epoetin alfa)	(1) For the treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection, and (2) for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery **Limitations of use:** Has not been shown to improve quality of life, fatigue, or patient well-being. It is not indicated for use: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. • In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. • In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. • In patients scheduled for surgery who are willing to donate autologous blood. • In patients undergoing cardiac or vascular surgery. • As a substitute for RBC transfusions in patients who require immediate correction of anemia. **Black box warning:** ESAs increase the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access and tumor progression or recurrence.	05/15/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Pure red cell aplasia (PRCA):** If severe anemia and low reticulocyte count develop during Retacrit™ treatment, withhold Retacrit™ and evaluate for PRCA. Permanently discontinue Retacrit™ in patients who develop PRCA following treatment with Retacrit™ or other erythropoietin protein drugs. Do not switch patients to other ESAs. • **Serious allergic reactions:** Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur. Permanently discontinue Retacrit™ and manage reactions. • **Severe cutaneous reactions:** Blistering and skin exfoliation reactions including Erythema multiforme and Stevens-Johnson Syndrome (SJS)/Toxic Epidermal Necrolysis (TEN), have been reported. Discontinue Retacrit™ if a severe cutaneous reaction, such as SJS/TEN, is suspected. • **Risk in patients with phenylketonuria (PKU):** Retacrit™ contains phenylalanine. henylalanine can be harmful to patients with PKU. Before prescribing Retacrit™ to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including Retacrit™. **ADVERSE REACTIONS** Most common adverse reactions*: arthralgia, bone pain, chills, cough, depression, dizziness, DVT, dysphagia, headache, hyperglycemia, hypertension, hypokalemia, injection site irritation or pain, insomnia, leukopenia, nausea and vomiting, medical device malfunction, muscle spasm, myalgia, pruritus, pyrexia, rash, stomatitis, thrombosis, upper respiratory tract infection, vascular occlusion, weigh decrease. *Common adverse reactions were varied among patients with different diagnosis.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lucemyra™ (lofexidine hydrochloride) Tablets, for oral use / US WorldMeds	Central alpha-2 adrenergic agonist	For mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults	05/16/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is three 0.18 mg tablets taken orally 4 times daily at 5- to 6-hour intervals. The total daily dosage should not exceed 2.88 mg (16 tablets) and no single dose should exceed 0.72 mg (4 tablets). • Treatment may be continued for up to 14 days with dosing guided by symptoms. • Dosage adjustments are recommended in hepatic or renal impairment, based on degree of impairment. **DOSAGE FORMS AND STRENGTHS** Tablets: 0.18 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Risk of hypotension, bradycardia, and syncope:** May cause a decrease in blood pressure, a decrease in pulse, and syncope. Monitor vital signs before dosing and advise patients on how to minimize the risk of these cardiovascular effects and manage symptoms. Monitor symptoms related to bradycardia and orthostasis. When using in outpatients, ensure that patients are capable of self-monitoring signs and symptoms. Avoid use in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, or chronic renal failure, as well as in patients with marked bradycardia. • **Risk of QT prolongation:** Prolongs the QT interval. Avoid use in patients with congenital long QT syndrome. Monitor ECG in patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias, hepatic or renal impairment, or in patients taking other medicinal products that lead to QT prolongation.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lucemyra™ (lofexidine hydrochloride) Tablets, for oral use / US WorldMeds (continuation)	Central alpha-2 adrenergic agonist	For mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults	05/16/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Increased risk of opioid overdose after opioid discontinuation:** Patients who complete opioid discontinuation are at an increased risk of fatal overdose should they resume opioid use. Use in conjunction with a comprehensive management program for treatment of opioid use disorder and inform patients and caregivers of increased risk of overdose. • **Risk of discontiuation symptoms:** Instruct patients not to discontinue therapy without consulting their healthcare provider. When discontinuing therapy, reduce dose gradually. **ADVERSE REACTIONS** Most common adverse reactions: orthostatic hypotension, bradycardia, hypotension, dizziness, somnolence, sedation, and dry mouth. **DRUG INTERACTIONS** • **Methadone:** Methadone and Lucemyra™ both prolong the QT interval. ECG monitoring is recommended when used concomitantly. • **Oral naltrexone:** Concomitant use may reduce efficacy of oral naltrexone. • **CYP2D6 inhibitors (e.g. paroxetine):** Concomitant use of paroxetine resulted in increased plasma levels of Lucemyra™. Monitor for symptoms of orthostasis and bradycardia with concomitant use of a CYP2D6 inhibitor. • **CNS depressant drugs:** Lucemyra™ potentiates the CNS depressant effects of benzodiazepines and may potentiate the CNS depressant effects of alcohol, barbiturates, and other sedating drugs. Advise patients to inform their healthcare provider of other medications they are taking, including alcohol.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lucemyra™ (lofexidine hydrochloride) Tablets, for oral use / US WorldMeds (continuation)	Central alpha-2 adrenergic agonist	For mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults	05/16/2018	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** The safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No studies have been performed to characterize the pharmacokinetics or establish safety and effectiveness in geriatric patients. Caution should be exercised when it is administered to patients over 65 years of age. Dosing adjustments similar to those recommended in patients with renal impairment should be considered. • **Hepatic impairment:** Hepatic impairment slows the elimination of Lucemyra™ but exhibits less effect on the peak plasma concentration than on AUC values following a single dose. Dosage adjustments are recommended based on the degree of hepatic impairment. • **Renal impairment:** Renal impairment slows the elimination of Lucemyra™ but exhibits less effect on the peak plasma concentration than on AUC values following a single dose. Dosage adjustments are recommended based on the degree of renal impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Aimovig™ (erenumab-aooe) Injection, for subcutaneous use / Amgen Inc.	Antimigraine Calcitonin gene-related peptide (CGRP) receptor antagonist	Preventive treatment of migraine in adults	05/17/2018.	**DOSAGE AND ADMINISTRATION** The recommended dose is 70 mg once monthly; some patients may benefit from a dosage of 140 mg once monthly. • Aimovig is for subcutaneous use and can be administrated in the abdomen, thigh, or upper arm. **DOSAGE FORMS AND STRENGTHS** • Injection: 70 mg/mL solution in a single-dose prefilled SureClick® autoinjector • Injection: 70 mg/mL solution in a single-dose prefilled syringe **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** No specific warnings have been identified. **ADVERSE REACTIONS** Most common adverse reactions: injection site reactions and constipation. **DRUG INTERACTIONS** No drug interactions identified at the moment. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness in pediatric patients have not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 and over. s. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lokelma™ (sodium zirconium cyclosilicate) Suspension, for oral use / AstraZeneca	Gastrointestinal agent Potassium binder	Treatment of hyperkalemia in adults **Limitation of use** Should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action	05/18/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 10g administered three times a day for up to 48 hours. For maintenance treatment, the recommended dose is 10g once daily. The dose is adjusted at one-week intervals as needed (by 5g daily) to obtain desired serum potassium target range. **DOSAGE FORMS AND STRENGTHS** For oral suspension: 5 g per packet and 10 g per packet. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Gastrointestinal:** Avoid use with severe constipation, bowel obstruction or impaction, because Lokelma™ has not been studied in patients with these conditions and may be ineffective and may worsen gastrointestinal conditions. • **Edema:** Lokelma™ contains sodium. Monitor for signs of edema. Advise patients to adjust dietary sodium, if appropriate. Increase the dose of diuretics as needed. **ADVERSE REACTIONS** Most common adverse reactions: mild to moderate edema **DRUG INTERACTIONS** In general, other oral medications should be administered at least 2 hours before or 2 hours after Lokelma™. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between these patients and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Doptelet™ (avatrombopag) Tablets, for oral use / Dova Pharmaceuticals, Inc.	Blood modifier agent Thrombopoietin receptor agonist (TPO-RA)	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a medical procedure	05/21/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is based on patient's platelet count prior to a scheduled procedure: • For patients with platelet count less than 40 x10^9/L: 60mg (3 tablets) once daily for 5 days. • For patients with platelet count from 40 x10^9/L to less than 50 x10^9/L: 40mg (2 tablets) once daily for 5 days. Start 10 to 13 days prior to scheduled procedure. Patients should undergo their procedure within 5 to 8 days after the last dose. **DOSAGE FORMS AND STRENGTHS** Tablet: 20 mg **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Thrombotic/Thromboembolic complications:** TPO receptor agonists have been associated with thrombotic and thromboembolic complications in patients with chronic liver disease. Monitor platelet counts and for thromboembolic events and institute treatment promptly. **ADVERSE REACTIONS** Most common adverse reactions: pyrexia, abdominal pain, nausea, headache, fatigue, and edema peripheral. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Lactation:** Breastfeeding not recommended during treatment. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Studies did not include sufficient numbers of subjects aged 65 and over.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yonsa™ (abiraterone acetate) Tablets, for oral use / Sun Pharmaceutical Industries Inc.	Antineoplastic agent CYP17 inhibitor Note: Yonsa™ is an ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga™)	In combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer (CRPC)	05/22/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 500 mg (four 125 mg tablets) administered orally once daily in combination with methylprednisolone 4 mg administered orally twice daily. • Patients receiving Yonsa™ should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. • To avoid medication errors and overdose, be aware that Yonsa™ tablets may have different dosing and food effects than other abiraterone acetate products. **DOSAGE FORMS AND STRENGTHS** Tablets: 125 mg. **CONTRAINDICATIONS** • Pregnancy. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** May cause hypertension, hypokalemia, or fluid retention; control hypertension and correct hypokalemia prior to treatment; monitoring recommended. • **Endocrine and metabolic:** (1) Mineralocorticoid excess may occur; increased risk of hypertension, hypokalemia, and fluid retention; control hypertension and correct hypokalemia prior to treatment; monitoring recommended. (2) Adrenocortical insufficiency has been reported; increased risk with unusual stress or corticosteroids withdrawal or dose reductions; monitoring recommended and increased dosage of corticosteroid may be needed before, during, and after stressful situations.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yonsa™ (abiraterone acetate) Tablets, for oral use / Sun Pharmaceutical Industries Inc. (continuation)	Antineoplastic agent CYP17 inhibitor Note: Yonsa™ is an ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga™)	In combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer (CRPC)	05/22/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** (1) Do not use in patients with baseline severe hepatic impairment (Child-Pugh C). (2) Severe hepatotoxicity has been reported, including fulminant hepatitis, acute liver failure and deaths; monitoring recommended and treatment interruption, dosage adjustment, or discontinuation may be required. (3) Development of a concurrent elevation of ALT and total bilirubin in the absence of biliary obstruction or other causes responsible for the concurrent elevation may occur; permanent discontinuation of therapy may be warranted. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, joint swelling or discomfort, edema, hot flush, diarrhea, vomiting, cough, hypertension, dyspnea, urinary tract infection and contusion. **DRUG INTERACTIONS** • **CYP3A4 Inducers:** Avoid concomitant strong CYP3A4 inducers during treatment. If a strong CYP3A4 inducer must be co-administered, increase dosing frequency/ • **CYP2D6 Substrates:** Avoid co-administration with CYP2D6 substrates that have a narrow therapeutic index. If an alternative treatment cannot be used, exercise caution and consider a dose reduction of the concomitant CYP2D6 substrate. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. However, not indicated for use in women. • **Females and males of reproductive potential:** Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for at least 3 weeks after the final dose. • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Yonsa™ (abiraterone acetate) Tablets, for oral use / Sun Pharmaceutical Industries Inc. (continuation)	Antineoplastic agent CYP17 inhibitor Note: Yonsa™ is an ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga™)	In combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer (CRPC)	05/22/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Geriatric use:** No overall differences in safety or effectiveness were observed between these elderly patients and younger patients. • **Hepatic impairment:** For patients with baseline moderate hepatic impairment (ChildPugh Class B), reduce the starting dose to 125 mg once daily. For patients who develop hepatotoxicity during treatment, hold until recovery. Retreatment may be initiated at a reduced dose. Yonsa™ should be discontinued if patients develop severe hepatotoxicity. Do not use Yonsa™ in patients with baseline severe hepatic impairment (Child-Pugh Class C).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Palynziq™ (pegvaliase-pqpz) Injection, for subcutaneous use / BioMarin Pharmaceutical Inc.	Endocrine-Metabolic agent Phenylalanine-metabolizing enzyme	To reduce blood phenylalanine concentrations in adult patients with phenylketonuria a who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management **Black box warning** Risk of anaphylaxis	05/24/2018	**DOSAGE AND ADMINISTRATION** • Obtain baseline blood phenylalanine concentration before initiating treatment. • The recommended initial dose is 2.5 mg subcutaneously once weekly for 4 weeks. • Titrate the dosage in a step-wise manner over at least 5 weeks based on tolerability to achieve a dosage of 20 mg subcutaneously once daily. • Consider increasing the dosage to a maximum of 40 mg subcutaneously once daily in patients who have been on 20 mg once daily continuously for at least 24 weeks and who have not achieved either a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L. • Discontinue Palynziq in patients who have not achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily. • Reduce the dosage and/or modify dietary protein and phenylalanine intake, as needed, to maintain blood phenylalanine concentrations within a clinically acceptable range and above 30 micromol/L. **DOSAGE FORMS AND STRENGTHS** Injection: 2.5 mg/0.5 mL, 10 mg/0.5 mL, and 20 mg/mL in a single-dose prefilled syringe. **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Palynziq™ (pegvaliase-pqpz) Injection, for subcutaneous use / BioMarin Pharmaceutical Inc. (continuation)	Endocrine-Metabolic agent Phenylalanine-metabolizing enzyme	To reduce blood phenylalanine concentrations in adult patients with phenylketonuria a who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management **Black box warning** Risk of anaphylaxis	05/24/2018	**WARNINGS AND PRECAUTIONS** • **Immunologic:** (1) Anaphylaxis has been reported generally within 1 hour after administration with most occurring within the first year of dosing; symptoms include syncope, hypotension, hypoxia, dyspnea, wheezing, chest discomfort/tightness, tachycardia, angioedema, throat tightness, skin flushing, rash, urticaria, pruritus, and gastrointestinal symptoms; consider premedication; monitoring recommended. (2) Other hypersensitivity reactions have been reported; consider premedication; appropriate management, dose adjustment, and temporary drug interruption recommended. **ADVERSE REACTIONS** Most common adverse reactions: injection site reactions, arthralgia, hypersensitivity reactions, headache, generalized skin reactions lasting at least 14 days, pruritus, nausea, abdominal pain, oropharyngeal pain, vomiting, cough, diarrhea, and fatigue. **DRUG INTERACTIONS** • **Other PEGylated products:** Monitor for hypersensitivity reactions, including anaphylaxis, with concomitant treatment. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Studies did not include patients aged 65 years and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Imvexxy™ (estradiol) Vaginal Inserts / TherapeuticsMD, Inc.	Endocrine-Metabolic agent Estrogen	Treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse) due to menopause **Black box warning** Endometrial cancer, cardiovascular disorders, breast cancer and probable dementia	05/29/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 1 vaginal insert daily for 2 weeks, followed by 1 insert twice weekly. **DOSAGE FORMS AND STRENGTHS** Vaginal inserts: n 4 mcg or 10 mcg estradiol. **CONTRAINDICATIONS** • Undiagnosed abnormal genital bleeding. • Known, suspected, or history of breast cancer. • Known or suspected estrogen-dependent neoplasia. • Active DVT, PE, or history of these conditions. • Active arterial thromboembolic disease (e.g. stroke and MI), or a history of these conditions. • Known anaphylactic reaction or angioedema with Imvexxy™. • Known liver impairment or disease. • Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders. **WARNINGS AND PRECAUTIONS** • **Angioedema:** Hereditary angioedema; estrogens may exacerbate symptoms of angioedema. • **Cardiovascular:** (1) Increased risk of stroke and DVT has been reported with estrogen-alone therapy. Increased risk of PE, DVT, stroke, and MI has been reported with estrogen plus progestin therapy. If these occur or is suspected, therapy should be discontinued immediately. Risk factors for arterial vascular disease and/or venous thromboembolism should be managed appropriately. (2) Hypertension may occur or worsen; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Imvexxy™ (estradiol) Vaginal Inserts / TherapeuticsMD, Inc. (continuation)	Endocrine-Metabolic agent Estrogen	Treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse) due to menopause **Black box warning** Endometrial cancer, cardiovascular disorders, breast cancer and probable dementia	05/29/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Endocrine and metabolic:** (1) Severe hypercalcemia may occur in women with bone metastases from breast cancer; discontinue. (2) Triglyceride elevation leading to pancreatitis or other complications may occur in patients with preexisting hypertriglyceridemia; consider discontinuation if pancreatitis occurs. (3) Hypothyroidism; estrogen increases thyroid-binding globulin levels which may require a dosage increase in thyroid replacement therapy; monitoring recommended. (4) Hypocalcemia may occur in patients with hypoparathyroidism. • **Gastrointestinal:** Gallbladder disease requiring surgery; estrogens reported to increase risk in postmenopausal women. • **Hepatic:** Hepatic impairment or history of cholestatic jaundice with past estrogen use or pregnancy; discontinue if cholestatic jaundice recurs. • **Ophthalmic:** Retinal vascular thrombosis has been reported; discontinuation may be necessary. • Reproductive: (1) Prolonged therapy; increased risk of breast or endometrial or ovarian cancer with duration of use. (2) Ovarian cancer; estrogens with or without progestin may increase risk. (2) Endometriosis may be exacerbated in patients with residual, post-hysterectomy endometriosis treated with estrogen alone; consider adding a progestin. • **Systemic absorption:** May occur with vaginal insert use; precautions associated with systemic estrogen alone therapy should be taken into account. . **ADVERSE REACTIONS** Most common adverse reactions: headache. **DRUG INTERACTIONS** • **CYP3A4 inducers and inhibitors:** Inducers and inhibitors of CYP3A4 may affect estrogen drug metabolism and decrease or increase the estrogen plasma concentration.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Imvexxy™ (estradiol) Vaginal Inserts / TherapeuticsMD, Inc. (continuation)	Endocrine-Metabolic agent Estrogen	Treatment of moderate to severe dyspareunia (vaginal pain during sexual intercourse) due to menopause **Black box warning** Endometrial cancer, cardiovascular disorders, breast cancer and probable dementia	05/29/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Not indicated for use in pregnancy/. • **Pediatric use:** Not indicated in children. • **Geriatric use:** An increased risk of probable dementia in women over 65 years of age was reported.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Consensi™ (amlodipine and celecoxib) Tablets, for oral use / Kitov Pharma Ltd.	Anti-hypertensive and anti-rheumatic Calcium channel blocker and nonsteroidal anti-inflammatory drug combination	Treatment of both hypertension and pain associated with osteoarthritis **Limitations of use** Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily **Black box warnings** Risk of serious cardiovascular and gastrointestinal events	05/31/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 5 mg/200 mg (amlodipine/celecoxib) orally once daily. For small, elderly, or frail patients or hepatic impairment, start at 2.5 mg/200 mg (amlodipine/celecoxib) orally once daily. Titrate to 5 mg/200 mg or 10 mg/200 mg once daily as needed for blood pressure control. Use the lowest effective dosage of celecoxib for the shortest duration consistent with individual treatment goals. If analgesic therapy is no longer indicated, discontinue Consensi™ and initiate patient on alternative antihypertensive therapy. **DOSAGE FORMS AND STRENGTHS** Tablets (amlodipine/celecoxib): 2.5 mg/200 mg, 5 mg/200 mg, or 10 mg/200 mg. **CONTRAINDICATIONS** • Known hypersensitivity to amlodipine, celecoxib, or any inactive ingredients • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs • In the setting of CABG surgery • Demonstrated allergic-type reactions to sulfonamide **WARNINGS AND PRECAUTIONS** • **Beers Criteria:** Avoid use in elderly patients with heart failure as fluid retention may occur and exacerbate heart failure. • **Cardiovascular:** (1) Patients with heart failure are at increased risk of myocardial infarction, hospitalization for heart failure, and death; avoid use in patients with severe heart failure unless benefit outweighs risk; ; monitoring recommended. (2) Avoid use in patients with recent myocardial infarction unless benefit outweighs risk; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Consensi™ (amlodipine and celecoxib) Tablets, for oral use / Kitov Pharma Ltd. (continuation)	Anti-hypertensive and anti-rheumatic Calcium channel blocker and nonsteroidal anti-inflammatory drug combination	Treatment of both hypertension and pain associated with osteoarthritis **Limitations of use** Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily **Black box warnings** Risk of serious cardiovascular and gastrointestinal events	05/31/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Cardiovascular:** (3) Worsening angina or acute myocardial infarction may occur with initiation or dose increase; increased risk with severe obstructive coronary artery disease. (4) An impaired response to antihypertensive component may occur with celecoxib component; monitoring recommended. (5) Symptomatic hypotension may occur; increased risk with severe aortic stenosis; monitoring recommended when switching from amlodipine monotherapy; adjust dose, if necessary. (6) Fluid retention or edema may occur with use. • **Dermatologic:** Serious skin reactions (e.g. erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis), potentially fatal, may occur without warning; discontinue if signs or symptoms occur. • **Endocrine and metabolic:** Hyperkalemia may occur even in patients without renal impairment. • **Gastrointestinal (GI):** GI adverse events (e.g. ulceration, bleeding, inflammation, or perforation of the esophagus, stomach, or intestines), potentially fatal, may occur; increased risk with prior history of peptic ulcer disease or GI bleeding, concomitant use of aspirin, corticosteroids, SSRIs, or anticoagulants, longer duration of NSAID use, smoking, alcohol use, older age, debilitated health status, advanced liver disease, and coagulopathy; avoid use in patients at high risk unless benefit outweighs risk, monitoring recommended, and discontinue use if a serious GI event is suspected. • **Hematologic:** (1) Bleeding events may occur; increased risk in patients with coagulation disorders, or concomitant use of warfarin, other anticoagulants, antiplatelet agents (e.g. aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors; monitoring recommended. (2) Anemia has been reported in patients treated with NSAIDs.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Consensi™ (amlodipine and celecoxib) Tablets, for oral use / Kitov Pharma Ltd. (continuation)	Anti-hypertensive and anti-rheumatic Calcium channel blocker and nonsteroidal anti-inflammatory drug combination	Treatment of both hypertension and pain associated with osteoarthritis **Limitations of use** Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily **Black box warnings** Risk of serious cardiovascular and gastrointestinal events	05/31/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Hepatic:** (1) Moderate or severe hepatic impairment; use not recommended. (2) Elevated liver enzyme levels and rare cases of severe injury (e.g. fulminant hepatitis, liver necrosis, hepatic failure), including fatalities, have been reported; discontinue immediately if signs of liver disease or systemic manifestations (e.g. eosinophilia, rash) occur. • **Immunologic:** (1) Anaphylactic reactions may occur in patients with or without known celecoxib hypersensitivity; may cause allergic type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. (2) Fever and inflammation may be masked; may diminish utility of diagnostic signs in detecting infections. • **Renal:** (1) Severe renal insufficiency; use not recommended. (2) Avoid use in patients with advanced renal disease unless benefit outweighs risk; monitoring recommended. (3) Renal injury, including renal papillary necrosis, has been reported with long-term NSAID administration. (4) Renal decompensation may develop if renal prostaglandins have a compensatory role in maintaining renal perfusion; increased risk with impaired renal function, dehydration, hypovolemia, heart failure, hepatic dysfunction, older age, and concomitant use of diuretics and ACE inhibitors or angiotensin II receptor blockers; discontinuation usually leads to recovery to pretreatment state. • **Reproductive:** Avoid use in the third trimester (30 weeks) of pregnancy due to potential for NSAID-associated premature closure of the fetal ductus arteriosus. • **Respiratory:** Exacerbation of asthma and life threatening or less severe asthmatic episodes may occur in certain susceptible individuals, including those with preexisting asthma; monitoring recommended in patients with asthma and without known aspirin sensitivity

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Consensi™ (amlodipine and celecoxib) Tablets, for oral use / Kitov Pharma Ltd. (continuation)	Anti-hypertensive and anti-rheumatic Calcium channel blocker and nonsteroidal anti-inflammatory drug combination	Treatment of both hypertension and pain associated with osteoarthritis **Limitations of use** Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily **Black box warnings** Risk of serious cardiovascular and gastrointestinal events	05/31/2018	**ADVERSE REACTIONS** Most common adverse reactions to celecoxib in arthritis trials: abdominal pain, diarrhea, dyspepsia, flatulence, peripheral edema, accidental injury, dizziness, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, rash. Most common adverse reactions to amlodipine: edema. **DRUG INTERACTIONS** • **Drugs that interfere with hemostasis (e.g. warfarin, aspirin, SSRIs/SNRIs):** Monitor patients for bleeding.Concomitant use of CONSENSI and analgesic doses of aspirin is not generally recommended. • **ACE Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers:** Concomitant use with Consensi™ may diminish the antihypertensive effect of these drugs. Monitor blood pressure. • **ACE Inhibitors and ARBs:** Concomitant use with Consensi™ in elderly, volume depleted, or those with renal impairment may result in deterioration of renal function. In such high risk patients, monitor for signs of worsening renal function. • **Diuretics:** NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects. • **Digoxin:** Concomitant use with Consensi™ can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels. • **Simvastatin:** Do not exceed 20 mg of simvastatin per day in patients taking amlodipine. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use in pregnant women starting at 30 weeks of gestation (third trimester).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Consensi™ (amlodipine and celecoxib) Tablets, for oral use / Kitov Pharma Ltd. (continuation)	Anti-hypertensive and anti-rheumatic Calcium channel blocker and nonsteroidal anti-inflammatory drug combination	Treatment of both hypertension and pain associated with osteoarthritis **Limitations of use** Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily **Black box warnings** Risk of serious cardiovascular and gastrointestinal events	05/31/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Lactation:** The individual components of Consensi™ are present in human breast milk at low levels. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Increased risk of renal, cardiovascular, or gastrointestinal adverse events in the elderly; monitoring recommended. • **Hepatic impairment:** The daily recommended dose of celecoxib in patients with moderate hepatic impairment (Child-Pugh Class B) should be reduced by 50%. Because Consensi™ is not available in lower strengths of celecoxib, Consensi™ is not recommended in patients with moderate hepatic impairment. Additionally, the use of Consensi™ in patients with severe hepatic impairment is not recommended. • **Renal impairment:** Consensi™ is not recommended in patients with severe renal insufficiency. • **Poor CYP2C19 metabolizers:** Use not recommended in known or suspected poor CYP2C19 metabolizers.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Kymriah™ (tisagenlecleucel) Suspension for Intravenous Infusion / Novartis Pharmaceuticals Corporation	Antineoplastic agent Chimeric antigen receptor T cell (CAR-T) therapy	For use in patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) and patients with relapsed or refractory (r/r) large B-cell lymphoma **New indication:** For the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma and DLBCL arising from follicular lymphoma	05/01/2018	The approval of Kymriah™ in adult patients with r/r DLBCL is based on the pivotal phase II JULIET clinical trial. In this study, Kymriah™ showed an overall response rate (ORR) of 50%, with 32% of patients achieving a complete response (CR) and 18% achieving a partial response (PR) in 68 patients evaluated for efficacy. The median duration of response was not reached among these patients, indicating sustainability of response. Kymriah™ is now the only CAR-T cell therapy to receive FDA approval for two distinct indications in non-Hodgkin lymphoma (NHL) and B-cell ALL.
Tafinlar™ (dabrafenib) Capsules / GlaxoSmithKline	Antineoplastic agent Kinase inhibitor	For the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test **New indication:** In combination with Mekinist™ (trametinib), for the treatment of anaplastic thyroid cancer (ATC) that cannot be removed by surgery or has spread to other parts of the body (metastatic), and has a type of abnormal gene, BRAF V600E (BRAF V600E mutation-positive)	05/04/2018	The efficacy of Tafinlar and Mekinist in treating ATC was shown in an open-label clinical trial of patients with rare cancers with the BRAF V600E mutation. Data from trials in BRAF V600E mutation-positive, metastatic melanoma or lung cancer and results in other BRAF V600E mutation-positive rare cancers provided confidence in the results seen in patients with ATC. The trial measured the percent of patients with a complete or partial reduction in tumor size (overall response rate). Of 23 evaluable patients, 57 percent experienced a partial response and 4 percent experienced a complete response; in nine (64 percent) of the 14 patients with responses, there were no significant tumor growths for six months or longer. This is the first FDA-approved treatment for patients with this aggressive form of thyroid cancer.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Darzalex™ (daratumumab) Injection / Janssen Biotech, Inc.	Antineoplastic agent Human anti-CD38 monoclonal antibody	For the treatment of patients with multiple myeloma **New indication:** In combination with Velcade™ (bortezomib), melphalan, and prednisone – VMP – for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT)	05/07/2018	The approval of Darzalex™ in combination with VMP is supported by data from the Phase 3 ALCYONE (MMY3007) study. The combination of Darzalex™ with VMP reduced the risk of disease progression or death by 50%, compared to treatment with VMP alone. The median progression-free survival (PFS) for Darzalex-VMP had not yet been reached, compared to a median PFS of 18.1 months for patients who received VMP alone. Darzalex™ is the first monoclonal antibody approved for newly diagnosed patients with this disease.
Briviact™ (brivaracetam) Tablets, Solution and Injection / UCB, Inc.	Anticonvulsant Selective, high-affinity synaptic vesicle protein 2A ligand and analog of levetiracetam	For the treatment of partial-onset seizures in patients with epilepsy. **Patient population altered:** As monotherapy and adjunctive therapy in the treatment of partial onset (focal) seizures in patients age four years and older	05/10/2018	This approval provides the option to use Briviact™ in pediatric patients as a tablet or oral solution. The safety of Briviact™ injection has not been established in pediatric patients, Briviact™ injection is indicated for the treatment of partial-onset seizures only in patients 16 years of age and older.
Actemra™ (tocilizumab) Injection / Genentech USA, Inc.	Antirheumatic Humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody	For the treatment rheumatoid arthritis; systemic juvenile idiopathic arthritis (SJIA); polyarticular juvenile idiopathic arthritis (PJIA); giant cell arteritis; and CAR T cell-induced severe or life-threatening cytokine release syndrome **New dosage regimen:** Subcutanous formulation for the treatment of active polyarticular PJIA in patients two years of age and older	05/11/2018	The subcutaneous formulation of Actemra™ for the treatment of active PJIA in patients two years of age and older. Actemra™ can be given alone or in combination with methotrexate (MTX) in patients with PJIA. In 2013, the FDA approved the intravenous formulation of Actemra™ for patients two years of age and older with active PJIA.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Gilenya™ (fingolimod) Capsules / Novartis	Immune modulator Sphingosine 1-phosphate receptor modulator	For the treatment of patients with relapsing forms of multiple sclerosis **Patient population altered:** To treat relapsing multiple sclerosis in children and adolescents age 10 years and older	05/11/2018	This is the first FDA approval of a drug to treat MS in pediatric patients.
Truvada™ (emtricitabine and tenofovir) Tablets / Gilead Sciences, Inc.	Antiretroviral Combination of nucleoside analog HIV-1 reverse transcriptase inhibitors	In combination with other antiretroviral agents for the treatment of HIV-1 infection, and for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in people at high risk **Patient population altered:** To reduce the risk of sexually acquired HIV-1 in at-risk adolescents (PrEP)	05/15/2017	Truvada™ for PrEP is now indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg.
Taltz™ (ixekizumab) Injection / Eli Lilly and Company	Antipsoriatic Humanized interleukin-17A antagonist	For the treatment of plaque psoriasis and psoriatic arthritis **New indication:** For the treatment of psoriasis involving genital area	05/17/2018	Taltz™ is the first and only treatment approved by the FDA for moderate-to-severe plaque psoriasis involving genital area.
Arnuity Ellipta™ (fluticasone furoate) Inhalation Powder / GlaxoSmithKline	Antiasthma Inhaled corticosteroid	For the maintenance treatment of asthma **Patient population altered:** To include children from as young as 5 years	05/17/2018	This approval makes Arnuity Ellipta™ one of the few once-daily treatments for asthma licenced in the US in this younger age group.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Prolia™ (denosumab) Injection / Amgen Inc.	Immunological agent Monoclonal antibody RANK ligand (RANKL) inhibitor	For the treatment of postmenopausal women with osteoporosis at high risk for fracture, for the treatment of bone loss in patients with prostate or breast cancer undergoing hormone ablation therapy, as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, and for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture **New indication:** For the treatment of glucocorticoid-induced osteoporosis (GIOP) in men and women at high risk of fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy	05/18/2018	The approval is based on data from a study which showed patients on glucocorticoid therapy who received Prolia™ had greater gains in bone mineral density (BMD) compared to those who received active comparator (risedronate).
Xeljanz™ (tofacitinib) Tablets / Pfizer Inc.	Antirheumatic agent Janus kinase (JAK) inhibitor	For the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, and moderately to severely active ulcerative colitis **New indication:** for the treatment of adult patients with moderately to severely active ulcerative colitis (UC)	05/30/2018	The approval was based on data from several studies: OCTAVE Induction 1, OCTAVE Induction 2, OCTAVE Sustain, and OCTAVE Open (an ongoing open label long-term extension study). Data from all studies met their respective primary endpoints, showing a statistically significant, greater proportion of patients in remission at week 8 in the induction studies and in remission at week 52 in the maintenance study in patients with moderately to severely active UC treated with tofacitinib compared to placebo. Remission was defined as a Mayo score of 2 points or lower, with no individual subscore exceeding 1 point, and a rectal bleeding subscore of 0.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Yonsa™ (abiraterone acetate) Tablets / Sun Pharmaceutical Industries Inc.	Antineoplastic agent CYP17 inhibitor	In combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer (CRPC)	05/22/2018	Yonsa™ is an ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga™).

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Phytonadione Tablets 5 mg / Amneal Pharmaceuticals LLC	Antidote Vitamin K	05/11/2018	Generic for: Mephyton
Colesevelam Hydrochloride Tablets 625mg / Impax Laboratories, Inc.	Anti-hyperlipidemic Bile acid sequestrant	05/16/2018	Generic for: Welchol
Methylphenidate Hydrochloride for Extended Release Oral Suspension 5 mg/mL / Actavis Pharma, Inc.	Central nervous system stimulant	05/17/2018	Generic for: Quillivant XR
Tadalafil Tablets 2.5mg, 5mg, 10mg and 20mg / Teva Pharmaceuticals USA, Inc.	Cardiovascular agent	05/22/2018	Generic for: Cialis
Oxybutynin Chloride Transdermal Gel 10% (100mg/packet) / Par Pharmaceutical, Inc.	Urinary antispasmodic Anticholinergic/Antimuscarinic	05/31/2018	Generic for: Gelnique

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
DSUVIA™ (sufentanil) Sublingual Tablets - formerly ARX-04 / AcelRx Pharmaceuticals, Inc.	05/09/2018; 05/24/2018	Treatment for: Pain	DSUVIA™ (sufentanil) is an investigational synthetic opioid analgesic formulation administered sublingually for the treatment of patients experiencing moderate-to-severe acute pain in a medically supervised setting. AcelRx resubmitted the NDA for DSUVIA™ and the FDA accepted the resunmission.	Moderate
Roclatan™ (latanoprost and netarsudil) / Aerie Pharmaceuticals, Inc.	05/15/2018	Treatment for: Glaucoma or ocular hypertension	Roclatan™ (latanoprost/netarsudil ophthalmic solution) is a fixed dose combination of two approved drugs -- the prostaglandin analog latanoprost (Xalatan™) and Rho kinase inhibitor netarsudil (Rhopressa™) -- in development for the treatment of patients with glaucoma or ocular hypertension. Aerie submits a NDA for Roclatan™.	Moderate
Ryaltris™ (mometasone furoate and olopatadine hydrochloride) Nasal Spray / Glenmark Pharmaceuticals, Inc.	05/22/201	Treatment for: Allergic Rhinitis	Ryaltris™ is an investigational steroid and antihistamine fixed-dose combination nasal spray in development as a treatment for seasonal allergic rhinitis in patients 12 years of age and older. Glenmark Pharmaceuticlas submits a NDA for Ryaltris™.	Moderate
CAM2038 (buprenorphine) / Camurus and Braeburn Pharmaceuticals	05/28/2018	Treatment for: Opiate Dependence	CAM2038 (buprenorphine) is a long-acting partial opioid agonist formulation in development for the treatment of opioid dependence. It can be dosed weekly or monthly. Braeburn resubmitted the NDA for CAM2038.	High

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)