February 9, 2021

COM-2021-010

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 October 2020 to December 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

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NEW FDA-APPROVED INDICATIONS
(October 2020 - December 2020)

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
October 2020	**Opdivo™ (nivolumab) Injection**	**Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody**	Treatment of melanoma, non-small cell lung cancer, small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma	In combination with Yervoy™ (ipilimumab), for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM)
	Wakix™ (pitolisant) Tablets	Central nervous system agent	Treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy	Treatment of cataplexy in adult patients with narcolepsy
	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent; Programmed death receptor-1 (PD-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, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, and cutaneous squamous cell carcinoma	As monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma
	Venclexta™ (venetoclax) Tablets	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	Treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	In combination with azacitidine, or decitabine, or low-dose cytarabine (LDAC) for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy [Full approval granted; Venclexta was previously granted provisional approval in this setting under the FDA's accelerated approval program in November 2018]
November 2020	**Brilinta™ (ticagrelor) Tablets**	Platelet aggregation inhibitor; P2Y12 platelet inhibitor	(1) To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel. Brilinta also reduces the risk of stent thrombosis in patients who have been stented	To reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA)

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	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
November 2020			for treatment of ACS; (2) To reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes mellitus (T2DM)	
	Keytruda™ (pembrolizumab) for Injection	Antineoplastic agent	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, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer	In combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test
	Vimpat™ (lacosamide) Tablets, Injection, Oral Solution	Anti-convulsant	Treatment of partial-onset seizures	As an adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older
	Xofluza™ (baloxavir marboxil) Granules for Oral Suspension	Anti-infective agent; Antiviral	Treatment of influenza	Post-exposure prophylaxis of influenza in people 12 years of age and older
December 2020	**Hetlioz™ (tasimelteon) Capsules**	Central nervous system agent	Treatment of Non-24-Hour Disorder in adults	Treatment of nighttime sleep disturbances associated with Smith-Magenis Syndrome (SMS) in patients 16 years of age and older
	Xolair™ (omalizumab) Subcutaneous Injection	Respiratory agent; Immunological agent	(1) Moderate to severe persistent asthma in patients 6 years of age and older; (2) Chronic idiopathic urticaria in adults and adolescents 12 years of age and older	Nasal polyps in adult patients 18 years of age and older
	Gavreto™ (pralsetinib) Capsules	Antineoplastic agent	Treatment of adult patients with metastatic rearranged during transfection (RET) fusion- positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test	Treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer (MTC) who require systemic therapy, or with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
	Saxenda™ (liraglutide) Injection	Endocrine and metabolic agent	Treatment of obesity	Patient population altered: To include treatment of obesity in adolescents (12–17 years) with

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
December 2020				a body weight above 60 kg and an initial body mass index (BMI) corresponding to 30 kg/m2 or greater for adults, as an adjunct to reduced-calorie meals and increased physical activity
	Benlysta™ (belimumab) Injection	Immunological agent	Treatment of patients with systemic lupus erythematosus	Treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy
	Kineret™ (anakinra) Injection	Immunological agent	Treatment of rheumatoid arthritis and neonatal-onset multisystem inflammatory disease (NOMID)	Treatment of deficiency of IL-1 receptor antagonist (DIRA)
	Iclusig™ (ponatinib) Tablets	Antineoplastic agent	Treatment of chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL)	For adult patients with chronic-phase (CP) CML with resistance or intolerance to at least two prior kinase inhibitors
	Xeomin™ (incobotulinumtoxinA) Injection	Musculoskeletal agent	Treatment of cervical dystonia, blepharospasm, glabellar lines, upper limb spasticity, and excessive drooling	Patient population altered: Treatment of patients aged 2 years and older with chronic sialorrhea, or drooling
	Xpovio™ (selinexor) Tablets	Antineoplastic agent	Treatment of patients adult patients with multiple myeloma (RRMM) and relapsed or refractory diffuse large B-cell lymphoma (DLBCL)	Treatment of adult patients with multiple myeloma who have received at least one prior therapy
	Tagrisso™ (osimertinib) Tablets	Antineoplastic agent	(1) Treatment of adult patients with metastatic EGFR T790M mutationpositive non-small cell lung cancer (NSCLC) , as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy; (2) First-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test	As adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

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
(October 2020 - December 2020)

	Drug name	Therapeutic class	Indication(s)	Generic for:
October 2020	Fosfomycin Tromethamine Granules for Oral Solution 3 grams (base)/single-dose sachet	Anti-infective agent	Uncomplicated urinary tract infection in women	Monurol
	Azelaic Acid Topical Foam 15%	Dermatological agent	Rosacea	Finacea
	Tavaborole Topical Solution 5%	Antifungal	Onychomycosis of the toenails	Kerydin
	Pomalidomide Capsules 1 mg, 2 mg, 3 mg and 4 mg	Antineoplastic agent	(1) Kaposi's sarcoma, HIV-negative or AIDS-related disease after failure of HAART; (2) Multiple myeloma	Pomalyst
November 2020	Gemmily (ethinyl estradiol and norethindrone acetate) Capsules 0.02 mg / 1 mg	Contraceptive	Contraception	Taytulla
	Brinzolamide Ophthalmic Suspension 1%	Ophthalmic agent	(1) Glaucoma; (2) Ocular hypertension	Azopt
	Nitazoxanide Tablets 500 mg	Anti-infective agent; Antiprotozoal	(1) Giardiasis; (2) Cryptosporidiosis	Alinia
December 2020	Efinaconazole Topical Solution 10%	Anti-infective agent; Antifungal	Onychomycosis due to dermatophyte, Toenails	Jublia

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

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