

New drugs

[Learn more](#)

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Akynzeo [®] (fosnetupitant/palonosetron) [*] injection Helsinn	Selective NK1 receptor antagonist/5-HT3 receptor antagonist	In combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy	May 2018
Crysvita [®] (burosumab-twza) [†] Ultragenyx, Kyowa Kirin	FGF-23 antagonist	Treatment of X-linked hypophosphatemia in patients ≥ 1 year of age	TBD
Jynarque [™] (tolvaptan) [†] Otsuka	Vasopressin V2-receptor antagonist	To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease	TBD
Tavalisse [™] (fostamatinib) [*] Rigel	Tyrosine kinase inhibitor	Treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to previous treatment	May 2018

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

New generics

[Learn more](#)

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Biltricide [®] (praziquantel) Bayer	Par [†]	600 mg tablets	Infections due to Schistosoma and liver flukes	April 20, 2018
DermOtic [®] (fluocinolone acetonide) Hill Dermaceuticals	Patrin ^{†§}	0.01% ear drops	Eczematous external otitis	TBD
Invanz [®] (ertapenem) Merck	Acs Dobfar Spa [†]	1 gm injection	Bacterial infections	TBD
Zavesca [®] (miglustat) Actelion	Amerigen [†]	100 mg capsules	Type 1 Gaucher disease	April 18, 2018

†A-rated generic manufacturer TBD: To be determined
§Branded generic marketed as Flac

Indications/label updates

[Learn more](#)

Drug name Manufacturer(s)	Type	Description
Afinitor Disperz [®] (everolimus) Novartis	Expanded indication	Adjunctive treatment of patients ≥ 2 years of age with tuberous sclerosis complex-associated partial-onset seizures
Emend [™] (fosaprepitant dimeglumine) Merck	Expanded indication	Prevention of nausea and vomiting associated with emetogenic cancer chemotherapy in patients ≥ 6 months of age

Drug name Manufacturer(s)	Type	Description
Exparel [®] (bupivacaine liposome) Pacira	New indication	Postsurgical regional analgesia
Opdivo [®] (nivolumab) Bristol-Myers Squibb	New indication	In combination with Yervoy for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma
Rubraca [®] (rucaparib) Clovis Oncology	New indication	Maintenance treatment of adults with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
Tagrisso [®] (osimertinib) Astra Zeneca	New indication	First-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations
Trelegy [®] Ellipta [®] (fluticasone furoate/umeclidinium/vilanterol) GlaxoSmithKline, Innoviva	Expanded indication	Maintenance treatment of airflow obstruction for chronic obstructive pulmonary disease
Vonvendi [®] [von Willebrand factor (recombinant)] Shire	Expanded indication	Perioperative management of bleeding in adults diagnosed with von Willebrand disease
Yervoy [®] (ipilimumab) Bristol-Myers Squibb	New indication	In combination with Opdivo for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma

Drug safety news

[Learn more](#)

Drug name Manufacturer(s)	Description
Diprolene® / Diprolene® AF (augmented betamethasone dipropionate) Merck	The <i>Warnings and Precautions</i> section of the Diprolene ointment, Diprolene AF cream and Diprolene lotion drug labels were updated with information regarding visual disturbance.
Flagyl® (metronidazole) Pfizer	The <i>Warnings</i> section of the Flagyl drug label was updated with information regarding the risk of hepatotoxicity and death in patients with Cockayne Syndrome.
Brand Lamictal® (lamotrigine) and generic lamotrigine products	Lamictal can cause a rare but very serious reaction called hemophagocytic lymphohistiocytosis (HLH) that excessively activates the immune system. HLH causes severe inflammation throughout the body and can lead to hospitalization and death, especially if the reaction is not diagnosed and treated quickly.
Olux® (clobetasol propionate) Mylan	The <i>Warnings and Precautions</i> section of the Olux drug label was updated with information regarding ophthalmic adverse reactions.
Rituxan® (rituximab) Biogen and Genentech	The <i>Warnings and Precautions</i> section of the Rituxan drug label was updated with information regarding embryo-fetal toxicity.
Samsca® (tolvaptan) Otsuka	The <i>Boxed Warning</i> , <i>Contraindications</i> , and <i>Warnings and Precautions</i> sections of the Samsca drug label were updated with information regarding use in patients with autosomal dominant polycystic kidney disease outside of the FDA approved Risk Evaluation and Mitigation Strategy and the risk of hepatotoxicity.
Solu-Medrol® (methylprednisolone sodium succinate) Pfizer	The <i>Contraindications</i> section of the Solu-Medrol drug label was updated with information regarding the 40 mg formulation including lactose monohydrate produced from cow's milk. The <i>Warnings and Precautions</i> section was also updated to include information regarding the treatment of acute allergic conditions.
Viberzi® (eluxadolone) Allergan	The <i>Warnings and Precautions</i> section of the Viberzi drug label was updated with information regarding constipation.

Drug recalls/withdrawals/shortages/discontinuations

[Learn more](#)

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
BD PosiFlush™ Heparin Lock Flush Syringe, BD™ Pre-Filled Normal Saline Syringe BD Medical	Syringes	Recall	BD Medical announced a recall of some lots of heparin lock flush and normal saline syringes due to a potential for contamination with <i>Serratia marcescens</i> bacterium.
Levetiracetam, levofloxacin and linezolid injection products AuroMedics	Levetiracetam 500 mg/100 mL, 1000 mg/100 mL, and 1500 mg/100 mL injection products; Levofloxacin 250 mg/50 mL, 500 mg/100 mL, and 750 mg/150 mL injection products; Linezolid 600 mg/300 mL injection	Recall	AuroMedics announced a user-level recall of all remaining unexpired lots of levetiracetam, levofloxacin, and linezolid injection products due to leaking bags.
Easy Touch® Insulin Syringe MHC Medical Products	29G 1 mL ½ inch and 29G 0.5 mL ½ inch insulin syringes	Recall	MHC Medical Products announced the voluntary recall of two lots of Easy Touch insulin syringe 29G 1 mL ½ inch and Easy Touch insulin syringe 29G 0.5 mL ½ inch syringe products, due to mislabeling. While the case carton and poly bag (immediate package) are correctly labeled, some retail shelf cartons are incorrectly labeled as lot # 45016, which is associated with the Easy Touch 29G, 0.5 mL ½ inch insulin syringe.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Olysio® (simeprevir) Janssen	150 mg capsule	Discontinuation	<p>Janssen announced the discontinuation of Olysio due to a significant decline in utilization and the availability of effective therapies, such as pangenotypic combination regimens, which address the current medical need in treating hepatitis C virus (HCV) infection.</p> <p>The discontinuation was not due to any safety, efficacy or quality issues. Janssen will voluntarily withdraw the New Drug Application for Olysio in the U.S. and product will no longer be available, effective May 25, 2018.</p> <p>Olysio is indicated for the treatment of adults with chronic HCV infection in combination with Sovaldi® (sofosbuvir) in patients with HCV genotype 1 without cirrhosis or with compensated cirrhosis and in combination with peginterferon alfa and ribavirin in patients with HCV genotype 1 or 4 without cirrhosis or with compensated cirrhosis.</p>
Progesterone injection Fresenius Kabi, Teva, West-Ward	500 mg/10 mL injection	Shortage	<p>Progesterone injection has been unavailable due to manufacturing delays and increased demand for the drug.</p> <p>Fresenius Kabi estimates that the product will be available by the second quarter of 2018. Teva estimates that the product will be available by mid-May 2018. West-Ward estimates that product will be available in May 2018.</p> <p>Progesterone injection is indicated in amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.</p>
Talwin™ (pentazocine) Hospira	30 mg/mL injection	Discontinuation	<p>The FDA announced the discontinuation of Talwin 30 mg/mL injection. The product discontinuation is not due to product quality, safety or efficacy concerns.</p> <p>Talwin is indicated for the management of pain and used as a preoperative or preanesthetic and as a supplement for surgical anesthesia.</p>

Key guideline/literature updates

Topic	Reference
Breast Cancer Screening in Women at Higher-Than-Average Risk: American College of Radiology	<i>Journal of the American College of Radiology</i> . March 2018
Disease-modifying therapies for adults with multiple sclerosis – American Academy of Neurology	<i>Neurology</i> . April 2018
Evaluation and Management of Testosterone Deficiency – American Urological Association	<i>American Urological Association</i> . February 2018
Hoarseness (Dysphonia) - American Academy of Otolaryngology - Head and Neck Surgery Foundation	<i>Otolaryngology–Head and Neck Surgery</i> . March 2018
Initial Management of Acute Pancreatitis - American Gastroenterological Association Institute	<i>Gastroenterology</i> . March 2018
Latent Tuberculosis Infection – World Health Organization	<i>World Health Organization</i> . April 2018
Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Adults – U.S. Preventive Services Task Force	<i>U.S. Preventative Services Task Force</i> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Risk Reduction</i> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia</i> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma – Version 3.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</i> . April 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 4.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer</u> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 4.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer</u> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma</u> . April 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection – Version 2.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection</u> . April 2018



optum.com/optumrx

OptumRx specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners. This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxHighlights is published by the OptumRx Clinical Services Department.

© 2018 Optum, Inc. All rights reserved.