

New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Apadaz [™] (benzhydrocodone/ acetaminophen) [*] KemPharma	Opioid receptor agonist/ acetaminophen	Short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	TBD
Biktarvy [®] (bictegravir/emtricitabine/ tenofovir alafenamide) [*] Gilead	HIV integrase inhibitors/ nucleoside reverse transcriptase inhibitors (NRTI)/ NRTI	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy	February 2, 2018
Dexycu [™] (dexamethasone intraocular suspension) Icon Biosciences	Corticosteroid	Treatment of postoperative inflammation	TBD
Erleada [™] (apalutamide) [*] Janssen Biotech	Androgen receptor antagonist	Treatment of patients with non-metastatic, castration-resistant prostate cancer	February 15, 2018

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
HyperRAB [®] (rabies immune globulin [human]) [†] 300 IU/mL and 1500 IU/5 mL vials Grifols	Vaccine	Postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies, except persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer, who should receive only vaccine	Late April – May 2018
Imbruvica [®] (ibrutinib) tablets Pharmacyclics	Kinase inhibitor	Mantle cell lymphoma; Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL); CLL/SLL with 17p deletion; Waldenström's macroglobulinemia; Marginal zone lymphoma; Chronic graft-versus-host disease after failure of one or more lines of systemic therapy	February 27, 2018
Makena [®] (hydroxyprogesterone caproate) subcutaneous injection [†] AMAG	Progestin	To reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth	Second half of March 2018
Osmolex ER [™] (amantadine) tablets [†] Osmotica	N-methyl-D-aspartate (NMDA) receptor antagonist	Treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients	TBD
Symdeko [™] (tezacaftor/ivacaftor and ivacaftor) [†] Vertex	Cystic fibrosis transmembrane conductance regulator (CFTR) corrector/CFTR potentiator	Treatment of patients with cystic fibrosis aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on <i>in vitro</i> data and/or clinical evidence	February 15, 2018
Symfi Lo [™] (efavirenz/lamivudine/tenofovir disoproxil fumarate) Mylan	Non-nucleoside reverse transcriptase inhibitor/ nucleos(t)ide reverse transcriptase inhibitor (NRTI)/ NRTI	Complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing at least 35 kg	TBD

*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
Namenda XR[®] (memantine) Allergan	Amneal [†] , Par [†] , Apotex [†] , Lupin [†] , Mylan [†] , Sun [†] , Zydus [†]	7 mg, 14 mg, 21 mg and 28 mg extended- release capsules	Moderate to severe dementia associated with Alzheimer's	February 21, 2018 [¥]
Syprine[®] (trientine) Valeant	Teva [†]	250 mg capsules	Wilson's disease	February 9, 2018

[†]A-rated generic manufacturer [¥]Amneal, Lupin, Mylan, and Par; Apotex, Sun, and Zydus are TBD

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Avycaz[®] (ceftazidime/avibactam) Allergan	New indication	Treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by certain susceptible gram-negative microorganisms in patients 18 years and older
Feraheme[®] (ferumoxytol) AMAG	Expanded indication	Treatment of iron deficiency anemia in adults who have intolerance to oral iron or have had unsatisfactory response to oral iron
Imfinzi[®] (durvalumab) AstraZeneca	New indication	Treatment of patients with unresectable stage III non-small cell lung cancer whose disease has not progressed following chemotherapy and radiation therapy
Luzu[®] (luliconazole) Valeant	Expanded indication	Topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis

Drug name Manufacturer(s)	Type	Description
Norditropin® FlexPro (somatropin) NovoNordisk	New indication, updated warnings	Treatment of idiopathic short stature, height standard deviation score < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and growth failure due to Prader-Willi syndrome Two warnings regarding otitis media and cardiovascular disorders in Turner Syndrome and childhood onset adult growth hormone deficiency were removed from the Norditropin FlexPro drug label.
Verzenio™ (abemaciclib) Eli Lilly	Expanded indication	Use in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer
Zytiga® (abiraterone acetate) Janssen	Expanded indication	Treatment of metastatic high-risk castration-sensitive prostate cancer in combination with prednisone

Drug safety news

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Drug name Manufacturer(s)	Description
Clarithromycin products	A new warning will be added to clarithromycin drug labels regarding a potential increased risk of heart problems or death that can occur years after use. This update is based on a large clinical trial which observed an unexpected increase in deaths among patients with coronary heart disease who received a two-week course of clarithromycin that became apparent after patients had been followed for one year or longer. There is no clear explanation for how clarithromycin would lead to more deaths than placebo.
Exondys 51™ (eteplirsen) Sarepta Therapeutics	A <i>Warning and Precaution</i> section was added to the Exondys 51 drug label regarding hypersensitivity reactions.
Ocaliva® (obeticholic acid) Intercept	A new <i>Boxed Warning</i> was added to the Ocaliva drug label regarding hepatic decompensation and failure in incorrectly dosed primary biliary cholangitis patients with Child-Pugh Class B or C decompensated cirrhosis.

Rexulti® (brexpiprazole) Otsuka	An update was added to the <i>Warning and Precautions</i> section of the Rexulti drug label regarding pathological gambling and other compulsive behaviors.
Uloric® (febuxostat) Takeda	An update was added to the <i>Warnings and Precautions</i> section of the Uloric drug label regarding serious skin reactions.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Aminocaproic acid injection Hospira	5 g/20 mL (250 mg/mL) injection	Shortage	Aminocaproic acid injection has been unavailable due to manufacturing delays. Hospira's estimated availability of aminocaproic acid injection is April 2018. Aminocaproic acid injection is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, fresh whole blood transfusions, fibrinogen infusions, and other emergency measures may be required.
Gericare® Eye Wash Kareway Products	4 oz (118 mL) bottle	Recall	Kareway Products conducted a consumer-level recall of Gericare Eye Wash due to potential microbial contamination which compromises sterility.
0.9% sodium chloride irrigation B. Braun Medical	1000 mL plastic container	Recall	B. Braun Medical announced a user-level recall of one lot of sodium chloride irrigation due to a customer complaint reporting particulate matter within the recalled lot. This particulate matter has been identified as polyethylene, which is consistent with the material used to manufacture the container cap.
Sumavel® DosePro® (sumatriptan) Endo	6 mg/0.5 mL injection	Discontinuation	The FDA announced the discontinuation of Endo's Sumavel DosePro 6 mg/0.5 mL injection. The product discontinuation is not due to product quality, safety or efficacy concerns. Sumavel DosePro 4 mg/ 0.5 mL injection was discontinued in October 2016. Sumavel DosePro is indicated in adults for the acute treatment of migraine, with or without aura, and the acute treatment of cluster headache.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Sylatron [®] (peginterferon alfa-2b) Merck	200 mcg, 300 mcg, 600 mcg vials	Discontinuation	<p>The FDA announced the discontinuation of Merck's Sylatron. The product discontinuation is not due to product quality, safety or efficacy concerns. The 200 mcg and 300 mcg vials will be discontinued on or near December 2019, and the 600 mcg vial will be discontinued on or near December 2018.</p> <p>Sylatron is an alpha interferon indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.</p>

Key guideline/literature updates

Topic	Reference
Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older	<i>Morbidity and Mortality Weekly Report</i> . February 2018
Advisory Committee on Immunization Practices Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger	<i>Morbidity and Mortality Weekly Report</i> . February 2018
The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Anticoagulation During Cardiopulmonary Bypass	<i>The Annals of Thoracic Surgery</i> . February 2018
Cardiovascular Disease and Breast Cancer - A Scientific Statement From the American Heart Association	<i>Circulation</i> . February 2018
<i>Clostridium difficile</i> Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America and Society for Healthcare Epidemiology of America	<i>Clinical Infectious Diseases</i> . February 2018
Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease – Mineral and Bone Disorder: Kidney Disease: Improving Global Outcomes 2017 Update	<i>Annals of Internal Medicine</i> . February 2018

Topic	Reference
Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology	<i>Journal of Clinical Oncology</i> . February 2018
The Science Behind Biosimilars – Entering a New Era of Biologic Therapy	<i>Arthritis and Rheumatology</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer – Version 4.2017	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers</i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers</i> . February 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma – Version 2.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma – Version 4.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes – Version 2.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas.</u> February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer – Version 2.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> February 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas</u></i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction – Version 1.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction</u></i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue</u></i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management – Version 2.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Distress Management</u></i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship – Version 3.2017	<i><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship</u></i> . February 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV – Version 1.2018	<i><u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People Living with HIV</u></i> . February 2018



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