July 10, 2020

COM-2020-053

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 2020 to June 2020.

For more details regarding FDA approvals, you can visit the FDA website (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. 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
(April 2020 - June 2020)

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
April 2020	**Braftovi™ (encorafenib) Capsules**	Antineoplastic agent	In combination with binimetinib (Mektovi™), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test	In combination with cetuximab (Erbitux™) for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy
	Imbruvica™ (ibrutinib) Capsules and Tablets	Antineoplastic agent	Mantle cell lymphoma (MCL); Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL); Waldenström's macroglobulinemia (WM); Marginal zone lymphoma (MZL); Chronic graft versus host disease (cGVHD)	In combination with rituximab for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
	Jublia™ (efinaconazole) Topical Solution	Antifungal	Treatment of onychomycosis of the toenails	Patient population altered: To include children 6 years of age and older
	Zejula™ (niraparib) Capsules	Antineoplastic agent	Treatment of patients with ovarian, fallopian tube, or primary peritoneal cancer	First-line monotherapy maintenance treatment for women with platinum-responsive advanced ovarian cancer regardless of biomarker status
May 2020	**Reblozyl™ (luspatercept-aamt) Injection**	Blood modifier agent; Erythroid maturation agent (EMA)	Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions	Treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
	Farxiga™ (dapagliflozin) Tablets	Antidiabetic; Sodium-glucose cotransporter 2 (SGLT2) inhibitor	Treatment of type 2 diabetes mellitus: - as an adjunct to diet and exercise to improve glycemic control in adults - to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors	Treatment of heart failure: - to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV)
	Lynparza™ (olaparib) Tablets	Antineoplastic agent; Poly ADP ribose polymerase (PARP) inhibitor	Treatment of ovarian cancer, breast cancer, and pancreatic cancer	- In combination with bevacizumab as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous

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				recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability - Treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC)
	Pomalyst™ (pomalidomide) Capsules	Antineoplastic agent; Thalidomide analogue	Treatment of multiple myeloma	Treatment of AIDS-related and HIV-negative Kaposi sarcoma
	Opdivo™ (nivolumab) Injection	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer (NSCLC), advanced small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma	In combination with Yervoy™ (ipilimumab), for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations
May 2020	**Rubraca™ (rucaparib) Tablets**	Antineoplastic agent; Poly (ADP-ribose) polymerase (PARP) inhibitor	Treatment of ovarian cancer	Treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
	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), and small cell lung cancer (SCLC)	- First-line (initial) treatment for adults with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations - In combination with bevacizumab (Avastin™) for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy
	Alunbrig™ (brigatinib) Tablets	Antineoplastic agent; Anaplastic lymphoma kinase (ALK) inhibitor	Treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test, who have progressed on or are intolerant to crizotinib	First-line treatment of ALK-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
	Dupixent™ (dupilumab) Injection	Interleukin-4 receptor alpha antagonist	Treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription	Patient population altered: To included children aged 6 to 11 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable

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May 2020			therapies or when those therapies are not advisable Add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitation of Use: Not for the relief of acute bronchospasm or status asthmaticus Add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)	
	Brilinta™ (ticagrelor) Tablets	Platelet aggregation inhibitor; P2Y12 platelet inhibitor	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 for treatment of ACS]	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)
June 2020	**Recarbrio™ (imipenem, cilastatin, and relebactam) for Injection**	**Anti-infective agent; Antibacterial**	Treatment of complicated urinary tract infections (cUTI), complicated intra-abdominal infections (cIAI)	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP)
	Opdivo™ (nivolumab) Injection	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, and hepatocellular carcinoma	Treatment of patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy
	Gardasil 9™ (human papillomavirus 9-valent vaccine, recombinant) Injection	Vaccine	In females 9 through 45 years of age: For the prevention of cervical, vulvar, vaginal, and anal caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31,	For the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58

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			33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11 In males 9 through 45 years of age: For the prevention of anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11	
June 2020	**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, and endometrial carcinoma	As monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment option As monotherapy for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation As monotherapy for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer
	Cosentyx™ (secukinumab) Injection	Dermatological agents; Antipsoriatic; Selective interleukin-17A (IL-17A) inhibitor	Treatment of plaque psoriasis, ankylosing spondylitis, and psoriatic arthritis	Treatment of non-radiographic axial spondyloarthritis
	Tazverik™ (tazemetostat) Tablets	**Antineoplastic agent; Methyltransferase inhibitor**	Treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection	Treatment of: Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options
	Crysvita™ (burosumab-twza) Injection	Endocrine and metabolic agent; Fibroblast growth factor 23 (FGF23) blocking antibody	Treatment of X-linked hypophosphatemia (XLH)	Treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adults and pediatric patients 2 years of age and older
	Xpovio™ (selinexor) Tablets	Antineoplastic agent; Selective Inhibitor of Nuclear Export (SINE) XPO1 antagonist	Treatment of patients adult patients with multiple myeloma (RRMM)	Treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy

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June 2020	**Bavencio™ (avelumab) Injection**	Antineoplastic agent; programmed death ligand-1 (PD-L1) blocking antibody	Treatment of patients with metastatic Merkel cell carcinoma (MCC); patients with advanced or metastatic urothelial carcinoma; and in combination with axitinib for patients with advanced renal cell carcinoma	Maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy

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 2020 – June 2020)

	Drug name	Therapeutic class	Generic for:
April 2020	Albuterol Sulfate Metered Inhalation Aerosol 0.09mg base/inhalation	Antiasthma	Proventil HFA
	Clocortolone Pivalate Cream 0.1%	Dermatologic agent	Cloderm
May 2020	Ivermectin Lotion 0.5%	Anti-infective agent; Anthelmintic	Sklice
	Desonide Topical Gel 0.05%	Dermatological agent; Corticosteroid	Desonate Gel
	Calcipotriene and Betamethasone Dipropionate Topical Suspension 0.005% / 0.064%	Dermatological agent; Corticosteroid and Vitamin D	Taclonex Scalp
	Posaconazole Oral Suspension 40mg/ mL	Anti-infective agent; Antifungal	Noxafil Oral Suspension
	Icosapent Ethyl Capsules 1 gm	Antihyperlipidemic	Vascepa
June 2020	Halobetasol Propionate Topical Lotion 0.05%	Corticosteroid	Ultravate Lotion
	Betamethasone Dipropionate Topical Spray 0.05%	Corticosteroid	Sernivo
	Methylphenidate Hydrochloride Extended-Release Orally Disintegrating Tablets 8.6 mg, 17.3 mg and 25.9 mg	Central nervous system stimulant; Amphetamine	Cotempla XR-ODT
	Pantoprazole Sodium for Delayed-Release Oral Suspension 40 mg (base)	Proton pump inhibitor	Protonix for Delayed-Release Oral Suspension

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

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