October 7, 2020

COM-2020-077

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 2020 to September 2020.

For more details regarding FDA approvals, you can visit the FDA website (www.fda.gov) and other trustworthy drug information sources. 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. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

NEW FDA-APPROVED INDICATIONS
(July 2020 - September 2020)

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
July 2020	**Dysport™ (abobotulinumtoxinA) Injection**	Acetylcholine release inhibitor and neuromuscular blocking agent	• Treatment of cervical dystonia in adults • Temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults < 65 years of age • Treatment of spasticity in patients 2 years of age and older	Treatment of lower and upper limb spasticity in patients 2 years of age and older, including spasticity caused by cerebral palsy (C.P.) Note: Dysport™ was first approved specifically for pediatric lower limb spasticity caused by C.P. Later, Dysport™ was granted with an additional indication for pediatric upper limb spasticity, excluding upper limb spasticity caused by C.P., due to Orphan Drug exclusivity granted to another manufacturer. An orphan exclusivity waive by manufacturers permits the indication expansion.
	Botox™ (onabotulinumtoxinA) Injection	Acetylcholine release inhibitor and neuromuscular blocking agent	Treatment for Hyperhidrosis, Cervical Dystonia, Urinary Incontinence, Migraine Prevention, Upper Limb Spasticity, Lower Limb Spasticity, Blepharospasm, Strabismus, Spasticity	Treatment of lower and upper limb spasticity in patients 2 years of age and older, including spasticity caused by cerebral palsy (C.P.) Note: Botox™ was first approved specifically for pediatric patients with upper limb spasticity. Later, Botox™ was granted with an additional indication for pediatric lower limb spasticity, excluding spasticity caused by C.P. An orphan exclusivity waive by manufacturers permit the indication expansion.
	Tremfya™ (guselkumab) Injection	Interleukin-23 blocker	Treatment of moderate-to-severe plaque psoriasis in adults	Treatment of active psoriatic arthritis in adults
	Qutenza™ (capsaicin) Transdermal Patch	TRPV1 channel agonist	Treatment of neuropathic pain associated with post-herpetic neuralgia (PHN)	Treatment of neuropathic pain associated with diabetic peripheral neuropathy of the feet
	Stelara™ (ustekinumab) Injection	Interleukin-12 and -23 blocker	Treatment of moderate to severe plaque psoriasis (Ps), active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), and moderately to severely active ulcerative colitis (U.C.)	Patient population altered: To include pediatric patients (6-11 years of age) with moderate to severe Ps
	Tecentriq™ (atezolizumab) Injection	Antineoplastic agent; Programmed death-ligand 1 (PD-L1) blocking antibody	Treatment of urothelial carcinoma, non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), small cell lung	In combination with Cotellic™ (cobimetinib) and Zelboraf™ (vemurafenib) for the treatment of BRAF V600 mutation-positive advanced melanoma

2 Street 1, Suite 500 Guaynabo, PR 00968 | 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)
			cancer (SCLC), and hepatocellular carcinoma	
July 2020	**Spravato™ (esketamine) Nasal Spray**	Antidepressant; Non-competitive N-methyl D-aspartate (NMDA) receptor antagonist	In conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults	In conjunction with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior
	Epidiolex™ (cannabidiol) Oral Solution	Antiepileptic	Treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome	Treatment of seizures associated with tuberous sclerosis complex (TSC) in patients one year of age and older
August 2020	**Dovato™ (dolutegravir and lamivudine) Tablets**	Anti-infective agent; Antiretroviral	As a complete regimen for the treatment of HIV-1 infection in adults with no antiretroviral (ARV) treatment history and with no known resistance to either dolutegravir (DTG) or lamivudine (3TC)	As a complete regimen for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable ARV regimen with no history of treatment failure and no known resistance to the individual components of Dovato™
September 2020	**Trelegy Ellipta™ (fluticasone furoate, umeclidinium, and vilanterol) Inhalation Powder**	Respiratory agent; Inhaled corticosteroid, long-acting muscarinic antagonist (LAMA), and long-acting beta2-adrenergic agonist (LABA) combination	Maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	Maintenance treatment of asthma in patients aged 18 years and older
	Kalydeco™ (ivacaftor) Tablets and Oral Granules	Respiratory agent; Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator	Treatment of cystic fibrosis (C.F.) in patients ages six months and older who have one mutation in the CFTR gene that is responsive to ivacaftor	**Patient population altered:** To include use in children with C.F. ages four months to less than six months old who have at least one mutation in their CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data
	Xeljanz™ (tofacitinib) Tablets and Oral Solution	Janus kinase (JAK) inhibitor	Treatment of rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis	Treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA)
	Fetroja™ (cefiderocol) Injection	Anti-infective agent; Antibacterial	Treatment of complicated urinary tract infections (cUTI)	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)
	Nucala™ (mepolizumab) Injection	Respiratory agent	Add-on maintenance treatment of patients ≥6 years with severe eosinophilic asthma, and treatment of adult patients with eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome)	Treatment of patients ≥12 years with hypereosinophilic syndrome (HES)
	Haegarda™ (C1 esterase inhibitor (human)) Subcutaneous Injection	Immunological agent	To prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients	**Patient population altered:** To include use in pediatric patients 6 years of age and older

2 Street 1, Suite 500 Guaynabo, PR 00968 | 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)
September 2020	**Simponi Aria™ (golimumab) Injection**	Tumor necrosis factor (TNF) blocker	Treatment of adult patients with moderately to severely active Rheumatoid Arthritis (R.A.) in combination with methotrexate, adult patients with active Psoriatic Arthritis (PsA), and adult patients with active Ankylosing Spondylitis (AS)	Treatment of active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older **Patient population altered:** To include use in patients 2 years of age and older with PsA

References:

- U.S. 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 2020 - September 2020)

	Drug name	Therapeutic class	Generic for:
July 2020	Deferasirox Oral Granules 90 mg, 180 mg and 360 mg	Antidote	Jadenu Sprinkle
	Metyrosine Capsules 250 mg	Agent for pheochromocytoma	Demser
August 2020	Cyprofloxacin and Dexamethasone Otic Suspension Drops (0.3%/0.1%)	Anti-infective; Antibacterial/steroid combination	Cyprodex
September 2020	Sorafenib Tosylate Tablets 200mg (base)	Antineoplastic agent	Nexavar
	Lapatinib Ditosylate Tablets 250 mg (base)	Antineoplastic agent	Tykerb

References:

- U.S. 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

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com