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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……

- No security warning or drug safety communication published during September 2018.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tiglutik™ (riluzole) Oral Suspension / ITF Pharma	Neuromuscular agent Note: Orphan drug designation	Treatment of amyotrophic lateral sclerosis (ALS)	09/05/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 50 mg (10 mL), twice daily, taken orally, every 12 hours. **DOSAGE FORMS AND STRENGTHS** Oral suspension: 50 mg/10 mL (5 mg/mL) in 300 mL multiple-dose bottle. **CONTRAINDICATIONS** • History of severe hypersensitivity reactions to riluzole or to any of its components. **WARNINGS AND PRECAUTIONS** • **Hematologic:** Neutropenia, including severe neutropenia (ANC less than 500/mm(3)) has been reported. • **Hepatic:** (1) Hepatic injury, including fatalities, have been reported with use, increased risk with concomitant hepatotoxic drugs; monitoring is recommended and discontinuation may be necessary. (2) Asymptomatic elevations of hepatic transaminase have been reported; may recur upon rechallenge. Monitoring is recommended and discontinuation may be necessary. (3) Use not recommended in patient with baseline hepatic transaminases levels greater than 5 times ULN or if the patient develops these elevations. • **Respiratory:** Interstitial lung disease, including hypersensitivity pneumonitis has been reported; immediate discontinuation may be necessary. **ADVERSE REACTIONS** Most common adverse reactions: oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain. **DRUG INTERACTIONS** • **Strong to moderate CYP1A2 inhibitors:** Co-administration may increase TIGLUTIK-associated adverse reactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tiglutik™ (riluzole) Oral Suspension / ITF Pharma (continuation)	Neuromuscular agent Note: Orphan drug designation	Treatment of amyotrophic lateral sclerosis (ALS)	09/05/2018	**DRUG INTERACTIONS** (continuation) • **Strong to moderate CYP1A2 inducers:** Co-administration may result in decreased efficacy. • **Hepatotoxic drugs:** TIGLUTIK-treated patients that take other hepatotoxic drugs may be at increased risk for hepatotoxicity **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between patients 65 years and over and younger patients. • **Hepatic impairment:** Use is not recommended in patients with baseline elevations of serum aminotransferases greater than 5 times ULN or evidence of liver dysfunction (e.g. elevated bilirubin). • **Japanese patients:** Japanese patients are more likely to have higher riluzole concentrations. Consequently, the risk of adverse reactions may be greater in Japanese patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cassipa™ (buprenorphine and naloxone) Sublingual Film / Teva Pharmaceuticals USA, Inc.	Partial-opioid agonist and opioid antagonist combination	Maintenance treatment of opioid dependence Notes: • Cassipa™ should be used as part of a complete treatment plan to include counseling and psychological support. • Prescription use of this product is limited under the Drug Addiction Treatment Act.	09/07/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is a single daily dose. Cassipa™ should only be used after induction and stabilization of the patient, and the patient has been titrated to a dose of 16 mg buprenorphine using another marketed product. **DOSAGE FORMS AND STRENGTHS** Sublingual film: 16 mg buprenorphine with 4 mg naloxone. **CONTRAINDICATIONS** • Hypersensitivity to buprenorphine or naloxone. **WARNINGS AND PRECAUTIONS** • **Addiction, abuse, and misuse:** Buprenorphine can be abused in a similar manner to other opioids. Monitor patients for conditions indicative of diversion or progression of opioid dependence and addictive behaviors. Multiple refills should not be prescribed early in treatment or without appropriate patient follow-up visits. • **Respiratory depression:** Life threatening respiratory depression and death have occurred in association with buprenorphine use. Warn patients of the potential danger of self-administration of benzodiazepines or other CNS depressants while under treatment with Cassipa™ . • **Unintentional pediatric exposure:** Advise patients to store Cassipa™ safely out of the sight and reach of children. Buprenorphine can cause severe, possibly fatal, respiratory depression in children. • **Neonatal opioid withdrawal syndrome (NOWS):** NOWS is an expected and treatable outcome of prolonged use of opioids during pregnancy. • **Adrenal insufficiency:** If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cassipa™ (buprenorphine and naloxone) Sublingual Film / Teva Pharmaceuticals USA, Inc. (continuation)	Partial-opioid agonist and opioid antagonist combination	Maintenance treatment of opioid dependence Notes: • Cassipa™ should be used as part of a complete treatment plan to include counseling and psychological support. • Prescription use of this product is limited under the Drug Addiction Treatment Act.	09/07/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Risk of opioid withdrawal with abrupt discontinuation:** If treatment is temporarily interrupted or discontinued, monitor patients for withdrawal and treat appropriately. • **Risk of hepatitis, hepatic events:** Monitor liver function tests prior to initiation and during treatment and evaluate suspected hepatic events. • **Precipitation of opioid withdrawal signs and symptoms:** An opioid withdrawal syndrome is likely to occur with parenteral misuse of Cassipa™ by individuals physically dependent on full opioid agonists, or by sublingual administration before the agonist effects of other opioids have subsided. • **Risk of overdose in opioid-naïve patients:** There have been reported deaths of opioid-naïve individuals who received a 2 mg sublingual dose of buprenorphine sublingual tablet for analgesia. Cassipa™ is not appropriate as an analgesic. **ADVERSE REACTIONS** Most common adverse reactions: oral hypoesthesia, glossodynia, oral mucosal erythema, headache, nausea, vomiting, hyperhidrosis, constipation, signs and symptoms of withdrawal, insomnia, pain, and peripheral edema. **DRUG INTERACTIONS** • **Benzodiazepines:** Use caution in prescribing Cassipa™ for patients receiving benzodiazepines or other CNS depressants and warn patients against concomitant self-administration/misuse. • **CYP3A4 Inhibitors and Inducers:** Monitor patients starting or ending CYP3A4 inhibitors or inducers for potential over- or under-dosing. • **Antiretrovirals:** Patients who are on chronic buprenorphine treatment should have their dose monitored if NNRTIs are added to their treatment regimen. Monitor patients taking buprenorphine and atazanavir with and without ritonavir. Dose reduction of buprenorphine may be warranted.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Cassipa™ (buprenorphine and naloxone) Sublingual Film / Teva Pharmaceuticals USA, Inc. (continuation)	Partial-opioid agonist and opioid antagonist combination	Maintenance treatment of opioid dependence Notes: • Cassipa™ should be used as part of a complete treatment plan to include counseling and psychological support. • Prescription use of this product is limited under the Drug Addiction Treatment Act.	09/07/2018	**DRUG INTERACTIONS** (continuation) • **Serotonergic drugs:** Concomitant use may result in serotonin syndrome. Discontinue Cassipa™ if serotonin syndrome is suspected. **USE IN SPECIFIC POPULATIONS** • **Lactation:** Buprenorphine passes into mother's milk. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Monitor for sedation and respiratory depression. • **Hepatic impairment:** Buprenorphine/naloxone products are not recommended in patients with severe hepatic impairment and may not be appropriate for patients with moderate hepatic impairment.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xelpros™ (latanoprost) Ophthalmic Emulsion / Sun Pharmaceutical Industries Inc.	Prostaglandin $F_{2\alpha}$ analog	For reduction of elevated intraocular pressure in patients with open-angle glaucoma, or ocular hypertension	09/12/2018	**DOSAGE AND ADMINISTRATION** The recommended dose in one drop in the affected eye(s) once daily in the evening. **DOSAGE FORMS AND STRENGTHS** Ophthalmic emulsion containing latanoprost 50 mcg/mL (0.005%). **CONTRAINDICATIONS** • Known hypersensitivity to latanoprost or any other ingredients in this product. **WARNINGS AND PRECAUTIONS** • **Ophthalmic:** (1) Bacterial keratitis have been reported. (2) Macular edema, including cystoid macular edema, has been reported; use caution in patients with aphakia, pseudophakia who have a torn posterior lens capsule, or known risk factors for macular edema. (3) Pigmentation of the iris, periorbital tissues (eyelid) and eyelashes has been reported; increases with duration of use; iris pigmentation may be permanent; pigmentation of periorbital tissues and eyelash changes are often reversible, (4) Eyelash and eye vellus hair changes, including increased thickness, pigmentation, and number of lashes or hairs, and misdirected growth, has been reported; changes are typically reversible after discontinuation. (5) Use caution in patients with a history of intraocular inflammation (iritis/uveitis); use not recommended in patients with active intraocular inflammation as inflammation may be exacerbated. (6) Contact lenses should be removed prior to administration, and may be reinserted 15 minutes following administration **ADVERSE REACTIONS** Most common adverse reactions: eye pain/stinging, ocular hyperemia, conjunctival hyperemia, eye discharge, growth of eyelashes, and eyelash thickening.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Xelpros™ (latanoprost) Ophthalmic Emulsion / Sun Pharmaceutical Industries Inc.	Prostaglandin $F_{2\alpha}$ analog	For reduction of elevated intraocular pressure in patients with open-angle glaucoma, or ocular hypertension	09/12/2018	**DRUG INTERACTIONS** • **Thimerosal:** Precipitation may occur if drugs containing thimerosal are used concomitantly with Xelpros™. If such drugs are used, they should be administered at least five (5) minutes apart. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Pregnancy Category C. • **Pediatric use:** Safety and effectiveness have not been established • **Geriatric use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lumoxiti™ (moxetumomab pasudotox-tdfk) Injection, for intravenous use / AstraZeneca	Antineoplastic agent Anti-CD22 recombinant immunotoxin Note: Orphan drug designation	Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA) **Limitations of use** Not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min) **Black box warning** Capillary leak syndrome and hemolytic uremic syndrome	09/13/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 0.04 mg/kg as an intravenous infusion over 30 minutes on Days 1, 3, and 5 of each 28-day cycle. • Consider low-dose aspirin on Days 1 to 8 of each 28-day cycle. • Premedicate with an acetaminophen antipyretic, antihistamine, and H2- receptor antagonist prior to all infusions. **DOSAGE FORMS AND STRENGTHS** For injection: 1 mg lyophilized cake or powder in a single-dose vial for reconstitution and further dilution. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Endocrine and metabolic:** Electrolyte abnormalities has been reported; monitoring recommended. • **Hematologic:** Avoid use in patients with prior history of severe thrombotic microangiopathy or hemolytic uremic syndrome. • **Immunologic:** Infusion related reactions have been reported; may occur during any cycle of treatment. Premedication with antihistamines and antipyretics recommended. For severe reactions, interrupt treatment and administer appropriate medical management. • **Renal:** Renal toxicity, including acute kidney injury, renal failure, renal impairment, serum creatinine increased and proteinuria, has been reported; increased risk patients who experience hemolytic uremic syndrome, those age 65 years and older, or those with baseline renal impairment. Monitoring recommended and dose delay may be necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Lumoxiti™ (moxetumomab pasudotox-tdfk) Injection, for intravenous use / AstraZeneca (continuation)	Antineoplastic agent Anti-CD22 recombinant immunotoxin	Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA) **Limitations of use** Not recommended in patients with severe renal impairment (CrCl ≤ 29 mL/min) **Black box warning** Capillary leak syndrome and hemolytic uremic syndrome	09/13/2018	**ADVERSE REACTIONS** Most common adverse reactions: infusion related reactions, edema, nausea, fatigue, headache, pyrexia, constipation, anemia, diarrhea, and laboratories abnormalities (e.g. creatinine increased, ALT increased, hypoalbuminemia, AST increased, hypocalcemia, and hypophosphatemia). **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Females of reproductive potential:** To avoid potential exposure to the fetus, women of reproductive potential should use effective contraception during treatment and for at least 30 days after the last dose is received. Verify the pregnancy status of females of reproductive potential prior to initiating. • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Ajovy™ (fremanezumab-vfrm) Injection, for subcutanous use / Teva Pharmaceuticals USA, Inc.	Humanized monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) ligand	Preventive treatment of migraine in adults.	09/14/2018	**DOSAGE AND ADMINISTRATION** There are two subcutaneous dosing options available to administer the recommended dosage: • 225 mg monthly, or • 675 mg every 3 months (quarterly) The 675 mg quarterly dosage is administered as three consecutive injections of 225 mg each. **DOSAGE FORMS AND STRENGTHS** Injection: 225 mg/1.5 mL solution in a single-dose prefilled syringe. **CONTRAINDICATIONS** • Serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. **WARNINGS AND PRECAUTIONS** • **Immunologic:** Hypersensitivity reactions, including rash, pruritus, drug hypersensitivity, and urticaria, have been reported; if reaction occurs, consider discontinuation and institute appropriate therapy. **ADVERSE REACTIONS** Most common adverse reactions: injection site reactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 and over.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Copiktra™ (duvelisib) Capsules, for oral use / Verastem, Inc.	Antineoplastic agent Dual phosphoinositide-3-kinase (PI3K)-delta/PI3K-gamma inhibitor Note: Orphan drug designation	Treatment of adult patients with: • Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies • Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies **Black box warning** Fatal and serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis	09/24/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 25 mg twice daily. Dosage must be modified for toxicity. **DOSAGE FORMS AND STRENGTHS** Capsules: 25 mg, 15 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Serious and fatal cutaneous reactions have occurred; fatal cases included drug reaction with eosinophilia and systemic symptoms (DRESS) and toxic epidermal necrolysis(TEN). Interruption and dose adjustment upon resolution may be necessary depending on severity. Discontinue if severe cutaneous reaction does not improve, worsens, or recurs; for life-threatening cutaneous reactions; and patients with Steven-Johnson Syndrome, TEN, or DRESS of any grade. • **Gastrointestinal:** Serious, including fatal, diarrhea or colitis has occurred; monitoring recommended and interruption and dose adjustment upon resolution may be necessary depending on severity. Discontinuation necessary for recurrent Grade 3 diarrhea or recurrent colitis of any grade or with life-threatening diarrhea or colitis. • **Hematologic:** Grade 3 and 4 neutropenia has been reported; monitoring recommended. Interruption and dosage adjustment may be necessary depending on severity. • **Hepatic:** Grade 3 and 4 ALT and/or AST elevations have been reported; monitoring recommended. Interruption and dosage adjustment may be necessary depending on severity.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Copiktra™ (duvelisib) Capsules, for oral use / Verastem, Inc. (continuation)	Antineoplastic agent Dual phosphoinositide-3-kinase (PI3K)-delta/PI3K-gamma inhibitor Note: Orphan drug designation	Treatment of adult patients with: • Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies • Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies **Black box warning** Fatal and serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis	09/24/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Immunologic:** (1) Cytomegalovirus (CMV) reactivation/infection has occurred; consider prophylactic antivirals during treatment; if CMV infection occurs, interruption or discontinuation may be required. Dose adjustment upon resolution may be necessary. (2) Serious infections have been reported, including fatalities; dose adjustment, interruption of therapy, or discontinuation may be needed. • **Respiratory:** (1) Serious, including fatal, cases of Pneumocystis jirovecii pneumonia (PJP) have occurred; provide prophylaxis during treatment. Interruption or permanent discontinuation may be required. (2) Serious, including fatal, pneumonitis without an apparent infectious cause has occurred; interruption and dosage adjustment upon resolution may be necessary depending on severity. Discontinue if non-infectious pneumonitis recurs or does not respond to steroid therapy or for severe or life-threatening non-infectious pneumonitis. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea or colitis, neutropenia, rash, fatigue, pyrexia, cough, nausea, upper respiratory infection, pneumonia, musculoskeletal pain, and anemia. **DRUG INTERACTIONS** • **CYP3A inducers:** Avoid co-administration with strong CYP3A inducers. • **CYP3A inhibitors:** Monitor for Copiktra™ toxicities when coadministered with strong or moderate CYP3A inhibitors. Reduce Copiktra™ dose to 15 mg twice daily when co-administered with strong CYP3A4 inhibitors. • **CYP3A substrates:** Monitor for signs of toxicities when coadministering Copiktra™ with sensitive CYP3A substrates.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Copiktra™ (duvelisib) Capsules, for oral use / Verastem, Inc. (continuation)	Antineoplastic agent Dual phosphoinositide-3-kinase (PI3K)-delta/PI3K-gamma inhibitor Note: Orphan drug designation	Treatment of adult patients with: • Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies • Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies **Black box warning** Fatal and serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis	09/24/2018	**USE IN SPECIFIC POPULATIONS** (continuation) • **Pregnancy:** May cause fetal harm. • **Females and males of reproductive potential:** Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose • **Lactation:** Advise women not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** . No major differences in efficacy or safety were observed between patients less than 65 years of age and patients 65 years of age and older.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Emgality™ (galcanezumab-gnlm) Injection, for subcutaneous use / Eli Lilly and Company	Antimigraine Calcitonin gene-related peptide (CGRP) antagonist	Preventive treatment of migraine in adults	09/27/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg. **DOSAGE FORMS AND STRENGTHS** • Injection: 120 mg/mL solution in a single-dose prefilled pen. • Injection: 120 mg/mL solution in a single-dose prefilled syringe. **CONTRAINDICATIONS** • Serious hypersensitivity to galcanezumab-gnlm or to any of the excipients **WARNINGS AND PRECAUTIONS** • **Immunologic:** Hypersensitivity reactions (e.g. rash, urticaria, and dyspnea) have been reported, may occur days after administration, and may be prolonged; discontinue use if serious or severe reactions occur and initiate appropriate therapy. **ADVERSE REACTIONS** Most common adverse reactions: injection site reactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 and over.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vizimpro™ (dacomitinib) Tablets, for oral use / Pfizer Inc.	Antineoplastic agent Pan-human epidermal growth factor receptor tyrosine kinase inhibitor (TKI)	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test	09/27/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 45 mg once daily. **DOSAGE FORMS AND STRENGTHS** Tablets: 15 mg, 30 mg, and 45 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Dermatologic:** Rash and exfoliative skin reactions have been reported with increased risk of incidence and severity with sun exposure; therapy interruption and dose adjustment may be necessary. • **Gastrointestinal:** Severe and fatal diarrhea has been reported; therapy interruption and dose adjustment may be necessary. • **Respiratory:** Severe and fatal interstitial lung disease (ILD)/pneumonitis has been reported; monitoring recommended and therapy interruption may be necessary. Permanently discontinue if ILD is confirmed. • **Reproductive:** May cause fetal harm; advise females of reproductive potential to use effective contraception during treatment and for at least 17 days after the final dose. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea, rash, paronychia, stomatitis, decreased appetite, dry skin, decreased weight, alopecia, cough, and pruritus. **DRUG INTERACTIONS** • **Proton Pump Inhibitors (PPIs):** Avoid use with Vizimpro™; use locally-acting antacids or H2-receptor antagonist; administer Vizimpro™ at least 6 hours before or 10 hours after H2-receptor antagonist.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vizimpro™ (dacomitinib) Tablets, for oral use / Pfizer Inc. (continuation)	Antineoplastic agent Pan-human epidermal growth factor receptor tyrosine kinase inhibitor (TKI)	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test	09/27/2018	**DRUG INTERACTIONS** (continuation) • **CYP2D6 Substrates:** Avoid concomitant use with Vizimpro™ where minimal increases in concentration of the CYP2D6 substrate may lead to serious or life-threatening toxicities. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Females of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for at least 17 days after the final dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** Analyses across this population suggest a higher incidence of Grade 3 and 4 adverse reactions, more frequent dose interruptions, and more frequent discontinuations for adverse reactions in patients 65 years or older as compared to those younger than 65 years. • **Renal impairment:** No dose adjustment is recommended for patients with mild or moderate renal impairment (CrCl 30 to 89 mL/min estimated by Cockcroft-Gault). The recommended dose has not been established for patients with severe renal impairment (CrCl < 30 mL/min). • **Hepatic impairment:** No dose adjustment is recommended in patients with mild (total bilirubin ≤ upper limit of normal [ULN] with AST > ULN or total bilirubin > 1 to 1.5 × ULN with any AST) or moderate (total bilirubin > 1.5 to 3 × ULN and any AST) hepatic impairment. The recommended dose has not been established for patients with severe hepatic impairment (total bilirubin > 3 to 10 × ULN and any AST).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arikayce™ (amikacin liposome) Inhalation Suspension, for oral inhalation / Insmed, Inc.	Anti-infective agent Antibacterial Aminoglycoside	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy **Limitations of use** • As only limited clinical safety and effectiveness data for Arikayce™ are currently available, reserve Arikayce™ for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patient. • Arikayce™ has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce™ is not recommended for patients with non-refractory MAC lung disease.	09/28/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is once daily oral inhalation of the contents of one 590 mg/8.4 mL Arikayce™ vial. • Pre-treatment with inhaled bronchodilator should be considered in patients with a history of hyperreactive airway disease. • Use Arikayce™ vials only with the Lamira Nebulizer System. **DOSAGE FORMS AND STRENGTHS** Sterile, aqueous, liposome suspension for oral inhalation in a unit-dose glass vial containing amikacin 590 mg/8.4 mL. **CONTRAINDICATIONS** • Known hypersensitivity to any aminoglycoside. **WARNINGS AND PRECAUTIONS** • **Hypersensitivity pneumonitis:** Reported with Arikayce™ treatment; if hypersensitivity pneumonitis occurs, discontinue Arikayce™ and manage patients as medically appropriate. • **Hemoptysis:** Higher frequency of hemoptysis has been reported with Arikayce™ treatment. If hemoptysis occurs, manage the patients as medically appropriate. • **Bronchospasm:** Higher frequency of bronchospasm has been reported with Arikayce™ treatment. Treat patients as medically appropriate if this occurs during treatment with Arikayce™. • **Exacerbations of underlying pulmonary disease:** Higher frequency of exacerbations of underlying pulmonary disease has been reported with Arikayce™ treatment. Treat patients as medically appropriate if this occurs during treatment with Arikayce™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arikayce™ (amikacin liposome) Inhalation Suspension, for oral inhalation / Insmed, Inc. (continuation)	Anti-infective agent Antibacterial Aminoglycoside	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy **Limitations of use** • As only limited clinical safety and effectiveness data for Arikayce™ are currently available, reserve Arikayce™ for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patient. • Arikayce™ has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce™ is not recommended for patients with non-refractory MAC lung disease.	09/28/2018	**WARNINGS AND PRECAUTIONS** (continuation) • **Ototoxicity:** Higher frequency of ototoxicity has been reported with Arikayce™ treatment. Closely monitor patients with known or suspected auditory or vestibular dysfunction. If patients develop tinnitus this may be an early symptom of ototoxicity. • **Nephrotoxicity:** Aminoglycosides can cause nephrotoxicity. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing Arikayce™. • **Neuromuscular blockade:** Aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function. If neuromuscular blockade occurs, it may be reversed by the administration of calcium salts but mechanical assistance may be necessary . • **Embryo-Fetal Toxicity:** Aminoglycosides can cause total, irreversible, bilateral congenital deafness in pediatric patients exposed in utero. **ADVERSE REACTIONS** Most common adverse reactions: dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia and exacerbation of underlying pulmonary disease, diarrhea, and nausea. **DRUG INTERACTIONS** • **Drugs with neurotoxic, nephrotoxic, or ototoxic potential:** Avoid concomitant use of Arikayce™ with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. • **Ethacrynic acid, furosemide, urea, or mannitol:** Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of Arikayce™ with ethacrynic acid, furosemide, urea, or intravenous mannitol.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Arikayce™ (amikacin liposome) Inhalation Suspension, for oral inhalation / Insmed, Inc. (continuation)	Anti-infective agent Antibacterial Aminoglycoside	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy **Limitations of use** • As only limited clinical safety and effectiveness data for Arikayce™ are currently available, reserve Arikayce™ for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patient. • Arikayce™ has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce™ is not recommended for patients with non-refractory MAC lung disease.	09/28/2018	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Although systemic absorption of amikacin following oral inhalation is expected to be low, systemic exposure to aminoglycoside antibacterial drugs may be associated with total, irreversible, bilateral congenital deafness when administered to pregnant women [see Warning and Precautions. Advise pregnant women of the potential risk to a fetus. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** No overall differences in safety and effectiveness were observed between elderly subjects and younger subjects. • **Hepatic impairment:** Arikayce™ has not been studied in patients with hepatic impairment. No dose adjustments based on hepatic impairment are required since amikacin is not hepatically metabolized. • **Renal impairment:** Arikayce™ has not been studied in patients with renal impairment. Given the low systemic exposure to amikacin following administration of Arikayce™, clinically relevant accumulation of amikacin is unlikely to occur in patients with renal impairment. However, renal function should be monitored in patients with known or suspected renal impairment, including elderly patients with potential age-related decreases in renal function.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Libtayo™ (cemiplimab-rwlc) Injection, for intravenous use / Sanofi	Antineoplastic agent Programmed death receptor-1 (PD-1) blocking antibody	Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation	09/28/2018	**DOSAGE AND ADMINISTRATION** The recommended dose is 350 mg as an intravenous infusion over 30 minutes every 3 weeks. **DOSAGE FORMS AND STRENGTHS** Injection: 350 mg/7 mL (50 mg/mL) solution in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Severe and fatal immune-mediated adverse reactions:** Immune-mediated adverse reactions can occur in any organ system or tissue, including the following: pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions and nephritis and renal dysfunction. Monitor. Evaluate clinical chemistries at baseline and periodically. Withhold or permanently discontinue Libtayo™ and administer corticosteroids based on the severity of reaction. • **Infusion-related reactions:** Interrupt, slow rate of infusion or permanently discontinue based on severity of reaction. **ADVERSE REACTIONS** Most common adverse reactions: fatigue, rash and diarrhea. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Females of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between subjects 65 years or older and younger subjects.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Actemra™ (tocilizumab) Injection / Genentech USA, Inc.	Anti-rheumatic agent Humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody	**Previous indication(s):** 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:** Subcutaneous formulation for the treatment of active SJIA in patients two years of age and older	09/12/2018	The FDA has approved the subcutaneous (SC) formulation of Actemra ™ for the treatment of active SJIA in patients two years of age and older. In 2011, FDA approved the intravenous (IV) formulation of Actemra™ for patients two years of age and older with active SJIA. Actemra™ IV is administered in a medical office. Now physicians would have the option of prescribing Actemra™ SC, a prefilled syringe that can be injected at home.
Symjepi™ (epinephrine) Injection / Adamis Pharmaceuticals Corporation	Vasopressor Anaphylaxis therapy agent Non-selective alpha and betaadrenergic receptor agonist	**Previous indication(s):** Emergency treatment of allergic reactions (Type I) including anaphylaxis **Patient population altered:** To treat patients weighing 33-66 pounds	09/27/2018	The FDA has approved a lower dose version (0.15mg) of Symjepi™ for the emergency treatment of allergic reactions (Type I) including anaphylaxis. Symjepi™ Injection was previously approved in a higher dose (0.3mg) for the emergency treatment of allergic reactions (Type I), including anaphylaxis, in patients weighing 66 pounds or greater. The lower dose version (0.15mg) is intended to potentially treat patients weighing 33-66 pounds. Both Symjepi™ products will provide two single-dose injections syringes of epinephrine (adrenaline), which is considered the drug of choice for immediate administration in acute anaphylactic reactions.

New FDA Approved Indications

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Fycompa™ (perampanel) Tablets and Oral Suspension / Eisai Inc.	Central nervous system agent Antiepileptic Non-competitive AMPA glutamate receptor antagonist	**Previous indication(s):** Treatment of partial-onset seizures, and as adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy **Patient population altered:** For use in pediatric patients 4 years and older for the treatment of partial-onset seizures with or without secondarily generalized seizures	09/28/2018	Fycompa™ was initially approved for adjunctive use in POS, and was later approved as adjunctive therapy for PGTC seizures in patients with epilepsy 12 years of age and older, and then as monotherapy for POS with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older.

New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tiglutik™ (riluzole) Oral Suspension, / ITF Pharma	Neuromuscular agent	Treatment of amyotrophic lateral sclerosis (ALS)	09/05/2018	Tiglutik™ is an easy-to-swallow, thickened, oral suspension formulation of the approved drug riluzole. Tiglutik™ received orphan drug designation.
Cassipa™ (buprenorphine and naloxone) Sublingual Film / Teva Pharmaceuticals USA, Inc.	Partial-opioid agonist and opioid antagonist combination	Maintenance treatment of opioid dependence	09/07/2018	Cassipa™ provides a new dosage strength (16 milligrams/4 milligrams) of buprenorphine and naloxone sublingual film, which is also approved in both brand name and generic versions and in various strengths.
Xelpros™ (latanoprost) Ophthalmic Emulsion / Sun Pharmaceutical Industries Inc.	Prostaglandin $F_{2\alpha}$ analog	For reduction of elevated intraocular pressure in patients with open-angle glaucoma, or ocular hypertension	09/12/2018	Xelpros™ is the first and only form of latanoprost that is not formulated with benzalkonium chloride (BAK), a preservative commonly used in topical ocular preparations.
Xolair™ (omalizumab) Subcutaneous Injection / Genentech	Immunological agent Monoclonal antibody	Treatment of patients with moderate to severe persistent asthma, and chronic idiopathic urticarial	09/20/2018	The FDA has approved 75 mg/0.5 mL and 150 mg/1 mL single-dose prefilled syringes for Xolair™ as an additional formulation for both allergic asthma and chronic idiopathic urticaria indications.
Arikayce™ (amikacin liposome) Inhalation Suspension / Insmed, Inc.	Anti-infective agent Antibacterial Aminoglycoside	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy	09/28/2018	Arikayce™ is the first drug to be approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, established to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 600 mg/200 mg/300 mg / Aurobindo Pharma Limited	Anti-infective agent; Antiretriviral	09/04/2018	Generic for: Atripla
Ticagrelor Tablets 60mg and 90mg / Watson Laboratories, Inc.	Hematological agent; Platelet aggregation inhibitor	09/04/2018	Generic for: Brilinta
Carmustine for Injection USP, 100 mg/vial / Navinta LLC	Antineoplastic agent	09/11/2018	Generic for: BiCNU
Albendazole Tablets 200 mg / Cipla Ltd.	Anti-infective agent; Antihelmintic	09/21/2018	Generic for: Albenza

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

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Drug/Manufacturer	Date	Indications	Comments	Impact
Esketamine Nasal Spray / Janssen Pharmaceuticals, Inc.	09/04/2018	Treatment for: Depression	Esketamine is a rapid acting, investigational glutamate receptor modulator antidepressant in development for use in patients with treatment-resistant depression. Janssen submitted an NDA for esketamine.	Moderate
Tenapanor / Ardelyx, Inc.	09/13/2018	Treatment for: Irritable Bowel Syndrome	Tenapanor is a first-in-class, small-molecule inhibitor of gastrointestinal NHE3 in development for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). Ardelyx submitted an NDA for tenapanor.	High
Erdafitinib / Janssen Pharmaceuticals, Inc.	09/18/2018	Treatment for: Urothelial Carcinoma	Erdafitinib is an investigational, once-daily oral pan-fibroblast growth factor receptor (FGFR) in development for the treatment of patients with locally advanced or metastatic urothelial cancer. Janssen submitted an NDA for erdafitinib.	High
Lumateperone / Intra-Cellular Therapies, Inc.	09/28/2018	Treatment for: Schizophrenia	Lumateperone is first-in-class antipsychotic in development for the treatment of schizophrenia. Lumateperone provides selective and simultaneous modulation of serotonin, dopamine, and glutamate - three neurotransmitter pathways implicated in severe mental illness. Intra-Cellular Therapies, Inc. completed de submission of the NDA for lumateperone.	High

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)
- Products Full Prescribing Information