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PharmNOTES

Summary about new FDA-approved products,
new indications, first-time generics,
and WHAT IS IN THE PIPELINE.
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urac ACCREDITED
Pharmacy Benefit Management
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NEWS……

No safety communication published during May 2019.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Dengvaxia™ (dengue tetravalent vaccine, live) Injection, for subcutaneous use / Sanofi Pasteur, Inc.	Vaccine	For the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4; for use in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas. Limitations of use: • Not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination. • The safety and effectiveness of have not been established in individuals living in dengue non-endemic areas who travel to dengue endemic areas.	05/01/2019	**DOSAGE AND ADMINISTRATION** The recommended vaccination schedule is three doses (0.5 mL each) 6 months apart (at month 0, 6, and 12). **DOSAGE FORMS AND STRENGTHS** Suspension for injection (0.5 mL) supplied as a lyophilized powder to be reconstituted with the supplied diluent. **CONTRAINDICATIONS** • A history of severe allergic reaction to a previous dose of Dengvaxia™ or to any component of Dengvaxia™. • Immunocompromised individuals **WARNINGS AND PRECAUTIONS** • In persons not previously infected by dengue virus, an increased risk of severe dengue disease can occur following vaccination with Dengvaxia™ and subsequent infection with any dengue virus serotype. • There is no FDA-cleared test available to determine a previous dengue infection. **ADVERSE REACTIONS** Most common adverse reactions: headache, injection site pain, malaise, asthenia and myalgia. **DRUG INTERACTIONS** • False negative tuberculin purified protein derivative (PPD) test results may occur within 1 month following vaccination with Dengvaxia™.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyndaqel™ (tafamidis meglumine) Capsules and Vyndamax™ (tafamidis) Capsules, for oral use / Pfizer Inc.	Cardiovascular agent; Transthyretin stabilizer Note: Orphan drug designation	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization	05/03/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is either: • Vyndaqel™ 80 mg orally once daily, or • Vyndamax™ mg orally once daily Vyndaqel™ and Vyndamax™ are not substitutable on a per mg basis. **DOSAGE FORMS AND STRENGTHS** Capsules: Tafamidis meglumine 20 mg and tafamidis 61 mg. **CONTRAINDICATIONS** None. **ADVERSE REACTIONS** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. **DRUG INTERACTIONS** • **BCRP Substrates:** Tafamidis inhibits breast cancer resistant protein (BCRP) in vitro and may increase exposure of substrates of this transporter (e.g., methotrexate, rosuvastatin, imatinib) following Vyndaqel™ 80 mg or Vyndamax™ 61 mg. Dose adjustment may be needed for these substrates.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vyndaqel™ (tafamidis meglumine) Capsules and Vyndamax™ (tafamidis) Capsules, for oral use / Pfizer Inc. (continuation)	Cardiovascular agent; Transthyretin stabilizer Note: Orphan drug designation	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization	05/03/2019	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on animal studies, may cause fetal harm. • Females of reproductive potential: • **Lactation:** Advise not to breastfeed. Consider pregnancy planning and prevention for females of reproductive potential. • **Pediatric use:** Safety and effectiveness have not been established in pediatric patients. • **Geriatric use:** No dosage adjustment is required for elderly patients (≥65 years).

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Piqray™ (alpelisib) Tablets, for oral use / Novartis Pharmaceuticals Corporation	Antineoplastic agent; Kinase inhibitor	In combination with fulvestrant, for the treatment of post-menopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen	05/24/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 300 mg (two 150 mg tablets) taken orally once daily with food. For adverse reactions, consider dose interruption, dose reduction, or discontinuation. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg, 150 mg, 200 mg. **CONTRAINDICATIONS** • Severe hypersensitivity to PIQRAY or to any of its components. **WARNINGS AND PRECAUTIONS** • **Severe hypersensitivity:** Permanently discontinue. Promptly initiate appropriate treatment. • **Severe cutaneous reactions:** Cases of severe cutaneous reactions, including Stevens-Johnson syndrome (SJS) and Erythema Multiforme (EM) were reported. Do not initiate treatment in patients with a history of SJS, EM, or Toxic Epidermal Necrolysis (TEN). Interrupt if signs or symptoms of severe cutaneous reactions are present, until etiology of the reaction has been determined. Consider consultation with a dermatologist. Permanently discontinue if SJS, EM, or TEN is confirmed.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Piqray™ (alpelisib) Tablets, for oral use / Novartis Pharmaceuticals Corporation (continuation)	Antineoplastic agent; Kinase inhibitor	In combination with fulvestrant, for the treatment of post-menopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen	05/24/2019	**WARNINGS AND PRECAUTIONS** (continuation) • **Hyperglycemia:** Severe hyperglycemia, including ketoacidosis, was reported. The safety of Piqray™ in patients with Type 1 or uncontrolled Type 2 diabetes has not been established. Before initiating treatment, test fasting plasma glucose, HbA1c, and optimize blood glucose. After initiating treatment, monitor periodically. Initiate or optimize anti-hyperglycemic medications as clinically indicated. Interrupt, reduce dose, or discontinue if severe hyperglycemia occurs. • **Pneumonitis:** Severe cases of pneumonitis and interstitial lung disease have been reported. Monitor for clinical symptoms or radiological changes. Interrupt or discontinue if severe pneumonitis occurs. • **Diarrhea:** Severe cases of diarrhea, including dehydration and acute kidney injury, have been reported. Most patients experience diarrhea (Grade ≤ 2) during treatment. Advise patients to start antidiarrheal treatment, increase oral fluids, and notify their healthcare provider if diarrhea occurs. Interrupt, reduce dose, or discontinue if severe diarrhea occurs. • **Embryo-fetal toxicity:** Can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Also, refer to the Full Prescribing Information of fulvestrant for pregnancy and contraception information. **ADVERSE REACTIONS** Most common adverse reactions: glucose increased, creatinine increased, diarrhea, rash, lymphocyte count decreased, GGT increased, nausea, ALT increased, fatigue, hemoglobin decreased, lipase increased, decreased appetite, stomatitis, vomiting, weight decreased, calcium decreased, glucose decreased, aPTT prolonged, and alopecia.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Piqray™ (alpelisib) Tablets, for oral use / Novartis Pharmaceuticals Corporation (continuation)	Antineoplastic agent; Kinase inhibitor	In combination with fulvestrant, for the treatment of post-menopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen	05/24/2019	**DRUG INTERACTIONS** • **CYP3A4 Inducers:** Avoid co-administration with a strong CYP3A4 inducer. • **BCRP Inhibitors:** Avoid the use of BCRP inhibitors in patients treated with Piqray™. If unable to use alternative drugs, closely monitor for increased adverse reactions. • **CYP2C9 Substrates:** Closely monitor when co-administered with CYP2C9 substrates where decreases in the plasma concentration of these drugs may reduce activity. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Can cause fetal harm. Verify the pregnancy status in females of reproductive potential prior to initiating. • **Females and males of reproductive potential:** Advise females of reproductive potential, and male patients with female partners of reproductive potential, to use effective contraception during treatment and for 1 week after the last dose. • **Lactation:** Advise not to breastfeed. • **Pediatric use:** Safety and efficacy in pediatric patients have not been established. • **Geriatric use:** No overall differences in effectiveness were observed between patients ≥ 65 years of age compared to younger patients. There are an insufficient number of patients ≥ 75 years of age to assess whether there are differences in safety or effectiveness.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zolgensma™ (onasemnogene abeparvovec-xioi) Suspension, for Intravenous Infusion / Novartis Pharmaceuticals Corporation	Gene therapy Note: Orphan drug designation	Treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene Limitation of Use: • The safety and effectiveness of repeat administration of have not been evaluated. • The use in patients with advanced SMA (e.g. complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.	05/24/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 1.1 × 1014 vector genomes (vg) per kg of body weight. Starting one day prior to Zolgensma™ infusion, administer systemic corticosteroids equivalent to oral prednisolone at 1 mg/kg of body weight per day for a total of 30 days. At the end of the 30 day period of systemic corticosteroid treatment, check liver function by clinical examination and by laboratory testing. For patients with unremarkable findings, taper the corticosteroid dose over the next 28 days. If liver function abnormalities persist, continue systemic corticosteroids (equivalent to oral prednisolone at 1 mg/kg/day) until findings become unremarkable, and then taper the corticosteroid dose over the next 28 days. Consult expert(s) if patients do not respond adequately to the equivalent of 1 mg/kg/day oral prednisolone. **DOSAGE FORMS AND STRENGTHS** Zolgensma™ is a suspension for intravenous infusion, supplied as single-use vials; Zolgensma™ is provided in a kit containing 2 to 9 vials, as a combination of 2 vial fill volumes (either 5.5 mL or 8.3 mL); All vials have a nominal concentration of 2.0 × 10^13 vector genomes (vg) per mL; Each vial of Zolgensma™ contains an extractable volume of not less than either 5.5 mL or 8.3 mL. **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Zolgensma™ (onasemnogene abeparvovec-xioi) Suspension, for Intravenous Infusion / Novartis Pharmaceuticals Corporation (continuation)	Gene therapy Note: Orphan drug designation	Treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene Limitation of Use: • The safety and effectiveness of repeat administration of have not been evaluated. • The use in patients with advanced SMA (e.g. complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.	05/24/2019	**WARNINGS AND PRECAUTIONS** • **Thrombocytopenia:** Monitor platelet counts before Zolgensma™ infusion, and weekly for the first month and then every other week for the second and third month until platelet counts return to baseline. • **Elevated Troponin-I:** Monitor troponin-I before Zolgensma™ infusion, and weekly for the first month and then monthly for the second and third month until troponin-I level returns to baseline. **ADVERSE REACTIONS** Most common adverse reactions: elevated aminotransferases and vomiting. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Use in premature neonates before reaching full term gestational age is not recommended because concomitant treatment with corticosteroids may adversely affect neurological development. Delay until full-term gestational age is reached.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Tibsovo™ (ivosidenib) Tablets / Agios Pharmaceuticals, Inc.	Antineoplastic agent; Isocitrate dehydrogenase-1 (IDH1) inhibitor	**Previous indication(s):** Treatment of patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) who have an IDH1 mutation **New indication:** To include adult patients with newly diagnosed AML with a susceptible IDH1 mutation as detected by an FDA-approved test who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy	05/02/2019	Tibsovo™ received initial FDA approval in July 2018 for adult patients with R/R AML and an IDH1 mutation. The approval is based on results from a clinical trial that included 28 adult patients (median age: 77 years; range: 64-87)) with newly diagnosed AML with an IDH1 mutation who were assigned to receive a 500 mg daily dose. The primary endpoint is the combined complete remission (CR) and complete remission with partial hematologic improvement (CRh) rate. CRh is defined as <5% of blasts in the bone marrow, no evidence of disease and partial recovery of peripheral blood counts (platelets >50,000/microliter and ANC >500/microliter). Result showed a CR+CRh rate of 42.9% (95% CI: 24.5, 62.8). The CR rate was 28.6% (95% CI 13.2, 48.7) and the CRh rate was 14.3% (95% CI 4.0, 32.7).
Kadcyla™ (ado-trastuzumab emtansine) Injection / Genentech, Inc.	Antineoplastic agent; HER2-targeted antibody	**Previous indication(s):** Treatment of patients with HER2-positive, late-stage (metastatic) breast cancer **New indication:** For adjuvant (after surgery) treatment of people with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant (before surgery) taxane and Herceptin™ (trastuzumab)-based treatment	05/03/2019	The approval is based on results from a study showing Kadcyla™ significantly reduced the risk of invasive breast cancer recurrence or death from any cause (invasive disease-free survival; iDFS) by 50% (HR=0.50, 95% CI 0.39-0.64, p<0.0001) compared to Herceptin™ as an adjuvant treatment in people with HER2-positive EBC who have residual invasive disease after neoadjuvant taxane and Herceptin-based treatment. At three years, 88.3% of people treated with Kadcyla™ did not have their breast cancer return compared to 77.0% treated with Herceptin™, an absolute improvement of 11.3%.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Sorilux™ (calcipotriene) Foam / Mayne Pharma US	Dermatological agent; Antipsoriatic; Vitamin D analog	**Previous indication(s):** Topical treatment of plaque psoriasis **Patient population altered:** To include adolescent patients aged 12 years and older	05/06/2019	-
Xeomin™ (incobotulinumtoxin A) Injection / Merz Pharmaceuticals	Musculoskeletal agent; Neuromuscular blocker; Botulinum toxin type A	**Previous indication(s):** Treatment of cervical dystonia, blepharospasm (previously treated with onabotulinumtoxin A), glabellar lines, upper limb spasticity, and excessive drooling **New indication:** First-line treatment of blepharospasm in adult patients	5/10/2019	The approval was based on results from a trial in a total of 61 treatment-naïve patients who had a diagnosis of blepharospasm with a baseline Jankovic Rating Scale (JRS) Severity sub-score ≥2. JRS is the most commonly used clinical scale to measure severity and frequency of blepharospasm. Patients were defined as treatment-naïve if at least 12 months had passed since their last toxin treatment. The primary efficacy endpoint was the change from baseline in JRS Severity sub-score determined at week 6 after the Xeomin™ injection. The treatment group demonstrated statistically significant improvement compared to placebo, with a difference of -1.2 (p=0.0004). The safety findings were similar to previous studies and in line with the known safety profile of Xeomin™.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Cyramza™ (ramucirumab) Injection / Eli Lilly and Company	Antineoplastic agent; Vascular endothelial growth factor receptor 2 (VEGFR2) antagonist	**Previous indication(s):** Treatment of advanced or metastatic **gastric cancer or gastro-esophageal junction adenocarcinoma** with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy; metastatic **non-small cell lung cancer** with disease progression on or after platinum-based chemotherapy; metastatic **colorectal cancer** with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine **New indication:** Treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥400 ng/mL and have been treated with sorafenib	5/10/2019	The approval was based on the results from a study of Cyramza™ compared to placebo in patients with HCC who have been treated with sorafenib and are AFP-High (AFP ≥400 ng/mL), were Cyramza™ showed a statistically significant benefit in the primary endpoint of overall survival (OS) and in the secondary endpoint of progression-free survival (PFS).
Eylea™ (aflibercept) Injection / Regeneron Pharmaceuticals, Inc.	Ophthalmologic agent; VEGF inhibitor	**Previous indication(s):** Treatment of neovascular age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema **New indication:** Treatment of diabetic retinopathy	05/13/2019	The approval was based on results from a study in patients with moderately severe to severe non-proliferative diabetic retinopathy (NPDR). The study met its one-year (52-week) primary endpoint and key secondary endpoints. On the primary endpoint at one year, 80% and 65% of patients receiving Eylea™ on an every 8- and every 16-week interval, respectively, experienced a two-step or greater improvement from baseline on the Diabetic Retinopathy Severity Scale (DRSS), compared to 15% of patients receiving sham injection ($p<0.0001$). Regarding the two key secondary endpoints, which achieved statistical significance, treatment with Eylea™ also sowed both a reduction in vision-threatening complications and in development of diabetic macular edema.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Bavencio™ (avelumab) Injection / EMD Serono, Inc.	Antineoplastic agent; Programmed death ligand-1 (PD-L1) blocking antibody	**Previous indication(s):** Treatment of metastatic Merkel cell carcinoma (MCC) and advanced or metastatic urothelial carcinoma **New indication:** In combination with axitinib (Inlyta) ™ for the first-line treatment of advanced renal cell carcinoma (RCC)	05/14/2019	This is the first FDA approval for an anti-PD-L1 therapy as part of a combination regimen for patients with advanced RCC. The approval was based on results from a study in which the combination significantly improved median progression-free survival (PFS) compared with sunitinib by more than five months (HR: 0.69; 95% CI: 0.56–0.84; 2-sided p-value=0.0002).
Venclexta™ (venetoclax) Tablets / AbbVie Inc.	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	**Previous indication(s):** Treatment of previously treated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), and newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy **New indication:** Treatment of previously untreated CLL or SLL	05/15/2019	This approval was based on results from a study that demonstrated superior progression-free survival (PFS) in patients treated with Venclexta ™plus obinutuzumab compared to patients who received chlorambucil plus obinutuzumab, a commonly used standard of care. Venclexta™ plus obinutuzumab reduced the risk of progression or death by 67% compared with chlorambucil plus obinutuzumab (HR: 0.33, 95% CI: 0.22, 0.51; p<0.0001).
Gattex™ (teduglutide) for Injection / NPS Pharmaceuticals, Inc.	Gastrointestinal agent	**Previous indication(s):** Treatment of short bowel syndrome **Patient population altered:** To include pediatric patients 1 year of age and older	05/16/2019	-

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Fragmin™ (dalteparin sodium) Injection	Anticoagulant; Low molecular weight heparin (LMWH)	**Previous indication(s):** Prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction; Prophylaxis of DVT in abdominal surgery, hip replacement surgery or medical patients with severely restricted mobility during acute illness; Extended treatment of symptomatic VTE to reduce the recurrence in adult patients with cancer **Patient population altered:** To include pediatric patients one month of age and older	05/16/2019	-
Jakafi™ (ruxolitinib) Tablets / Incyte Corporation	Antineoplastic agent; Janus kinase (JAK) inhibitor	**Previous indication(s):** Treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults; polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea **New indication:** Treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older	05/24/2019	Jakafi™ is the first and only FDA-approved treatment for this indication. This approval was based on the results from a study of Jakafi™ in combination with corticosteroids in patients with steroid-refractory grade II-IV acute GVHD. The efficacy of Jakafi™ was evaluated based upon Day 28 overall response rate (ORR). The Day 28 ORR in 49 patients refractory to steroids alone was 57%, with a complete response (CR) rate of 31%.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Vraylar™ (cariprazine) Capsules / Allergan plc	Central nervous system agent; Antipsychotic; Dopamine D3/D2 receptor partial agonist	**Previous indication(s):** Treatment of schizophrenia, and manic or mixed episodes associated with bipolar I disorder **New indication:** Treatment of depressive episodes associated with bipolar I disorder	05/24/2019	This approval was based on results from three studies in which cariprazine demonstrated greater improvement than placebo for the change from baseline to week six on the Montgomery Asberg Depression Rating scale (MADRS) total score.
Revlimid™ (lenalidomide) Capsules / Celgene Corporation	Immunological agent; Immune modulator	**Previous indication(s):** Treatment of multiple myeloma (MM), in combination with dexamethasone; MM, following autologous hematopoietic stem cell transplantation; Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities; Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies **New indication:** In combination with rituximab for the treatment of previously treated follicular lymphoma (FL) or marginal zone lymphoma (MZL)	05/28/2019	This is the first FDA-approved combination treatment regimen for patients with these indolent forms of non-Hodgkin's lymphoma (NHL) that does not include chemotherapy. This approval was based on the results from a study that demonstrated a statistically significant improvement in the primary endpoint of progression-free survival (PFS). The median PFS was 39.4 months for patients treated with this combination versus 14.1 months for patients treated with rituximab-placebo (HR: 0.46; 95% CI, 0.34-0.62; p<0.0001).

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Qternmet XR™ (dapagliflozin, metformin hydrochloride and saxagliptin) Extended-Release Tablets, for oral use / AstraZeneca	Sodium-glucose cotransporter 2 (SGLT2) inhibitor, biguanide and dipeptidyl peptidase-4 (DPP-4) inhibitor combination	As an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus	05/02/2019	Limitations of use: • Qternmet XR™ is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. • Qternmet XR™ initiation is intended only for patients currently taking metformin.
Ruzurgi™ (amifampridine) Tablets, for oral use / Jacobus Pharmaceutical Company Inc.	Potassium channel blocker Note: Orphan drug designation	Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age	05/06/2019	This is the first FDA-approval of a treatment specifically for pediatric patients with LEMS. Amifampridine was also recently FDA-approved under the brand name Firdapse™. However, Firdapse™ is only indicated for use in adult patients with LEMS.
Nayzilam™ (midazolam) Nasal Spray / UCB, Inc.	Benzodiazepine Note: Schedule IV controlled substance	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (e.g. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older	05/17/2019	This is the first FDA-approved nasal option for treating seizure clusters. Midazolam was already available in the market as an injection and oral syrup. However, these formulation have different indications. • Injectable midazolam is indicated for preoperative sedation/anxiolysis/amnesia; induction of general anesthesia; ptocedural sedation; and sedation of mechanically ventilated patients. • Oral midazolam is indicated for pediatric patients for perioperative sedation/anxiolysis/amnesia; and for pediatric patient for procedural sedation.

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Sapropterin Dihydrochloride Tablets 100 mg / Par Pharmaceutical, Inc.	Endocrine and metabolic agent; Metabolic modifier	05/10/2019	Generic for: Kuvan
Micafungin Sodium Injection 50 mg (base)/vial and 100 mg (base)/vial / Fresenius Kabi USA, LLC	Antifungal	05/17/2019	Generic for: Mycamine
Sildenafil Citrate for Oral Suspension 10mg (base)/mL / Novitium Pharma LLC	Cardiovascular agent; Antihypertensive agent	05/31/2019	Generic for: Revatio for Oral Suspension

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

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Bempedoic acid / Esperion Therapeutics, Inc.	05/05/2019	Treatment for: Hypercholesterolemia	Bempedoic acid is a first-in-class, ATP Citrate Lyase (ACL) inhibitor in development for the treatment of patients with elevated low-density lipoprotein cholesterol (LDL-C). Esperion announced FDA acceptance of the NDA for bempedoic acid.	High
Talicia (amoxicillin, omeprazole and rifabutin) Capsules / RedHill Biopharma Ltd.	05/07/2019	Treatment for: Helicobacter pylori Infection	Talicia is a fixed-dose oral combination of rifabutin and amoxicillin (both antibiotics), and omeprazole (a proton pump inhibitor (PPI)), in development for the treatment of Helicobacter pylori infection. RedHill Biopharma submitted an NDA for Talicia.	Moderate
Twirla (ethinyl estradiol and levonorgestrel) Transdermal System / Agile Therapeutics, Inc.	05/17/2019	Treatment for: Contraception	Twirla is an investigational low-dose combined hormonal contraceptive patch in development as a form of birth control. Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. Agile Therapeutics resubmitted their NDA for Twirla.	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)