

July 23, 2018

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Dear provider of pharmaceutical services,

As you may know, drugs that are already in the market can gain FDA-approval for the treatment of additional diseases/conditions. These new indications can represent important new therapies for advancing patient care. For this reason, it is important for pharmacists to keep up to date with these approvals. To help you with this matter, we will be sending periodic updates regarding drugs that gained FDA-approval for the treatment of additional disease/conditions. In addition, we will be giving an update regarding first-time generic approvals.

Attached you will find an update of new indications and first-time generics approved by the FDA from January 2018 to June 2018.

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://www.fda.gov/aboutfda/contactfda/ucm2005606.htm>, 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 138.

Regards,

Pharmacy 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.

**NEW FDA-APPROVED INDICATIONS
(January 2018 – June 2018)**

	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
January 2018	Xgeva™ (denosumab)	Endocrine and metabolic agent; Bone density regulator; RANK ligand (RANKL) inhibitor	Prevention of skeletal-related events in patients with multiple myeloma; Treatment of giant cell tumor of bone; Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.	Prevention of skeletal-related events in patients with bone metastases from solid tumors in patients with multiple myeloma.
	Lynparza™ (olaparib)	Antineoplastic agent; Poly ADP ribose polymerase (PARP) inhibitor	Treatment of BRCA-mutated, advanced ovarian cancer; Maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer.	Treatment of germline BRCA-mutated metastatic breast cancer.
	Gilotrif™ (afatinib)	Antineoplastic agent; Kinase inhibitor	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations.	First-line treatment of patients with metastatic NSCLC whose tumors have the following non-resistant EGFR mutations, as detected by an FDA-approved test: L861Q, G719X and S768I.
	Opdivo™ (nivolumab)	Antineoplastic agent; Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-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.	Adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
	Trulance™ (plecanatide)	Gastrointestinal agent; Guanylate cyclase-C agonist	Treatment of chronic idiopathic constipation in adults.	Treatment of irritable bowel syndrome with constipation (IBS-C) in adults.
February 2018	Avycaz™ (avibactam and ceftazidime)	Antibiotic; Non-β lactam β-lactamase inhibitor and cephalosporin antibiotic combination	Treatment of complicated intra-abdominal infections, and complicated urinary tract infections.	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible Gram-negative microorganisms.
	Feraheme™ (ferumoxytol)	Iron replacement therapy	Treatment of iron deficiency anemia (IDA) in adult patients.	To broaden the existing label beyond the current chronic kidney disease (CKD)

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	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
				indication to include all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron.
	Zytiga™ (abiraterone)	Antineoplastic agent; CYP17 inhibitor	Treatment of patients with metastatic castration-resistant prostate cancer (CRPC).	Treatment of patients with metastatic high-risk CSPC (in combination with prednisone).
	Imfinzi™ (durvalumab)	Antineoplastic agent; Anti-programmed death ligand-1 (PD-L1) monoclonal antibody	Treatment of patients with metastatic urothelial carcinoma.	Treatment of patients with stage III NSCLC whose tumors are unresectable and whose cancer has not progressed after treatment with chemoradiation.
	Verzenio™ (abemaciclib)	Antineoplastic agent; Selective ATP-competitive inhibitor of cyclin dependent kinases (CDK) 4 and 6	In combination with fulvestrant for the treatment of women with HR+, HER2- advanced or metastatic breast cancer <u>with disease progression</u> following endocrine therapy, and as monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer <u>with disease progression</u> following endocrine therapy and prior chemotherapy in the metastatic setting.	In combination with an aromatase inhibitor (AI) <u>as initial endocrine-based therapy</u> for the treatment of postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer.
March 2018	Otiprio™ (ciprofloxacin)	Otic fluoroquinolone antibacterial	Treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement surgery.	For the treatment of acute otitis externa (AOE) in patients 6 months of age and older due to <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i> .
	Hizentra™ (immune globulin subcutaneous (human))	Immunological agent	Treatment of primary immunodeficiency.	Maintenance treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.
	Adcetris™ (brentuximab vedotin)	Antineoplastic agent; CD30-directed antibody-drug conjugate	Treatment of classic Hodgkin lymphoma (cHL) after relapse, cHL after stem cell transplant when a patient is at a high risk of relapse or progression,	First-line treatment of adult patients with stage III or IV cHL in combination with chemotherapy.

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			systemic anaplastic large cell lymphoma (ALCL) after failure of other treatment, primary cutaneous ALCL after failure of other treatment, and CD30-expressing mycosis fungoides.	
	Blincyto™ (blinatumomab)	Antineoplastic agent; CD19-directed CD3 T-cell engager	Treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).	Treatment of adults and children with B-cell precursor ALL who are in remission but still have minimal residual disease (MRD).
April 2018	Exparel™ (bupivacaine liposome)	Local anesthetic; Long-acting non-opioid local analgesic	For post-surgical local analgesia.	To include administration via interscalene brachial plexus block to produce postsurgical regional analgesia.
	Rubraca™ (rucaparib)	Antineoplastic agent; Poly ADP-ribose polymerase (PARP) inhibitor	Treatment of patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies.	Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
	Afinitor™ (everolimus)	Antineoplastic agent; mTOR inhibitor	Treatment of patients with advanced HR+, HER2-breast cancer; progressive neuroendocrine tumors of pancreatic origin (PNET); progressive neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin; advanced renal cell carcinoma; and subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex; and renal angiomyolipomas associated with tuberous sclerosis.	Adjunctive treatment of adult and pediatric patients aged 2 years and older with tuberous sclerosis complex-associated partial-onset seizures.
	Tagrisso™ (osimertinib)	Antineoplastic agent; Tyrosine kinase inhibitor (TKI) of EGFR	Treatment of patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer (NSCLC).	First-line treatment of patients with metastatic NSCLC whose tumors have the following EGFR mutations: exon 19 deletions or exon 21 L858R mutations (as detected by an FDA-approved test).

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	Drug name	Therapeutic class	Previous FDA- approved indication(s)	New FDA-approved indication(s)
	Tafinlar™ (dabrafenib)	Antineoplastic agent; Kinase inhibitor	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.	Adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection (in combination with Mekinist™ (trametinib)).
May 2018	Kymriah™ (tisagenlecleucel)	Antineoplastic agent; Chimeric antigen receptor T cell (CAR-T) therapy	Treatment of relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL).	Treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.
	Tafinlar™ (dabrafenib)	Antineoplastic agent; Kinase inhibitor	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E or K mutation as detected by an FDA-approved test.	Adjuvant treatment of unresectable or metastatic, BRAF V600E mutation-positive, anaplastic thyroid cancer (in combination with Mekinist™ (trametinib)).
	Darzalex™ (daratumumab)	Antineoplastic agent; Human anti-CD38 monoclonal antibody	Treatment of patients with multiple myeloma.	Treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (on combination with Velcade™ (bortezomib), melphalan, and prednisone – VMP).
	Taltz™ (ixekizumab)	Anti-psoriatic; Interleukin-17A antagonist	Treatment of plaque psoriasis and psoriatic arthritis.	Treatment of psoriasis involving genital area.
	Prolia™ (denosumab)	Immunological agent; Monoclonal antibody RANK ligand inhibitor	Treatment of postmenopausal women with osteoporosis at high risk for fracture, bone loss in patients with prostate or breast cancer undergoing hormone ablation therapy, and to increase bone mass in men with osteoporosis at high risk for fracture.	Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture.
	Xeljanz™ (tofacitinib)	Anti-rheumatic agent; Janus kinase (JAK) inhibitor	Treatment of adult patients with moderately to severely active rheumatoid arthritis, and active psoriatic arthritis.	Treatment of adult patients with moderately to severely active ulcerative colitis (UC).

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June 2018	Rituxan™ (rituximab)	Antineoplastic agent; CD20-directed cytolytic antibody	Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, Wegener's granulomatosis, and microscopic polyangiitis.	Treatment of adults with moderate to severe pemphigus vulgaris.
	Venclexta™ (venetoclax)	Antineoplastic agent; B-cell lymphoma-2 (BCL-2) inhibitor	Treatment of patients with chronic lymphocytic leukemia (CLL), with 17p deletion.	Treatment of people with CLL or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy (in combination with Rituxan™ (rituximab)).
	Keytruda™ (pembrolizumab)	Antineoplastic agent; Programmed death receptor-1 (PD-1)-blocking antibody	Treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, and gastric cancer.	(1) Treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test. (2) Treatment of patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.
	Avastin™ (bevacizumab)	Antineoplastic agent; Monoclonal IgG1 antibody	Treatment of colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer, fallopian tube cancer, and peritoneal cancer.	Treatment of women with advanced (stage III or IV) ovarian cancer following initial surgical resection.

References:

- US Food and Drug Administration (FDA). Available at: www.fda.gov
- New Drugs Approvals. Drugs.com. Available at: <https://www.drugs.com/newdrugs.html>

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**NEW FDA-APPROVED GENERICS
(January 2018 – June 2018)**

	Drug name	Therapeutic class	Generic for:
January 2018	Remifentanyl Hydrochloride Injection 1 mg base/vial, 2 mg base/vial and 5mg base/vial	Opioid analgesic	Ultiva™
February 2018	Trientine Hydrochloride Capsules 250mg	Antidote; Heavy metal chelator	Syprine™
	Sumatriptan Succinate and Naproxen Sodium Tablets 85mg (base)/ 500mg (base)	Antimigraine agent (Sumatriptan: Selective agonist of 5-hydroxytryptamine types 1B and 1D receptors; Naproxen: NSAID)	Treximet™
March 2018	Cinacalcet Hydrochloride Tablets 30 mg (base), 60 mg (base), and 90 mg (base)	Calcimimetic; Calcium regulator	Sensipar™
April 2018	Everolimus Tablets 0.25 mg, 0.5 mg and 0.75 mg	Antineoplastic agent; mTOR Kinase Inhibitor	Zortress™
	Ertapenem Sodium for Injection 1 gram (base)/vial	Antibiotic; Carbapenem	Invanz™
	Miglustat Capsules 100 mg	Endocrine and metabolic agent; Glucosylceramide synthase inhibitor	Zavesca™
May 2018	Phytonadione Tablets 5 mg	Antidote; Vitamin K	Mephyton™
	Colesevelam Hydrochloride Tablets 625mg	Anti-hyperlipidemic; Bile acid sequestrant	Welchol™
	Methylphenidate Hydrochloride for Extended Release Oral Suspension 5 mg/mL	Central nervous system stimulant	Quillivant™ XR
	Tadalafil Tablets 2.5mg, 5mg, 10mg and 20mg	Cardiovascular agent	Cialis™
	Oxybutynin Chloride Transdermal Gel 10% (100mg/packet)	Urinary antispasmodic; Anti-cholinergic/Anti-muscarinic	Gelnique™
June 2018	Clindamycin Phosphate and Benzoyl Peroxide Topical Gel 1.2%/ 3.75%	Anti-acne; Antibacterial	Onexton™
	Buprenorphine Hydrochloride and Naloxone Hydrochloride Sublingual Film 2 mg/0.5 mg, 8 mg/2 mg, 4 mg/1 mg and 12 mg/3 mg	Dependency agent; Opioid medication; Narcotic	Suboxone™ Sublingual Film

References:

- US Food and Drug Administration (FDA). Available at: www.fda.gov
- New Drugs Approvals. Drugs.com. Available at: <https://www.drugs.com/newdrugs.html>

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