

July 10, 2019

COM-2019-031

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 April 2019 to June 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.

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Regards,

Clinical Department

**NEW FDA-APPROVED INDICATIONS
(April 2019 – June 2019)**

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
April 2019	Ibrance™ (palbociclib)	Antineoplastic agent; Cyclin-dependent kinase 4/6 (CDK4/6) inhibitor	Treatment of ER+, HER2- metastatic breast cancer	In combination with an aromatase inhibitor or fulvestrant to include men with HR+, HER2- advanced or metastatic breast cancer
	Keytruda™ (pembrolizumab)	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer (NSCLC), 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	(1) As monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemo-radiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations (2) In combination with Inlyta™ (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma (RCC)
	Benlysta™ (belimumab)	Immunological agent; B-lymphocyte stimulator-specific inhibitor	Treatment of patients with systemic lupus erythematosus	Patient population altered: To include children with lupus from as young as five years of age
	Praluent™ (alirocumab)	Anti-hyperlipidemic; Cardiovascular agent; PCSK9 (pro-protein convertase subtilisin/kexin type 9) inhibitor monoclonal antibody	Treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C	To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease
	Mavyret™ (glecaprevir and pibrentasvir)	Anti-infective; Antiviral; Combination of an NS3/4A protease inhibitor, and pibrentasvir, an NS5A inhibitor	Treatment of all major genotypes (GT1-6) of chronic hepatitis C	Patient population altered: To include children ages 12 to 17
May 2019	Tibsovo™ (ivosidenib)	Antineoplastic agent; Isocitrate dehydrogenase-1 (IDH1) inhibitor	Treatment of patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) who have an IDH1 mutation	To include adult patients with newly diagnosed AML with a susceptible IDH1 mutation as detected by an FDA-approved

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			test who are ≥ 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy
Kadcyla™ (ado-trastuzumab emtansine)	Antineoplastic agent; HER2-targeted antibody	Treatment of patients with HER2-positive, late-stage (metastatic) breast cancer	For adjuvant (after surgery) treatment of people with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant (before surgery) taxane and Herceptin™ (trastuzumab)-based treatment
Sorilux™ (calcipotriene)	Dermatological agent; Antipsoriatic; Vitamin D analog	Topical treatment of plaque psoriasis	Patient population altered: To include adolescent patients aged 12 years and older
Xeomin™ (incobotulinumtoxin A)	Musculoskeletal agent; Neuromuscular blocker; Botulinum toxin type A	Treatment of cervical dystonia, blepharospasm (previously treated with onabotulinumtoxin A), glabellar lines, upper limb spasticity, and excessive drooling	First-line treatment of blepharospasm in adult patients
Cyramza™ (ramucirumab)	Antineoplastic agent; Vascular endothelial growth factor receptor 2 (VEGFR2) antagonist	Treatment of advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy; metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy; metastatic colorectal cancer with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine	Treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥ 400 ng/mL and have been treated with sorafenib
Eylea™ (aflibercept)	Ophthalmologic agent; VEGF inhibitor	Treatment of neovascular age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema	Treatment of diabetic retinopathy
Bavencio™ (avelumab)	Antineoplastic agent; Programmed death ligand-1 (PD-L1) blocking antibody	Treatment of metastatic Merkel cell carcinoma (MCC) and advanced or metastatic urothelial carcinoma	In combination with axitinib (Inlyta)™ for the first-line treatment of advanced renal cell carcinoma (RCC)
Venclexta™ (venetoclax)	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	Treatment of previously treated chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), and newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy	Treatment of previously untreated CLL or SLL

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	Gattex™ (teduglutide)	Gastrointestinal agent	Treatment of short bowel syndrome	Patient population altered: To include pediatric patients 1 year of age and older
	Fragmin™ (dalteparin sodium)	Anticoagulant; Low molecular weight heparin (LMWH)	Treatment of metastatic Merkel cell carcinoma (MCC) and advanced or metastatic urothelial carcinoma	In combination with axitinib (Inlyta)™ for the first-line treatment of advanced renal cell carcinoma (RCC)
	Jakafi™ (ruxolitinib)	Antineoplastic agent; Janus kinase (JAK) inhibitor	Treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis in adults; polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea	Treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older
	Vraylar™ (cariprazine)	Central nervous system agent; Antipsychotic; Dopamine D3/D2 receptor partial agonist	Treatment of schizophrenia, and manic or mixed episodes associated with bipolar I disorder	Treatment of depressive episodes associated with bipolar I disorder
	Revlimid™ (lenalidomide)	Immunological agent; Immune modulator	Treatment of multiple myeloma (MM), in combination with dexamethasone; MM, following autologous hematopoietic stem cell transplantation; Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities; Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies	In combination with rituximab for the treatment of previously treated follicular lymphoma (FL) or marginal zone lymphoma (MZL)
June 2019	Zerbaxa™ (ceftolozane and tazobactam)	Anti-infective agent; Antibiotic; Cephalosporin and beta-lactamase inhibitor combination	Treatment of: (1) complicated intra-abdominal Infections (cIAI), used in combination with metronidazole (2) complicated urinary tract infections (cUTI), including pyelonephritis	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)
	Emgality™ (galcanezumab-gnlm)	Central nervous system agent; Antimigraine; calcitonin gene-related peptide (CGRP) antagonist	Preventive treatment of migraine	Treatment of episodic cluster headache
	Emflaza™ (deflazacort)	Glucocorticoid	Treatment of Duchenne muscular dystrophy (DMD)	Patient population altered: To include patients with DMD who are between 2 and 5 years-old

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Keytruda™ (pembrolizumab)	Antineoplastic agent; PD-1 (programmed death receptor-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma (with disease progression on or after platinum-containing chemotherapy), classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, and renal cell carcinoma	As monotherapy in patients whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1) or in combination with platinum and fluorouracil (FU), for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma
Victoza™ (liraglutide)	Antidiabetic; Glucagon-like peptide-1 (GLP-1) receptor agonist	To improve glycemic control in patients with type 2 diabetes mellitus, and to reduce the risk of heart attack, stroke and cardiovascular death in adults with type 2 diabetes and established cardiovascular disease	Patient population altered: To include the treatment of pediatric patients 10 years or older with type 2 diabetes
Dextenza™ (dexamethasone)	Ophthalmic agent; Corticosteroid intracanalicular insert	Treatment of post-surgical ocular pain	Treatment of ocular inflammation following ophthalmic surgery
Botox™ (onabotulinumtoxinA)	Acetylcholine release inhibitor and a neuromuscular blocking agent	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency; Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults; Prophylaxis of headaches in adult patients with chronic migraine; Treatment of upper and lower limb spasticity in adult patients; Treatment of cervical dystonia in adult patients; Treatment of severe axillary hyperhidrosis in adult patients; Treatment of blepharospasm associated with dystonia in patients 12 years of age and older; Treatment of strabismus in patients 12 years of age and older	Patient population altered: Treatment of pediatric patients (2 to 17 years of age) with upper limb spasticity
Symdeko™ (ivacaftor/tezacaftor and ivacaftor)	Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator and CFTR corrector combination	Treatment of cystic fibrosis (CF) in patients who have two copies of the F508del mutation, or who have at least one mutation in the CF gene that is responsive to treatment with Symdeko™	Patient population altered: For use in children with cystic fibrosis ages 6 through 11 years

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 (April 2019 – June 2019)

	Drug name	Therapeutic class	Generic for:
April 2019	Naftifine Hydrochloride Topical Gel 2%	Dermatological agent; Antifungal	Naftin Gel 2%
	Loteprednol Etabonate Ophthalmic Suspension 0.5%	Ophthalmologic agent; Corticosteroid	Lotemax Ophthalmic Suspension 0.5%
	Valrubicin Intravesical Solution 40mg/mL	Antineoplastic agent; Anthracycline	Valstar
	Naloxone Hydrochloride Nasal Spray 4mg/spray	Opioid antagonist	Narcan Nasal Spray
	Everolimus Tablets for Oral Suspension 2 mg, 3 mg, and 5 mg	Antineoplastic agent	Afinitor Disperz
	Rufinamide Oral Suspension 40mg/mL	Central nervous system agent; Anticonvulsant	Banzel Oral Suspension
	Pentamidine Isethionate for Inhalation Solution 300mg/vial	Anti-infective agent; Antiprotozoal	Nebupent
May 2019	Bosentan Tablets 62.5 mg and 125 mg	Anti-hypertensive agent; endothelin receptor antagonist	Tracleer
	Sapropterin Dihydrochloride Tablets 100 mg	Endocrine and metabolic agent; Metabolic modifier	Kuvan
	Micafungin Sodium Injection 50 mg (base)/vial and 100 mg (base)/vial	Antifungal	Mycamine
June 2019	Sildenafil Citrate for Oral Suspension 10mg (base)/mL	Cardiovascular agent; Antihypertensive agent	Revatio for Oral Suspension
	Diclofenac Sodium Injection 37.5 mg/mL Single-Dose Vials	NSAID	Dyloject
	Tobramycin Inhalation Solution 300 mg/4 mL	Antibiotic; Aminoglycoside	Bethkis

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>