

October 2019

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## New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Aklief</b> <sup>®</sup> (trifarotene) Galderma Laboratories	Retinoid receptor agonist	Topical treatment of acne vulgaris in patients 9 years of age and older	October 8, 2019
<b>Amzeeq</b> <sup>™</sup> (minocycline) 4% topical foam Foamix	Tetracyclines	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older	January 2020
<b>Beovu</b> <sup>®</sup> (brolucizumab)* Novartis	Anti-VEGF antibody	Treatment of neovascular (wet) age-related macular degeneration	October 9, 2019
<b>Biorphen</b> <sup>®</sup> (phenylephrine) Eton Pharmaceuticals	Alpha-1 adrenergic receptor agonist	Treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia	November 3, 2019

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Bonsity™</b> (teriparatide) Pfenex	Parathyroid hormone	Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Bonsity reduces the risk of vertebral and nonvertebral fractures; To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy; Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis	TBD
<b>Bortezomib</b> injection Dr. Reddy's	Proteasome inhibitor	Treatment of adult patients with multiple myeloma and treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy.	TBD
<b>Fasenra®</b> (benralizumab) single-dose autoinjector* AstraZeneca	Interleukin-5 receptor (IL-5R) alpha inhibitor	Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype	October 6, 2019
<b>Fiasp®</b> (insulin aspart injection) 100 units/mL PenFill cartridge Novo Nordisk	Insulins	To improve glycemic control in adults with diabetes mellitus	September 25, 2019
<b>Hemady™</b> (dexamethasone) 20 mg tablet† Dexcel Pharma	Corticosteroid	In combination with other antimyeloma products for the treatment of adults with multiple myeloma	TBD
<b>Quzyttir™</b> (cetirizine) injection TerSera Therapeutics	Second generation antihistamine	Treatment of acute urticaria in adults and children 6 months of age and older	TBD

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Relafen™ DS</b> (nabumetone) 1000 mg tablet Carwin Associates	Non-steroidal anti-inflammatory	Relief of signs and symptoms of osteoarthritis and rheumatoid arthritis	September 25, 2019
<b>Reyvow™</b> (lasmiditan)* Eli Lilly	Serotonin 5-HT <sub>1F</sub> receptor agonist	Acute treatment of migraine with or without aura in adults	January 11, 2020
<b>Scenesse®</b> (afamelanotide)*† Clinuvel	Melanocortin receptor 1 agonist	To increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria	TBD
<b>Secuado®</b> (asenapine) transdermal systems Noven Pharmaceuticals	5-HT <sub>2a</sub> and dopamine D <sub>1</sub> /D <sub>2</sub> antagonist	Treatment of adults with schizophrenia	TBD
<b>Trikafta™</b> (elexacaftor/ tezacaftor/ivacaftor; ivacaftor)*† Vertex	Cystic fibrosis transmembrane conductance regulator modulators	Treatment of cystic fibrosis in patients aged 12 years and older who have at least one <i>F508del</i> mutation in the cystic fibrosis transmembrane conductance regulator gene	October 22, 2019
<b>Vumerity™</b> (diroximel fumarate) Biogen and Alkermes	Nrf2 pathway activator	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	November 4, 2019

\*New molecular entity †Orphan Drug TBD: To be determined

## New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Levsin</b> <sup>®</sup> (hyoscyamine sulfate) Mylan	BPI Labs <sup>†</sup>	0.5 mg/mL injection	Peptic ulcer; spastic colitis, spastic bladder, cystitis, pylorospasm, and associated abdominal cramps; irritable bowel syndrome and functional gastrointestinal disorders; neurogenic bladder and neurogenic bowel disturbances; reduce gastrointestinal motility during diagnostic procedures; pancreatitis; heart block; antidote for poisoning by anticholinesterase agents; anesthesia; and urology procedures	October 9, 2019
<b>Soolantra</b> <sup>®</sup> (ivermectin) Galderma	Teva <sup>†</sup>	1% cream	Inflammatory lesions of rosacea	October 15, 2019

†A-rated generic manufacturer

## New authorized brand alternatives

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Drug name Manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Otovel</b> <sup>®</sup> (ciprofloxacin/fluocinolone) Laboratorios Salvat/Arbor	Wilshire Pharmaceuticals	0.3% / 0.025% otic solution	Acute otitis media with tympanostomy tubes in pediatric patients	October 30, 2019
<b>Soolantra</b> <sup>®</sup> (ivermectin) Galderma	Prasco	1% cream	Inflammatory lesions of rosacea	October 16, 2019

## Indications/label updates

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Drug name Manufacturer(s)	Type	Description
<b>Baxdela</b> <sup>®</sup> (delafloxacin) Melinta Therapeutics	New indication	Treatment of adults with community-acquired bacterial pneumonia caused by certain susceptible microorganisms
<b>Botox</b> <sup>®</sup> (onabotulinumtoxinA) Allergan	Expanded indication	Treatment of lower limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
<b>Cinvanti</b> <sup>®</sup> (aprepitant) Heron Therapeutics	Expanded indication	In combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy as a single-dose regimen
<b>Descovy</b> <sup>®</sup> (emtricitabine/tenofovir alafenamide) Gilead	New indication	In at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis to reduce the risk of human immunodeficiency virus-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex
<b>Entresto</b> <sup>®</sup> (sacubitril/valsartan) Novartis	New indication	Treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces N-terminal pro-B-type natriuretic peptide and is expected to improve cardiovascular outcomes.
<b>Erelzi</b> <sup>™</sup> (etanercept-szzs) Sandoz	New indications	Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis; and treatment of adults with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
<b>Farxiga</b> <sup>®</sup> (dapagliflozin) AstraZeneca	New indication	Reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors
<b>Keppra</b> <sup>®</sup> (levetiracetam) UCB Pharma	Expanded indication	Treatment of partial-onset seizures in patients 1 month of age and older
<b>Keppra XR</b> <sup>™</sup> (levetiracetam) UCB Pharma	Expanded indication	Treatment of partial-onset seizures in patients 12 years of age and older

<b>Liletta</b> <sup>®</sup> (levonorgestrel-releasing intrauterine system) Medicines360	Expanded indication	Prevention of pregnancy for up to 6 years
<b>Nplate</b> <sup>®</sup> (romiplostim) Amgen	Expanded indication	Treatment of adults with immune thrombocytopenia who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
<b>Orenitram</b> <sup>®</sup> (treprostinil) United Therapeutics	Expanded indication	Treatment of pulmonary arterial hypertension to delay disease progression and to improve exercise capacity
<b>Stelara</b> <sup>®</sup> (ustekinumab) Janssen	New indication	Treatment of adults with moderately to severely active ulcerative colitis
<b>Tybost</b> <sup>®</sup> (cobicistat) Gilead	Expanded indication	To increase systemic exposure of atazanavir or Prezista <sup>®</sup> (darunavir) (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of human immunodeficiency virus 1 infection in adults and in pediatric patients: weighing at least 35 kg co-administered with atazanavir or weighing at least 40 kg co-administered with darunavir
<b>Ultomiris</b> <sup>®</sup> (ravulizumab-cwvz) Alexion Pharmaceuticals	New indication	Treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy
<b>Wilate</b> <sup>®</sup> (von Willebrand factor/coagulation factor VIII complex [human]) Octapharma	New indication	In adolescents and adults with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and for on-demand treatment and control of bleeding episodes
<b>Xarelto</b> <sup>®</sup> (rivaroxaban) Janssen	New indication	Prophylaxis of venous thromboembolism (VTE) and VTE related death during hospitalization and post hospital discharge in adults admitted for acute illness and are at risk for thromboembolic complications and not at high risk of bleeding
<b>Xigduo</b> <sup>®</sup> XR (dapagliflozin/metformin) extended-release AstraZeneca	New indication	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

<b>Xofluza</b> <sup>®</sup> (baloxavir marboxil) Genentech	Expanded indication	Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are: otherwise healthy, or at high risk of developing influenza-related complications
<b>Zejula</b> <sup>®</sup> (niraparib) GlaxoSmithKline	Expanded indication	Treatment of adults with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status defined by either: (1) A deleterious or suspected deleterious BRCA mutation, or (2) Genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. (3) Select patients for therapy based on an FDA-approved companion diagnostic for Zejula

### Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
<b>Alprazolam</b> Mylan	0.5 mg tablets	Recall	Mylan announced a consumer-level recall of one batch of alprazolam 0.5 mg tablets due to the remote potential for foreign material on the tablets.  Alprazolam tablets are indicated for the management of anxiety disorder, the short-term relief of symptoms of anxiety, and for the treatment of panic disorder, with or without agoraphobia.
<b>Embeda</b> <sup>®</sup> (morphine/naltrexone) Pfizer	Morphine/naltrexone: 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60/2.4 mg, 80 mg /3.2 mg, and 100 mg/4 mg extended release capsules	Discontinuation	Pfizer announced the discontinuation of Embeda extended-release capsules due to business reasons. The discontinuation was not due to safety, efficacy or quality issues. Sales of Embeda will end on November 15, 2019 and the product is anticipated to be unavailable by early 2020.  Embeda is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

<p><b>Ranitidine</b> AvKare, Dr. Reddy's, Novitium and Lannett</p>	<p>AvKare, Dr. Reddy's, and Novitium: 150 mg and 300 mg capsules</p> <p>Lannett: 15 mg/mL oral solution</p>	<p>Recall</p>	<p>AvKare, Dr. Reddy's, Novitium, and Lannett announced voluntary, consumer-level recalls of prescription ranitidine due to potential contamination with N-nitrosodimethylamine (NDMA).</p> <p>Dr. Reddy's initially announced retail level recalls for prescription and over-the-counter (OTC) ranitidine in early October; however, the recall of prescription ranitidine products has been escalated to the consumer level. The recall of OTC ranitidine remains at the retail level.</p> <p>Ranitidine is an OTC and prescription drug. Ranitidine is an H2 (histamine-2) blocker, which decreases the amount of acid created by the stomach. OTC ranitidine is approved to prevent and relieve heartburn associated with acid ingestion and sour stomach.</p> <p>Prescription ranitidine is approved for multiple indications, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease.</p>
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**Key guideline/literature updates**

Topic	Reference
American Academy of Neurology – Vaccine preventable infections and immunization in multiple sclerosis	<a href="#"><i>Neurology</i></a> . August 2019
American College of Cardiology and the American Heart Association – Prevention of Cardiovascular Disease	<a href="#"><i>Journal of the American College of Cardiology</i></a> . September 2019
American Society of Clinical Oncology - Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer	<a href="#"><i>Journal of Clinical Oncology</i></a> . August 2019
American Academy of Neurology and the American Headache Society - Pharmacologic Treatment for Pediatric Migraine Prevention	<a href="#"><i>Neurology</i></a> . September 2019



Topic	Reference
American Academy of Neurology and the American Headache Society - Acute Treatment of Migraine in Children and Adolescents	<a href="#"><u>Neurology</u></a> . September 2019
American Thoracic Society and Infectious Diseases Society of America - Diagnosis and Treatment of Adults with Community-acquired Pneumonia	<a href="#"><u>American Journal of Respiratory and Critical Care Medicine</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers – Version 3.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cutaneous Melanoma – Version 3.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans</u></a> . October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma</u></a> . October 2019

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 2.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue – Version 2.2019	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u></a> October 2019
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation – Version 1.2020	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u></a> October 2019



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