

Medical Drugs Excluded At Launch List

Effective December 13, 2024

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
Casgevy (exagamglogene autotemcel)	Treatment of patients aged 12 years and older with transfusion-dependent β -thalassemia	01/17/2024	01/17/2025
Aurlumyn (iloprost)	Treatment of severe frostbite in adults to reduce the risk of digit amputations.	02/15/2024	02/15/2025
Amtagvi (lifileucel)	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.	02/16/2024	02/16/2025
Exblifep (cefepime/enmetazobactam)	Treatment of patients 18 years of age and older with complicated urinary tract infections including pyelonephritis, caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex.	02/23/2024	02/23/2025
Letybo (letibotulinumtoxinA-wlbg)	temporary improvement in the appearance of moderate to severe glabellar (frown) lines associated with corrugator and/or procerus muscle activity in adult patients	03/04/2024	03/04/2025
Jubbonti (denosumab-bbdz)	Treatment of postmenopausal women with osteoporosis at high risk for fracture. Treatment to increase bone mass in men with osteoporosis at high risk for fracture. Treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.	03/05/2024	03/05/2025
Wyost (denosumab-bbdz)	Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy	03/05/2024	03/05/2025

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Tyenne (tocilizumab-aazg)	Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs. Treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older. Treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.	03/06/2024	03/06/2025
Lenmeldy (atidarsagene autotemcel)	Treatment of children with pre-symptomatic late infantile, presymptomatic early juvenile or early symptomatic early juvenile metachromatic leukodystrophy.	03/18/2024	03/18/2025
Vafseo (vadadustat)	Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.	3/27/2024	3/27/2025
Anktiva (nogapendekin alfa inbakicept-pmln)	Treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors.	04/22/2024	04/22/2025
Beqvez (fidanacogene elaparvovec-dzkt)	Treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and, do not have neutralizing antibodies to adeno-associated virus serotype Rh74var capsid as detected by an FDA-approved test.	04/26/2024	04/26/2025
Hercessi (trastuzumab-strf)	Indicated for adjuvant breast cancer treatment and metastatic breast cancer.	04/29/2024	04/29/2025
Imdelltra (tarlatamab-dlle)	Treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.	05/16/2024	05/16/2025
Rytelo (imetelstat)	Treatment of adult patients with low-to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).	06/06/2024	06/06/2025

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Yimmugo (immune globulin intravenous, human - dira)	Treatment of primary humoral immunodeficiency (PI) including but not limited to the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia (XLA), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID) in patients 2 years of age and older.	06/17/2024	06/17/2025
Piasky (crovalimab-akkz)	Treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.	06/20/2024	06/20/2025
Kisunla (donanemab-azbt)	Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.	07/02/2024	07/02/2025
Epysqli (eculizumab-aagh)	The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.	07/23/2024	07/23/2025
Erzofri (paliperidone palmitate)	Treatment of schizophrenia in adults; and for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants.	07/29/2024	07/29/2025
Tecelra (afamitresgene autoleucel)	Treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the melanoma-associated antigen A4 antigen as determined by FDA-approved or cleared companion diagnostic devices	08/05/2024	08/25/2025
Otulfi (ustekinumab-aauz)	<ul style="list-style-type: none"> Otulfi indications: <ul style="list-style-type: none"> Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy Adults and pediatric patients 6 years and older with active psoriatic arthritis (PsA). Adult patients with moderately to severely active Crohn's disease (CD), and Adult patients with moderately to severely active ulcerative colitis (UC). 	10/01/2024	10/01/2025
Aucatzyl (obecabtagene autoleucel)	Treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.	11/08/2024	11/08/2025
Ziihera (zanidatamab-hrii)	Treatment of adults with previously treated, unresectable or metastatic HER2-positive biliary tract	11/20/2024	11/20/2025

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	cancer, as detected by an FDA-approved test.		
Rapiblyk (landiolol)	for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.	11/22/2024	11/25/2025
Bizengri (zenocutuzumab-zbco)	treatment of adults with advanced, unresectable or metastatic non-small cell lung cancer harboring a neuregulin 1 gene fusion with disease progression on or after prior systemic therapy and advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.	11/25/2024	11/25/2025
Unloxcyt (cosibelimab-ipdl)	treatment of adults with metastatic cutaneous squamous cell carcinoma or locally advanced CSCC who are not candidates for curative surgery or curative radiation	12/13/2024	12/13/2025