

RxHighlights

July 2022

New drugs

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|-------------------------------------|---|--------------------|
| Kyzatrex® (testosterone undecanoate) Marius | Testosterone replacement therapy | Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone, luteinizing hormone) above the normal range; Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone deficiency, pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range. | TBD |
| Ultomiris® (ravulizumab-cwvz) 245 mg/3.5 mL solution in a single dose prefilled cartridge Alexion | C5 complement inhibitor | Treatment of adult patients with paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy | TBD |
| Zonisade™ (zonisamide) Azurity | Anticonvulsant | Adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients 16 years and older | TBD |
| Zoryve™ (roflumilast) Arcutis Biotherapeutics | Phosphodiesterase-4 inhibitor | Topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older | August 2, 2022 |

TBD: To be determined

New generics

| Drug name manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|---|--|--|--|--------------------|
| Toviaz® (fesoterodine) Pfizer | Aurobindo†, Dr. Reddy's†, Zydus† and Ascend/Alkem† | 4 mg and 8 mg extended-release tablets | Overactive bladder, neurogenic detrusor overactivity | July 3, 2022 |

†A-rated generic manufacturer

New authorized brand alternatives

| Drug name manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|--|----------------------------|---|---|--------------------|
| Suprep® Bowel Prep Kit (sodium sulfate/potassium sulfate/magnesium sulfate) Braintree | Affordable Pharmaceuticals | sodium sulfate 17.5g/ potassium sulfate 3.13g/ magnesium sulfate 1.6g) per 6 oz. oral solution | Cleansing of the colon as a preparation for colonoscopy | July 8, 2022 |

Indications/Label updates

| Drug name manufacturer(s) | Type | Description |
|--|---------------------|---|
| Benlysta® (belimumab) GSK | Expanded indication | Treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy |
| Comirnaty® (COVID-19 vaccine, mRNA) Pfizer/BioNTech | Expanded indication | Active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older |

| Drug name manufacturer(s) | Type | Description |
|--|-----------------------------------|---|
| COVID-19 vaccine, adjuvanted Novavax | Emergency use authorization (EUA) | <p>The FDA announced the EUA of Novavax's COVID-19 vaccine, adjuvanted, for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.</p> <p>The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices unanimously recommended a primary series of 2 doses of Novavax COVID-19 vaccine, adjuvanted for individuals 18 years of age and older, under the EUA issued by the FDA.</p> |
| Diacomit® (stiripentol) Biocodex | Expanded indication | Treatment of seizures associated with Dravet syndrome in patients 6 months to less than 2 years of age years of age and weighing 7 kg or more and taking clobazam |
| Opzelura® (ruxolitinib) Incyte | New indication | Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older |
| Stelara® (ustekinumab) Janssen | Expanded indication | Treatment of patients 6 years or older with active psoriatic arthritis |
| Xalkori® (crizotinib) Pfizer | New indication | Treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor that is anaplastic lymphoma kinase positive |

Drug recalls/Withdrawals/Shortages/Discontinuations

| Drug name manufacturer(s) | Strength(s) and dosage form(s) | Type | Description |
|--|--|--------|---|
| Insulin glargine Mylan | 100 units/mL injection | Recall | The FDA announced a voluntary consumer-level recall of one lot of Mylan's interchangeable biosimilar insulin glargine (insulin glargine-yfgn) prefilled pens because of the potential for the label to be missing on some pens. Insulin glargine is indicated to improve glycemic control in patients with type 1 or type 2 diabetes mellitus. |
| Magnesium citrate saline laxative oral solution Vi-Jon | Various lemon, cherry and grape flavor 10 fl. oz. oral solution products | Recall | Vi-Jon announced an expansion to the voluntary consumer-level recall of various brands of magnesium citrate saline laxative oral solution products to include all lots of flavors because they contain <i>Gluconacetobacter liquefaciens</i> . Magnesium citrate saline laxative is used for relief of occasional constipation. |

Key guideline/Literature updates

| Topic | Reference |
|--|---|
| Centers for Disease Control and Prevention – Monkeypox and Smallpox Vaccine Guidance | <i>Centers for Disease Control and Prevention</i> . June 2022 |
| Endocrine Society - Management of Hyperglycemia in Hospitalized Adult Patients in Non-Critical Care Settings | <i>The Journal of Clinical Endocrinology & Metabolism</i> . June 2022 |
| National Institutes of Health – COVID-19 Treatment | <i>COVID-19 Treatment Guidelines</i> . August 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 5 .2022 | <i>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</i> . July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer - Version 1.2023 | <i>NCCN Clinical Practice Guidelines in Oncology: Bone Cancer</i> . August 2022 |

| Topic | Reference |
|---|--|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 1.2023 | <i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia.</i> August 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 3.2022 | <i>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 2.2022 | <i>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 2.2023 | <i>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</i> August 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 1.2023 | <i>NCCN Clinical Practice Guidelines in Oncology: Occult Primary.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 3.2022 | <i>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers - Version 1.2023 | <i>NCCN Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening - Version 2.2022 | <i>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</i> July 2022 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 2.2022 | <i>NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology.</i> July 2022 |



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