

# Medical Drugs Excluded At Launch List

Effective September 14, 2023



This list contains provider-administered drugs that are newly approved by the Food and Drug Administration (FDA). Drugs on this list are being evaluated by PreferredOne for safety, efficacy, and coverage consideration. Completion of review and decision of coverage will be made within 12 months of FDA approval. Prior to review and decision, these medications will not be covered. For more information, see Pharmacy Policy PP/R001 – Review of New FDA-Approved Drugs and Clinical Indications.

DRUG TRADE NAME	TARGET INDICATION	FDA APPROVAL	REMOVAL FROM LIST
<b>Imjudo</b> (tremelimumab-actl)	Used in combination with Imfinzi (durvalumab) for the treatment of unresectable hepatocellular carcinoma (uHCC) in adult patients.	10/21/2022	10/21/2023
<b>Tecvayli</b> (teclistamab-cqyv)	Relapsed or refractory multiple myeloma in patients who have received at least four previous lines of therapy. Previous lines of therapy must include a protease inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.	10/25/2022	10/21/2023
<b>Tzield</b> (teplizumab-mzww)	Delaying the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D.	11/17/2022	11/17/2023
<b>Hemgenix</b> (etranacogene dezaparvec)	Adults with Hemophilia B (congenital Factor IX deficiency)	11/22/2022	11/17/2023
<b>Elahere</b> (mirvetuximab soravtansine-gynx)	Folate receptor alpha (FR $\alpha$ )-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer	11/24/2022	10/21/2023
<b>Rebyota</b> (fecal microbiota, live -jslm)	Prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older. It is for use after an individual has completed antibiotic treatment for recurrent CDI	11/30/2022	11/17/2023
<b>Lunsumio</b> (mosunetuzumab-axgb)	To treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma	12/22/2022	10/21/2023
<b>Sunlenca</b> (lenacapavir)	To treat adults with HIV whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations	12/22/2022	12/22/2023
<b>Briumvi</b> (ublituximab-xiiy)	Treatment of relapsing forms of multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	12/28/2022	12/28/2023

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<b>Leqembi</b> (lecanemab-irmb)	Treatment of Alzheimer's disease (AD) with mild cognitive impairment or mild dementia stage of disease.	1/6/2023	1/6/2024
<b>Lamzede</b> (velmanase alfa-tyvc)	To treat non-central nervous system manifestations of alpha-mannosidosis	2/16/2023	2/16/2024
<b>Syfovre</b> (pegcetacoplan)	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	2/17/2023	2/17/2024
<b>Altuviio</b> (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	Adults and children with hemophilia A (congenital factor VIII deficiency) for: Routine prophylaxis to reduce the frequency of bleeding episodes; (2) On-demand treatment and control of bleeding episodes; and (3) Perioperative management of bleeding.	2/22/2023	2/22/2024
<b>Rezzayo</b> (rezafungin)	Treatment of candidemia and invasive candidiasis.	3/22/2023	3/22/2024
<b>Zynyz</b> (retifanlimab-dlwr)	Programmed death receptor-1 (PD-1)-blocking antibody for the treatment of Merkel cell carcinoma	3/22/2023	3/22/2024
<b>Qalsody</b> (tofersen)	Treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene	4/25/2023	4/25/2024
<b>Epkinly</b> (epcoritamab-bysp)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy	5/19/2023	5/19/2024
<b>Vyvgart Hytrulo</b> (efgartigimod alfa and hyaluronidase-qvfc), subcutaneous injection	Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive	6/20/2023	6/20/2024
<b>Elevidys</b> (delandistrogene moxeparvovec-rokl)	Treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.	6/22/2023	6/22/2024

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<b>Rystiggo</b> (rozanolixizumab-noli)	Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive	6/27/2023	6/27/2024
<b>Roctavian</b> (valoctocogene roxaparvovec-rvox)	Treatment of adults with severe hemophilia A (congenital factor VIII (FVIII) deficiency with FVIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test	6/29/2023	6/29/2024
<b>Beyfortus</b> (nirsevimab-alip)	Prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	7/17/2023	10/1/2023
<b>Vanflyta</b> (quizartinib)	Treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3-ITD positive as detected by an FDA-approved test	7/20/2023	7/20/2024
<b>Ycanth</b> (cantharidin)	Topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older	7/24/2023	7/24/2024
<b>Izervay</b> (avacincaptad pegol intravitreal solution)	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	8/4/2023	8/4/2024
<b>Talvey</b> (talquetamab-tgvs)	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody	8/9/2023	8/9/2024
<b>Elrexio</b> (elranatamab-bcmm)	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody	8/14/2023	8/14/2024
<b>Daxxify</b> (daxibotulinumtoxinA-lanm)	Treatment of cervical dystonia in adult patients	8/14/2023	8/14/2024
<b>Hepzato Kit</b> (melphalan/hepatic delivery system)	A liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.	8/14/2023	8/14/2024

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<b>Veopoz</b> (pozelimab-bbfg)	Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease	8/18/2023	8/18/2024
<b>Eylea HD</b> (afibercept)	Treatment of Neovascular (Wet) age-related macular degeneration; Diabetic macular edema; and Diabetic retinopathy	8/18/2023	8/18/2024