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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
From: JUNE 2019

Date: 7/8/2019

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2019

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NEWS……

Drug Issue	Date	News/Event
Warning for women of childbearing age about possible safety risks of dietary supplements containing vinpocetine	06/03/2019	The FDA is warning about safety concerns regarding the use of supplements containing an ingredient called vinpocetine by women of childbearing age. According to data reviewed by the FDA, consumption of vinpocetine is associated with adverse reproductive effects such as miscarriage or harm fetal development. These findings are particularly concerning since products containing vinpocetine are widely available for use by women of childbearing age. Vinpocetine is a synthetically produced compound that is used in some products marketed as dietary supplements, either by itself or combined with other ingredients. Vinpocetine may be referred to on product labels as Vinca minor extract, lesser periwinkle extract, or common periwinkle extract. Dietary supplements containing vinpocetine are often marketed for uses that include enhanced memory, focus, or mental acuity; increased energy; and weight loss.
Warnings to companies selling illegal, unapproved kratom drug products marketed for opioid cessation, pain treatment and other medical uses	06/25/2019	The FDA issued warning letters to two marketers and distributors of kratom products for illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms, and treating pain, as well as other medical conditions like depression, anxiety and cancer. In addition, the FDA continues to warn consumers not to use product containing kratom or its psychoactive compounds, mitragynine and 7-hydroxymitragynine. Kratom is not legally marketed in the U.S. as a drug or dietary supplement, and while it is important to gather more evidence, data suggest that certain substances in kratom have opioid properties that expose users to the risks of addiction, abuse and dependence. The FDA is actively evaluating available scientific information on this issue. The FDA encourages more research to better understand kratom's safety profile, including the use of kratom combined with other drugs.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Polivy™ (polatuzumab vedotin-piiq) Injection, for intravenous use / Genentech, Inc.	Antineoplastic agent; CD79b-directed antibody	In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies	06/10/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 1.8 mg/kg as an intravenous infusion over 90 minutes every 21 days for 6 cycles in combination with bendamustine and a rituximab product. Subsequent infusions may be administered over 30 minutes if the previous infusion is tolerated. Premedicate with an antihistamine and antipyretic. **DOSAGE FORMS AND STRENGTHS** For injection: 140 mg of polatuzumab vedotin-piiq as a lyophilized powder in a single-dose vial. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Peripheral neuropathy:** Monitor patients for peripheral neuropathy and modify or discontinue dose accordingly. • **Infusion-related reactions:** Premedicate with an antihistamine and antipyretic. Monitor patients closely during infusions. Interrupt or discontinue infusion for reactions. • **Myelosuppression:** Monitor complete blood counts. Manage using dose delays or reductions and growth factor support. Monitor for signs of infection. • **Serious and opportunistic infections:** Closely monitor patients for signs of bacterial, fungal, or viral infections. • **Progressive Multifocal Leukoencephalopathy (PML):** Monitor patients for new or worsening neurological, cognitive, or behavioral changes suggestive of PML.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Polivy™ (polatuzumab vedotin-piiq) Injection, for intravenous use / Genentech, Inc. (continuation)	Antineoplastic agent; CD79b-directed antibody	In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, after at least two prior therapies	06/10/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Tumor Lysis Syndrome:** Closely monitor patients with high tumor burden or rapidly proliferative tumors. • **Hepatotoxicity:** Monitor liver enzymes and bilirubin. • **Embryo-Fetal Toxicity:** Can cause fetal harm. **ADVERSE REACTIONS** Most common adverse reactions: neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia. **DRUG INTERACTIONS** • **Strong CYP3A inhibitors or inducers:** Concomitant use of strong CYP3A inhibitors or inducers has the potential to affect the exposure to unconjugated monomethyl auristatin E (MMAE). **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating. • **Females and males of reproductive potential:** Advise females of reproductive potential to use effective contraception during treatment and for 3 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 5 months after the final dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Hepatic impairment:** Hepatic impairment has the potential to increase exposure to MMAE. Monitor patients for adverse reactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments

Kanjinti™ (trastuzumab-anns) Injection, for intravenous use / Amgen Inc.	Antineoplastic agent; HER2/neu receptor antagonist
	
	Note: Biosimilar to Herceptin™
		Treatment of:
		• HER2 overexpressing breast cancer
		• HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma
			06/13/2019	**DOSAGE AND ADMINISTRATION**
				<u>For Adjuvant Treatment of HER2-Overexpressing Breast Cancer</u>
				• Administer at either:
				  • Initial dose of 4 mg/kg over 90 minute IV infusion, then 2 mg/kg over 30 minute IV infusion weekly for 12 weeks (with paclitaxel or docetaxel) or 18 weeks (with docetaxel and carboplatin). One week after the last weekly dose of Kanjinti™, administer 6 mg/kg as an IV infusion over 30–90 minutes every three weeks to complete a total of 52 weeks of therapy, or
				  • Initial dose of 8 mg/kg over 90 minutes IV infusion, then 6 mg/kg over 30–90 minutes IV infusion every three weeks for 52 weeks.
				
				<u>For Metastatic HER2-Overexpressing Breast Cancer</u>
				• Initial dose of 4 mg/kg as a 90 minute IV infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute IV infusions.
				
				<u>For Metastatic HER2-Overexpressing Gastric Cancer</u>
				• Initial dose of 8 mg/kg over 90 minutes IV infusion, followed by 6 mg/kg over 30 to 90 minutes IV infusion every 3 weeks.
				
				Patients must be selected for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.
				
				Do not substitute Kanjinti™ for or with ado-trastuzumab emtansine.
				
				DOSAGE FORMS AND STRENGTHS
				For Injection: 420 mg lyophilized powder in a multiple-dose vial for reconstitution.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Kanjinti™ (trastuzumab-anns) Injection, for intravenous use / Amgen Inc.	Antineoplastic agent; HER2/neu receptor antagonist Note: Biosimilar to Herceptin™	Treatment of: • HER2 overexpressing breast cancer • HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma	06/13/2019	**CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Exacerbation of chemotherapy-induced neutropenia. **ADVERSE REACTIONS** Most common adverse reactions: headache, nausea, chills, neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, dysgeusia, congestive heart failure, insomnia, cough and rash. **DRUG INTERACTIONS** • **Anthracycline:** Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Verify the pregnancy status prior to initiation. • **Females of reproductive potential:** Advise to use effective contraception during treatment and for 7 months following the last dose. • **Pediatric use:** Safety and effectiveness have not been established.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyleesi™ (bremelanotide) Injection, for subcutaneous use / AMAG Pharmaceuticals, Inc.	Central nervous system agent; Melanocortin receptor agonist	Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition, • Problems with the relationship, or • The effects of a medication or drug substance **Limitations of use** Not indicated for treatment of HSDD in postmenopausal women or in men. • Not indicated to enhance sexual performance.	06/21/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 1.75 mg subcutaneously via the auto-injector to the abdomen or thigh, as needed, at least 45 minutes before anticipated sexual activity. • Do not administer more than one dose within 24 hours. • More than 8 doses per month is not recommended. **DOSAGE FORMS AND STRENGTHS** Subcutaneous injection: 1.75 mg/0.3 mL solution. **CONTRAINDICATIONS** • Uncontrolled hypertension or known cardiovascular disease. **WARNINGS AND PRECAUTIONS** • **Transient increase in blood pressure and decrease in heart rate:** Occurs after each dose and usually resolves within 12 hours. Consider the patient's cardiovascular risk before initiating Vyleesi™ and periodically during treatment and ensure blood pressure is well-controlled. Vyleesi™ is not recommended in patients at high risk for cardiovascular disease. • **Focal hyperpigmentation:** Reported by 1% of patients who received up to 8 doses per month, including involvement of the face, gingiva and breasts. Higher risk in patients with darker skin and with daily dosing. Resolution was not confirmed in some patients. Consider discontinuing Vyleesi™ if hyperpigmentation develops.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyleesi™ (bremelanotide) Injection, for subcutaneous use / AMAG Pharmaceuticals, Inc.	Central nervous system agent; Melanocortin receptor agonist	Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: • A co-existing medical or psychiatric condition, • Problems with the relationship, or • The effects of a medication or drug substance **Limitations of use** • Not indicated for treatment of HSDD in postmenopausal women or in men. • Not indicated to enhance sexual performance.	06/21/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Nausea:** Reported by 40% of patients who received up to 8 monthly doses, requiring anti-emetic therapy in 13% of patients and leading to premature discontinuation for 8% of patients. Improved for most patients with the second dose. Consider discontinuing Vyleesi™ or initiating anti-emetic therapy for persistent or severe nausea. **ADVERSE REACTIONS** Most common adverse reactions: nausea, flushing, injection site reactions, headache, and vomiting. **DRUG INTERACTIONS** • Vyleesi™ may slow gastric emptying and impact absorption of concomitantly administered oral medications. • Vyleesi™ may significantly decrease the systemic exposure of orally administered naltrexone; avoid use with orally administered naltrexone-containing products intended to treat alcohol or opioid addiction. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. Use during pregnancy is not recommended. Advise patients to discontinue Vyleesi™ if pregnancy is suspected. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Vyleesi™ during pregnancy. Pregnant women exposed to Vyleesi™ and healthcare providers are encouraged to call the Vyleesi™ Pregnancy Exposure Registry. • **Females of reproductive potential:** Advise females of reproductive potential to use effective contraception while taking Vyleesi™, and to discontinue Vyleesi™ if pregnancy is suspected.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zirabev™ (bevacizumab-bvzr) Injection, for intravenous use / Pfizer Inc.	Antineoplastic agent; Vascular endothelial growth factor (VEGF) inhibitor Note: Biosimilar to Avastin™	Treatment of: • Metastatic colorectal cancer: (1) with fluorouracil-based chemotherapy for first- or second-line treatment; (2) with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen • Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first-line treatment • Recurrent glioblastoma in adults • Metastatic renal cell carcinoma, with interferon alfa • Persistent, recurrent, or metastatic cervical cancer, with paclitaxel and cisplatin or paclitaxel and topotecan **Limitations of use** Not indicated for adjuvant treatment of colon cancer	06/27/2019	**DOSAGE AND ADMINISTRATION** Metastatic colorectal cancer (2.2) • 5 mg/kg every 2 weeks with bolus-IFL • 10 mg/kg every 2 weeks with FOLFOX4 • 5 mg/ kg every 2 weeks or 7.5 mg/kg every 3 weeks with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first-line bevacizumab product containing regimen First-line non–squamous non–small cell lung cancer • 15 mg/kg every 3 weeks with carboplatin and paclitaxel Recurrent glioblastoma • 10 mg/kg every 2 weeks Metastatic renal cell carcinoma • 10 mg/kg every 2 weeks with interferon alfa Persistent, recurrent, or metastatic cervical cancer • 15 mg/kg every 3 weeks with paclitaxel and cisplatin or paclitaxel and topotecan **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) in a single-dose vial. **CONTRAINDICATIONS** • None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zirabev™ (bevacizumab-bvzr) Injection, for intravenous use / Pfizer Inc. (continuation)	Antineoplastic agent; Vascular endothelial growth factor (VEGF) inhibitor Note: Biosimilar to Avastin™	Treatment of: • Metastatic colorectal cancer: (1) with fluorouracil-based chemotherapy for first- or second-line treatment; (2) with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen • Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first-line treatment • Recurrent glioblastoma in adults • Metastatic renal cell carcinoma, with interferon alfa • Persistent, recurrent, or metastatic cervical cancer, with paclitaxel and cisplatin or paclitaxel and topotecan **Limitations of use** Not indicated for adjuvant treatment of colon cancer	06/27/2019	**WARNINGS AND PRECAUTIONS** • **Gastrointestinal perforations and fistula:** Discontinue for gastrointestinal perforations, tracheoesophageal fistula, grade 4 fistula, or fistula formation involving any organ. • **Surgery and wound healing complications:** Discontinue in patients who develop wound healing complications that require medical intervention or necrotizing fasciitis. Withhold for at least 28 days prior to elective surgery. Do not administer for at least 28 days after surgery, and until the wound is fully healed. • **Hemorrhage:** Severe or fatal hemorrhages have occurred. Do not administer for recent hemoptysis. Discontinue for Grade 3-4 hemorrhage. • **Arterial Thromboembolic Events (ATE):** Discontinue for severe ATE. • **Venous Thromboembolic Events (VTE):** Discontinue for Grade 4 VTE. • **Hypertension:** Monitor blood pressure and treat hypertension. Withhold if not medically controlled; resume once controlled. Discontinue for hypertensive crisis or hypertensive encephalopathy. • **Posterior Reversible Encephalopathy Syndrome (PRES):** Discontinue. • **Renal injury and proteinuria:** Monitor urine protein. Discontinue for nephrotic syndrome. Withhold until less than 2 grams of protein in urine. • **Infusion–Related Reactions:** Decrease rate for infusion-related reactions. Discontinue for severe infusion-related reactions and administer medical therapy. • **Embryo-fetal toxicity:** May cause fetal harm. Advise females of potential risk to fetus and need for use of effective contraception.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zirabev™ (bevacizumab-bvzr) Injection, for intravenous use / Pfizer Inc. (continuation)	Antineoplastic agent; Vascular endothelial growth factor (VEGF) inhibitor Note: biosimilar to Avastin™	Treatment of: • Metastatic colorectal cancer: (1) with fluorouracil-based chemotherapy for first- or second-line treatment; (2) with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen • Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first-line treatment • Recurrent glioblastoma in adults • Metastatic renal cell carcinoma, with interferon alfa • Persistent, recurrent, or metastatic cervical cancer, with paclitaxel and cisplatin or paclitaxel and topotecan **Limitations of use** Not indicated for adjuvant treatment of colon cancer	06/27/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Ovarian failure:** Advise females of the potential risk. • **Congestive Heart Failure (CHF):** Discontinue in patients who develop CHF. **ADVERSE REACTIONS** Most common adverse reactions: epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Females of reproductive potential:** Advise to use effective contraception during treatment and for 6 months after the last dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and effectiveness of bevacizumab products in pediatric patients have not been established.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Zerbaxa™ (ceftolozane and tazobactam) Injection / Cubist Pharmaceuticals, Inc.	Anti-infective agent; Antibiotic; Cephalosporin and beta-lactamase inhibitor combination	**Previous indication(s):** Treatment of: • complicated intra-abdominal Infections (cIAI), used in combination with metronidazole • complicated urinary tract infections (cUTI), including pyelonephritis **New indication:** Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)	06/03/2019	The FDA approved Zerbaxa™ for the treatment of adult patients with HABP/VABP caused by the following susceptible Gram-negative microorganisms: Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Serratia marcescens. Of note, to reduce the development of drug-resistant bacteria and maintain the effectiveness of Zerbaxa™ and other antibacterial drugs, Zerbaxa™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. The approval is based on results of a study that compared Zerbaxa™ intravenously every 8 hours to meropenem intravenously every 8 hours for 8 to 14 days for the treatment of adult patients with HABP/VABP. Efficacy was assessed based on all-cause mortality at Day 28 and clinical cure, defined as complete resolution or significant improvement in signs and symptoms of the index infection at the test-of-cure (TOC) visit which occurred 7 to 14 days after the end of treatment. Zerbaxa™ was non-inferior to meropenem for 28-day all-cause mortality, 24.0% and 25.3% respectively, for a weighted proportion difference of 1.1 (stratified 95% CI: -5.13, 7.39; non-inferiority margin of 10%). In addition, Zerbaxa™ was non-inferior to meropenem for clinical response at Test-of-Cure, 54.4% and 53.3% respectively, for a weighted proportion difference of 1.1 (stratified 95% CI: -6.17, 8.29; non-inferiority margin of 12.5%).

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Emgality™ (galcanezumab-gnlm) Injection / Eli Lilly and Company	Central nervous system agent; Antmigraine; calcitonin gene-related peptide (CGRP) antagonist	**Previous indication(s):** Preventive treatment of migraine **New indication:** Treatment of episodic cluster headache	06/04/2019	This approval was based on results of a study including 106 patients, which were randomized 1:1 to receive once-monthly injections of Emgality™ 300 mg (N=49) or placebo (N=57). The baseline number of weekly cluster headache attacks was 17.8 for Emgality™ and 17.3 for placebo. Patients on Emgality™ experienced an average of 8.7 fewer weekly cluster headache attacks over Weeks 1 to 3 versus 5.2 fewer weekly attacks for patients on placebo (p=0.036). With Emgality™, 71.4% of patients had their weekly cluster headache attacks cut in half or more from baseline at Week 3 versus 52.6% of patients with placebo (p=0.046).
Emflaza™ (deflazacort) Tablets and Oral Suspension / PTC Therapeutics, Inc.	Glucocorticoid	**Previous indication(s):** Treatment of Duchenne muscular dystrophy (DMD) **Patient population altered:** To include patients with DMD who are between 2 and 5 years-old	06/07/2019	-

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Keytruda™ (pembrolizumab) for Injection / Merck	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	**Previous indication(s):** Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma (with disease progression on or after platinum-containing chemotherapy), classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, and renal cell carcinoma **New indication:** As monotherapy in patients whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1) or in combination with platinum and fluorouracil (FU), for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma	06/10/2019	This approval was based on results from a study where Keytruda™ demonstrated a significant improvement in overall survival (OS) compared with the EXTREME regimen (cetuximab with carboplatin or cisplatin plus FU), a standard treatment, as monotherapy in patients whose tumors expressed PD-L1 (CPS ≥1) (HR=0.78; 95% CI: 0.64-0.96; p=0.0171) and in combination with chemotherapy in the total study population (HR=0.77; 95% CI: 0.63-0.93; p=0.0067). With this new indications, Keytruda™ is the first anti-PD-1 therapy approved in the first-line setting as monotherapy in patients whose tumors express PD-L1 (CPS ≥1) or in combination with chemotherapy regardless of PD-L1 expression for patients with metastatic or with unresectable, recurrent HNSCC and the first anti-PD-1 therapy to demonstrate a statistically significant improvement in OS in these patients.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Victoza™ (liraglutide) Injection / Novo Nordisk	Antidiabetic; Glucagon-like peptide-1 (GLP-1) receptor agonist	**Previous indication(s):** To improve glycemic control in patients with type 2 diabetes mellitus, and to reduce the risk of heart attack, stroke and cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. **Patient population altered:** To include the treatment of pediatric patients 10 years or older with type 2 diabetes	06/17/2019	-
Dextenza™ (dexamethasone) Ophthalmic Insert / Ocular Therapeutix, Inc.	Ophthalmic agent; Corticosteroid intracanalicular insert	**Previous indication(s):** Treatment of post-surgical ocular pain **New indication:** Treatment of ocular inflammation following ophthalmic surgery	06/20/2019	Dextenza™ is the first FDA-approved intracanalicular insert, a novel route of administration that delivers drug to the surface of the eye without the need for eye drops. Dextenza™ was first approved by the FDA for the treatment of ocular pain following ophthalmic surgery. With this new indication, Dextenza™ is approved for the treatment of both ocular inflammation and pain following ophthalmic surgery. This approval was based on results from three studies in which patients received Dextenza™ or a vehicle immediately upon completion of cataract surgery. In all three trials, Dextenza™ had a higher proportion of patients than the vehicle group who were pain free on post-operative Day 8.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Botox™ (onabotulinumtoxinA) Injection / Allergan plc	Acetylcholine release inhibitor and a neuromuscular blocking agent	**Previous indication(s):** Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency; Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults; Prophylaxis of headaches in adult patients with chronic migraine; Treatment of upper and lower limb spasticity in adult patients; Treatment of cervical dystonia in adult patients; Treatment of severe axillary hyperhidrosis in adult patients; Treatment of blepharospasm associated with dystonia in patients 12 years of age and older; Treatment of strabismus in patients 12 years of age and older **Patient population altered:** Treatment of pediatric patients (2 to 17 years of age) with upper limb spasticity	06/20/2019	-

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Symdeko™ (ivacaftor/tezacaftor and ivacaftor) Tablets / Vertex Pharmaceuticals Incorporated	Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination	**Previous indication(s):** Treatment of cystic fibrosis (CF) in patients who have two copies of the F508del mutation, or who have at least one mutation in the CF gene that is responsive to treatment with Symdeko™ **Patient population altered:** For use in children with cystic fibrosis ages 6 through 11 years	06/21/2019	-

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Nucala™ (mepolizumab) Injection / GlaxoSmithKline	Respiratory agent; Interleukin-5 antagonist monoclonal antibody	• Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype • Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)	06/06/2019	The FDA has approved two new methods for administering Nucala™, an auto-injector and a pre-filled safety syringe, for patients or caregivers to administer once every four weeks, after a healthcare professional decides it is appropriate. This is the first anti-IL5 biologic to be licensed in the US for at-home administration, and the first respiratory biologic to be approved for administration via an auto-injector.
Myxredlin™ (insulin human in sodium chloride injection) / Celerity Pharms	Endocrine and metabolic agent; Antidiabetic; Short-acting human insulin	To improve glycemic control in adults and pediatric patients with diabetes mellitus	06/21/2019	Myxredlin™ is an intravenous short-acting human insulin that should be administered only under medical supervision with close monitoring of blood glucose and potassium levels. Other short-acting human insulins that were already available in the market include Humulin R™ and Novolin R™, which can be administered IV or subcutaneous.
Thiola EC™ (tiopronin) delayed-release tablets / Retrophin, Inc.	Genitourinary agent	In combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria, who are not responsive to these measures alone	06/28/2019	Thiola EC™ is a new enteric-coated formulation of Thiola™ (tiopronin). This new formulation can be administered with or without food, an advantage over the original formulation which has limiting food restrictions (at least one hour before or two hours after meals). In addition, this new formulation have the potential to reduce the number of tablets needed. The recommended initial dosage for both formulations in adult patients is 800 mg per day and in clinical studies the average dosage was about 1,000 mg per day. However, the original formulation of Thiola™ is only available in 100 mg tablet, while Thiola EC™ will be available in 100 mg and 300 mg delated-release tablet.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Diclofenac Sodium Injection 37.5 mg/mL Single-Dose Vials / Mylan Laboratories Limited	NSAID	06/18/2019	Generic for: Dyloject
Tobramycin Inhalation Solution 300 mg/4 mL / Teva Pharmaceuticals USA, Inc.	Antibiotic; Aminoglycoside	06/26/2019	Generic for: Bethkis

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Luspatercept / Celgene Corporation	06/04/2019	Treatment for: Anemia associated to myelodysplastic syndromes (MDS) and beta-thalassemia	Luspatercept is a first-in-class erythroid maturation agent (EMA) in development for the treatment of myelodysplastic syndromes (MDS)-associated anemia and beta-thalassemia-associated anemia. Celgene announced that the FDA the accepted the BLA for luspatercept.	High
Ozanimod / Celgene Corporation	06/06/2019	Treatment for: Multiple Sclerosis, Ulcerative Colitis	Ozanimod is an investigational selective sphingosine 1-phosphate (S1P) 1 and 5 receptor modulator in development for the treatment of patients with relapsing multiple sclerosis, and ulcerative colitis. Celgene announced that the FDA the accepted the NDA for ozanimod.	Moderate
Avapritinib / Blueprint Medicines Corporation	06/14/2019	Treatment for: Gastrointestinal Stromal Tumor	Avapritinib is a potent and highly selective KIT and PDGFRα inhibitor in development for the treatment of PDGFRα Exon 18 mutant gastrointestinal stromal tumors (GIST) and fourth-line GIST. Blueprint Medicines Corporation submitted a NDA for avapritinib.	High
Brinavess (vernakalant) Intravenous Injection / Cardiome Pharma Corporation	06/24/2019	Treatment for: Atrial Fibrillation	Brinavess (vernakalant) is an investigational antiarrhythmic drug in development for the rapid conversion of adult patients with recent onset atrial fibrillation (AF). Cardiome Pharma Corporation resubmitted a NDA for Brinavess (vernakalant).	Moderate

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

References:

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