Capital Rx

Medication Pipeline Report

2022 - Q3

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Glossary:

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

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 Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.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 **09/30/2022**

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LUMRYZ (SODIUM OXYBATE), *PO,* AVADEL PHARMACEUTICALS; FLAMEL TECHNOLOGIES

Indication	Narcolepsy
Approval Date	07/18/2022
Clinical Overview	Narcolepsy is a chronic daytime sleepiness disorder characterized by loss of muscle tone, hypnagogic (transitional state between wakefulness to sleep) hallucinations, and sleep paralysis. Narcolepsy can negatively impact daily life, psychological and social growth, and cognitive and functional development. It is equally common in men and women, occurring in 25 to 50 per 100,000 people.
Considerations	Orphan Drug designation • REMs program required
Select Alternative Therapies	Xyrem (sodium oxybate) PO, Xywav (calcium, magnesium, potassium, and sodium oxybates) PO

CIMERLI (RANIBIZUMAB-EQRN), *IVT*, COHERUS BIOSCIENCES

Indication	Diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, myopic choroidal neovascularization, neovascular (wet) age-related macular degeneration
Approval Date	08/02/2022
Clinical Overview	Diabetic retinopathy and age-related macular degeneration are leading causes of vision loss and impairment. The most common type of macular degeneration is the dry form, where slow breakdown of light sensitive macula cells occurs. About 11 million people in the US are affected by some form of macular degeneration.
Considerations	Healthcare administered
Select Alternative Therapies	Lucentis (ranibizumab) IVT, Byooviz (ranibizumab-nuna) IVT (not indicated for diabetic macular edema or diabetic retinopathy), Avastin (bevacizumab) IV, Beovu (brolucizumab-dbll) IVT

HADLIMA HC (ADALIMUMAB-BWWD), *INJ*, SAMSUNG BIOEPIS, ORGANON

Indication	Ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis
Approval Date	08/15/2022
Clinical Overview	Therapies for the treatment of inflammatory conditions represent one of the highest total medication cost areas. Hadlima is the first approved high-concentration (100 mg/mL) biosimilar of Humira. As of August 2022, there are 8 approved biosimilar low-concentration (50 mg/mL) Humira products.
Considerations	Citrate-free, high-concentration biosimilar formulation of Humira (adalimumab)
Select Alternative Therapies	Humira (adalimumab) SC

ZYNTEGLO (BETIBEGLOGENE AUTOTEMCEL), *IV*, BLUEBIRD BIO

Indication	Beta thalassemia in patients who require regular red blood cell transfusions
Approval Date	08/17/2022
Clinical Overview	Beta thalassemia is a rare blood disorder that leads to decreased red blood cells and severe anemia. Symptomatic cases are estimated to affect 1 in 100,000 patients in the general population. This disease is more prevalent in the Middle East, Central Asia, Africa, and the Mediterranean. It can cause severe damage to the heart, liver, and other organs, causing death in up as many as 85% of the untreated population.
Considerations	Orphan Drug and Breakthrough Therapy designations • Healthcare administered
Select Alternative Therapies	Reblozyl (luspatercept) SC

XENPOZYME (OLIPUDASE ALFA-RPCP), *IV*, SANOFI

Indication	Acid sphingomyelinase deficiency (ASMD)
Approval Date	08/31/2022
Clinical Overview	ASMD is a rare, progressive genetic disorder resulting from a deficiency of the enzyme acid sphingomyelinase, leading to accumulations of the lipid sphingomyelin in tissues throughout the body. Many cases go undiagnosed, so the prevalence is estimated in about 1 in 250,000 individuals.
Considerations	Orphan Drug and Breakthrough Therapy designations • Healthcare administered
Select Alternative Therapies	There are currently no FDA-approved therapies for ASMD. Current treatments are supportive and address specific symptoms as they occur.

SPEVIGO (SPESOLIMAB-SBZO), *IV*, BOEHRINGER INGELHEIM

Indication	Generalized pustular psoriasis (GPP)
Approval Date	09/01/2022
Clinical Overview	GPP is a rare, potentially life-threatening neutrophilic skin condition. Individuals with GPP experience episodes of widespread eruptions of painful, sterile pustules. If left untreated, it can be life-threatening due to complications such as sepsis and multiorgan failure.
Considerations	Healthcare administered • Breakthrough Therapy and Orphan Drug designations
Select Alternative Therapies	Infliximab IV, Enbrel (etanercept) IV, methotrexate PO

STIMUFEND (PEGFILGRASTIM-FPGK), *SC*, FRESENIUS KABI

Indication	To decrease the incidence of infection in cancer patients receiving myelosuppressive chemotherapy associated with febrile neutropenia
Approval Date	09/01/2022
Clinical Overview	Febrile neutropenia can increase the risk of infections as well as morbidity and mortality in patients receiving chemotherapy. Recombinant human granulocyte colony stimulating factor (G-CSF) has been used to reduce the duration and degree of neutropenia.
Considerations	Biosimilar
Select Alternative Therapies	Neulasta (pegfilgrastim) SC and its biosimilars: Fylnetra SC, Nyvepria SC, Fulphila SC, Udenyca SC, Ziextenzo SC)

SOTYKTU (DEUCRAVACITINIB), *PO*, BRISTOL-MYERS SQUIBB

Indication	Plaque psoriasis
Approval Date	09/09/2022
Clinical Overview	Plaque psoriasis is a chronic autoimmune skin condition that is characterized by well-demarcated, thick plaques with a scaly appearance. These plaques can itch and burn and are commonly on the scalp, trunk, and extensor body surface. Plaque psoriasis is the most common subtype of psoriasis, affecting 80-90% of adults with psoriasis.
Considerations	Under investigation for psoriatic arthritis, ulcerative colitis, Crohn's disease, irritable bowel syndrome, lupus nephritis, and systemic lupus erythematosus indications.
Select Alternative Therapies	Otezla (apremilast) PO, Humira (adalimumab) SC, Enbrel (etanercept) SC

ROLVEDON (EFLAPEGRASTIM-XNST), *SC*, SPECTRUM PHARMACEUTICALS

Indication	To decrease the incidence of infection in cancer patients receiving myelosuppressive chemotherapy associated with febrile neutropenia
Approval Date	09/09/2022
Clinical Overview	Febrile neutropenia can increase the risk of infections as well as morbidity and mortality in patients receiving chemotherapy. Recombinant human granulocyte colony stimulating factor (G-CSF) has been used to reduce the duration and degree of neutropenia.
Select Alternative Therapies	Neulasta (pegfilgrastim) SC and its biosimilars: Fylnetra SC, Nyvepria SC, Fulphila SC, Udenyca SC, Ziextenzo SC)

TERLIVAZ (TERLIPRESSIN), *IV*, MALLINCKRODT

Indication	Hepatorenal syndrome
Approval Date	09/14/2022
Clinical Overview	Hepatorenal syndrome is an acute and life-threatening condition that occurs in people with advanced liver disease and involves a rapid reduction in kidney function. Left untreated, hepatorenal syndrome has a median survival time of approximately two weeks. It affects approximately 30,000 to 40,000 individuals in the US annually.
Considerations	Recommended by the American Association for the Study of Liver Diseases (AASLD) guidance and the American College of Gastroenterology (ACG) guidelines • Healthcare administered
Select Alternative Therapies	Terlipressin has been approved outside of the US for 30 years; a combination of midodrine, octreotide, and albumin is recommended as standard of care where terlipressin is not available.

SKYSONA (ELIVALDOGENE AUTOTEMCEL), *IV*, BLUEBIRD BIO

Indication	Adrenoleukodystrophy in male patients up to 17 years of age
Approval Date	09/16/2022
Clinical Overview	Adrenoleukodystrophy is a rare genetic condition characterized by progressive loss of white matter in the nervous system and degradation of the adrenal glands. Diagnosis is established given clinical findings and confirmed via genetic testing. The prevalence of adrenoleukodystrophy is 1 in 10,000 to 1 in 17,000 individuals in the general population.
Considerations	Healthcare administered, one time dose • Accelerated Approval – continued approval for this indication will be contingent upon confirmation of clinical benefit
Select Alternative Therapies	Currently, allogeneic hematopoietic stem cell transplantation is the standard of care and the only treatment that can stop the progression of neurological symptoms in children.

PEDMARK (SODIUM THIOSULFATE), *IV*, FENNEC PHARMACEUTICALS

Indication	Chemotherapy-induced ototoxicity in pediatric patients
Approval Date	09/20/2022
Clinical Overview	Platinum-based chemotherapy is the treatment of choice in many cancer cases but can be toxic to the ears. Cisplatin treatment frequently causes permanent and irreversible bilateral hearing loss. The prevalence of permanent hearing loss in children treated with cisplatin is approximately 60%.
Considerations	Healthcare administered
Select Alternative Therapies	There are currently no FDA-approved therapies for reducing the risk of cisplatin induced hearing loss.

VEGZELMA (BEVACIZUMAB-ADCD), *IV*, CELLTRION

Indication	Kidney, non-small cell lung, colorectal, ovarian, brain and central nervous systems, and cervical cancers
Approval Date	09/27/2022
Clinical Overview	VEGF is a potent factor that is displayed in many tumors. High levels of VEGF are present in many types of cancers and may indicate a poor prognosis. Anti-VEGF inhibitors are helpful treatments in cancers that exhibit high levels of VEGF.
Considerations	Healthcare administered
Select Alternative Therapies	Mvasi (bevacizumab-awwb) IV, Zirabev (bevacizumab-bvzr) IV, Alymsys (bevacizumab-maly) IV

ZONISADE (ZONISAMIDE), *PO*, AZURITY PHARMACEUTICALS

Indication	Adjunct therapy for the treatment of partial onset seizures in epilepsy
Approval Date	07/15/2022
Clinical Overview	Epilepsy is a brain disorder that causes repeated and unprovoked seizures. Partial (also known as focal) seizures occur in only a small area of the brain, and a person may or may not lose consciousness. Epilepsy affects approximately 65 million people globally. It can lead to complications such as learning disabilities, anxiety, and depression, causing burden on patients and their families.
Considerations	First and only FDA-approved oral liquid formulation of zonisamide
Select Alternative Therapies	Vimpat (lacosamide) PO, Lyrica (pregabalin) PO, carbamazepine PO

ZORYVE (ROFLUMILAST), *TOP*, ARCUTIS BIOTHERAPEUTICS

Indication	Plaque psoriasis
Approval Date	07/29/2022
Clinical Overview	Plaque psoriasis is a chronic autoimmune skin condition that is characterized by well-demarcated, thick plaques with a scaly appearance. These plaques can itch and burn and are commonly on the scalp, trunk and extensor body surface. Plaque psoriasis is the most common subtype of psoriasis, affecting 80-90% of adults with psoriasis. The prevalence of psoriasis in adults in the US is 3.0%.
Considerations	Under investigation for atopic dermatitis
Select Alternative Therapies	Tazorac (tazarotene) TOP, Vtama (Tapinarof) TOP, systemic therapies for plaque psoriasis – Cimzia (certolizumab pegol) SC, Simponi (golimumab) SC

KYZATREX (TESTOSTERONE UNDECANOATE), *PO*, MARIUS PHARMACEUTICALS

Indication	Deficiency or absence of endogenous testosterone (hypogonadism)
Approval Date	08/02/2022
Clinical Overview	Hypogonadism results from inability of the testis to produce an appropriate amount of testosterone, leading to impaired spermatogenesis, low energy levels, decreased muscle mass, and weight gain. Low levels of testosterone increase the risk of developing type 2 diabetes and obesity. It affects 40% of men older than 45 years old and 30-50% of men with obesity or type 2 diabetes.
Select Alternative Therapies	Tlando (testosterone undecanoate) PO, Jatenzo (testosterone undecanoate) PO, Aveed (testosterone undecanoate) IM

AUVELITY (BUPROPRION HYDROCHLORIDE; DEXTROMETHORPHAN HYDROBROMIDE), *PO*, AXSOME THERAPEUTICS

Indication	Major depressive disorder in adults
Approval Date	08/19/2022
Clinical Overview	Major depressive disorder is characterized by symptoms such as low mood and energy, diminished pleasure from activities, fatigue, and possibly suicidal ideations. Depressive disorders have an estimated 21% prevalence in the US and is considered highly disabling, affecting daily life and relationships.
Considerations	Rapid onset of action – most antidepressants show effects after weeks of treatment • Breakthrough Therapy Designation
Select Alternative Therapies	Spravato (esketamine hydrochloride) IN, sertraline PO, venlafaxine PO

KONVOMEP (OMEPRAZOLE; SODIUM BICARBONATE), *PO*, AZURITY PHARMACEUTICALS

Indication	Active benign gastric ulcer and reduction of risk of upper gastrointestinal bleeding in critically ill patients
Approval Date	08/30/2022
Clinical Overview	Peptic ulcer disease is a defect of the inner lining of the GI tract due to gastric acid secretion, leading to ulcers that can cause stomach pain following a meal. It is commonly caused by a bacteria called H. Pylori or the use of non-steroidal anti-inflammatory drugs (NSAIDs), and the incidence is approximately 0.7 cases per 1000 person-years. Stress ulceration followed by upper GI bleeds in critically ill patients have an incidence of around 2-6%, and commonly develop as a complication during treatment in intensive care.
Considerations	Option for patients with difficulty swallowing
Select Alternative Therapies	Zegerid (omeprazole, sodium bicarbonate powder) PO, omeprazole PO, pantoprazole PO, esomeprazole PO

DAXXIFY (DAXIBOTULINUMTOXINA-LANM), *IM*, REVANCE THERAPEUTICS

Indication	Glabellar frown lines
Approval Date	09/08/2022
Clinical Overview	Botulinum toxin is commonly used for migraines, overactive bladder, and for cosmetic purposes. The clinical effect of botulinum toxin is the result of a reversible inhibition acetylcholine release, preventing the contraction of muscle.
Considerations	For cosmetic use only • Under investigation for cervical dystonia, upper limb spasticity, and plantar fasciitis indications
Select Alternative Therapies	Botox (onabotulinumtoxinA) IM, Dysport (abobotulinumtoxinA) IM, Xeomin (incobotulinumtoxinA) IM

OMLONTI (OMIDENEPAG ISOPROPYL), *OPHT*, SANTEN

Indication	Open-angle glaucoma or ocular hypertension
Approval Date	09/22/2022
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	Phase 3 clinical trials showed non-inferiority of Omlonti to latanoprost, a cheaper generic alternative
Select Alternative Therapies	Lumigan (bimatoprost) OPHT, Xalatan (latanoprost) OPHT, Travatan Z (travoprost) OPHT

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
KRYSTEXXA *Pegloticase*	Horizon Therapeutics	INJ	Chronic gout	07/08/2022
XALKORI *Crizotinib*	Pfizer	PO	Inflammatory myofibroblastic tumor	07/14/2022
DIACOMIT *Stiripentol*	Biocodex	PO	Dravet syndrome in children as young as 6 months	07/14/2022
OPZELURA *Ruloxitinib phosphate*	Incyte	TOP	Vitiligo	7/18/2022
DIACOMIT *Stiripentol*	Biocodex	PO	Dravet syndrome in children as young as 6 months	07/14/2022
HULIO *Adalimumab-fkjp*	Mylan Pharmaceuticals	SC	Crohn's disease and juvenile idiopathic arthritis	07/14/2022
HYRIMOZ *Adalimumab-adaz*	Sandoz	SC	Crohn's disease and juvenile idiopathic arthritis	07/18/2022
BENLYSTA *Belimumab*	GSK	IV	Active lupus nephritis in pediatric patients	07/27/2022
AMJEVITA *Adalimumab-atto*	Amgen	SC	Juvenile idiopathic arthritis	07/28/2022
ABRILADA *Adalimumab-afzb*	Pfizer	SC	Crohn's disease and juvenile idiopathic arthritis	07/29/2022
STELARA *Ustekinumab*	Janssen	SC	Active psoriatic arthritis	07/29/2022
ENHERTU *Fam-trastuzumab deruxtecan-nxki*	Daiichi Sankyo	IV	HER-2+ NSCLC and HER2-low breast cancer	08/05/2022
CALQUENCE *Acalabrutinib tablet*	AstraZeneca	PO	Chronic lymphocytic leukemia and mantle cell lymphoma	08/03/2022
MYFEMBREE *Estradiol; norethindrone acetate; relugolix*	Myovant Sciences	PO	Endometriosis	08/05/2022
NUBEQA *Darolutamide*	Bayer	PO	Metastatic hormone-sensitive prostate cancer (in combination with docetaxel)	08/05/2022
XOFLUZA *Baloxavir marboxil*	Genentech/Roche	PO	Influenza in children 5 years and older	08/11/2022

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
MIRENA *Levonogestrel*	Bayer	IU	8 years of pregnancy prevention	08/18/2022
IMBRUVICA *Ibrutinib*	Janssen	PO	Pediatric patients with chronic graft-vs-host disease	08/24/2022
PEMAZYRE *Pemigatinib*	Incyte	PO	Myelodisplastic syndromes	8/25/2022
ORKAMBI *Ivacaftor; lumacaftor*	Vertex	PO	Cystic fibrosis in children 12-24 months	09/02/2022
IMFINZI *Durvalumab*	AstraZeneca	IV	Advanced biliary tract cancer with chemotherapy	09/05/2022
APONVIE *Apretitant*	Heron Therapeutics	IV	Prevention of postoperative nausea and vomiting	09/16/2022
RETEVMO *Selpercatinib*	Eli Lilly	PO	Locally advanced or metastatic non-small cell lung cancer with a rearranged during transfection gene fusion	09/21/2022
DUPIXENT *Dupilumab*	Regeneron	SC	Prurigo nodularis	09/28/2022

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
Albrioza *Taurursodiol/sodium phenylbutyrate*	Amylyx	PO	Amyotrophic lateral sclerosis	9/29/2022
Futibatinib	Taiho Oncology	PO	Biliary tract cancer	9/30/22
SPN-830 *Apomorphine*	Supernus Pharmaceuticals	SC	Parkinson's disease	10/2022
Oxlumo *Lumasiran*	Alnylam Pharmaceuticals	SC	Primary hyperoxaluria	10/06/2022
Furoscix *Furosemide*	scPharmaceuticals	SC	Heart failure	10/08/2022
AMP-100 *Chloroprocain*	Harrow Health Sintetica	OPHT	Local anesthesia	10/16/2022
Cipaglucosidase alfa	Amicus Therapeutics	IV	Pompe disease	10/29/2022
Tzield *teplizumab*	Provention Bio	IV	Delay of type 1 diabetes in at-risk individuals	11/17/2022
EtranaDez *etranacogenedezaparvovec*	CSL Behring	IV	Hemophilia B	11/2022
Sparsentan	Travere Therapeutics	PO	IgA nephropathy	11/17/2022
Poziotinib	Spectrum Pharmaceuticals, Inc	PO	Non-small cell lung cancer	11/24/2022
Pegcetacoplan	Apellis	IVT	Geographic atrophy secondary to age-related macular degeneration	11/26/2022
Mirvetuximab soravtansine	ImmunoGen	IV	FRα-high platinum-resistant ovarian cancer	11/28/2022
Brexafemme *Ibrexafungerp citrate*	Scynexis	PO	Vulvovaginal candidiasis	11/30/2022
Omblastys *1311-omburtamab*	Y-mAbs	IV	Neuroblastoma	11/30/2022
Rylaze *Asparaginase erwinia chrysanthemi (recombinant)-rywn*	Jazz Pharmaceuticals	IM; IV	Acute lymphocytic leukemia	12/2022
Vraylar *Cariprazine hydrochloride*	Abbvie	PO	Major depressive disorder	12/2022

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	PENDING FDA APPROVAL DATE
Adagrasib	Mirati Therapeutics	PO	Non-small cell lung cancer	12/14/2022
Tuoyi *Toripalimab*	Junshi/Coherus	IV	Nasopharyngeal carcinoma	12/23/2022
Lenacapavir	Gilead Sciences	SC	HIV-1 infection	12/27/2022
TG-1101 *Ublutuximab*	TG Therapeutics	IV	Multiple sclerosis	12/28/2022
Mosunetuzumab	Genentech (Roche)	IV	Follicular lymphoma	12/29/2022
Palovarotene	Ipsen (Clementia)	PO	Prevention of heterotopic ossification in patients with fibrodysplasia ossificans progressive	12/29/2022
Tremelimumab	AstraZeneca	IV	Unresectable hepatocellular carcinoma	4Q 2022
Rebyota *RBX2660 fecal microbiota transplant*	Ferring	PR	Recurrent Clostridioides difficile (C. diff) infection	4Q 2022
Firdapse *Amiframpridine phosphate*	BioMarin	PO	Lambert-Eaton myasthenic syndrome	4Q 2022