

May 23, 2019

COM-2019-022

Dear provider of pharmaceutical services,

Attached you will find an update of new indications and first-time generics approved by the FDA from January 2019 to March 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
(January 2019 – March 2019)**

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
January 2019	Cabometyx™ (cabozantinib) Tablets	Antineoplastic agent; Tyrosine kinase inhibitor	Treatment of advanced renal cell carcinoma (RCC)	For hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
	Osphena™ (ospemifene) Tablets	Endocrine-Metabolic agent; Selective Estrogen Receptor Modulator; Estrogen agonist/antagonist	To treat women experiencing moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy (VVA) due to menopause	To treat moderate to severe vaginal dryness, another symptom of VVA due to menopause
February 2019	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent; Human 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, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, and Merkel cell carcinoma	For the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection
	Lonsurf™ (tipiracil hydrochloride and trifluridine) Capsules	Antineoplastic agent; Thymidine phosphorylase inhibitor and nucleoside metabolic inhibitor combination	Treatment of patients with previously treated metastatic colorectal cancer (mCRC)	Treatment for adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy
	Soliqua™ 100/33 (insulin glargine and lixisenatide) Injection	Endocrine and metabolic agent; Antidiabetic; Combination of a long-acting human insulin analog (insulin glargine) and a glucagon-like peptide-1 (GLP-1) receptor agonist	As an add-on to diet and exercise in adults with type 2 diabetes who are uncontrolled on long-acting insulin or lixisenatide	To include patients uncontrolled on oral antidiabetic medicines



	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
March 2019	Tecentriq™ (atezolizumab) Injection	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of advanced urothelial carcinoma; the treatment of metastatic non-small cell lung cancer (NSCLC); extensive-stage small cell lung cancer	(1) For use in combination with Abraxane for the treatment of metastatic triple-negative breast cancer (2) For the initial (first-line) treatment of adults with extensive-stage small cell lung cancer (ES-SCLC)
	Cimzia™ (certolizumab pegol) Injection	Immunological agent; Anti-TNF	Treatment of Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis	Treatment for non-radiographic axial spondyloarthritis (nr-axSpA)

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
 (January 2019 – March 2019)**

	Drug name	Therapeutic class	Generic for:
January 2019	Lurasidone Hydrochloride Tablets 20 mg, 40 mg, 60 mg, 80 mg and 120 mg	Central nervous system agent; Antipsychotic	Latuda
	Ingenol Mebutate Topical Gel 0.015%	Dermatological agent	Picato Gel 0.015%
	Ingenol Mebutate Topical Gel 0.05%	Dermatological agent	Picato Gel 0.05%
	Vigabatrin Tablets 500 mg	Central nervous system agent; Anticonvulsant	Sabril
	Wixela Inhub (fluticasone propionate and salmeterol inhalation powder) 100 mcg/50 mcg, 250 mcg/50 mcg and 500 mcg/50 mcg	Antiasthma	Advair Diskus
February 2019	Levomilnacipran Hydrochloride Extended Release Capsule 20 mg (base), 40 mg (base), 80 mg (base) and 120 mg (base)	Central nervous system agent; Antidepressant; Serotonin-Norepinephrine Reuptake Inhibitor (SNRI)	Fetzima
March 2019	Fulvestrant Injection 50mg/mL	Antineoplastic agent; Antiestrogen	Faslodex
	Bepotastine Besilate Ophthalmic Drops 1.5 %	Ophthalmologic agent; Antihistamine	Bepreve
	Pyridostigmine Bromide Syrup 60 mg/5 mL	Cholinergic agent	Mestinon Syrup
	Naftifine Hydrochloride Topical Gel 1%	Dermatological agent; Antifungal	Naftin Gel 1%
	Aliskiren Hemifumarate Tablets 150 mg (base) and 300 mg (base)	Antihypertensive	Tekturna
	Ambrisentan Tablets 5 mg and 10 mg	Antihypertensive; Endothelin receptor antagonist	Letairis

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>