Capital Rx

Medication Pipeline Report

2022 - Q4

TABLE OF CONTENTS

Glossary:

PO — Oral
IV — Intravenous
SC — Subcutaneous
IM — Intramuscular
IN — Intranasal
PR — Rectal
INJ — Injectable
TD — Transdermal
ID — Intradermal
IVT — Intravitreal
OPHT — Ophthalmic
IT — Intrathecal

Welcome to the ***Capital Rx Pipeline Report***. This quarterly publication is developed by our Clinical Pharmacists and is prepared using a wide range of clinical resources. The Capital Rx Pipeline Report is designed to keep you up to date on the latest drug approvals and well-versed on what is to come in the FDA drug pipeline. Our pipeline report is one of the many ways we, at Capital Rx, demonstrate our commitment to providing clients and partners the tools and resources they desire.

WHO WE ARE

Capital Rx is a next generation pharmacy benefits manager, overseeing prescription benefit plans on behalf of employers, unions, and government entities. Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change. Through our platform approach, Capital Rx delivers data-driven insights and actionable strategies that reduce costs, while improving patient outcomes. Our commitment to innovation, technology and service is the reason why Capital Rx is among the fastest-growing PBMs in the country.

The drug pipeline is subject to change: information in this report is current as of **12/28/2022**

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FUROSCIX (FUROSEMIDE) SELF-ADMINISTERED SC CARTRIDGE WITH ON-BODY INFUSOR PUMP, SCPHARMACEUTICALS, INC.

Approval Date	10/07/2022
Indication	Treatment of congestion due to fluid overload in certain adults with chronic heart failure
Clinical Overview	Heart Failure (HF) is a clinical syndrome that can result from disorders of the heart structure, heart function, or metabolic abnormalities. The symptoms of HF are attributed to impaired left ventricular myocardial function and include dyspnea, fatigue, and fluid retention. Heart failure affects approximately 6.5 million people in the United States.
Considerations	First and only self-administered subcutaneous loop diuretic • FDA-approved for adults with New York Heart Association (NYHA) class II/ III chronic heart failure
Select Alternative Therapies	furosemide PO/IV, bumetanide PO/IV, torsemide PO/IV

IMJUDO (TREMELIMUMAB-ACTL) IV, ASTRAZENECA

Approval Date	10/21/2022
Indication	Treatment of adult patients with unresectable hepatocellular carcinoma in combination with durvalumab and patients with metastatic non-small cell lung cancer in combination with durvalumab and platinum-based chemotherapy
Clinical Overview	Imjudo is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody. Imjudo blocks the activity of CTLA-4, contributing to T-cell activation, which primes the immune response to cancer and fosters cell cancer death.
Considerations	Healthcare administered
Select Alternative Therapies	Tecentriq (atezolizumab) IV + Avastin (bevacizumab) IV, Nexavar (sorafenib) IV, Lenvima (lenvatinib) IV, Keytruda (pembrolizumab) IV

TECVAYLI (TECLISTAMAB-CQYV) SC, JANSSEN

Approval Date	10/25/2022
Indication	Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
Clinical Overview	Multiple myeloma is a type of blood cancer; relapsed/refractory multiple myeloma is defined as non-responsive or progressive on therapy or within 60 days of the last treatment in patients who achieved a minimal response or better on prior therapy. Common symptoms of multiple myeloma are bone damage and pain, fatigue and weakness, and frequent infections.
Considerations	Healthcare administered
Select Alternative Therapies	Abecma (idecabtagene vicleucel) IV, Carvykti (ciltacabtagene autoleucel) IV, Revlimid (lenalidomide) PO + dexamethasone PO, Velcade (bortezomib) SC/IV + cyclophosphamide IV + dexamethasone PO

ELAHERE (MIRVETUXIMAB SORAVTANSINE-GYNX) IV, IMMUNOGEN

Approval Date	11/14/2022
Indication	Treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens
Clinical Overview	Ovarian cancer is a type of cancer that originates in the cells from the ovary, fallopian tube, or peritoneum. It affects an estimated 195,770 women in the US and survival rate at 5 years is less than 50%. There is currently no targeted therapy in patients with ovarian cancer that express a high level of FRα.
Considerations	Orphan Drug Designation • Healthcare administered • Indication is approved under accelerated approval based on tumor response rate and durability of response and continued approval for this indication may be contingent upon clinical benefit in a confirmatory trial
Select Alternative Therapies	Cytotoxic chemotherapy

TZIELD (TEPLIZUMAB-MZWV) IV, SANOFI, PROVENTION BIO

Approval Date	11/17/2022
Indication	To delay the onset of Stage 3 Type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 Type 1 Diabetes
Clinical Overview	Stage 3 Type 1 Diabetes is associated with significant health risks, including diabetic ketoacidosis, which can be life threatening. Patients who progress to Stage 3 eventually will require insulin injections for life. Approximately 1.6 million people in the US suffer from Type 1 Diabetes.
Considerations	Healthcare administered • Breakthrough Therapy Designation • Weight based dosing
Select Alternative Therapies	There are currently no other disease-modifying treatments available to delay the onset of Type 1 Diabetes

HEMGENIX (ETRANACOGENE DEZAPARVOVC-DRLB) IV, CSL BEHRING

Approval Date	11/22/2022
Indication	Treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis, have current or historical life-threatening hemorrhage, or have repeated and serious spontaneous bleeding episodes
Clinical Overview	Hemophilia B is a rare X-linked recessive disease that interferes with the normal coagulation process, causing bleeding in soft tissue, joints, and internal organs. Hemophilia B occurs in 1 in 30,000 live male births, where approximately half of all patients have severe disease.
Considerations	Healthcare administered
Select Alternative Therapies	Prophylaxis with Factor IX products: Ixinity (coagulation factor IX recombinant) IV, AlphaNine SD (coagulation factor IX human)

REBYOTA (FECAL MICROBIOTA, LIVE-JSLM) PR, REBIOTIX, FERRING PHARMACEUTICALS

Approval Date	11/30/2022
Indication	Prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI.
Clinical Overview	CDI is one of the most common hospital-acquired infections where colonization by the bacteria occurs via the fecal-oral route. The infection can be characterized by severe diarrhea, stomach tenderness or pain, fever, and nausea; the biggest risk factor of C. Difficile is recent antibiotic therapy. Every year there are between 365,000 and 462,000 patients diagnosed with C. Difficile and of those 29,000 patients die.
Considerations	Oral formulation of Rebyota is in development • Healthcare administered
Select Alternative Therapies	Vancocin (vancomycin) PO, Dificid (fidaxomicin) PO, Zinplava (bezlotoxumab) IV

REZLIDHIA (OLUTASIDENIB) PO, FORMA THERAPEUTICS, RIGEL PHARMACEUTICALS

Approval Date	12/01/2022
Indication	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation
Clinical Overview	AML is one of the most common types of leukemia in adults, with about 20,000 new cases reported in the US each year. Although the majority of patients with AML initially respond to induction chemotherapy and achieve a complete remission, most will eventually relapse.
Considerations	Orphan Drug Designation
Select Alternative Therapies	Tibsovo (ivosidenib) PO

KRAZATI (ADAGRASIB) PO, MIRATI

Approval Date	12/12/2022
Indication	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) who have received at least one prior systemic therapy
Clinical Overview	NSCLC originates as a tumor formed in the lungs and includes the subsets of adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. Lung cancer affects approximately 230,000 individuals in the US annually, and 80-85% of lung cancers are NSCLC. The most well-known risk factor of NSCLC is smoking.
Considerations	Krazati's indication is approved under accelerated approval. Continued approval may be contingent on verification and description of a clinical benefit in confirmatory trials. • An additional indication of colorectal cancer is under investigation • Orphan Drug Designation
Select Alternative Therapies	Lumakras (sotorasib) PO

IDACIO (ADALIMUMAB-AACF) SC, FRESENIUS KABI

Approval Date	12/13/2022
Indication	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis
Clinical Overview	Therapies for the treatment of inflammatory conditions represent one of the highest total cost areas for payers and systems. Hadlima is the first approved high-concentration (100 mg/mL) biosimilar of Humira. As of December 2022, there are 8 approved biosimilar low-concentration (50 mg/mL) Humira products.
Considerations	Biosimilar to Humira
Select Alternative Therapies	Humira (adalimumab) SC biosimilars: Amjevita, Hadlima, Cyltezo, Abrilada, Yusimry, Hulio, Hyrimoz, Idacio

ADSTILADRIN (NADOFARAGENE FIRADENOVEC-VNCG) INTRAVESICAL, FERRING PHARMACEUTICALS

Approval Date	12/16/2022
Indication	Treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
Clinical Overview	Bladder cancer originates in the tissues of the bladder and affects about 57,000 men and 18,000 women in the US annually. Most newly diagnosed bladder cancers are classified as NMIBC, a type of cancer that has grown through the lining of the bladder but hasn't yet invaded the muscle layer. Treatment often includes removing the tumor and the use of BCG but as many as 40% of patients will fail BCG therapy.
Considerations	Healthcare administered • Breakthrough Therapy Designation
Select Alternative Therapies	Keytruda (pembrolizumab) IV

LUNSUMIO (MOSUNETUZUMAB-AXGB) IV, GENENTECH

Approval Date	12/22/2022
Indication	Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy
Clinical Overview	Non-Hodgkin lymphoma consists of a diverse group of malignant neoplasms variously derived from B-cells, T-cells, killer cells, and their progenitors. Follicular lymphoma is a type of non-Hodgkin lymphoma that accounts for 20%-30% of all cases.
Considerations	Healthcare administered • Indication is approved under accelerated approval based on tumor response rate and durability of response and continued approval for this indication may be contingent upon clinical benefit in a confirmatory trial
Select Alternative Therapies	Kymriah (tisagenlecleucel) IV, Yescarta (axicabtagene ciloleucel) IV, Breyanzi (lisocabtagene maraleucel) IV

SUNLENCA (LENACAPAVIR) SC, PO, GILEAD

Approval Date	12/22/2022
Indication	Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
Clinical Overview	HIV is a virus that attacks and destroys infection fighting CD4 cells of the immune system, making it difficult for the body to fight off infections and certain cancers. Without treatment, HIV can advance to AIDs. It is transmissible via body fluids from infected people. In 2021, 650,000 people worldwide died from HIV-related causes and 1.5 million people acquired HIV.
Considerations	Two initiation options: PO only regimen or PO and SC regimen, followed by maintenance SC regimen • Twice yearly treatment
Select Alternative Therapies	Rukobia (fostemsavir) PO

BRIUMVI (UBLITUXIMAB-XIIY) IV, TG THERAPEUTICS

Approval Date	12/28/2022
Indication	Treatment of relapsing forms multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults
Clinical Overview	Relapsing-remitting multiple sclerosis is defined by inflammatory attacks on myelin, the layers of insulating membranes surrounding nerve fibers in the central nervous system. These attacks cause small, localized areas of damage which produce the symptoms of multiple sclerosis, such as numbness or tingling, fatigue, weakness, and walking difficulties. The disease affects at least 2.2-2.3 million people worldwide.
Considerations	Healthcare administered • Orphan Drug Designation • First and only anti-CD20 monoclonal antibody approved for relapsing multiple sclerosis
Select Alternative Therapies	Aubagio (teriflunomide) PO, Vumerity (diroximel fumarate) PO

SEZABY (PHENOBARBITAL SODIUM) IV, SUN PHARMACEUTICAL INDUSTRIES

Approval Date	11/17/2022
Indication	Treatment of neonatal seizures in term and preterm infants
Clinical Overview	Neonatal seizures occur during the first 28 days of a baby's life. These seizures are characterized by chewing motions and "bicycling" movements, but testing is required to confirm the diagnosis. Some causes of neonatal seizures include lack of oxygen, infection, or stroke before or during birth.
Considerations	Healthcare administered
Select Alternative Therapies	Sezaby is the only product specifically indicated for neonatal seizures in term and preterm infants

IYUZEH (LATANOPROST OPHTHALMIC SOLUTION) OPTH, THEA PHARMA

Approval Date	12/14/2022
Indication	Reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension
Clinical Overview	Ocular hypertension is increased pressure in the eye and can lead to glaucoma. Open-angle glaucoma is characterized by optic nerve damage that results in visual field loss and irreversible blindness if left untreated. It affects an estimated 3.4 million people in the US.
Considerations	Only preservative-free form of latanoprost available in the United States
Select Alternative Therapies	Lumigan (bimatoprost) OPTH, Xalatan (latanoprost) OPTH, Travatan Z (travoprost) OPTH

ADDITIONAL BRAND APPROVALS

BRAND NAME *(generic name)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
TROGARZO *Ibalizumab-uiyk*	Theratechnologies	IV	Treatment-experienced HIV	10/03/2022
OXLUMO *lumasiran*	Alnylam	INJ	Advanced primary hyperoxaluria Type 1	10/07/2022
RINVOQ *upadacitinib*	Abbvie	PO	Active non-radiographic axial spondyloarthritis (nr-axSpA)	10/21/2022
COTELLIC *cobimetinib*	Genentech	PO	Histiocytic neoplasms	10/28/2022
LIBTAYO *cemiplimab-rwlc*	Sanofi	IV	Non-small cell lung cancer	11/8/2022
IMFINZI *durvalumab*	AstraZeneca	IV	Metastatic non-small cell lung cancer (with Imjudo)	11/11/2022
REZVOGLAR *insulin glargine*	Eli Lilly	SC	Type 1 and Type 2 Diabetes; interchangeable biosimilar to Lantus	11/18/2022
TRULICITY *dulaglutide*	Eli Lilly	SC	Adjunct to diet and exercise to improve glycemic control in Type 2 Diabetes	11/17/2022
JYLAMVO *methotrexate solution*	Therakind	PO	Acute lymphoblastic leukemia, mycosis fungoides, relapsed/ refaractory non-Hodgkin lymphoma, rheumatoid arthritis, severe psoriasis	11/29/2022
BREXAFEMME *ibrexafungerp*	Scynexis	PO	Reduction in incidence of recurrent vulvovaginal candidiasis	11/30/2022
VIVIMUSTA *bendamustine hydrochloride*	Slayback	IV	Chronic lymphocytic leukemia, Indolent B-cell non-Hodgkin lymphoma	12/07/2022
ZEJULA *niraparib*	GlaxoSmithKline	PO	Maintenance and treatment of adult patients with BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy	12/08/2022
TECENTRIQ *atezolizumab*	Genentech, Roche	IV	Alveolar soft part sarcoma	12/09/2022
TASCENSO ODT *fingolimod*	Handa	PO	Relapsing forms of multiple sclerosis	12/09/2022
IBRANCE *palbociclib*	Pfizer	PO	In combination with an aromatase inhibitor as initial endo-crine-based therapy	12/13/2022
CYTALUX *pafolacianine*	On Target Labs	IV	Malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung	12/16/2022

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(generic name)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
PT027 *albuterol/budesonide*	Avillion and AstraZeneca	Inhaled	Asthma	1/01/2023
NexoBrid	Lovance	TOP	Burn tissue (eschar)	1/01/2023
BAN2401 IV *lecanemab*	Esai	IV	Alzheimer's disease	1/06/2023
vonozapran	Phathom Pharmaceuticals	PO	Erosive esophagitis and relief of heartburn	1/11/2023
ACER-001 *sodium phenylbutyrate*	Acer Therapeutics and Relief Therapeutics	PO	Urea cycle disorders	1/15/2023
Spikevax *COVID-19 vaccine, mRNA*	Moderna	IM	Prevention of COVID-19 in individuals >18 years of age	1/31/2023
daprodustat	GlaxoSmithKline	PO	Anemia of chronic kidney disease	2/01/2023
donanemab	Lilly	IV	Alzheimer's disease	2/04/2023
RE-021 *sparsentan*	Travere Therapeutics	PO	IgA nephropathy	2/17/2023
RAD1901 *elacestrant*	Radius Health and Menarini	PO	ER+/HER2-advanced or metastatic breast cancer	2/17/2023
Vyjuvek *beremagene geperpavec*	Krystal Biotech	TOP	Dystrophic epidermolysis bullosa	2/17/2023
ESN363 *fezolinetant*	Astellas	PO	Vasomotor symptoms associated with menopause	2/22/2023
APL-2 *pegcetacoplan*	Apellis	IVT	Geographic atrophy secondary to age-related macular degeneration	2/26/2023
Altuviiio *efanesoctocog alfa*	Sanofi	IV	Hemophilia A	2/28/2023
Omav *omaveloxolone*	Reata Pharmaceuticals	PO	Friedrich's ataxia	2/28/2023
AMG 423 *omecamtiv mecarbil*	Cytokinetics	PO	Heart failure with reduced ejection fraction	2/28/2023
NNZ-2566 *trofinetide*	Acadia Pharmaceuticals	PO	Rett syndrome	3/12/2023
CD101 IV *rezafungin*	Cidara and Melinta	IV	Candidemia and invasive candidiasis	3/22/2023
BHV-3500 *zavegepant*	Biohaven	IN	Acute treatment of migraine	3/23/2023

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(generic name)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
CDZ173 *leniolisib*	Novartis	PO	Activated phosphoinositide 3-kinase delta syndrome	03/29/2023
Evkeeza *evinacumab-dgnb*	Regeneron	IV	Homozygous familial hypercholesteremia	3/30/2023
Roctavian *valoctocogene roxaparvovec*	BioMarin	IV	Severe hemophilia A	3/31/2023
LY3074828 *mirikizumab*	Lilly	IV/SC	Ulcerative colitis	1Q 2023
Lamzede *velmanase alfa*	Chiesi	IV	Alpha-mannosidosis	1Q 2023