

March 2, 2020

COM-2020-011

Dear provider of pharmaceutical services,

Attached you will find an update of new indications and first-time generics approved by the U.S. Food and Drugs Administration (FDA) from October 2019 to December 2019.

For more details regarding FDA approvals, you can visit the FDA website (www.fda.gov) and other trustworthy sources of drugs information. If you will like to, you can also subscribe to “FDA email updates”, at <https://updates.fda.gov/SubscriptionManagement>, to receive important FDA news and information as they become available.

On PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 137.

Regards,

Clinical Department

**NEW FDA-APPROVED INDICATIONS
(October 2019 – December 2019)**

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
October 2019	Entresto™ (sacubitril and valsartan)	Cardiovascular agent; Neprilysin inhibitor and angiotensin II receptor blocker	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
	Descovy™ (emtricitabine and tenofovir alafenamide)	Antiretroviral; Nucleoside analog HIV-1 reverse transcriptase inhibitor (NRTI) and nucleotide reverse transcriptase inhibitor (NtRTI) fixed-dose combination	Treatment of HIV-1 infection	For pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection
	Xarelto™ (rivaroxaban)	Anticoagulant; Factor Xa inhibitor	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)	Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
	Xofluza™ (baloxavir marboxil)	Anti-infective agent; Antiviral; Polymerase acidic (PA) endonuclease inhibitor	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
	Nplate™ (romiplostim)	Hematopoietic agent; Thrombopoietin receptor agonist	Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP)	To treat newly diagnosed and persistent adult ITP patients who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy

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October 2019	Farxiga™ (dapagliflozin)	Antidiabetic; Sodium-glucose cotransporter-2 inhibitor	Treatment of adults with type 2 diabetes mellitus (T2D)	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
	Botox™ (onabotulinumtoxinA) Injection / Allergan plc	Acetylcholine release inhibitor and a neuromuscular blocking agent	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)
	Stelara™ (ustekinumab)	Immunological agent; Interleukin-12 and -23 antagonist	Treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD)	Treatment of moderately to severely active ulcerative colitis (UC)
	Zejula™ (niraparib)	Antineoplastic agent; Poly ADP-ribose polymerase (PARP) inhibitor	Treatment of ovarian, fallopian tube, or primary peritoneal cancer	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
	Baxdela™ (delafloxacin)	Anti-infective agent; Antibacterial; Fluoroquinolone	Treatment of acute bacterial skin and skin structure infections	Treatment of community-acquired bacterial pneumonia caused by designated susceptible bacteria
November 2019	Calquence™ (acalabrutinib)	Antineoplastic agent	Treatment of mantle cell lymphoma (MCL)	Treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
	Tecentriq™ (atezolizumab)	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), and small cell lung cancer (SCLC)	In combination with chemotherapy (Abraxane™ [paclitaxel protein-bound; nab-paclitaxel] and carboplatin) for the initial (first-line) treatment of

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
December 2019				adults with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations
	Xeljanz XR™ (tofacitinib)	Janus kinase (JAK) inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis, and active psoriatic arthritis	Treatment of adult patients with moderately to severely active ulcerative colitis (UC), after an inadequate response or intolerance to TNF blockers
December 2019	Vascepa™ (icosapent ethyl)	Anti-hyperlipidemic and Cardiovascular agent	As an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia	As an adjunct to statin therapy to reduce the risk of cardiovascular events
	Xtandi™ (enzalutamide)	Antineoplastic agent; Androgen receptor inhibitor	Treatment of castration-resistant prostate cancer (CRPC)	Treatment of metastatic castration-sensitive prostate cancer
	Fiasp™ (insulin aspart)	Antidiabetic; Rapid-acting human insulin analog	To improve glycemic control in patients with diabetes mellitus	Patient population altered: To include children with diabetes.
	Lynparza™ (olaparib)	Antineoplastic agent; Poly ADP ribose polymerase (PARP) inhibitor	Treatment of ovarian cancer, and breast cancer	Treatment of pancreatic cancer

References:

- US Food and Drug Administration (FDA). Available at: www.fda.gov
- New Indications & Dosage Forms for Existing Drugs. Drugs.com. Available at: <https://www.drugs.com/new-indications.html>

**FDA-APPROVED GENERICS
(October 2019 – December 2019)**

	Drug name	Therapeutic class	Generic for:
October 2019	No first generics approved during October 2019.		
November 2019	No first generics approved during November 2019.		
December 2019	Sucralfate Oral Suspension 1gm/10mL	Antiulcer	Carafate Oral Suspension
	Fingolimod Hydrochloride Capsules 0.5mg (base)	Multiple sclerosis agent; Sphingosine 1-Phosphate Receptor Modulator	Gilenya
	Everolimus Tablets 2.5 mg, 5 mg, 7.5 mg, and 10 mg	Antineoplastic agent	Afinitor
	Sodium Tetradecyl Sulfate Injection 60 mg/2mL	Cardiovascular agent	Sotradecol
	Etonogestrel and Ethinyl Estradiol Vaginal Ring (EluRyng) 0.120 mg/0.015 mg per day	Contraceptive	NuvaRing
	Alvimopan Capsules 12 mg	Gastrointestinal Agent; Opioid Antagonist	Entereg
	Diazoxide Oral Suspension 50 mg/mL	Cardiovascular agent; Endocrine and metabolic agent	Proglycem Oral Suspension
	Apixaban Tablets 2.5 mg and 5 mg	Anticoagulant	Eliquis
	Ziprasidone Mesylate Injection 20 mg (base) /mL	Antipsychotic	Geodon Injection
	Mirabegron Extended Release Tablets 25 mg	Genitourinary agent	Myrbetriq

References:

- US Food and Drug Administration (FDA). Available at: www.fda.gov
- Latest Generic Drug Approvals. Drugs.com. Available at: <https://www.drugs.com/generic-approvals.html>