

# RxHighlights

February 2024

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## New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Amtagvi™</b> (lifileucel) <sup>†</sup> Iovance Biotherapeutics	Tumor-derived autologous T cell immunotherapy	Treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor	February 22, 2024
<b>Aurlumyn™</b> (iloprost) <sup>†</sup> Eicos Sciences	Vasodilator	Treatment of severe frostbite in adults to reduce the risk of digit amputations	TBD
<b>Eohilia™</b> (budesonide) <sup>†</sup> Takeda	Corticosteroid	12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis	February 14, 2024
<b>Exblifep®</b> (cefepime/enmetazobactam)* Allegra Therapeutics	Beta-lactam/b-lactamase inhibitor	Treatment of patients 18 years of age and older with complicated urinary tract infections including pyelonephritis, caused by the following susceptible microorganisms: <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Pseudomonas aeruginosa</i> , <i>Proteus mirabilis</i> , and <i>Enterobacter cloacae</i> complex	TBD

\*New molecular entity; <sup>†</sup>Orphan drug; TBD: To be determined

## New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
<b>Simlandi</b> <sup>®</sup> (adalimumab-ryvk) Alvotech and Teva	Tumor necrosis factor	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa and uveitis	TBD
<b>Udenyca</b> <sup>®</sup> <b>Onbody</b> <sup>™</sup> (pegfilgrastim-cbqv) Coherus	Hematological Agents	For adult patients to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia; or increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome)	February 21, 2024

TBD: To be determined

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## New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Alrex</b> <sup>®</sup> (loteprednol) Bausch and Lomb	Armas <sup>†</sup>	0.2% ophthalmic suspension	Seasonal allergic conjunctivitis	February 9, 2024
<b>BromSite</b> <sup>®</sup> (bromfenac) Sun	Lupin <sup>†</sup>	0.075% ophthalmic solution	Postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery	February 13, 2024
<b>Emflaza</b> <sup>®</sup> (deflazacort) PTC Therapeutics	Aurobindo <sup>†</sup>	6 mg, 18 mg, 30 mg, 36 mg tablets	Duchenne muscular dystrophy	February 9, 2024
<b>Rectiv</b> <sup>®</sup> (nitroglycerin) AbbVie	Cosette <sup>†§</sup>	0.4% rectal ointment	Pain associated with chronic anal fissure	February 23, 2024

†A-rated generic manufacturer; §180-day market exclusivity

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### New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
<b>Alrex</b> <sup>®</sup> (loteprednol) Bausch and Lomb	Bausch and Lomb	0.2% ophthalmic suspension	Seasonal allergic conjunctivitis	February 9, 2024
<b>BromSite</b> <sup>®</sup> (bromfenac) Sun	Sun	0.075% ophthalmic solution	Postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery	February 13, 2024

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### Indications/Label updates

Drug name manufacturer(s)	Type	Description
<b>Biktary</b> <sup>®</sup> (bictegravir/emtricitabine/tenofovir alafenamide) Gilead	Expanded indication	Treatment of human immunodeficiency virus type 1 infection in adults and pediatric patients weighing at least 14 kg to replace the current antiretroviral regimen in those who are virologically-suppressed on a stable antiretroviral regimen with <i>no known or suspected substitutions associated with resistance to bictegravir or tenofovir</i>
<b>Onivyde</b> <sup>®</sup> (irinotecan liposome injection) Ipsen	New indication	In combination with oxaliplatin, fluorouracil and leucovorin for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma
<b>Tagrisso</b> <sup>®</sup> (osimertinib) AstraZeneca	Expanded indication	In combination with pemetrexed and platinum-based chemotherapy, for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
<b>Veklury</b> <sup>®</sup> (remdesivir) Gilead	Expanded indication	Treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 kg) who are: (1) hospitalized, or (2) not hospitalized and have mild-to-moderate COVID-19 and, are at high risk for progression to severe COVID-19, including hospitalization or death

Drug name manufacturer(s)	Type	Description
<b>Xolair®</b> (omalizumab) Novartis	New indication	The reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy

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**Drug safety news / Drug updates**

Drug name manufacturer(s)	Description
<b>COVID-19 vaccines (Omicron variant XBB.1.5)</b> Pfizer/BioNTech, Moderna, and Novavax	The Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices voted unanimously that another dose of one of the 2023-2024 (monovalent, XBB containing) COVID-19 vaccines should be given to individuals 65 years of age and older.

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**Drug recalls/Withdrawals/Shortages/Discontinuations**

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
<b>Eye ointment products</b> Brassica Pharma	Various	Recall	Brassica Pharma announced a consumer level recall of multiple lots of eye ointment products because of potential lack of sterility noted during an inspection conducted by the FDA.  These eye ointments are used to temporarily relieve burning and irritation of the eye and discomfort due to dryness of the eye or exposure to wind or sun, and as a protectant against further irritation.

## Key guideline/Literature updates

Topic	Reference
Allergy Immunology Joint Task Force on Practice Parameters - Anaphylaxis	<a href="#"><i>Annals of Allergy, Asthma &amp; Immunology</i></a> . December 2023
American Society of Colon and Rectal Surgeons - Management of Inherited Adenomatous Polyposis Syndromes	<a href="#"><i>Diseases of the Colon &amp; Rectum</i></a> . February 2024
National Institutes of Health – Final COVID-19 Treatment Guidelines	<a href="#"><i>National Institutes of Health</i></a> . February 2024
Pediatric Infectious Diseases Society and the Infectious Diseases Society of America - Diagnosis and Management of Acute Bacterial Arthritis in Pediatrics	<a href="#"><i>Journal of the Pediatric Infectious Diseases Society</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia - Version 1.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 3.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cervical Cancer - Version 2.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 3.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 2.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous - Version 1.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Cutaneous</i></a> . February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 1.2024	<a href="#"><i>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes</i></a> .

Topic	Reference
	February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroblastoma - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Neuroblastoma.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 4.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Central Nervous System Cancers.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 3.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection - Version 2.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.</u></a> February 2024

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u></a> February 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Palliative Care - Version 1.2024	<a href="#"><u>NCCN Clinical Practice Guidelines in Oncology: Palliative Care.</u></a> February 2024



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