

October 29, 2018

COM-2018-021

Dear provider of pharmaceutical services,

As mentioned on a previous communication, with the intention of helping you to keep up to date with new indications and first-time generics approved by the FDA, we will be sending periodic updates regarding this new approval.

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

**NEW FDA-APPROVED INDICATIONS
(July 2018 – September 2018)**

	Drug name	Therapeutic class	Previous FDA-approved indication(s)	New FDA-approved indication(s)
July 2018	Cinryze™ (C1 esterase inhibitor (human))	Immune modulator; C1-esterase inhibitor	Prophylaxis against angioedema attacks in patients with hereditary angioedema (HAE)	Patient population altered: Prophylaxis against angioedema attacks in children aged 6 years and older with HAE
	Xeomin™ (incobotulinumtoxinA)	Musculoskeletal agent; Botulinum toxin type A	Treatment of cervical dystonia, blepharospasm, glabellar lines, upper limb spasticity	Treatment of chronic sialorrhea, or excessive drooling, in adult patient
	Opdivo™ (nivolumab)	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC), and hepatocellular carcinoma	Opdivo™ in combination with Yervoy™ (ipilimumab) for the treatment of MSI-H or dMMR mCRC
	Xtandi™ (enzalutamide)	Antineoplastic agent; Androgen receptor inhibitor	Treatment of men with metastatic castration-resistant prostate cancer (CRPC)	Treatment of men with non-metastatic CRPC
	Kisqali™ (ribociclib)	Antineoplastic agent; Inhibitor of cyclin-dependent kinase (CDK) 4 and 6 indicated	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer	(1) In combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women, with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy (2) In combination with fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial

	Drug name	Therapeutic class	Previous FDA-approved indication(s)	New FDA-approved indication(s)
				endocrine-based therapy or following disease progression on endocrine therapy
August 2018	Granix™ (tbo-filgrastim)	Hematopoietic agent / Blood modifier agent; Colony stimulating factor (CSF)	For the reduction in the duration of severe neutropenia in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs	Patient population altered: For use in pediatric patients 1 month and older
	Orkambi™ (ivacaftor and lumacaftor)	Respiratory agent; Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination	Treatment of patients 6 years and older with cystic fibrosis (CF) who have two copies of the <i>F508del</i> mutation in their CFTR gene	Patient population altered: For use in pediatric patients ages 2 through 5 years with CF who have two copies of the F508del-CFTR mutation
	Kalydeco™ (ivacaftor)	Respiratory agent; Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator	Treatment of cystic fibrosis (CF) in patients ages 2 years and older who have one of 38 ivacaftor-responsive mutations in the CFTR gene based on clinical and/or in vitro assay data	Patient population altered: For use in pediatric patients ages 12 to <24 months with CF who have at least one mutation in their CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro assay data
	Lenvima™ (lenvatinib)	Antineoplastic agent; Multiple receptor tyrosine kinase (RTK) inhibitor	Treatment of patients with: (1) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC), and (2) Advanced renal cell carcinoma (aRCC), previously treated with an anti-angiogenic therapy (in combination with everolimus)	First-line treatment of patients with unresectable hepatocellular carcinoma (HCC)

	Drug name	Therapeutic class	Previous FDA-approved indication(s)	New FDA-approved indication(s)
	Opdivo™ (nivolumab)	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC), and hepatocellular carcinoma	Treatment of metastatic small cell lung cancer (SCLC) whose cancer has progressed after platinum-based chemotherapy and at least one other line of therapy (two or more prior lines of therapy)
September 2018	Symjepi™ (epinephrine)	Vasopressor; Anaphylaxis therapy agent; Non-selective alpha and beta-adrenergic receptor agonist	Emergency treatment of allergic reactions (Type I) including anaphylaxis	Patient population altered: To treat patients weighing 33-66 pounds
	Fycompa™ (perampanel)	Central nervous system agent; Antiepileptic; Non-competitive AMPA glutamate receptor antagonist	Treatment of partial-onset seizures, and as adjunctive therapy in the treatment of primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy	Patient population altered: For use in pediatric patients 4 years and older for the treatment of partial-onset seizures with or without secondarily generalized seizures

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:
July 2018	Emtricitabine Capsules 200 mg / Cipla USA Inc.	Antiretroviral	Emtriva™
	Budesonide Extended-Release Tablets 9 mg / Actavis Laboratories FL, Inc.	Steroid	Uceris™ Extended-Release Tablets
	Roflumilast Tablets 500 mcg / Mylan Pharmaceuticals Inc.	Respiratory agent/ Phosphodiesterase inhibitor	Daliresp™
	Colesevelam Hydrochloride for Oral Suspension 1.875 grams/packet and 3.75 grams/packet / Glenmark Pharmaceuticals Inc.	Anti-hyperlipidemic; Bile acid sequestrant	Welchol™ for Oral Suspension
	Asenapine Maleate Sublingual Tablets 5 mg (base) and 10 mg (base) / Sigma pharm Laboratories LLC	Antipsychotic	Saphris™
	Teriflunomide Tablets 7 mg and 14 mg / Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.	Psychotherapeutic and neurological agent	Aubagio™
	Temsirolimus Intravenous Solution 25 mg/mL / Accord Healthcare Inc.	Antineoplastic agent	Torisel™
August 2018	Tadalafil Tablets 20mg / Mylan Pharmaceuticals Inc.	Antihypertensive and genitourinary agent; Phosphodiesterase 5 inhibitor	Adcirca™
	Epinephrine (Autoinjector) Injection 0.15 mg/delivery and 0.3 mg/delivery / Teva Pharmaceuticals USA, Inc.	Adrenergic agent; Vasopressor	EpiPen™ Jr. and EpiPen™
September 2018	Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 600 mg/200 mg/300 mg / Aurobindo Pharma Limited	Anti-infective agent; Antiretroviral	Atripla™
	Ticagrelor Tablets 60mg and 90mg / Watson Laboratories, Inc.	Hematological agent; Platelet aggregation inhibitor	Brilinta™
	Carmustine for Injection USP, 100 mg/vial / Navinta LLC	Antineoplastic agent	BiCNU™
	Albendazole Tablets 200 mg / Cipla Ltd.	Anti-infective agent; Anthelmintic	Albenza™

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>