Capital Rx

Medication Pipeline Report

2022 - Q1

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Glossary:

PO — Oral
IV — Intravenous
SC — Subcutaneous
IM — Intramuscular
INJ — Injectable
TD — Transdermal
ID — Intradermal
IVT — Intravitreal
NAS — Nasal
INH — Inhaled
TOP — Topical

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 Determined to transform an outdated model, **Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.** Through our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 **04/05/2022**

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CIBINQO (ABROCITINIB), *PO*, PFIZER

Indication	Moderate to severe atopic dermatitis in adults with refractory disease not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable
Approval Date	1/14/2022
Clinical Overview	Atopic dermatitis (AD), a common type of eczema, is a chronic inflammatory skin condition associated with dry skin, intense itching, and thickening of the skin. The scratching and skin damage caused by AD can lead to secondary infections. More than 9.6 million children and about 16.5 million adults in the United States have AD.
Considerations	Cibinqo and Rinvoq both received FDA approval for the treatment of AD on January 14, 2022, and represent the first oral JAK inhibitors for AD
Select Alternative Therapies	Xeljanz/Xeljanz XR (tofacitinib) PO, Rinvoq (upadacitinib) PO, Olumiant (baricitinib) PO, Dupixent (dupilumab) SC, Adbry (tralokinumab) SC

KIMMTRAK (TEBENTAFUSP-TEBN), *IV*, IMMUNOCORE

Indication	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma
Approval Date	1/25/2022
Clinical Overview	Occular melanoma, the most common primary cancer of the eye in adults, affects about 2,000 adults in the Unites States each year. White males with lightly pigmented skin and eyes are most frequently affected, and incidence increases steadily with age. Despite being the most common primary intraocular malignancy in adults, diagnosis is rare and up to 50% of people with uveal melanoma will eventually develop metastatic disease.
Considerations	First FDA-approved therapy for unresectable or metastatic uveal melanoma and the first drug of its class [T-cell receptor therapeutic (TCR)] • Priority Review Designation • Healthcare Administered
Select Alternative Therapies	Keytruda (pembrolizumab) IV, Yervoy (ipilimumab) IV, Opdivo (nivolumab) IV, dacarbazine IV

VABYSMO (FARICIMAB-SVOA), *IVT*, ROCHE

Indication	Treatment of wet age-related macular degeneration and diabetic macular edema
Approval Date	1/28/2022
Clinical Overview	The leading causes of blindness and visual impairment include age-related macular degeneration (AMD), diabetic retinopathy (DR), and diabetic macular edema (DME). AMD is a common eye condition and a leading cause of vision loss among people 60 years of age and older. Approximately 1.1 million have wet AMD, which is a subtype of AMD associated with a more sudden loss of central vision. DME is a consequence of DR that causes a buildup of fluid in the area of the retina called the macula. The incidence of DME increases with the severity and duration of diabetes, occurring in about 3% to 20% of diabetic patients. DME affects approximately 750,000 people in the United States and this number is expected to grow as the prevalence of diabetes increases.
Considerations	Biologic Data Exclusivity • Healthcare Administered
Select Alternative Therapies	Eylea (aflibercept) IVT, Lucentis (ranibizumab) IVT, Beovu (brolucizumab-dbll) IVT

ENJAYMO (SUTIMLIMAB-JOME), *IV*, BIOVERATIV; SANOFI

Indication	To decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease
Approval Date	2/4/2022
Clinical Overview	Cold agglutinin disease (CAD) is a rare type of autoimmune hemolytic anemia that affects approximately 5,000 individuals in the United States. CAD causes the body to destroy red blood cells, resulting in blood clots, requiring blood transfusions, and shortening an individual's lifespan. There are estimated to be approximately 5,000 patients living with CAD in the United States, most commonly affecting women in their 60s and 70s.
Considerations	Healthcare Administered • Orphan Drug Exclusivity • Biologic Data Exclusivity • Priority Review Designation
Select Alternative Therapies:	Treatment of CAD depends on the severity of the clinical manifestations and is primarily supportive. Rituximab IV may be used off-label, alone or in combination with chemotherapy agents, such as bendamustine IV or fludarabine IV, in some patients. There are currently no other approved therapies for CAD.

PYRUKYND (MITAPIVAT), *PO*, AGIOS

Indication	Treatment of hemolytic anemia in adults with pyruvate kinase deficiency
Approval Date	2/17/2022
Clinical Overview	Pyruvate kinase deficiency (PKD) is a rare, genetic condition. PKD causes red blood cells to become fragile, resulting in hemolytic anemia, which can range from mild to severe. Other symptoms of the disease commonly include jaundice, recurrent gallstones, and splenomegaly. It is estimated that there are approximately 1,500 to 4,000 patients with PDK in the United States. PKD is believed to occur in 1 in 20,000 Caucasians.
Considerations	Priority Review Designation
Select Alternative Therapies	Treatment of PKD is supportive, and may include blood transfusions, folic acid supplementation, splenectomy, and iron chelation therapy. There are currently no other approved therapies for PKD.

CARVYKTI (CILTACABTAGENE AUTOLEUCEL), *IV*, JANSSEN; LEGEND BIOTECH

Indication	Treatment of multiple myeloma after four previous therapies
Approval Date	2/28/2022
Clinical Overview	Multiple myeloma (MM) is an incurable cancer that forms in plasma cells, found in bone marrow. The overgrowth of cancerous plasma cells crowd-out normal functioning blood cells, leading to low blood counts and severe complications. The median age at diagnosis of MM is 69 years. It is estimated that almost 35,000 American adults were diagnosed with MM in 2021.
Considerations	Formerly known as Cilta-Cel • Healthcare Administered • Breakthrough Therapy Designation • Orphan Drug Designation
Select Alternative Therapies	Abecma (idecabtagene vicleucel) IV

VONJO (PACRITINIB), *PO*, CTI BIOPHARMA

Indication	Treatment of intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets
Approval Date	2/28/2022
Clinical Overview	Myelofibrosis (MF) is a rare bone marrow cancer. About one-third of people with MF will experience severe thrombocytopenia as a result of dysregulated Janus kinase 2 signaling. Severe thrombocytopenia is associated with a higher risk of bleeding, increased risk of leukemic transformation, and shorter overall survival. It is estimated that MF affects about 21,000 people in the United States.
Considerations	Accelerated Approval • CTI has made a post-marketing commitment to conduct a Phase 3 trial further evaluating safety and efficacy
Select Alternative Therapies	Jakafi (ruxolitinib) PO and Inrebic (fedratinib) PO are FDA approved therapies for MF. However, thrombocytopenia is a concern with these agents, and they are not indicated for MF with low platelet counts.

OPDUALAG (NIVOLUMAB; RELATLIMAB-RMBW), *IV*, BRISTOL-MYERS SQUIBB

Indication	Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma
Approval Date	3/18/2022
Clinical Overview	Malignant melanoma is a common skin cancer affecting melanin cells in the upper layer of the skin or similar cells often found in moles. Most early-stage melanomas are treatable but have high metastatic potential and can quickly spread to other organs. It is estimated that that 7,650 deaths from melanoma will occur in the United States in 2022. The average age of diagnosis is 65 years, and melanoma is 20 times more common in White people than in Black people.
Considerations	Biologic Data Exclusivity • Healthcare Administered
Select Alternative Therapies	Opdivo (nivolumab) IV, Opdivo/Yervoy (nivolumab/ipilimumab) IV, Keytruda (pembrolizumab) IV

ZTALMY (GANAXOLONE), *PO*, MARINUS PHARMACEUTICALS

Indication	Treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients 2 years of age and older
Approval Date	3/18/2022
Clinical Overview	Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) is a rare disorder involving mutations in the CDKL5 gene, causing epileptic activity and disruption in brain development. CDD is characterized by seizures beginning in infancy followed by significant delays in development. CDD has an incidence of 1 in 40,000 to 60,000 newborns.
Considerations	To be scheduled as a controlled substance • Additional formulations and indications underdevelopment
Select Alternative Therapies	The management of CDD is primarily symptom-based, due to the lack of specific therapies. Various antiepileptic drugs are used off-label for CDD but have limited evidence of efficacy.

PLUVICTO (LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN), *IV*, ADVANCED ACCELERATOR APPLICATIONS; NOVARTIS

Indication	Treatment of adult patients with prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer
Approval Date	3/23/2022
Clinical Overview	Prostate cancer is the second most common cancer among men. It is estimated that there will be over 260,000 new cases of prostate cancer in the United States in 2022, resulting in over 34,000 deaths. Prostate cancer is more likely to develop in older men and in non-Hispanic Black men. The average age of men at diagnosis is about 66 years.
Considerations	Priority Review Designation • New Chemical Entity Exclusivity • Healthcare Administered
Select Alternative Therapies	Zytiga (abiraterone) PO, Xtandi (enzalutamide) PO, Yonsa (abiraterone, micronized) PO

TLANDO (TESTOSTERONE UNDECANOATE), *PO*, ANTARES PHARMA; LIPOCINE

Indication	Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone
Approval Date	3/28/2022
Clinical Overview	Male hypogonadism is a condition in which not enough testosterone is produced in the body. This condition may can begin early in life, before puberty, or during adulthood. The use of testosterone replacement therapy (TRT) is recommended in hypogonadal patients who display signs and symptoms of the deficiency and have documented low testosterone levels.
Considerations	Previously received tentative approval in December 2020, but was not yet eligible for final approval and marketing due to the exclusivity period granted to Jatenzo (testosterone undecanoate) PO
Select Alternative Therapies	There are many TRT products available in a variety of dosage forms, including topical and injectable formulations. Jatenzo (testosterone undecanoate) PO is the only other FDA-approved oral testosterone undecanoate product currently available.

QUVIVIQ (DARIDOREXANT), *PO*, INDORSIA

Indication	Treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance
Approval Date	1/7/2022
Clinical Overview	Insomnia is the most prevalent sleep disorder in the general population, accounting for about 5 million office visits annually in the United States. First-line treatment options include behavioral therapy and cognitive behavioral therapy. Pharmacotherapy may include benzodiazepines, nonbenzodiazepine hypnotics (also commonly referred to as “Z drugs”), melatonin agonists, atypical antidepressants, and orexin modulators.
Considerations	To be scheduled as a controlled substance
Select Alternative Therapies	Belsomra (suvorexant) PO, Dayvigo (lemborexant) PO

RYALTRIS (MOMETASONE FUROATE; OLOPATADINE HCL), *NAS*, GLENMARK; HIKMA

Indication	Treatment of symptoms of seasonal allergic rhinitis in patients 12 years of age and older
Approval Date	1/13/2022
Clinical Overview	Allergic rhinitis is an inflammatory allergic response to seasonal or perennial allergens or irritants. Allergic rhinitis affects 10%–25% of the world population, with 30 to 60 million people affected annually in the United States. The most effective way to manage allergic rhinitis is by avoidance of allergens that trigger symptoms. Medications, available over the counter and as prescriptions, include nasal corticosteroids and antihistamines, oral antihistamines, oral montelukast, decongestants, and immunotherapy.
Considerations	New Combination Exclusivity • Competitor product Dymista is available generically and is also approved for patients as young as 6 years of age
Select Alternative Therapies	Dymista (azelastine hydrochloride; fluticasone propionate) NAS

XELSTRYM (DEXTROAMPHETAMINE), *TD*, HISAMITSU; NOVEN PHARMACEUTICALS

Indication	Treatment of Attention Deficit/Hyperactivity Disorder in adults and pediatric patients 6 years and older
Approval Date	3/22/2022
Clinical Overview	Attention Deficit/Hyperactivity Disorder (ADHD) is one of the most common neurodevelopmental disorders in childhood, and many patients will require treatment into adulthood. ADHD is characterized by inattention, hyperactivity, and impulsivity that can interfere with functioning or development. It has been estimated that 9.4% of the population is affected by childhood ADHD, while 3-5% of the US population is affected by ADHD into adulthood.
Considerations	Scheduled as a CII substance
Select Alternative Therapies	Stimulant medications, including methylphenidate and amphetamine derivates, have many generic and brand name options on the market. However, Xelstrym is the first-and-only FDA-approved transdermal amphetamine patch.

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
DESCOVY *emtricitabine; tenofovir alafenamide fumarate*	Gilead	PO	HIV-1 infection	1/7/2022
RINVOQ *upadacitinib*	AbbVie	PO	Moderate to severe atopic dermatitis	1/14/2022
VEKLURY *remdesivir*	Gilead	IV	COVID-19	1/21/2022
SKYRIZI *risankizumab-rzaa*	AbbVie	SC	Psoriatic arthritis	1/21/2022
SOLOSEC *secnidazole*	Lupin; Symbiomix Therapeutics	PO	Bacterial vaginosis and trichomoniasis (pediatrics)	1/26/2022
DELSTRIGO *doravirine; lamivudine; tenofovir disoproxil fumarate*	Merck	PO	HIV-1 infection (pediatrics)	1/27/2022
PIFELTRO *doravirine*	Merck	PO	HIV-1 infection (pediatrics)	1/27/2022
VONVENDI *von Willebrand factor (recombinant)*	Baxalta; Shire; Takeda	IV	Von Willebrand disease	1/28/2022
SPIKEVAX *COVID-19 vaccine*	Moderna	IM	COVID-19	1/31/2022
CABENUVA KIT *cabotegravir; rilpivirine*	ViiV Healthcare; Janssen	IM	HIV-1 infection	1/31/2022
FLEQSUVY *baclofen*	Azurity Pharmaceuticals	PO	Spasticity in multiple sclerosis	2/4/2022
daptomycin	Sagent Pharmaceuticals	IV	Staphylococcus blood infections (pediatrics)	2/7/2022
RELEUKO *filgrastim-ayow*	Amneal Pharmaceuticals; Kashiv Biosciences	IV/SC	Neutropenia in cancer patients	2/25/2022
ASPRUZYO SPRINKLE *ranolazine*	Sun	PO	Chronic angina	2/28/2022
NALOXONE AUTO-INJECTOR *naloxone*	Kaleo Pharma	IM/SC	Opioid overdose	2/28/2022

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
ACTEMRA *tocilizumab*	Chugai; Genentech; Roche	IV	Giant cell arteritis	2/28/2022
OPDIVO *nivolumab*	Bristol-Myers Squibb; Ono Pharmaceutical	IV	Non-small cell lung cancer	3/4/2022
ADLARITY *donepezil*	Corium	TD	Dementia associated with Alzheimer's Disease	3/11/2022
LYNPARZA *olaparib*	AstraZeneca; Merck	PO	Breast cancer	3/11/2022
RINVOQ *upadacitinib*	AbbVie	PO	Ulcerative colitis	3/16/2022
KEYTRUDA *pembrolizumab*	Merck	IV	Endometrial carcinoma	3/21/2022
HYFTOR *sirolimus*	Nobelpharma	TOP	Facial angiofibromas	3/22/2022
FINTEPLA *fenfluramine*	Zogenix	PO	Lennox-Gastaut syndrome	3/25/2022
OZEMPIC *semaglutide*	Novo Nordisk	SC	Type 2 Diabetes	3/28/2022

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
RUZURGI *amifampridine*	Jacobus Pharmaceutical	PO	Lambert-Eaton myasthenic syndrome	Tentative Approval
AK105 *penpulimab*	Akeso Biopharma; Chia Tai Tianqing	IV	Nasopharyngeal cancer	Pending (1H 2022)
BEVZ92 *bevacizumab*	Amneal; Insud Pharma; mAbxience	IV	Colorectal cancer	Pending (2Q 2022)
LY3298176 *tirzepatide*	Eli Lilly	SC	Type 2 diabetes	Pending (2Q 2022)
LUPIFIL-P *pegfilgrastim*	Lupin	SC	Cancer patients receiving myelosuppressive chemotherapy	Pending (04/2022)
TAPINAROF *tapinarof*	Dermavant	TOP	Plaque psoriasis	Pending (2Q 2022)
REGN-COV2 *casirivimab; imdevimab*	Regeneron	SC	COVID-19	Pending (04/13/2022)
ALN-TTRSC02 *vutrisiran*	Alnylam Pharmaceuticals; Arbutus Biopharma	SC	Familial amyloid polyneuropathy	Pending (04/14/2022)
MYK-461 *mavacamten*	Bristol-Myers Squibb; MyoKardia	PO	Hypertrophic cardiomyopathy	Pending (04/28/2022)
HMPL-012 *surufatinib*	Hutchmed	PO	Pancreatic neuroendocrine tumors	Pending (04/30/2022)
TAB001 *toripalimab*	Coherus BioSciences; Junshi Biosciences	INJ	Nasopharyngeal cancer	Pending (04/30/2022)
CUPRIOR *trientine tetrahydrochloride*	GMP-Orphan; Orphalan	PO	Wilson's disease	Pending (05/2022)
TYVASO *treprostinil*	MannKind Corporation; United Therapeutics	INH	Pulmonary arterial hypertension; Lung disease-associated pulmonary hypertension	Pending (05/2022); Pending (05/2022)
VABYSMO *faricimab-svoa*	Roche	IVT	Diabetic retinopathy	Pending (05/2022)
VONOPRAZEN *vonoprazan*	Phathom Pharmaceuticals; Takeda	PO	Eradication of Heliobacter pylori	Pending (05/03/2022)
RADICAVA *edaravone*	Mitsubishi Tanabe	PO	Lou Gehrig's disease	Pending (05/12/2022)

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
YCANTH *cantharidin*	Verrica	TOP	Molluscum contagiosum	Pending (05/24/2022)
AT2221 *miglustat*	Amicus Therapeutics	PO	Pompe disease	Pending (05/29/2022)
BI 655130 *spesolimab*	Boehringer Ingelheim	IV	Pustular psoriasis	Pending (06/2022)
TG-1101 *ublituximab*	TG Therapeutics	IV	Chronic lymphocytic leukemia	Pending (06/25/2022)
SPR994 *tebipenem pivoxil hydrobromide*	Meiji Seika; Spero Therapeutics	PO	Complicated UTI; Acute pyelonephritis	Pending (06/27/2022)
AMX0035 *tauroursodeoxycholic acid;* *sodium phenylbutyrate*	Amylyx Pharmaceuticals	PO	Lou Gehrig's disease	Pending (06/29/2022)