

RxHighlights

January 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Zelsuvi™ (berdazimer)* Ligand Pharmaceuticals	Nitric oxide-releasing compound	Topical treatment of molluscum contagiosum in adults and pediatric patients one year of age and older	Second Half of 2024

*New molecular entity

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Gralise® (gabapentin) Almatica	Zydus†	300 mg and 600 mg tablets	Postherpetic neuralgia	January 25, 2024
Indocin® (indomethacin) Zyla Life Sciences	ANI Pharmaceuticals ^{is}	25 mg/5 mL oral suspension	Rheumatoid arthritis; ankylosing spondylitis; osteoarthritis; acute painful shoulder (bursitis and/or tendinitis); and acute gouty arthritis	January 16, 2024
Korlym® (mifepristone) Corcept Therapeutics	Teva†	300 mg tablets	Control hyperglycemia secondary to hypercortisolism in adults with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery	January 19, 2024

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Nascoba [®] (cyanocobalamin) Par	Lupin [†] , Padagis [†]	500 mcg/0.1 mL nasal spray	Vitamin B12 maintenance therapy in adults with pernicious anemia; treatment of dietary, drug-induced, or malabsorption-related vitamin B12 deficiency not due to pernicious anemia; prevention of vitamin B12 deficiency in adults with vitamin B12 requirements in excess of normal	December 28, 2023
Prolensa [®] (bromfenac) Bausch Health	Lupin [†] §	0.07% ophthalmic solution	Postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery	January 9, 2024

[†]A-rated generic manufacturer
[§]180-day market exclusivity

New authorized brand alternatives

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Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Farxiga [®] (dapagliflozin) AstraZeneca	Prasco	5 mg and 10 mg tablets	Reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular (CV) death, and hospitalization for heart failure (HF) in adults with chronic kidney disease at risk of progression; reduce the risk of CV death, hospitalization for HF, and urgent HF visit in adults with HF; reduce the risk of hospitalization for HF in adults with type 2 diabetes mellitus (T2DM) and either established CV disease or multiple CV risk factors; adjunct to diet and exercise to improve glycemic control in adults with T2DM	January 3, 2024

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Xigduo® XR (dapagliflozin/metformin) AstraZeneca	Prasco	2.5 mg/1000 mg, 5 mg/500 mg, 5 mg/1000 mg; 10 mg/500 mg and 10 mg/51000 mg extended-release tablets	Adjunct to diet and exercise to improve glycemic control in adults with T2DM	January 3, 2024

Indications/Label updates

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Drug name manufacturer(s)	Type	Description
Avycaz® (ceftazidime/avibactam) AbbVie	Expanded indications	For the pediatric population from birth (at least 31 weeks gestational age) for the treatment of complicated intraabdominal infections; complicated urinary tract infections, including pyelonephritis; and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia
Balversa® (erdafitinib) Johnson & Johnson	Updated indication, accelerated approval converted to full approval	Treatment of adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy
Casgevy™ (exagamglogene autotemcel) Vertex	New orphan indication	Treatment of patients aged 12 years and older with transfusion-dependent β -thalassemia
Dupixent® (dupilumab) Regeneron and Sanofi	Expanded indication	Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis
Gammagard Liquid® (immune globulin infusion [human] 10% solution) Takeda	New indication	A therapy to improve neuromuscular disability and impairment in adult patients with chronic inflammatory demyelinating polyneuropathy

Drug name manufacturer(s)	Type	Description
Hyqvia® (immune globulin infusion 10% [human] with recombinant human hyaluronidase) Takeda	New orphan indication	Treatment of chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults
Keytruda® (pembrolizumab) Merck	Expanded indication	In combination with chemoradiotherapy, for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer
	Updated indication, accelerated approval converted to full approval	Treatment of patients with hepatocellular carcinoma secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen
Piqray® (alpelisib) Novartis	Expanded indication	In combination with fulvestrant for the treatment of adults with hormone receptor positive, human epidermal growth factor receptor 2 negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen

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Drug safety news / Drug updates

Drug name manufacturer(s)	Description
Bicillin® L-A (penicillin G benzathine) Pfizer	Pfizer’s Bicillin L-A injection has been a shortage since April 2023 due to increased demand. To bolster supply, the FDA is coordinating with Laboratories Delbert in conjunction with Provepharm and Direct Success to temporarily import their penicillin G benzathine product, Extencilline (benzathine benzylpenicillin), into the U.S. This product is not FDA-approved but is being given special authorization due to the shortage.
Glucagon-like peptide-1 receptor agonists (GLP-1 RAs)	The FDA announced results from a preliminary evaluation did not show a causal link between suicidal thoughts or actions in patients treated with GLP-1 RAs.
Prolia® (denosumab) Prolia	The FDA announced the addition of a <i>Boxed Warning</i> to the Prolia drug label regarding the risk of severe hypocalcemia in patients with advanced chronic kidney disease

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Robitussin® Honey CF Max Day Adult, Robitussin Honey CF Max Nighttime Adult Haleon	Various	Recall	<p>Haleon announced a consumer level recall of eight lots of Robitussin Honey CF Max Day Adult and Robitussin Honey CF Max Nighttime Adult to the consumer level due to microbial contamination.</p> <p>Robitussin Honey CF Max Day and Nighttime are cough syrups indicated for the temporary relief of symptoms occurring with cold or flu, hay fever, or other respiratory allergies.</p>
Vonvendi® (von Willebrand factor, recombinant) Takeda	650 IU	Withdrawal	<p>Takeda announced a consumer level withdrawal of two lots of Vonvendi because of misprinted product labels with an incorrect expiration date.</p> <p>Vonvendi is indicated for use in adults diagnosed with von Willebrand disease (VWD) for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, routine prophylaxis to reduce frequency of bleeding episodes in patients with severe Type 3 VWD receiving on-demand therapy.</p>
Zenzedi® (dextroamphetamine) Azurity	30 mg tablets	Recall	<p>Azurity announced a consumer level recall of one lot of Zenzedi 30 mg tablets because a bottle labeled as Zenzedi contained carbinoxamine tablets.</p> <p>Zenzedi is indicated for the treatment of narcolepsy and attention deficit disorder with hyperactivity.</p>

Key guideline/Literature updates

Topic	Reference
American Diabetes Association - Standards of Care in Diabetes 2024	<u>Diabetes Care</u> . January 2024
American Thoracic Society – Management of Adults with Acute Respiratory Distress Syndrome	<u>American Journal of Respiratory and Critical Care Medicine</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: B-Cell Lymphomas</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Castleman Disease - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Castleman Disease</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 4.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 3.2023	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer</u> . January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer</u> .

Topic	Reference
	January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer.</u> January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 1.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> January 2024
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 3.2024	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors.</u> January 2024

