pharmpiX

RX BENEFIT MANAGEMENT

PharmNOTES

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

From: AUGUST 2018

Date: 9/7/2018

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Table of Contents

NEWS……

Drug Issue	Date	News/Event
Increased risk of cancer relapse with long-term use after donor stem cell transplant with Zithromax, Zmax (azithromycin)	08/03/2018	The antibiotic Zithromax, Zmax (azithromycin) should not be given long-term to prevent bronchiolitis obliterans syndrome in patients with cancers of the blood or lymph nodes who undergo a donor stem cell transplant. Results of a clinical trial found an increased rate of relapse in cancers affecting the blood and lymph nodes, including death, in these patients. Cancer patients who undergo stem cell transplants from donors are at risk for bronchiolitis obliterans syndrome. The manufacturer of brand name azithromycin is providing a Dear Healthcare Provider letter* on this safety issue to health care professionals who care for patients undergoing donor stem cell transplants. Health care professionals should not prescribe long-term azithromycin for prophylaxis of bronchiolitis obliterans syndrome to patients who undergo donor stem cell transplants because of the increased potential for cancer relapse and death. *The Dear Healthcare Provider letter is available at: https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615362.pdf?utm_campaign=New%20FDA%20Drug%20Safety%20Communication%20on%20azithromycin&utm_medium=email&utm_source=Eloqua
The FDA takes additional action to mitigate shortages of EpiPen (epinephrine) auto-injector by extending expiration date for specific lots of medication	08/21/2018	The FDA took additional action to mitigate shortages of EpiPen (epinephrine) auto-injector by extending the expiration date of specific lots** of 0.3 milligram products marketed by Mylan by four months beyond the labeled expiration date. This change beyond the approved 20-month shelf life is based on stability data provided by Mylan and reviewed by the FDA. **Details regarding specific lots are available at: https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm?utm_campaign=FDA%20takes%20additional%20action%20to%20mitigate%20shortages%20of%20EpiPen%20%28epinephrine%29%20auto-injector%20by%20extending&utm_medium=email&utm_source=Eloqua
Occurrences of a serious infection of the genital area with sodium-glucose cotransporter-2 (SGLT2) inhibitors	08/29/2018	The FDA is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. The FDA is requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide. Health care professionals should: • Assess patients for Fournier's gangrene if they present with the symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary. • Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jornay PM™ (methylphenidate hydrochloride) Extended-Release Capsules, for oral use / Ironshore Pharmaceuticals & Development, Inc.	Central nervous system (CNS) stimulant	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older **Black box warning** Abuse and dependence	08/08/2018	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 20 mg daily. Dosage may be increased weekly in increments of 20 mg per day up to a maximum dose of 100 mg. • Jornay PM™ should be taken only in the evening. Time of administration should be adjusted between 6:30pm and 9:30pm to optimize tolerability and the efficacy the next morning and throughout the day. • Do not substitute for other methylphenidate products on a milligram-per-milligram basis. **DOSAGE FORMS AND STRENGTHS** Extended-release capsules: 20 mg, 40 mg, 60 mg, 80 mg, 100 mg. Exhibits both delayed-release and extended-release properties. **CONTRAINDICATIONS** • Known hypersensitivity to methylphenidate or product components. • Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days. **WARNINGS AND PRECAUTIONS** • **Cardiovascular:** (1) Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems. (2) Sudden death has been reported at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. (3) Sudden deaths, strokes, and myocardial infarctions have been reported at usual doses in adults. (4) Blood pressure and heart rate increases have been reported and may impact underlying medical conditions; monitoring recommended. (5) Peripheral vasculopathy (including Raynaud phenomenon) has been reported and has lead to digital ulceration or soft tissue breakdown in rare cases; monitoring recommended and dosage adjustment or discontinuation may be necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jornay PM™ (methylphenidate hydrochloride) Extended-Release Capsules, for oral use / Ironshore Pharmaceuticals & Development, Inc. (continuation)	Central nervous system (CNS) stimulant	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older **Black box warning** Abuse and dependence	08/08/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Concomitant use:** Avoid alcohol during therapy. • **Endocrine and metabolic:** Chronic use may cause weight loss and long-term growth suppression in pediatric patients; monitoring recommended and interruption may be necessary. • **Psychiatric:** (1) Preexisting psychotic disorder may be exacerbated. (2) Manic or mixed episodes may be induced by CNS stimulants in patients with preexisting bipolar disorder; discontinuation may be considered. (3) New psychotic or manic symptoms can occur at recommended doses; discontinuation may be necessary. • **Reproductive:** Priapism, sometimes requiring surgical intervention, has been reported in both pediatric and adult patients, especially after a dose increase, although may occur during drug withdrawal. **ADVERSE REACTIONS** Most common adverse reactions: decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, blood pressure increased. **DRUG INTERACTIONS** • **MAO Inhibitors:** Do not administer Jornay PM™ concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOI and CNS stimulates can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is apregnancy exposure registry that monitors pregnancy outcomes in women exposed to Jornay PM™ during pregnancy. Healthcare providers are encouraged to register patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jornay PM™ (methylphenidate hydrochloride) Extended-Release Capsules, for oral use / Ironshore Pharmaceuticals & Development, Inc. (continuation)	Central nervous system (CNS) stimulant	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older **Black box warning** Abuse and dependence	08/08/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Pediatric use:** Safety and efficacy in pediatric patients less than 6 years have not been established. • **Geriatric use:** Jornay PM™ has not been studied in patients older than 65 years of age.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arakoda™ (tafenoquine) Tablets, for oral use / 60 Degrees Pharmaceuticals, LLC	Anti-infective agent Antimalarial aminoquinoline	Prophylaxis of malaria in patients aged 18 years and older	08/08/2018	**DOSAGE AND ADMINISTRATION** Loading regimen o Timing: For each of the 3 days before travel to a malarious area. o Dosage: 200 mg (2 of the 100 mg tablets) once daily for 3 days. • Maintenance regimen o Timing: While in the malarious area. o Dosage: 200 mg (2 of the 100 mg tablets) once weekly – start 7 days after the last loading regimen dose. • Terminal prophylaxis regimen o Timing: In the week following exit from the malarious area. o Dosage: 200 mg (2 of the 100 mg tablets) one-time 7 days after the last maintenance dose. All patients must be tested for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to initiating treatment. In addition, pregnancy testing is recommended for females of reproductive potential prior to initiating treatment. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg of tafenoquine. **CONTRAINDICATIONS** • G6PD deficiency or unknown G6PD status. • Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown. • Patients with a history of psychotic disorders or current psychotic symptoms. • Known hypersensitivity reactions to tafenoquine, other 8-aminoquinolines, or any component of the product.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arakoda™ (tafenoquine) Tablets, for oral use / 60 Degrees Pharmaceuticals, LLC (continuation)	Anti-infective agent Antimalarial aminoquinoline	Prophylaxis of malaria in patients aged 18 years and older	08/08/2018	**WARNINGS AND PRECAUTIONS** • **Delayed adverse reactions:** Due to long-half-life (approximately 17 days), adverse reactions may be delayed in onset or duration. • **Hematologic:** (1) Hemolytic anemia and hemolysis may occur in patients with G6PD deficiency and G6PD testing is required prior to therapy initiation; decline in hemoglobin may also occur in patients testing normal for G6PD activity; monitoring recommended. (2) Methemoglobinemia may occur and therapy is recommended if signs or symptoms develop; close monitoring recommended in patients with nicotinamide adenine dinucleotide (NADH)-dependent methemoglobin reductase deficiency. • **Immune:** Serious hypersensitivity reactions (e.g. angioedema, urticaria) have been reported; due to long half-life, reaction may be delayed in onset or duration. If hypersensitivity reactions occur, discontinue use and institute appropriate therapy. • **Psychiatric:** Psychiatric adverse reactions, including sleep disturbances, depression/depressed mood, anxiety, and suicide attempt has been reported. Psychosis was reported in patients taking higher-than approved dose. If psychiatric symptoms (e.g. hallucinations, delusions, or grossly disorganized thinking or behavior) occur consider discontinuation of therapy and prompt evaluation by a mental health professional. If other psychiatric symptoms (e.g. changes in mood, anxiety, insomnia, and nightmares) occur prompt evaluation by a mental health profession should occur if they are moderate and last more than 3 days. • **Reproductive:** (1) May cause fetal harm, including hemolytic anemia, if fetus is G6PD-deficient; avoid pregnancy during therapy and use effective contraception for 3 months after therapy. (2) Hemolytic anemia may occur in infants who are G6PD deficient and exposed through breastmilk; G6PD testing required; avoid breastfeeding during and for 3 months after therapy if infant G6PD status unknown.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arakoda™ (tafenoquine) Tablets, for oral use / 60 Degrees Pharmaceuticals, LLC (continuation)	Anti-infective agent Antimalarial aminoquinoline	Prophylaxis of malaria in patients aged 18 years and older	08/08/2018	**ADVERSE REACTIONS** Most common adverse reactions: headache, dizziness, back pain, diarrhea, nausea, vomiting, , increased alanine aminotransferase (ALT), motion sickness, insomnia, depression, abnormal dreams, anxiety. **DRUG INTERACTIONS** • **Organic Cation Transporter-2 (OCT2) and Multidrug and Toxin Extrusion (MATE) Substrates:** Avoid co-administration with drugs that are substrates of OCT2 or MATE transporters. In vitro observations suggest the potential for increased concentrations of these substrates, which may increase the risk of toxicity of these drugs. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** The use of Arakoda™ during pregnancy may cause hemolytic anemia in a fetus who is G6PDdeficient. Treatment with Arakoda™ during pregnancy is not recommended. If a pregnancy is detected during treatment, discontinue Arakoda™ as soon as possible and switch to an alternative prophylactic drug for malaria during pregnancy. • **Females of reproductive potential:** Verify the pregnancy status in females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to avoid pregnancy or use effective contraception for 3 months after the final dose. • **Lactation:** Advise women not to breastfeed a G6PD-deficient infant or infant with unknown G6PD status during treatment and for 3 months after the last dose. • **Pediatric use:** Safety and efficacy in pediatric patients have not been established. • **Geriatric use:** Clinical trials din not include sufficient number of patinets aged 65 years an dolder.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Poteligeo™ (mogamulizumab-kpkc) Injection, for intravenous use / Kyowa Kirin, Inc.	Antineoplastic agent Humanized monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4) Note: Orphan drug designation	Treatment of adult patients with relapsed or refractory Mycosis Fungoides (MF) and Sézary Syndrome (SS), the most common subtypes of cutaneous T-cell lymphoma (CTCL), after at least one prior systemic therapy	08/08/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 1 mg/kg as an intravenous infusion over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle. **DOSAGE FORMS AND STRENGTHS** Injection: 20 mg/5 mL (4 mg/mL) solution in a single-dose via. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Serious skin adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis with some fatalities, have occurred; onset, affected areas, and appearance were variable; monitoring recommended and interruption or permanent discontinuation of therapy may be required. • **Immunologic:** (1) Infusion reactions have been reported; consider premedication; monitoring recommended and infusion rate reduction, therapy interruption, or discontinuation may be necessary. (2) Serious infections have occurred, including fatal and life-threatening cases; monitoring recommended. (3) Significant immune-mediated adverse reactions (e.g. myositis, myocarditis, polymyositis, hepatitis, pneumonitis, and a variant of Guillain-Barre syndrome), including fatal or life-threatening cases, have been reported; therapy interruption or discontinuation may be necessary; consider risk/benefit in patients with a history of autoimmune disease. (4) Increased risk of transplant complications, including severe, acute, and steroid-refractory graft-versus-host disease with fatalities, has been reported when therapy was followed by allogeneic hematopoietic stem cell transplantation; higher risk when given within a shorter time frame; monitoring recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Poteligeo™ (mogamulizumab-kpkc) Injection, for intravenous use / Kyowa Kirin, Inc. (continuation)	Antineoplastic agent Humanized monoclonal antibody (mAb) directed against CC chemokine receptor 4 (CCR4) Note: Orphan drug designation	Treatment of adult patients with relapsed or refractory Mycosis Fungoides (MF) and Sézary Syndrome (SS), the most common subtypes of cutaneous T-cell lymphoma (CTCL), after at least one prior systemic therapy	08/08/2018	**ADVERSE REACTIONS** Most common adverse reactions: rash, infusion related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection. **DRUG INTERACTIONS** No drug interaction studies have been conducted. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Not recommended in pregnancy or in women of childbearing potential not using contraception, • **Females of reproductive potential:** Verify pregnancy status prior to initiating. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months following the last dose. • **Pediatric use:** Safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No overall differences in effectiveness were observed between patients aged 65 years or more and younger patients. However, higher incidences of Grade 3 or higher and serious adverse events have been reported.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Annovera™ (ethinyl estradiol and segesterone acetate) Vaginal System / The Population Council	Estrogen and progestin vaginal contraceptive	For use by females of reproductive potential to prevent pregnancy for up to a year **Limitation of use** Not adequately evaluated in females with a body mass index of >29 kg/m2 **Black box warning** Cigarette smoking and serious cardiovascular events	08/10/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one Annovera™ inserted in the vagina. • The vaginal system must remain in place continuously for 3 weeks (21 days) followed by a 1-week (7-day) vaginal system-free interval. • One vaginal system provides contraception for thirteen 28-day cycles. **DOSAGE FORMS AND STRENGTHS** Annovera™ is a silicone elastomer vaginal system containing 103 mg segesterone acetate (SA) and 17.4 mg ethinyl estradiol (EE), which releases on average 0.15 mg/day of segesterone acetate and 0.013 mg/day of ethinyl estradiol. **CONTRAINDICATIONS** • A high risk of arterial or venous thrombotic diseases. • Current or history of breast cancer or other estrogen- or progestin-sensitive cancer. • Liver tumors, acute hepatitis, or severe (decompensated) cirrhosis. • Undiagnosed abnormal uterine bleeding. • Hypersensitivity to any of the components of Annovera™. • Use of Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. **WARNINGS AND PRECAUTIONS** • **Thrombotic disorders and other vascular problems:** Stop Annovera™ if a thrombotic or thromboembolic event occurs. Stop Annovera™ at least 4 weeks before and through 2 weeks after major surgery. Start Annovera™ no earlier than 4 weeks after delivery, in females who are not breastfeeding. Consider cardiovascular risk factors before initiating in all females, particularly those over 35 years. • **Liver disease:** Discontinue if jaundice occurs.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Annovera™ (ethinyl estradiol and segesterone acetate) Vaginal System / The Population Council (continuation)	Estrogen and progestin vaginal contraceptive	For use by females of reproductive potential to prevent pregnancy for up to a year **Limitation of use** Not adequately evaluated in females with a body mass index of >29 kg/m2 **Black box warning** Cigarette smoking and serious cardiovascular events	08/10/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Risk of liver enzyme elevations with concomitant hepatitis C treatment:** Stop Annovera™ prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir. Annovera™ can be restarted 2 weeks following completion of this regimen. • **Hypertension:** Do not prescribe Annovera™ for females with uncontrolled hypertension or hypertension with vascular disease. If used in females with well-controlled hypertension, monitor blood pressure and stop use if blood pressure rises significantly. • **Carbohydrate and lipid metabolic effects:** Monitor glucose in prediabetic and diabetic females taking Annovera™. Consider an alternate contraceptive method for females with uncontrolled dyslipidemias. • **Headache:** Evaluate significant change in headaches and discontinue Annovera™ if indicated. • **Bleeding irregularities and amenorrhea:** May cause irregular bleeding or amenorrhea. Evaluate for other causes if irregular bleeding or amenorrhea persists. **ADVERSE REACTIONS** Most common adverse reactions: headache/migraine, nausea/vomiting, vulvovaginal mycotic infection/candidiasis, abdominal pain lower/upper, dysmenorrhea, vaginal discharge, urinary tract infection, breast tenderness/pain/discomfort, bleeding irregularities including metrorrhagia, diarrhea, genital pruritus. **DRUG INTERACTIONS** • **CYP3A4 Inducers:** Drugs or herbal products that induce certain enzymes, including CYP3A4, may decrease the effectiveness of Annovera™ or increase breakthrough bleeding. Counsel patients to use a back-up or alternative method of contraception when enzyme inducers are used with Annovera™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Annovera™ (ethinyl estradiol and segesterone acetate) Vaginal System / The Population Council (continuation)	Estrogen and progestin vaginal contraceptive	For use by females of reproductive potential to prevent pregnancy for up to a year **Limitation of use** Not adequately evaluated in females with a body mass index of >29 kg/m2 **Black box warning** Cigarette smoking and serious cardiovascular events	08/10/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Discontinue if pregnancy occurs, because there is no reason to use CHCs during pregnancy. • **Lactation:** Lactation not recommended for nursing mothers; can decrease milk production. • **Pediatric use:** Safety and efficacy have been established in women of reproductive age. Use before menarche is not indicated. • **Geriatric use:** Is nto indicated in females who have reached menopause.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Galafold™ (migalastat) Capsules, for oral use / Amicus Therapeutics	Endocrine-Metabolic Agent Alpha-galactosidase A (alpha-Gal A) pharmacological chaperone Note: Orphan drug designation	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data	08/10/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 123 mg orally once every other day at the same time of day. It must be taken on an empty stomach (no food consumption at least 2 hours before and 2 hours after taking Galafold™). • Select adults with confirmed Fabry disease who have an amenable GLA variant. • Treatment is indicated for patients with an amenable GLA variant that is interpreted by a clinical genetics professional as causing Fabry disease (pathogenic, likely pathogenic) in the clinical context of the patient. Consultation with a clinical genetics professional is strongly recommended in cases where the amenable GLA variant is of uncertain clinical significance (VUS, variant of uncertain significance) or may be benign (not causing Fabry disease). **DOSAGE FORMS AND STRENGTHS** Capsules: 123 mg migalastat. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Renal:** Use not recommended in patients with severe renal impairment or end-stage renal disease requiring dialysis. **ADVERSE REACTIONS** Most common adverse reactions: headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** Clinical trials did not included sufficient number of patients 65 years and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Galafold™ (migalastat) Capsules, for oral use / Amicus Therapeutics (continuation)	Endocrine-Metabolic Agent Alpha-galactosidase A (alpha-Gal A) pharmacological chaperone Note: Orphan drug designation	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data	08/10/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Renal impairment:** Migalastat is substantially excreted by the kidneys. Use is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis (eGFR less than 30 mL/min/1.73 m2). No dosage adjustment is required in patients with mild to moderate renal impairment (eGFR at least 30 mL/min/1.73 m2 and above).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Onpattro™ (patisiran) Injection, for intravenous use / Alnylam Pharmaceuticals, Inc.	Endocrine-Metabolic Agents Small interfering ribonucleic acid (siRNA) Note: Orphan drug designation	Treatment of polyneuropathy caused by hereditary transthyretin-mediated amyloidosis (hATTR) in adults	08/10/2018	**DOSAGE AND ADMINISTRATION** For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg every 3 weeks by intravenous infusion. For patients weighing 100 kg or more, the recommended dosage is 30 mg. • Premedicate with a corticosteroid, acetaminophen, and antihistamines. **DOSAGE FORMS AND STRENGTHS** Lipid Complex Injection: 10 mg/5 mL (2 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Endocrine and metabolic:** Decrease in serum vitamin A levels have been reported; supplementation recommended. • **Infusion reactions:** Infusion-related reactions (e.g. flushing, back pain, nausea, abdominal pain, dyspnea, headache, hypertension and syncope) have been reported; monitoring and premedication required. If reactions occur, consider slowing or interrupting infusion and instituting medical management as clinically indicated; if serious or life-threatening, permanent discontinuation is necessary. • **Ophthalmic:** Ocular symptoms suggestive of vitamin A deficiency (e.g. night blindness), refer patient to an ophthalmologist. **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory tract infections and infusion-related reactions. **DRUG INTERACTIONS** No drug interaction studies have been conducted.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Onpattro™ (patisiran) Injection, for intravenous use / Alnylam Pharmaceuticals, Inc. (continuation)	Endocrine-Metabolic Agents Small interfering ribonucleic acid (siRNA) Note: Orphan drug designation	Treatment of polyneuropathy caused by hereditary transthyretin-mediated amyloidosis (hATTR) in adults	08/10/2018	**USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No dose adjustment is required in patients aged 65 years or more. • **Hepatic impairment:** No dose adjustment is necessary in patients with mild hepatic impairment (bilirubin ≤1 x ULN and AST >1 x ULN, or bilirubin >1.0 to 1.5 x ULN). Onpattro™ has not been studied in patients with moderate or severe hepatic impairment. • **Renal impairment:** No dose adjustment is necessary in patients with mild or moderate renal impairment (estimated glomerular filtration rate [eGFR] ≥30 to <90 mL/min/1.73m2). Onpattro™ has not been studied in patients with severe renal impairment or end-stage renal disease.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cequa™ (cyclosporine) Ophthalmic Solution, for topical ophthalmic use / Sun Pharmaceutical Industries Inc.	Ophthalmologic agent Calcineurin inhibitor immuno-suppressant	To increase tear production in patients with dry eye disease (keratoconjunctivitis sicca)	08/14/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is to instill one drop twice daily (approximately 12 hours apart) into each eye. The vial must be discarded immediately after using in both eyes. **DOSAGE FORMS AND STRENGTHS** Ophthalmic solution containing cyclosporine 0.9 mg/mL. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • To avoid the potential for eye injury and contamination, advise patients not to touch the vial tip to the eye or other surfaces. **ADVERSE REACTIONS** Most common adverse reactions: instillation site pain and conjunctival hyperemia. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Diacomit™ (stiripentol) Capsules and Powder for Oral Suspension / Biocodex	Anticonvulsant	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam Note: There are no clinical data to support the use of Diacomit™ as monotherapy in Dravet syndrome	08/20/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 50 mg/kg/day, administered by mouth in 2 or 3 divided doses. **DOSAGE FORMS AND STRENGTHS** • Capsule: 250 mg or 500 mg. • Powder for Oral Suspension: 250 mg or 500 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Endocrine and metabolic:** Decreases in appetite and weight have been reported; growth of pediatric patients should be carefully monitored. • **Hematologic:** Neutropenia and thrombocytopenia has been reported; monitoring is recommended. • **Neurologic:** Somnolence has been reported with increased risk with concomitant use of other CNS depressants, including alcohol; monitoring is recommended and dose adjustment may be necessary. • **Phenylketonuria:** Oral powder for suspension contains phenylalanine which can be harmful to patients with phenylketonuria; consider combined daily amount of phenylalanine from all sources. • **Psychiatric:** Increased risk of suicidal thoughts or behaviors; monitoring is recommended. • **Withdrawal:** Withdrawal symptoms may occur; gradually taper dose. If rapid discontinuation is required, monitoring is recommended. **ADVERSE REACTIONS** Most common adverse reactions: somnolence, decreased appetite, agitation, ataxia, weight decreased, hypotonia, nausea, tremor, dysarthria, and insomnia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Diacomit™ (stiripentol) Capsules and Powder for Oral Suspension / Biocodex (continuation)	Anticonvulsant	Treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam	08/20/2018	**DRUG INTERACTIONS** • **Clobazam:** Diacomit™ increases the plasma concentration of clobazam and its metabolite through metabolic inhibition of CYP3A4 and CYP2C19. Consider dose reduction of clobazam in case of adverse reactions. • **Substrates of CYP2C8, CYP2C19, P-gp and BCRP** may require a dose reduction. • **Substrates of CYP1A2, CYP2B6 and CYP3A4** may require a dose adjustment. • **Strong inducers of CYP1A2, CYP3A4 or CYP2C19:** Consider dose increase of Diacomit™. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. There is a pregnancy exposure registry that monitors pregnancy outcomes. Physicians are advised to recommend that pregnant patients enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. • **Pediatric use:** Safety and efficacy in pediatric patients below the age of 2 years have not been established. • **Geriatric use:** Clinical studies did not included patients aged 65 years or more. • **Renal impairment:** There is no formal study of the pharmacokinetics and metabolism of Diacomit™ in patients with renal impairment. However, since Diacomit™ metabolites are eliminated mainly through the kidney, administration to patients with moderate or severe renal impairment is not recommended. • **Hepatic impairment:** There has been no formal study of the pharmacokinetics of Diacomit™ in patients with liver impairment. However, since the drug is mainly metabolized by the liver, administration to patients with moderate or severe liver impairment is not recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Oxervate™ (cenegermin-bkbj) Ophthalmic Solution, for topical ophthalmic use / Dompé farmaceutici SpA	Ophthalmologic agent Recombinant human nerve growth factor (rhNGF) Note: Orphan drug designation	Treatment of neurotrophic keratitis	08/22/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one drop in the affected eye(s), 6 times per day at 2-hour intervals, for eight weeks. **DOSAGE FORMS AND STRENGTHS** Ophthalmic solution: cenegermin-bkbj 0.002% (20 mcg/mL) in a multiple-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Patients should remove contact lenses before applying Oxervate™ and wait 15 minutes after instillation of the dose before reinsertion. **ADVERSE REACTIONS** Most common adverse reactions: eye pain, ocular hyperemia, eye inflammation and increased lacrimation. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy have been established in the pediatric population. • **Geriatric use:** No overall differences in safety or effectiveness were observed between elderly and younger adult patient.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Inveltys™ (loteprednol etabonate) Ophthalmic Suspension, for topical ophthalmic use / Kala Pharmaceuticals, Inc	Ocular corticosteroid	Treatment of post-operative ocular inflammation and pain following ocular surgery	08/22/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is to instill one to two drops into the affected eye twice daily beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period. **DOSAGE FORMS AND STRENGTHS** Sterile preserved ophthalmic suspension containing 10 mg/mL of loteprednol etabonate. **CONTRAINDICATIONS** • In most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. **WARNINGS AND PRECAUTIONS** • **Immunologic:** (1) Increased susceptibility to secondary ocular infections. Infection may be enhanced or masked in acute purulent conditions of the eye. (2) Viral infections of the eye, including herpes simplex, may be prolonged or exacerbated with use; monitoring recommended with history of herpes simplex. (3) Fungal infections of the cornea may occur with long-term steroid use; consider fungus invasion with persistent corneal ulcerations. • **Ophthalmic:** (1) Glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation may occur with prolonged use; monitoring recommended if used for longer than 10 days. (2) Glaucoma; monitoring recommended. (3) Increased risk of perforation with topical corticosteroid use and presence of thin corneal or scleral tissue. • **Surgery:** May delay healing and increase risk of bleb formation after cataract surgery.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Inveltys™ (loteprednol etabonate) Ophthalmic Suspension, for topical ophthalmic use / Kala Pharmaceuticals, Inc. (continuation)	Ocular corticosteroid	Treatment of post-operative ocular inflammation and pain following ocular surgery	08/22/2018	**ADVERSE REACTIONS** Most common adverse reactions: eye pain and posterior capsular opacification. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Takhzyro™ (lanadelumab-flyo) Injection, for subcutanous use / Shire plc	Plasma kallikrein inhibitor (monoclonal antibody) Note: Orphan drug designation	Prophylaxis for the prevention of angioedema attacks in patients with hereditary angioedema (HAE) in patients 12 years and older	08/23/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 300 mg every 2 weeks. Dosing every 4 weeks may be considered in some patients. Patients may self-administer. **DOSAGE FORMS AND STRENGTHS** Injection: 300 mg/2 mL (150 mg/mL) solution in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Hypersensitivity reactions have been reported; discontinue use if a severe reaction occurs. **ADVERSE REACTIONS** Most common adverse reactions: njection site reactions, upper respiratory infections, headache, rash, myalgia, dizziness, and diarrhea. **DRUG INTERACTIONS** No drug interaction studies have been conducted.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Altreno™ (tretinoin) Lotion, for topical use / Ortho Dermatologics	Topical retinoid	Treatment of acne vulgaris in patients 9 years of age and older	08/23/2018	**DOSAGE AND ADMINISTRATION** The recommended dose to apply a thin layer to affected areas once daily (avoiding eyes, mouth, paranasal creases, and mucous membranes). **DOSAGE FORMS AND STRENGTHS** Lotion: 0.05%. Each gram contains 0.5 mg (0.05%) tretinoin. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Skin irritation:** Dryness, pain, erythema, irritation and exfoliation may occur with use. • **Ultraviolet light and environmental exposure:** Exposure to sunlight and sunlamps should be minimized. It is recommended to use sunscreen and protective clothing when sun exposure cannot be avoided. • **Fish allergies:** Use with caution if allergic to fish due to potential for allergenicity to fish protein. Advise patients to contact their healthcare provider if they develop pruritus or urticarial. **ADVERSE REACTIONS** Most common adverse reactions: dryness, pain, erythema, irritation and exfoliation (all at the application site). **USE IN SPECIFIC POPULATIONS** • **Geriatric use:** Clinical studies did not included patients aged 65 year or older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xerava™ (eravacycline) Injection, for intravenous use / Tetraphase Pharmaceuticals, Inc.	Anti-infective agent Fluorocycline antibiotic	Treatment of complicated intra-abdominal infections in patients 18 years of age and older **Limitations of use** • Xerava™ is not indicated for the treatment of complicated urinary tract infections (cUTI). • To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xerava™ and other antibacterial drugs, Xerava™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	08/27/2018	**DOSAGE AND ADMINISTRATION** The recommended dose n 1 mg/kg by intravenous infusion over approximately 60 minutes every 12 hours for a total duration of 4 to 14 days. **DOSAGE FORMS AND STRENGTHS** For injection: 50 mg of eravacycline (equivalent to 63.5 mg eravacycline dihydrochloride) as a lyophilized powder in a single-dose vial for reconstitution and further dilution. **CONTRAINDICATIONS** • Known hypersensitivity to eravacycline, tetracycline-class antibacterial drugs, or any of the excipients. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Photosensitivity may occur and has been reported with other tetracycline-class antibacterial drugs; discontinue if condition occurs. • **Endocrine and metabolic:** Anti-anabolic action which may lead to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests may occur and has been reported with other tetracycline-class antibacterial drugs; discontinue if conditions occurs. • **Gastrointestinal:** (1) Permanent discoloration of the teeth may occur when used during tooth development; more common during long-term use of the tetracycline-class drugs but has been observed following repeated short-term courses. (2) Enamel hypoplasia may occur and has been reported with tetracyclines. (3) *C.difficile* associated diarrhea (CDAD) has been reported with nearly all antibacterial agents and may range in severity. If CDAD is suspected or confirmed, antibacterial drug use not directed against *C.difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of *C.difficile*, and surgical evaluation should be instituted as clinically indicated.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xerava™ (eravacycline) Injection, for intravenous use / Tetraphase Pharmaceuticals, Inc. (continuation)	Anti-infective agent Fluorocycline antibiotic	Treatment of complicated intra-abdominal infections in patients 18 years of age and older **Limitations of use** • Xerava™ is not indicated for the treatment of complicated urinary tract infections (cUTI). • To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xerava™ and other antibacterial drugs, Xerava™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	08/27/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) Life-threatening hypersensitivity (anaphylactic) reactions have been reported; discontinue use if an allergic reaction occurs. (2) Overgrowth of nonsusceptible organisms, including fungi, may occur; discontinue therapy if such infections occur. • **Musculoskeletal:** Reversible inhibition of bone growth may occur when used during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years; shown to be reversible when therapy discontinued. • **Neurologic:** Pseudotumor cerebri may occur and has been reported with other tetracycline-class antibacterial drugs; discontinue if condition occurs. **ADVERSE REACTIONS** Most common adverse reactions: infusion site reactions, nausea, and vomiting. **DRUG INTERACTIONS** • **CYP3A inducers:** Concomitant use of strong CYP3A inducers decreases the exposure of eravacycline. Increase Xerava™ dose with concomitant use of a strong CYP3A inducer. • **Anticoagulants:** Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Like other tetracycline-class antibacterial drugs, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second and third trimester of pregnancy. • **Lactation:** Breastfeeding is not recommended during treatment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xerava™ (eravacycline) Injection, for intravenous use / Tetraphase Pharmaceuticals, Inc. (continuation)	Anti-infective agent Fluorocycline antibiotic	Treatment of complicated intra-abdominal infections in patients 18 years of age and older **Limitations of use** • Xerava™ is not indicated for the treatment of complicated urinary tract infections (cUTI). • To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xerava™ and other antibacterial drugs, Xerava™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.	08/27/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Pediatric use:** (1) Safety and efficacy in pediatric patients have not been established. (2) Premature infants are at increased risk for a decrease in fibula growth rate at oral tetracycline doses of 25 mg/kg every 6 hours; reversible upon discontinuation. • **Geriatric use:** No overall differences in safety or efficacy were observed. • **Hepatic impairment:** No dosage adjustment is warranted in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B). Adjust dosage in patients with severe hepatic impairment. • **Renal Impairment:** No dosage adjustment is necessary in patients with renal impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Delstrigo™ (doravirine, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Merck	Antiretroviral Nonnucleoside reverse transcriptase inhibitor [NNRTI] and nucleoside analogue reverse transcriptase inhibitors combination	Complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history **Black box warning** Post-treatment acute exacerbation od Hepatitis B	08/30/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one tablet taken orally once daily. • Dosage adjustment with rifabutin: Take one tablet of Delstrigo™ once daily, followed by one tablet of doravirine 100 mg (Pifeltro™) approximately 12 hours after the dose of Delstrigo™. • Testing: Prior to or when initiating, test for HBV infection. **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate. **CONTRAINDICATIONS** • Co-administration with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of Delstrigo™. • Previous hypersensitivity reaction to lamivudine. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** (1) Avoid concurrent or recent use of nephrotoxic agents. (2) Use with other antiretroviral medications for treatment of HIV-1 infection is not recommended. • **Immunologic:** (1) Immune reconstitution syndrome has been reported with combination antiretroviral therapy; monitoring recommended. (2) Autoimmune disorders, such as Graves disease, polymyositis, and Guillain-Barré syndrome, have been reported in the setting of immune reconstitution and may occur many months after initiation of therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Delstrigo™ (doravirine, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Merck (continuation)	Antiretroviral Nonnucleoside reverse transcriptase inhibitor [NNRTI] and nucleoside analogue reverse transcriptase inhibitors combination	Complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history **Black box warning** Post-treatment acute exacerbation od Hepatitis B	08/30/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Musculoskeletal:** (1) Decreases in bone mineral density have been associated with tenofovir disoproxil fumarate; monitoring should be considered. (2). Hypophosphatemia and osteomalacia associated with proximal renal tubulopathy have been reported. • **Renal:** New onset or worsening renal impairment, including acute renal failure and Fanconi syndrome, has been reported with tenofovir disoproxil fumarate; monitoring recommended. (2) Proximal renal tubulopathy manifesting as persistent or worsening bone pain, extremity pain, fracture, or muscle pain or weakness may occur; monitoring recommended. (3) Use not recommended in patients with renal impairment (CrCl less than 50 mL/min). **ADVERSE REACTIONS** Most common adverse reactions: dizziness, nausea, and abnormal dreams. **DRUG INTERACTIONS** • Delstrigo™ is a complete regimen. Co-administration with other antiretroviral medications for treatment of HIV-1 infection is not recommended. • Several clinically important drug interactions have been identified. See full prescribing information prior to and during treatment for important potential drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to Delstrigo™ during pregnancy. Healthcare providers are encouraged to register patients. • **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Delstrigo™ (doravirine, lamivudine and tenofovir disoproxil fumarate) Tablets, for oral use / Merck (continuation)	Antiretroviral Nonnucleoside reverse transcriptase inhibitor [NNRTI] and nucleoside analogue reverse transcriptase inhibitors combination	Complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history **Black box warning** Post-treatment acute exacerbation od Hepatitis B	08/30/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** Clinical studies did not included sufficient number of patients aged 65 years and older. • **Renal impairment:** Not recommended in patients with estimated creatinine clearance below 50 mL/min.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Jivi™ (antihemophilic factor [recombinant] PEGylated-aucl), for intravenous use / Bayer HealthCare Pharmaceuticals Inc.	Antihemophilic agent
	
	Recombinant DNA-derived, Factor VIII
		For use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
		• On-demand treatment and control of bleeding episodes
		• Perioperative management of bleeding
		• Routine prophylaxis to reduce the frequency of bleeding episodes
		
		Limitations of use
		• Jivi™ is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions.
		• Jivi™ is not indicated for use in previously untreated patients (PUPs).
		• Jivi™ is not indicated for the treatment of von Willebrand disease.
			08/30/2018	**DOSAGE AND ADMINISTRATION**
				For control of bleeding episodes and perioperative management:
				• Expected recovery: one unit per kilogram body weight will increase the Factor VIII level by 2 international units per deciliter (IU/dL). Each vial contains the labeled amount of recombinant Factor VIII in IU.
				• Required dose (IU) = body weight (kg) x desired Factor VIII rise (% of normal or IU/dL) x reciprocal of expected recovery (or observed recovery, if available).
				• Estimated Increment of Factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg).
				
				For routine prophylaxis:
				• The recommended initial regimen is 30–40 IU/kg twice weekly.
				• Based on the bleeding episodes:
				  ○ The regimen may be adjusted to 45–60 IU/kg every 5 days.
				  ○ A regimen may be further individually adjusted to less or more frequent dosing.
				
				DOSAGE FORMS AND STRENGTHS
				Lyophilized powder in single-use vials containing nominally 500, 1000, 2000, or 3000 IU.
				
				CONTRAINDICATIONS
				• History of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Jivi™ (antihemophilic factor [recombinant] PEGylated-aucl), for intravenous use / Bayer HealthCare Pharmaceuticals Inc. (continuation)	Antihemophilic agent Recombinant DNA-derived, Factor VIII	For use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes **Limitations of use** • Jivi™ is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions. • Jivi™ is not indicated for use in previously untreated patients (PUPs). • Jivi™ is not indicated for the treatment of von Willebrand disease.	08/30/2018	**WARNINGS AND PRECAUTIONS** • **Immunologic:** (1) Hypersensitivity reactions, including severe allergic reactions, have been reported; monitoring recommended and if reaction occurs, immediately discontinue therapy and initiate appropriate treatment. (2) Neutralizing antibodies may form; monitoring recommended. (3) Transient clinical immune responses associated with immunoglobulin M anti-polyethylene glycol antibodies have been reported, which manifested as symptoms of acute hypersensitivity and/or loss of drug effect, primarily in patients younger than 6 years of age (unapproved use); discontinuation may be necessary. **ADVERSE REACTIONS** Most common adverse reactions: headache, cough, nausea and fever. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Jivi™ is not for use in children < 12 years of age or in previously untreated patients (PUPs). • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 years and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Pifeltro™ (doravirine) Tablets, for oral use / Merck & Co., Inc.	Antiretroviral Non-nucleoside reverse transcriptase inhibitor (NNRTI)	Combination treatment of HIV-1 infection in adults with no prior antiretroviral treatment history	08/30/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is one tablet taken orally once daily. • Dosage adjustment with rifabutin: One tablet taken twice daily (approximately 12 hours apart). **DOSAGE FORMS AND STRENGTHS** Tablets: 100 mg doravirine **CONTRAINDICATIONS** • Co-administration with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of Pifeltro™. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Use with efavirenz, etravirine, or nevirapine is not recommended. • **Immunologic:** (1) Immune reconstitution syndrome has been reported with combination antiretroviral therapy. (2) Autoimmune disorders, such as Graves disease, polymyositis, and Guillain-Barré syndrome, have been reported in the setting of immune reconstitution and may occur many months after initiation of therapy. **ADVERSE REACTIONS** Most common adverse reactions: nausea, dizziness, headache, fatigue, diarrhea, abdominal pain, and abnormal dreams. **DRUG INTERACTIONS** Several clinically important drug interactions have been identified. See full prescribing information prior to and during treatment for important potential drug-drug interactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Pifeltro™ (doravirine) Tablets, for oral use / Merck & Co., Inc. (continuation)	Antiretroviral Non-nucleoside reverse transcriptase inhibitor (NNRTI)	Combination treatment of HIV-1 infection in adults with no prior antiretroviral treatment history	08/30/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to Pifeltro™ during pregnancy. Healthcare providers are encouraged to register patients. • **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission. • **Pediatric use:** Safety and efficacy have not been established in pediatric patients. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 years and older.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Granix™ (tbo-filgrastim) Injection / A-S Medication Solutions, LLC	Hematopoietic agent / Blood modifier agent Colony stimulating factor (CSF) Leukocyte growth factor	**Previous indication(s):** For the reduction in the duration of severe neutropenia in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs **Patient population altered:** Granix™ has been approved for use in pediatric patients 1 month and older	07/31/2018	Now Granix™ is indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. A new vial presentation have also been approved. The new vial presentation of the product will be available for use in 300mcg/1mL and 480mcg/1.6mL single-dose vials. The prefilled syringe presentations will continue to be available as well.
Orkambi™ (ivacaftor and lumacaftor) Tablets and Oral Granules / Vertex Pharmaceuticals Incorporated	Respiratory agent Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination	**Previous indication(s):** Treatment of patients 6 years and older with cystic fibrosis (CF) who have two copies of the *F508del*mutation in their CFTR gene **Patient population altered:** Orkambi™ has been approved for use in pediatric patients ages 2 through 5 years with CF who have two copies of the F508del-CFTR mutation	08/07/2018	This approval makes Orkambi™ the first medicine approved to treat the underlying cause of CF in this population. For the use of Orkambi™ in pediatric patients ages 2 through 5 years with CF who have two copies of the F508del-CFTR mutation, a new formulation have also been approved. Orkambi™ will be available as oral granules in two dosage strengths (lumacaftor 100mg/ivacaftor 125mg and lumacaftor 150mg/ivacaftor 188mg) for weight-based dosing.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Kalydeco™ (ivacaftor) Tablets and Oral Granules / Vertex Pharmaceuticals Incorporated	Respiratory agent Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator	**Previous indication(s):** Treatment of cystic fibrosis (CF) in patients ages 2 years and older who have one of 38 ivacaftor-responsive mutations in the CFTR gene based on clinical and/or in vitro assay data **Patient population altered:** Kalydeco™ has been approved for use in pediatric patients ages 12 to <24 months with CF who have at least one mutation in their CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro assay data	08/15/2018	This is the first approval of a CFTR modulator in this age group.
Lenvima™ (lenvatinib) Capsules / Eisai Inc.S	Antineoplastic agent Multiple receptor tyrosine kinase (RTK) inhibitor	**Previous indication(s):** Treatment of patients with: (1) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC), and (2) Advanced renal cell carcinoma (aRCC), previously treated with an anti-angiogenic therapy (in combination with everolimus) **New indication(s):** First-line treatment of patients with unresectable hepatocellular carcinoma (HCC)	08/15/2018	This approval was based on results from REFLECT (Study 304), where Lenvima™ demonstrated a proven treatment effect on overall survival (OS) by statistical confirmation of non-inferiority, as well as statistically significant superiority and clinically meaningful improvements in progression-free survival (PFS) and objective response rate (ORR) when compared with sorafenib in patients with previously untreated unresectable HCC.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Eylea™ (aflibercept) Injection / Regeneron Pharmaceuticals, Inc.	Ophthalmologic agent VEGF inhibitor	**Previous indication(s):** Treatment of patients with neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy **New dosage regimen:** 12-week dosing schedule	08/16/2018	The FDA has approved a supplemental Biologics License Application (sBLA) for Eylea™ (aflibercept) Injection in patients with wet age-related macular degeneration (wet AMD). The sBLA was based on second-year data from the Phase 3 VIEW 1 and 2 trials in which patients with wet AMD were treated with a modified 12-week dosing schedule (doses given at least every 12 weeks, and additional doses as needed). Eylea™ is also approved in wet AMD for every four- or eight-week dosing intervals after three initial monthly doses.
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking antibody	**Previous indication(s):** 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, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC), and hepatocellular carcinoma **New indication(s):** Treatment of metastatic small cell lung cancer (SCLC) whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy (two or more prior lines of therapy)	08/16/2018	Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma **New indication(s):** **Label revision/expansion –** In combination with pemetrexed (Alimta™) and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations	08/20/2018	Keytruda™ in combination with pemetrexed and carboplatin was first approved in 2017 for the first-line treatment of patients with metastatic nonsquamous NSCLC.
Imbruvica™ (ibrutinib) Capsules and Tablets / Janssen Pharmaceuticals, Inc.	Antineoplastic agent Oral Bruton's tyrosine kinase (BTK) inhibitor	**Previous indication(s):** Treatment of mantle cell lymphoma, chronic lymphocytic leukemia, Waldenström's macroglobulinemia, small lymphocytic lymphoma, marginal zone lymphoma, and chronic graft versus host disease **New indication(s):** **Label revision/expansion –** In combination with rituximab for the treatment of Waldenström's macroglobulinemia	08/24/2018	Waldenström's macroglobulinemia (WM) is a rare blood cancer. Imbruvica first received FDA approval in WM as a monotherapy in January 2015, making it the first FDA-approved therapy for the disease.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Orkambi™ (ivacaftor and lumacaftor) Tablets and Oral Granules / Vertex Pharmaceuticals Incorporated	Respiratory agent Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination	Treatment of patients 2 years and older with cystic fibrosis (CF) who have two copies of the *F508del*mutation in their CFTR gene	08/07/2018	Orkambi™ will be available as oral granules in two dosage strengths (lumacaftor 100mg/ivacaftor 125mg and lumacaftor 150mg/ivacaftor 188mg) for weight-based dosing, for the use in pediatric patients ages 2 through 5 years with CF who have two copies of the F508del-CFTR mutation.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Tadalafil Tablets 20mg / Mylan Pharmaceuticals Inc.	Antihypertensive and genitourinary agent Phosphodiesterase 5 inhibitor	08/03/2018	Generic for: Adcirca
Epinephrine (Autoinjector) Injection 0.15 mg/delivery and 0.3 mg/delivery / Teva Pharmaceuticals USA, Inc.	Adrenergic agent Vasopressor	08/16/2018	Generic for: EpiPen Jr. and EpiPen

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
NKTR-181 (loxicodegol) / Nektar Therapeutics	07/30/2018	Treatment for: Pain	NKTR-181 is a novel mu-opioid agonist molecule designed to have a slow rate of entry into the brain thus reducing abuse potential and CNS-mediated side effects. NKTR-181 is in development for the treatment of chronic low back pain in adult patients new to opioid therapy. Nektar Therapeutics submits a NDA for NKTR-181.	Moderate
Nayzilam (midazolam) Nasal Spray / UCB	08/13/2018	Treatment for: Seizure Clusters	Nayzilam is an investigational product for the acute treatment of seizures in patients who require control of intermittent bouts of increased seizure activity (e.g. seizure clusters, acute repetitive seizures). The FDA has accepted filling the NDA for Nayzilam. The FDA granted and orphan drug designation for Nayzilam.	High High
Iclaprim intravenous injection / Motif Bio plc	08/14/2018	Treatment for: Skin and Structure Infection	Iclaprim is an investigational broad-spectrum diaminopyrimidine antibiotic in development for the treatment of acute bacterial skin and skin structure infections (ABSSSIs). The FDA) has accepted for filing the NDA for iclaprim.	Moderate
Duobrii (halobetasol propionate and tazarotene) Lotion - formerly IDP-118 / Ortho Dermatologics	08/15/2018	Treatment for: Plaque Psoriasis	Duobrii is a corticosteroid and retinoid combination in development for the topical treatment of plaque psoriasis. Ortho Dermatologics resubmits the NDA for Duobrii.	Moderate
Gimoti (metoclopramide) Nasal Spray / Evoke Pharma, Inc.	08/16/2018	Treatment for: Gastroparesis	Gimoti is an intranasal formulation of the approved drug metoclopramide in development for the treatment of symptoms associated with diabetic gastroparesis in women. The FDA has accepted for review the NDA for Gimoti.	Moderate

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

References:

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