January 17, 2019

COM-2019-004

Dear provider of pharmaceutical services,

Attached you will find an update of new indications and first-time generics approved by the FDA from October 2018 to December 2018.

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://www.fda.gov/aboutfda/contactfda/ucm2005606.htm, 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 138.

Regards,

Pharmacy Department

IMPORTANT: This update is a summary of new indications and generics approvals and it is not intended to substitute the revision of literature to learn details about these approvals.

6 Street 1, Suite 101, Guaynabo, PR 00968-1770 Tel. 787.522.5252 | Fax 1.866.912.2830 www.pharmpix.com

NEW FDA-APPROVED INDICATIONS
(October 2018 – December 2018)

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
October 2018	**Hemlibra™ (emicizumab-kxwh) Injection**	Antihemophilic Agent; Monoclonal antibody	To prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	To prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors
	Gardasil 9 (human papillomavirus 9-valent vaccine, recombinant) Injection	Immunological Agent; Vaccine	For the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58	Patient population altered: To include individuals 27 through 45 years old
	Xarelto™ (rivaroxaban) Tablets	Anticoagulant; Factor Xa Inhibitor	To reduce the risk of stroke and systemic embolism in patients with non-valvular Afib; Treatment of DVT; Treatment of PE; To reduce in 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 (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD)
	Dupixent™ (dupilumab) Injection	Interleukin-4 receptor alpha antagonist	Treatment of adult patients with inadequately controlled moderate-to-severe atopic dermatitis	As an add-on maintenance treatment in patients aged 12 years and older with moderate-to-severe asthma
	Invokana™ (canagliflozin) Tablets	Sodium glucose co-transporter 2 (SGLT2) inhibitor	Treatment of type 2 diabetes (T2D)	To reduce the risk of cardiovascular events (including heart attack, stroke or death) in adults with T2D and established cardiovascular disease
	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma	In combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC)
November 2018	**Keytruda™ (pembrolizumab) for Injection**	Antineoplastic agent; PD-1 (programmed	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell	Treatment of patients with hepatocellular carcinoma (HCC) who have been

6 Street 1, Suite 101, Guaynabo, PR 00968-177(Tel. 787.522.5252 | Fax 1.866.912.2830 www.pharmpix.com

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
		death receptor-1)-blocking antibody	carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma	previously treated with sorafenib
	Adcetris™ (brentuximab vedotin) Injection	Antineoplastic agent; CD30-directed antibody-drug conjugate (ADC)	Treatment of Hodgkin lymphoma, anaplastic large cell lymphoma, and CD30-expressing mycosis fungoides	In combination with CHP chemotherapy (cyclophosphamide, doxorubicin, prednisone), for adults with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified
	Venclexta™ (venetoclax) Tablets	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	Treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with or without 17p deletion who have received at least 1 prior treatment	In combination with azacitidine or decitabine, or low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in patients who are age 75 years or older, or for those ineligibles for intensive induction chemotherapy due to coexisting medical conditions
December 2018	**Tecentriq™ (atezolizumab) Injection**	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of urothelial carcinoma and metastatic non-small cell lung cancer (with disease progression during or following platinum-containing chemotherapy, and have progressed on an appropriate FDA-approved targeted therapy if their tumor has EGFR or ALK gene abnormalities)	For the first-line treatment of people with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations
	Nplate™ (romiplostim)	Blood modifier agent; Thrombopoietin receptor agonist	Treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP)	Patient population altered: For the treatment of pediatric patients one year of age and older with ITP for at least six months who have had an insufficient response to

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
				corticosteroids, immunoglobulins or splenectomy
	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, NSCLC, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and hepatocellular carcinoma	Treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC)
	Lynparza™ (olaparib) Tablets	Antineoplastic agent; poly ADP ribose polymerase (PARP) inhibitor	Treatment of advanced ovarian cancer; for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer; and for the treatment of germline BRCA-mutated metastatic breast cancer	Maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy
	Envarsus XR™ (tacrolimus) Extended-Release Tablets	Immuno-suppressant	Prophylaxis of organ rejection in kidney transplant patients	To prevent organ rejection in de novo kidney transplant patients in combination with other immunosuppressants
	Ravicti™ (glycerol phenylbutyrate) Oral Liquid	Endocrine-Metabolic agent; Nitrogen-binding agent	Chronic management of patients with urea cycle disorders	Patient population altered: To include infants younger than two months of age living with a urea cycle disorder

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

NEW FDA-APPROVED GENERICS
(July 2018 – September 2018)

	Drug name	Therapeutic class	Generic for:
October 2018	Cefixime Capsules 400 mg	Anti-infective agent; Antibiotic; 3rd generation cephalosporin	Suprax Capsules
	Clobazam Tablets 10 mg and 20 mg	Central nervous system agent; Benzodiazepine	Onfi Tablets
	Clobazam Oral Suspension 2.5 mg/mL	Central nervous system agent; Anticonvulsant; Benzodiazepine	Onfi Oral Suspension
	Naproxen Sodium and Diphenhydramine Hydrochloride Tablets 220mg/25mg	Analgesic/Anti-inflammatory; Non-steroidal anti-inflammatory drug	Aleve PM
	Abiraterone Acetate Tablets 250 mg	Antineoplastic agent	Zytiga™ 250 mg
November 2018	N/A	N/A	N/A
December 2018	Toremifene Citrate Tablets 60 mg (base)	Antineoplastic agent	Fareston™
	Pimecrolimus Topical Cream 1%	Dermatological agent; Immunosuppresant	Elidel™

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

6 Street 1, Suite 101, Guaynabo, PR 00968-177(Tel. 787.522.5252 | Fax 1.866.912.2830 www.pharmpix.com