November 5, 2019

COM-2019-049

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 July 2019 to September 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

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.

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NEW FDA-APPROVED INDICATIONS
(July 2019 – September 2019)

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
July 2019	Otezla™ (apremilast)	Phosphodiesterase 4 (PDE4) inhibitor	Treatment of psoriatic arthritis, and plaque psoriasis	Treatment of oral ulcers associated with Behçet's Disease
	Keytruda™ (pembrolizumab)	Antineoplastic agent; Human 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, and renal cell carcinoma	As monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy
August 2019	Sirturo™ (bedaquiline)	Anti-mycobacterial	Treatment of pulmonary multi-drug resistant tuberculosis (MDR-TB)	Patient population altered: As part of combination therapy in pediatric patients over the age of 12 and younger than 18 and weighing at least 66 pounds (30 kilograms) with pulmonary MDR-TB), when an effective treatment regimen cannot otherwise be provided
	Myobloc™ (rimabotulinumtoxinB)	Neuromuscular agent; Acetylcholine release inhibitor	Treatment of cervical dystonia	Treatment of chronic sialorrhea
	Taltz™ (ixekizumab)	Interleukin-17A antagonist	Treatment of plaque psoriasis, psoriatic arthritis	Treatment of ankylosing spondylitis (AS)
September 2019	Ofev™ (nintedanib) Capsules	Tyrosine kinase inhibitor	Treatment of idiopathic pulmonary fibrosis	To slow the rate of decline in pulmonary function in adults with interstitial lung disease associated with systemic sclerosis or scleroderma
	Nucala™ (mepolizumab)	Antiasthma; Interleukin-5 antagonist monoclonal antibody	Add-on maintenance treatment of patients with severe eosinophilic asthma, and for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome)	Patient population altered: For use in children as young as 6 years old who are living with severe eosinophilic asthma

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	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
September 2019	Erleada™ (apalutamide)	Antineoplastic agent; Androgen receptor inhibitor	Treatment non-metastatic castration-resistant prostate cancer	Treatment of metastatic castration-sensitive prostate cancer
	Keytruda™ (pembrolizumab)	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, and renal cell carcinoma	Treatment of endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation
	Pifeltro™ (doravirine) and Delstrigo™ (doravirine, lamivudine, and tenofovir disoproxil fumarate)	Antiretroviral; Non-nucleoside reverse transcriptase inhibitor (NNRTI)	Treatment of HIV-1 infection	Patient population altered: To include adult patients with HIV-1 infection who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to Pifeltro™ or the individual components of Delstrigo™
	Invokana™ (canagliflozin) Tablets	Antidiabetic; Sodium glucose co-transporter 2 (SGLT2) inhibitor	Along with diet and exercise to lower glucose in adults with type 2 diabetes (T2D); To reduce the risk of major cardiovascular events in adults with T2D who have known cardiovascular disease	To reduce the risk of end-stage kidney disease (ESKD), worsening of kidney function, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes and diabetic kidney disease (nephropathy) with a certain amount of protein in the urine
	Rituxan™ (rituximab) Injection for Intravenous Use / Genentech, Inc.	Antineoplastic agent; Antirheumatic; CD20-directed antibody	Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, and rheumatoid arthritis	In combination with glucocorticoids, for the treatment of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in pediatric patients 2 years of age and older

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
September 2019	Crysvita™ (burosumab-twza) Injection / Ultragenyx Pharmaceutical Inc.	Metabolic modifier; Fibroblast growth factor 23 (FGF23) blocking antibody	Treatment of x-linked hypophosphatemia (XLH)	Patient population altered: To include pediatric patients 6 months of age and older

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
(July 2019 – September 2019)

	Drug name	Therapeutic class	Generic for:
July 2019	Febuxostat Tablets 40 mg and 80 mg	Antigout	Uloric
	Ketorolac Tromethamine and Phenylephrine Hydrochloride Irrigation Solution 0.3% (base)/1% (base)	Analgesic	Omidria
	Carboprost Tromethamine Injection 0.25mg (base)/mL	Endocrine and metabolic agent	Hemabate
	Pregabalin Capsules, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg	Anticonvulsant	Lyrica Capsules
	Pregabalin Oral Solution 20 mg/mL	Anticonvulsant	Lyrica Oral Solution
	Febuxostat Tablets 40 mg and 80 mg	Antigout	Uloric
August 2019	Halcinonide Topical Cream 0.1%	Dermatological agent; Corticosteroid	Halog Cream
	Levocarnitine SF Oral Solution 1 gram/10mL	Endocrine and metabolic agent	Carnitor SF
	Tafluprost Ophthalmic Solution/Drops 0.0015%	Ophthalmologic agent; Prostaglandin	Zioptan
	Sapropterin Dihydrochloride Oral Powder 100mg/packet and 500mg/packet	Endocrine and metabolic agent	Kuvan Powder for Oral Solution
	Posaconazole Delayed Release Tablets 100 mg	Antifungal	Noxafil Tablets
	Nitisinone Capsules 2 mg, 5 mg and 10 mg	Endocrine and metabolic agent	Orfadin Capsules
September 2019	Carfilzomib for Injection 60mg/vial	Antineoplastic agent	Kyprolis 60mg/vial
	Ivermectin Topical Cream 1%	Anti-infective agent; Anthelmintic	Soolantra
	Vilazodone Hydrochloride Tablets 10 mg, 20 mg, and 40 mg	Central nervous system agent; Antidepressant	Viibryd

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

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