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PharmNOTES

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

Date: 9/6/2019

urac ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2019

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NEWS……

- No new drug safety communication published during October 2019.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Aklief™ (trifarotene) Cream, for topical use / Galderma Laboratories, L.P.	Dermatological agent; Anti-acne; Topical retinoid	Topical treatment of acne vulgaris in patients 9 years of age and older	10/04/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is to apply a thin layer of cream to the affected areas of the face and/or trunk once a day, in the evening, on clean and dry skin. Contact with the eyes, lips, paranasal creases, and mucous membranes must be avoided. **DOSAGE FORMS AND STRENGTHS** Cream: 0.005% trifarotene. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Skin irritation:** Erythema, scaling, dryness, and stinging / burning may be experienced with use. A moisturizer should be used from initiation, and, if appropriate, reduce the frequency of application, suspend or discontinue use. • **Ultraviolet light and environmental exposure:** Exposure to sunlight and sunlamps should be minimized. Sunscreen and protective clothing should be used over treated areas when exposure cannot be avoided. **ADVERSE REACTIONS** Most common adverse reactions: application site irritation, application site pruritus, and sunburn. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy has not been established in pediatrics under the age of 9 years. • **Geriatric use:** Clinical trials did not include any subjects aged 65 years and over to determine whether they respond differently than younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Beovu™ (brolucizumab-dbll) Injection, for intravitreal use / Novartis Pharmaceuticals Corporation	Ophthalmologic agent; Vascular endothelial growth factor (VEGF) inhibitor	Treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD)	10/07/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 6 mg monthly (approximately every 25-31 days) for the first three doses, followed by one dose of 6 mg every 8-12 weeks. **DOSAGE FORMS AND STRENGTHS** Injection: 6 mg/0.05 mL solution for intravitreal injection in a single-dose vial. **CONTRAINDICATIONS** • Ocular or periocular infections. • Active intraocular inflammation. • Hypersensitivity. **WARNINGS AND PRECAUTIONS** • Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay. • Increases in intraocular pressure have been seen within 30 minutes of an intravitreal injection. • There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. **ADVERSE REACTIONS** Most common adverse reactions: vision blurred, cataract, conjunctival hemorrhage, eye pain, and vitreous floaters.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Beovu™ (brolucizumab-dbll) Injection, for intravitreal use / Novartis Pharmaceuticals Corporation (continuation)	Ophthalmologic agent; Vascular endothelial growth factor (VEGF) inhibitor	Treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD)	10/07/2019	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on its mechanism of action, treatment with Beovu™ may pose a risk to human embryo-fetal development. Beovu™ should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. • **Females of reproductive potential:** Highly effective contraception should be used during treatment and for at least one month after the last dose when stopping treatment. • **Pediatric use:** Safety and efficacy in pediatric patients has not been established. • **Geriatric use:** No significant differences in efficacy or safety were seen with increasing age in studies. No dosage regimen adjustment is required in patients 65 years and above.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Scenesse™ (afamelanotide) Implant, for subcutaneous use / Clinuvel Pharmaceuticals Ltd.	Dermatological agent; Melanocortin 1 receptor (MC1-R) agonist Notes: • Orphan drug dessignation • The manufacturer plans to distribute the drug directly to hospitals	To increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP)	10/08/2019	**DOSAGE AND ADMINISTRATION** A single implant, containing 16 mg of afamelanotide, is inserted by a healthcare professional* subcutaneously every 2 months, using an SFM Implantation Cannula or other implantation devices that have been determined by the manufacturer to be suitable. *Healthcare professional must completed training prior to administration. **DOSAGE FORMS AND STRENGTHS** Implant: 16 mg of afamelanotide **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Skin monitoring:** May induce darkening of pre-existing nevi and ephelides. Regular full body skin examination twice yearly is recommended to monitor all skin abnormalities. **ADVERSE REACTIONS** Most common adverse reactions: implant site reaction, nausea, oropharyngeal pain, cough, fatigue, dizziness, skin hyperpigmentation, somnolence, melanocytic nevus, respiratory tract infection, non-acute porphyria, and skin irritation. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in pediatric patients has not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Reyvow™ (lasmiditan) Tablets, for oral use / Eli Lilly and Company	Central nervous system agent; Antimigraine; Serotonin (5-HT) 1F receptor agonist Note: Pending controlled substance scheduling	Acute treatment of migraine with or without aura in adults Limitations of use: • Not indicated for the preventive treatment of migraine • A second dose has not been shown to be effective for the same migraine attack • Safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established	10/11/2019	**DOSAGE AND ADMINISTRATION** The recommended dose is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in 24 hours, and should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery. May be taken with or without food. **DOSAGE FORMS AND STRENGTHS** Tablets: 50 mg, 100 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Driving impairment:** Patients must be advised not to drive or operate machinery until at least 8 hours after taking each dose. Patients who cannot follow this advice should not take Reyvow™. Patients may not be able to assess their own driving competence and the degree of impairment caused by Reyvow™. • **Central nervous system (CNS) depression:** Reyvow™ may cause CNS depression and should be used with caution if used in combination with alcohol or other CNS depressants. • **Serotonin syndrome:** Reactions consistent with serotonin syndrome were reported. Discontinue if symptoms of serotonin syndrome occur. • **Medication overuse headache:** Detoxification may be necessary.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Reyvow™ (lasmiditan) Tablets, for oral use / Eli Lilly and Company (continuation)	Central nervous system agent; Antimigraine; Serotonin (5-HT) 1F receptor agonist Note: Pending controlled substance scheduling	Acute treatment of migraine with or without aura in adults Limitations of use: • Not indicated for the preventive treatment of migraine • A second dose has not been shown to be effective for the same migraine attack • Safety of treating an average of more than 4 migraine attacks in a 30-day period has not been established	10/11/2019	**ADVERSE REACTIONS** Most common adverse reactions: dizziness, fatigue, paresthesia, and sedation. **DRUG INTERACTIONS** • **Heart rate lowering drugs:** Reyvow™ may further lower heart rate when administered with heart rate lowering drugs. • **P-gp and Breast Cancer Resistant Protein (BCRP) substrates:** Avoid concomitant use. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Pediatric use:** Safety and efficacy in pediatric patients has not been established. • **Geriatric use:** Dizziness and a larger increase in systolic blood pressure occurred more frequently in patients who were at least 65 years of age compared to patients who were less than 65 years of age. Clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether there is a difference in efficacy in these patients compared to younger subjects. However, in clinical pharmacology studies, no clinically relevant effect on exposure was observed in elderly subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. • **Hepatic impairment:** Reyvow™ has not been studied in patients with severe hepatic impairment and its use in these patients is not recommended.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trikafta™ (elexacaftor, tezacaftor, and ivacaftor fixed dose combination and ivacaftor) Tablets / Vertex Pharmaceuticals Incorporated	Respiratory agent	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene; If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation	10/21/2019	**DOSAGE AND ADMINISTRATION** The recommended dose in adults and pediatric patients aged 12 years and older is as follows: • Morning dose: Two elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg tablets. • Evening dose: One ivacaftor 150 mg tablet Morning and evening dose should be taken approximately 12 hours apart with fat-containing food. Trikafta™ should not be used in patients with severe hepatic impairment and use not recommended in patients with moderate hepatic impairment unless the benefit exceeds the risk. Additionally, the dose must be reduced if used in patients with moderate hepatic impairment. The dose must also be reduced when co-administered with drugs that are moderate or strong CYP3A inhibitors. **DOSAGE FORMS AND STRENGTHS** Tablets: • Fixed dose combination containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg. • Co-packaged with: ivacaftor 150 mg. **CONTRAINDICATIONS** None.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trikafta™ (elexacaftor, tezacaftor, and ivacaftor fixed dose combination and ivacaftor) Tablets / Vertex Pharmaceuticals Incorporated (continuation)	Respiratory agent	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene; If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation	10/21/2019	**WARNINGS AND PRECAUTIONS** • **Elevated liver function tests (ALT, AST or bilirubin):** Liver function tests should be assessed prior to initiating treatment, every 3 months during the first year of treatment, and annually thereafter. In patients with a history of hepatobiliary disease or liver function test elevations, more frequent monitoring should be considered. Dosing should be interrupted in patients with ALT or AST >5 x upper limit of normal (ULN) or ALT or AST >3 x ULN with bilirubin >2 x ULN. Following resolution of transaminase elevations, consider the benefits and risks of resuming treatment. • **Cataracts:** Non-congenital lens opacities or cataracts have been reported in pediatric patients treated with ivacaftor-containing regimens. Baseline and follow-up examinations are recommended in pediatric patients initiating Trikafta™ treatment. **ADVERSE REACTIONS** Most common adverse reactions: headache, upper respiratory tract infection, abdominal pain, diarrhea, rash, alanine aminotransferase increased, nasal congestion, blood creatinine phosphokinase increased, aspartate aminotransferase increased, rhinorrhea, rhinitis, influenza, sinusitis and blood bilirubin increased. **DRUG INTERACTIONS** • **Strong CYP3A inducers:** Concomitant use with strong CYP3A inducers significantly decrease ivacaftor exposure and are expected to decrease elexacaftor and tezacaftor exposure, which may reduce Trikafta™ efficacy. Therefore, co-administration should be avoided.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trikafta™ (elexacaftor, tezacaftor, and ivacaftor fixed dose combination and ivacaftor) Tablets / Vertex Pharmaceuticals Incorporated (continuation)	Respiratory agent	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene; If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation	10/21/2019	**DRUG INTERACTIONS** (continuation) • **Strong or moderate CYP3A inhibitors:** Co-administration with strong or moderate CYP3A inhibitors, increase exposure of elexacaftor, tezacaftor, and/or ivacaftor. The dosage of Trikafta™ should be reduced when co-administered with strong or moderate CYP3A inhibitors. In addition, food or drink containing grapefruit should be avoided during treatment because it may increase exposure to Trikafta™. • **Other drugs:** Trikafta™ may also have effects on other drugs. Refer to full prescribing information for additional details regarding potential drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pediatric use:** Safety and efficacy in pediatrics younger than 12 years of age has not been established. • **Geriatric use:** Clinical studies did not include any patients aged 65 years and older. • **Renal impairment:** No dosage adjustment is recommended in patients with mild or moderate renal impairment. Trikafta™ has not been studied in patients with severe renal impairment or end-stage renal disease. Use with caution in these patients. • **Hepatic impairment:** No dose modification is recommended for patients with mild hepatic impairment. Use of Trikafta™ is not recommended in patients with moderate hepatic impairment unless the benefit exceeds the risk, in which case Trikafta™ should be used with caution and at a reduced dose. Patients with severe hepatic impairment should not be treated with Trikafta™. Liver function tests should be closely monitored.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Trikafta™ (elexacaftor, tezacaftor, and ivacaftor fixed dose combination and ivacaftor) Tablets / Vertex Pharmaceuticals Incorporated (continuation)	Respiratory agent	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene; If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation	10/21/2019	**USE IN SPECIFIC POPULATIONS** (continuation) • **Patients with severe lung dysfunction:** One clinical study included a total of 18 patients receiving Trikafta™ with percent predicted FEV1 <40 at baseline. The safety and efficacy in this subgroup were comparable to those observed in the overall population.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vumerity™ (diroximel fumarate) Delayed-Release Capsules, for oral use / Biogen	Multiple sclerosis agent	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	10/29/2019	**DOSAGE AND ADMINISTRATION** The recommended starting dose is 231 mg twice a day, orally, for 7 days. The maintenance dose after 7 days is 462 mg (administered as two 231 mg capsules) twice a day, orally. Blood tests are required prior to initiation. **DOSAGE FORMS AND STRENGTHS** Delayed-release capsules: 231 mg. **CONTRAINDICATIONS** • Known hypersensitivity to diroximel fumarate, dimethyl fumarate, or to any of the excipients of Vumerity™. • Co-administration with dimethyl fumarate. **WARNINGS AND PRECAUTIONS** • **Anaphylaxis and angioedema:** Discontinue and do not restart if these occur. • **Progressive Multifocal Leukoencephalopathy (PML):** Withhold Vumerity™ at the first sign or symptom suggestive of PML. • **Lymphopenia:** Obtain a CBC including lymphocyte count before initiating, after 6 months, and every 6 to 12 months thereafter. Consider interruption if lymphocyte counts <0.5 × 109/L persist for more than 6 months. • **Liver injury:** Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating and during treatment, as clinically indicated. Discontinue if clinically significant liver injury induced by Vumerity™ is suspected.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vumerity™ (diroximel fumarate) Delayed-Release Capsules, for oral use / Biogen (continuation)	Multiple sclerosis agent	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	10/29/2019	**ADVERSE REACTIONS** Most common adverse reactions: flushing, abdominal pain, diarrhea, and nausea. **DRUG INTERACTIONS** • **Dimethyl fumarate:** Vumerity™ is contraindicated in patients currently taking dimethyl fumarate, which is also metabolized to monomethyl fumarate. Vumerity™ may be initiated the day following discontinuation of dimethyl fumarate. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** May cause fetal harm. • **Pediatric use:** Safety and efficacy in pediatric patients has not been established. • **Geriatric use:** Clinical studies did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. • **Renal impairment:** Vumerity™ is not recommended in patients with moderate or severe renal impairment.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Entresto™ (sacubitril and valsartan) Tablets / Novartis Pharmaceuticals Corporation	Cardiovascular agent; Neprilysin inhibitor and angiotensin II receptor blocker	**Previous indication(s):** To reduce the risk of cardiovascular death or heart failure (HF) hospitalization in adult patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction **Patient Population Altered:** Treatment of symptomatic HF with systemic left ventricular systolic dysfunction in pediatric patients aged 1 year and older	10/01/2019	-
Descovy™ (emtricitabine and tenofovir alafenamide) Tablets / Gilead Sciences, Inc.	Antiretroviral; Nucleoside analog HIV-1 reverse transcriptase inhibitor (NRTI) and nucleotide reverse transcriptase inhibitor (NtRTI) fixed-dose combination	**Previous indication(s):** Treatment of HIV-1 infection **New indication:** For pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection	10/03/2019	This approval was based on data from the DISCOVER trial, which evaluated the safety and efficacy of Descovy™ for PrEP compared with that of Truvada™ (emtricitabine 200mg and tenofovir disoproxil fumarate 300mg) for PrEP in reducing the risk of acquiring HIV-1 infection. The primary efficacy endpoint was the incidence of documented HIV infection per 100 person-years after all participants had follow-up of at least 48 weeks and at least half had 96 weeks of follow-up. Results demonstrated that Descovy™ is non-inferior to Truvada™ in study participants who were at risk of HIV acquisition.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Xarelto™ (rivaroxaban) Tablets / Janssen Pharmaceuticals, Inc.	Anticoagulant; Factor Xa inhibitor	**Previous indication(s):** To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation; Treatment of deep vein thrombosis (DVT); Treatment of pulmonary embolism (PE); To reduce the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; Prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; In combination with aspirin, to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD) **New indication:** Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding	10/11/2019	With the approval of this new indication, Xarelto™ can be initiated for these patients during hospitalization and continued after discharge for a total recommended duration of 31 to 39 days.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Xofluza™ (baloxavir marboxil) Tablets / Genentech, Inc.	Anti-infective agent; Antiviral; Polymerase acidic (PA) endonuclease inhibitor	**Previous indication(s):** Treatment of influenza (the flu) in people 12 years of age and older who have had flu symptoms for no more than 48 hours and who are otherwise healthy, or at high risk of developing flu-related complications **Patient population altered:** To include who are at high risk of developing flu-related complications	10/16/2019	-
Nplate™ (romiplostim) / Amgen Inc.	Hematopoietic agent; Thrombopoietin receptor agonist	**Previous indication(s):** Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) **New indication:** To treat newly diagnosed and persistent adult ITP patients who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy	10/17/2019	This approval was based on an open-label, single-arm Phase 2 trial of adults with ITP diagnosed ≤6 months prior who had an insufficient response to first-line treatment. On the primary endpoint, the median number of months with platelet response (≥ 50 x 109/L) was 11 months during the 12-month treatment period (95% CI: 10, 11), with a median time to first platelet response of 2.1 weeks (95% CI: 1.1, 3.0). Additionally, 93% of patients achieved one or more platelet responses during the 12-month treatment period.
Farxiga™ (dapagliflozin) Tablets / AstraZeneca	Antidiabetic; Sodium-glucose cotransporter-2 inhibitor	**Previous indication(s):** Treatment of adults with type 2 diabetes mellitus (T2D) **New indication:** To reduce the risk of hospitalization for heart failure (hHF) in adults with T2D and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors	10/18/2019	This approval was based on results from the DECLARE-TIMI 58 CV outcomes trial, which showed that dapagliflozin can reduce the risk of HF in patients living with T2D with multiple CV risk factors or established CVD.

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; Prophylaxis of headaches in patients with chronic migraine; Treatment of upper and lower limb spasticity; Treatment of cervical; Treatment of severe axillary hyperhidrosis; Treatment of blepharospasm associated with; Treatment of strabismus **Patient population altered:** Treatment of pediatric patients (2 to 17 years of age) with lower limb spasticity, excluding spasticity caused by cerebral palsy (CP)	10/18/2019	-
Stelara™ (ustekinumab) Injection / Janssen Biotech, Inc.	Immunological agent; Interleukin-12 and -23 antagonist	**Previous indication(s):** Treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD) **New indication:** Treatment of moderately to severely active ulcerative colitis (UC)	10/18/2019	This approval was based on the Phase 3 UNIFI trial which achieved its primary endpoint of clinical remission. Results demonstrated that treatment with Stelara™ both induced and maintained clinical remission in a significantly greater proportion of adult patients with moderately to severely active UC compared to placebo.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Zejula™ (niraparib) Capsules / Tesaro Inc.	Antineoplastic agent; Poly ADP-ribose polymerase (PARP) inhibitor	**Previous indication(s):** Treatment of ovarian, fallopian tube, or primary peritoneal cancer **New indication:** Treatment of advanced ovarian, fallopian tube, or primary peritoneal cancer patients, who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status	10/23/2019	This approval was based on the QUADRA study, a Phase 2, multi-center, open label, single arm clinical study in women who received three or more treatments for advanced ovarian cancer. Results showed an objective response rate (ORR) of 24% (95% CI: 16–34). The median duration of response was 8.3 months.
Baxdela™ (delafloxacin) Tablets and Injection / Melinta Therapeutics	Anti-infective agent; Antibacterial; Fluoroquinolone	**Previous indication(s):** Treatment of acute bacterial skin and skin structure infections **New indication:** Treatment of community-acquired bacterial pneumonia caused by designated susceptible bacteria	10/24/2019	This approval was based on results from a Phase III, randomized, double-blind, study that compared the efficacy and safety of Baxdela™ to moxifloxacin. Results demonstrated that Baxdela™ met all key primary and secondary endpoints in the trial. In the intent-to-treat population (ITT), IV-to-oral Baxdela™ met the primary endpoint of statistical non-inferiority for the Early Clinical Response (ECR) at 96 hours after initiation of therapy. Baxdela™ also met the secondary endpoint of statistical non-inferiority compared to moxifloxacin based on the investigator's assessment of Success at the Test of Cure visit (5-10 days after last dose) in the ITT population.

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Fasenra™ (benralizumab) Injection / AstraZeneca	Antiasthma; Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody	Treatment of patients with severe eosinophilic asthma	10/03/2019	The FDA has approved the self-administration of Fasenra™ in a pre-filled, single-use auto-injector (the Fasenra Pen™). Before this approval, Fasenra™ was available in a prefilled syringe to be administered by a healthcare provider.
Hemady™ (dexamethasone) Tablets / Dexcel Pharma	Corticosteroid	In combination with other antimyeloma products for the treatment of adults with multiple myeloma	10/03/2019	Hemady™ is a new formulation of dexamethasone. Before this approval, dexamethasone was already available in the market in a variety of different formulations with different routes of administration (oral, injection, topical, and ophthalmic). In addition, it is generically available as an oral tablet, solution, and elixir.
Bonsity™ (teriparatide) Injection / Pfenex Inc.	Endocrine and metabolic agent; Parathyroid hormone analog	• Treatment of postmenopausal women with osteoporosis at high risk for fracture • Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture • Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture	10/04/2019	Bonsity™ is a new formulation of teriparatine. Before the approval of this new formulation, teriparatide was available under the brand name Forteo™, also as an injectable product for subcutaneous use. Of important note, Pfenex is waiting on FDA review to designate Bonsity™ as therapeutically equivalent (“A” rated) to Forteo™, which would permit its automatic substitution for Forteo™.

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Quzyttir™ (cetirizine hydrochloride injection) / TerSera Therapeutics LLC	Histamine-1 (H1) receptor antagonist	Treatment of acute urticaria in adults and children 6 months of age and older	10/04/2019	Quzyttir™ is a new dosage form of cetirizine. Specifically, it comes to be the first FDA-approved intravenous formulation of cetirizine. Before the approval of this new dosage form, cetirizine was already available in the market in various oral formulations, both generically requiring prescription and over-the-counter (OTC).
Pemfexy™ (pemetrexed) Injection / Eagle Pharms	Antineoplastic agent	Treatment of locally advanced or metastatic non-squamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic non-squamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic non-squamous non-small cell lung cancer after prior chemotherapy as a single agent; and malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin	10/09/2019	Pemfexy™ is a new formulation of pemetrexed injection that is ready-to-dilute. Pemetrexed is currently available in the market under the brand name Amlita™ as a lyophilized powder that must be reconstituted and then further dilution is required. Of note, Pemfexy™ has received tentative approval by the FDA.

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

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Secuado™ (asenapine) Transdermal System / Noven Pharmaceuticals, Inc.	Central nervous system agent; Atypical antipsychotic	Treatment of adults with schizophrenia	10/11/2019	Secuado™ is a new dosage form of asenapine that comes to be the first transdermal patch formulation for the treatment of adults with schizophrenia. Before the approval of this new dosage form, asenapine was already available in the market as a sublingual tablet under the brand name Saphris™, which is FDA-approved for the treatment of schizophrenia and bipolar I disorder.
Amzeeq™ (minocycline) Topical Foam / Foamix Pharmaceuticals	Anti-infective agent; Antibiotic; Tetracycline	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older	10/18/2019	Amzeeq™ is a new formulation of minocycline that comes to be the first topical minocycline.
Biorphen™ (phenylephrine hydrochloride) Injection / Eton Pharmaceuticals, Inc.	Alpha-1 adrenergic receptor agonist	Treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia	10/21/2019	Biorphen™ comes to be first ready-to-use formulation of phenylephrine. Before this approval, phenylephrine injection was only available as a highly concentrated formulation that required hospitals to manually dilute the concentrate prior to administration, or purchase ready-to-use formulations from compounding pharmacies.

New First Time Generic Drug Approval

- No first generics approved during October 2019.

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Triheptanoin / Ultragenyx Pharmaceutical Inc.	10/14/2019	Treatment for: Long-Chain Fatty Acid Oxidation Disorders	Triheptanoin is a synthetic triglyceride compound in development for the treatment of long-chain fatty acid oxidation disorders. The FDA has accepted the NDA for triheptanoin.	High High
FMX103 (minocycline) Topical Foam / Foamix Pharmaceuticals Ltd.	10/17/2019	Treatment for: Papulopustular Rosacea	FMX103 is a topical minocycline foam formulation in development for the treatment of moderate-to-severe papulopustular rosacea. The FDA has accepted the NDA for FMX103.	Moderate
HTX-011 (bupivacaine and meloxicam) / Heron Therapeutics, Inc.	10/01/2019; 10/28/2019	Treatment for: Postoperative Pain	HTX-011 is an investigational fixed-dose combination of a local anesthetic and a non-steroidal anti-inflammatory drug in development for the management of post-operative pain. Heron Therapeutic resubmitted the NDA for HTX-011 and the FDA has accepted the NDA resubmission.	Moderate
Satralizumab / Genentech	10/29/2019	Treatment for: Neuromyelitis Optica Spectrum Disorder	Satralizumab is an investigational humanized anti-interleukin-6 receptor (IL-6R) monoclonal antibody in development for the treatment of neuromyelitis optica spectrum disorder. The FDA has accepted the BLA for satralizumab.	High

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

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- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)