

June 2, 2020

**COM-2020-040**

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 January 2020 to March 2020.

For more details regarding FDA approvals, you can visit the FDA website ([www.fda.gov](http://www.fda.gov)) and other trustworthy sources of drug information. If you would like to, you can subscribe to receive email updates with important FDA news and information as they become available at the [FDA Subscription Management Center](#).

PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

**NEW FDA-APPROVED INDICATIONS  
(January 2020 - March 2020)**

	<b>Drug name</b>	<b>Therapeutic class</b>	<b>Previous FDA- approved indication(s)</b>	<b>New FDA-approved indication(s)</b>
<b>January 2020</b>	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, 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, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, and endometrial carcinoma	Treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy
	Ozempic™ (semaglutide) Injection	Antidiabetic; Glucagon-like peptide-1 (GLP-1) analog	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM)	To reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease
	Dificid™ (fidaxomicin)	Anti-infective agent; Antibacterial	Treatment of <i>Clostridioides difficile</i> -associated diarrhea (CDAD)	Patient population altered: To include children aged six months and older
<b>February 2020</b>	Nerlynx™ (neratinib) Tablets	Antineoplastic agent	Extended adjuvant treatment of early-stage, HER2-positive breast cancer	In combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
<b>March 2020</b>	Ofev™ (nintedanib) Capsules	Respiratory agent; Tyrosine kinase inhibitor (TKI)	<ul style="list-style-type: none"> <li>Treatment of idiopathic pulmonary fibrosis (IPF)</li> <li>Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)</li> </ul>	Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
	Epclusa™ (sofosbuvir and velpatasvir)	Anti-infective agent; Antiviral; Hepatitis C agent	To treat hepatitis C virus (HCV) in adults	Patient population altered: To treat HCV in pediatrics ages 6 years and older or weighing at least 37 pounds with any of the six HCV genotypes without cirrhosis or with mild cirrhosis; In combination with ribavirin for the treatment of pediatrics 6 years and older or weighing at least 37 pounds with severe cirrhosis
	Eucrisa™ (crisaborole) Ointment	Dermatological agent; Phosphodiesterase inhibitor	Treatment of mild-to-moderate atopic dermatitis	Patient population altered: To include pediatric patients 3 months of age and older with mild-to-moderate atopic dermatitis

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
<b>March 2020</b>	Taltz™ (ixekizumab) Injection	Dermatological agent; Antipsoriatic; Interleukin-17A antagonist	Treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis	Patient population altered: To include the treatment of pediatric patients (ages 6 to under 18) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
	Imfinzi™ (durvalumab) Injection	Antineoplastic agent; Anti-PD-L1 (programmed death ligand-1) human monoclonal antibody	Treatment of patients with locally advanced or metastatic urothelial carcinoma, and for the treatment of patients with unresectable non-small cell lung cancer that has not progressed after chemo-radiation	First-line treatment for adult patients with extensive-stage small cell lung cancer (ES-SCLC) in combination with standard-of-care (SoC) chemotherapies, etoposide plus either carboplatin or cisplatin (platinum-etoposide)

References:

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

### FDA-APPROVED GENERICS (January 2020 - March 2020)

	Drug name	Therapeutic class	Generic for:
<b>January 2020</b>	Hydrocodone Bitartrate Extended Release Capsules 10 mg, 15 mg, 20 mg, 30 mg, 40 mg and 50 mg	Analgesic; Opioid	Zohydro ER
<b>February 2020</b>	Olopatadine Hydrochloride Ophthalmic Solution 0.7% (base)	Antihistamine	Pazeo
	Albuterol Sulfate Inhalation Aerosol 90 mcg/actuation	Antiasthma	ProAir HFA
	Pyrimethamine Tablets, 25 m	Anti-infective agent	Daraprim
<b>March 2020</b>	Metformin Hydrochloride Oral Solution 500mg/ 5mL	Antidiabetic; Biguanide	Riomet
	Dabigatran Etxilate Capsules, 75 mg, 150 mg	Blood modifier agent; Anticoagulant	Pradaxa
	Esomeprazole Magnesium for Delayed-Release Oral Suspension 10 mg base/packet, 20mg base/packet and 40mg base/packet	Gastrointestinal agent; Proton pump inhibitor	Nexium Granules for Oral Suspension

References:

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