

## New drugs

[Learn more](#)

| Drug name<br>Manufacturer(s)  | Therapeutic category  | Indication(s)   | Launch information        |
|---|---|---|---------------------------|
| <b>Breztri Aerosphere™</b><br>(budesonide/glycopyrrolate/<br>formoterol)<br>AstraZeneca | Corticosteroid/ long-acting<br>muscarinic receptor antagonist/<br>long-acting beta 2 adrenergic<br>receptor agonist | Maintenance treatment of patients with chronic obstructive<br>pulmonary disease   | August 2, 2020            |
| <b>Byfavo™</b> (remimazolam)*<br>Cosmo Pharmaceuticals and<br>Acacia Pharma             | Benzodiazepine  | Induction and maintenance of procedural sedation in adults<br>undergoing procedures lasting 30 minutes or less  | 2 <sup>nd</sup> half 2020 |
| <b>Hulio®</b> (adalimumab-fkjp) <sup>§</sup><br>Mylan                                   | Tumor necrosis factor inhibitor   | Treatment of rheumatoid arthritis, juvenile idiopathic arthritis,<br>psoriatic arthritis, ankylosing spondylitis, adult Crohn's<br>disease, ulcerative colitis, and plaque psoriasis  | July 31, 2023             |
| <b>Inqovi®</b><br>(decitabine/cedazuridine) <sup>†*</sup><br>Astex Pharmaceuticals      | Nucleoside metabolic inhibitor  | Treatment of adult patients with myelodysplastic syndromes<br>(MDS), including previously treated and untreated, de novo<br>and secondary MDS with the following French-American-<br>British subtypes (refractory anemia, refractory anemia with<br>ringed sideroblasts, refractory anemia with excess blasts, and<br>chronic myelomonocytic leukemia) and intermediate-1,<br>intermediate-2, and high-risk International Prognostic Scoring<br>System groups | TBD                       |

|   |   |   |  |
|---|---|---|--|
| <p><b>Monjuvi</b>® (tafasitamab-cxix)<sup>†*</sup><br/>Morphosys and Incyte</p>                 | <p>Fc-modified monoclonal antibody</p>          | <p>In combination with Revlimid® (lenalidomide) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant</p>                      | <p>August 3, 2020</p>  |
| <p><b>Pataday</b>® Once Daily Relief Extra Strength<br/>(olopatadine)<sup>±</sup><br/>Alcon</p> | <p>Antihistamine</p>                            | <p>Temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander</p>   | <p>September 2020 (online retailers);<br/>February 2021 (retail sites)</p> |
| <p><b>Qwo</b>™ (collagenase clostridium histolyticum-aaes)<br/>Endo</p>                         | <p>Protease enzyme</p>                          | <p>Treatment of moderate to severe cellulite in the buttocks of adult women</p>   | <p>Spring 2021</p>   |
| <p><b>Rukobia</b>™ (fostemsavir)*<br/>ViiV Healthcare</p>                                       | <p>HIV attachment inhibitor</p>                 | <p>In combination with other antiretroviral(s), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations</p> | <p>July 7, 2020</p>  |
| <p><b>Tecartus</b>™ (brexucabtagene autoleucl)<sup>†*</sup><br/>Gilead</p>                      | <p>Chimeric antigen receptor T cell therapy</p> | <p>Treatment of adult patients with relapsed or refractory mantle cell lymphoma</p>   | <p>July 24, 2020</p>   |
| <p><b>Tralement</b>™ (trace elements)<br/>American Regent</p>                                   | <p>Trace element</p>                            | <p>In adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated</p>   | <p>TBD</p>   |
| <p><b>Upneeq</b>™ (oxymetazoline)<br/>Osmotica Pharmaceuticals</p>                              | <p>Alpha-adrenergic receptor agonist</p>        | <p>Treatment of acquired blepharoptosis in adults</p>   | <p>August 2020</p>   |

|  |                                  |   |             |
|--|----------------------------------|---|-------------|
| <b>Wynzora®</b><br>(calcipotriene/betamethasone dipropionate)<br>MC2 Therapeutics              | Vitamin D analog/ corticosteroid | Topical treatment of plaque psoriasis in patients 18 years of age and older                                 | TBD         |
| <b>Xeglyze™</b> (abametapir)*<br>Dr. Reddy   | Metalloprotease inhibitor        | Topical treatment of head lice infestation in patients 6 months of age and older                            | TBD         |
| <b>Xywav™</b><br>(calcium, magnesium, potassium, and sodium oxybates)†<br>Jazz Pharmaceuticals | Dopamine receptor agonist        | Treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy | End of 2020 |

\*New molecular entity; †Orphan Drug; ±New over-the-counter approval; §Biosimilar; TBD: To be determined

**New generics**

[Learn more](#)

| Drug name<br>Manufacturer(s)                 | Generic manufacturer(s) | Strength(s) &<br>dosage form(s) | Therapeutic use  | Launch information |
|--|-------------------------|---------------------------------|------------------|--------------------|
| <b>Demser®</b> (metyrosine)<br>Bausch Health | Amneal†±                | 250 mg capsules                 | Pheochromocytoma | July 29, 2020      |

†A-rated generic manufacturer ±Granted 180 days of marketing exclusivity

## Indications/label updates

[Learn more](#)

| Drug name<br>Manufacturer(s)   | Type                         | Description  |
|--|------------------------------|--|
| <b>Botox</b> <sup>®</sup> (onabotulinumtoxinA)<br>AbbVie and Allergan        | Expanded indication          | Treatment of spasticity in patients 2 years of age and older   |
| <b>Dysport</b> <sup>®</sup> (abobotulinumtoxinA)<br>Ipsen Biopharmaceuticals | Expanded indication          | Treatment of spasticity in patients 2 years of age and older   |
| <b>Epidiolex</b> <sup>®</sup> (cannabidiol)<br>Greenwich Biosciences         | New and expanded indications | Treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex in patients 1 years of age and older  |
| <b>Evotaz</b> <sup>®</sup> (atazanavir/cobicistat)<br>Bristol-Myers Squibb   | Expanded indication          | In combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 infection in adults and pediatric patients weighing at least 35 kg   |
| <b>Prezcobix</b> <sup>®</sup> (darunavir/cobicistat)<br>Janssen              | Expanded indication          | In combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 infection in treatment naïve and treatment-experienced adults and pediatric patients weighing at least 40 kg with no darunavir resistance-associated substitutions |
| <b>Qutenza</b> <sup>®</sup> (capsaicin)<br>Averitas Pharma                   | Expanded indication          | In adults for the treatment of neuropathic pain associated with postherpetic neuralgia and for neuropathic pain associated with diabetic peripheral neuropathy of the feet   |
| <b>Stelara</b> <sup>®</sup> (ustekinumab)<br>Janssen                         | Expanded indication          | Treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy  |
| <b>Tecentriq</b> <sup>®</sup> (atezolizumab)<br>Roche                        | New indication               | Treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma   |
| <b>Tremfya</b> <sup>®</sup> (guselkumab)<br>Janssen                          | New indication               | Treatment of adult patients with active psoriatic arthritis  |
| <b>Vectical</b> <sup>®</sup> (calcitriol)<br>Galderma                        | Expanded indication          | Topical treatment of mild to moderate plaque psoriasis in adults and pediatric patients 2 years and older  |

## Drug safety news

[Learn more](#)

| Drug name<br>Manufacturer(s) | Description   |
|------------------------------|---|
| <b>Naloxone</b>              | The FDA announced that in order to reduce the risk of death from opioid overdose, healthcare providers should discuss the availability of naloxone and consider prescribing it to patients who are prescribed opioid pain relievers, patients who are prescribed medicines to treat opioid use disorder, and for other patients at increased risk of opioid overdose. |

## Drug recalls/withdrawals/shortages/discontinuations

[Learn more](#)

| Drug name<br>Manufacturer(s)           | Dosage form(s)   | Type       | Description  |
|--|--|------------|--|
| <b>Fosaprepitant</b><br>Fresenius Kabi | 150 mg/ 10 mL injection  | Recall     | <p>Fresenius Kabi announced a voluntary user-level recall of some lots of fosaprepitant injection because the carton label and product insert incorrectly state the quantity of excipient edetate disodium as 5.4 mg/vial rather than the actual amount of 18.8 mg/vial.</p> <p>Fosaprepitant for injection, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin; and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.</p> |
| <b>Heparin</b><br>B. Braun Medical     | 20,000 units per 500 mL in 5% dextrose,<br>25,000 units per 500 mL in 5% dextrose,<br>25,000 units per 250 mL in 5% dextrose injection | Withdrawal | <p>B. Braun Medical announced a voluntary, consumer-level withdrawal of several lots of heparin sodium in 5% dextrose injection because of ongoing changes that B. Braun is performing to ensure their heparin products meet certain potency requirements.</p> <p>Heparin sodium is indicated for prophylaxis and treatment of venous thrombosis and pulmonary embolism; prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation; treatment of acute and chronic consumption coagulopathies (disseminated intravascular coagulation); prevention of clotting in arterial and cardiac surgery; prophylaxis and treatment of peripheral</p>              |

|   |  |          |  |
|---|--|----------|--|
|   |  |          | arterial embolism; and anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.   |
| <p><b>Metformin extended-release (ER)</b></p> <p>Granules Pharmaceuticals, Lupin, and Major</p> | <p>Lupin, Major: 500 mg ER tablets</p> <p>Granules Pharmaceuticals: 750 mg ER tablets</p> <p>Lupin: 1000 mg ER tablets</p> | Recall   | <p>Several manufacturers announced voluntary, consumer-level recalls of metformin ER tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit.</p> <p>Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.</p>   |
| <p><b>Nizatidine</b></p> <p>Teva and Amneal</p>   | <p>Teva: 150 mg &amp; 300 mg capsules</p> <p>Amneal: 15 mg/mL oral solution</p>  | Shortage | <p>The drug shortage of nizatidine is ongoing. Per Teva and Amneal, nizatidine capsules and oral solution are backordered and the estimated availability dates are unknown at this time.</p> <p>Nizatidine is indicated for the treatment of active duodenal ulcer; maintenance therapy for duodenal ulcer patients; treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis, and associated heartburn due to gastroesophageal reflux disease; and for the treatment of active benign gastric ulcer.</p> |

**Key guideline/literature updates**

| Topic  | Reference  |
|--|--|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma - Version 3.2020 | <p><a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: AIDS-Related Kaposi Sarcoma.</i></a></p> <p>July 2020</p> |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 6.2020              | <p><a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer.</i></a></p> <p>July 2020</p>              |

|  |   |
|--|---|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 5.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 2.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 3.2020                               | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u></a><br>July 2020                               |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 1.2021   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes - Version 1.2021 | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes.</u></a><br>July 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 2.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 2.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 2.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u></a><br>July 2020   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 2.2020   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u></a><br>July 2020   |

|  |   |
|--|---|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 2.2020                                 | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u></a><br>July 2020                                 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 3.2020                                     | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u></a><br>July 2020                                     |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal - Version 1.2020 | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal.</u></a><br>July 2020 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 1.2020                   | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u></a><br>July 2020                   |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Survivorship - Version 2.2020                                      | <a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Survivorship.</u></a><br>July 2020                                      |



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](https://www.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.

© 2020 Optum, Inc. All rights reserved.