Capital Rx

Medication Pipeline Report

2022 - Q2

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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
SL — Sublingual

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 Determined to transform an outdated model, Capital Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change.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 **07/05/2022**

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VIJOICE (ALPELISIB), *PO,* NOVARTIS

Indication	Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-related overgrowth spectrum requiring systemic therapy
Approval Date	4/5/2022
Clinical Overview	PIK3CA-related overgrowth spectrum (PROS) is a group of rare conditions characterized by focal or segmental overgrowth of parts of the body due to mutations in the PIK3CA gene. PROS can present with a range of symptoms, depending on the specific disorder, including megalencephaly, hypotonia, seizures, intellectual disability, and blood vessel anomalies. It is estimated that PROS affects 14 people per 1 million.
Considerations	Priority Review • Breakthrough Therapy • Orphan Drug • Novartis markets alpelisib under the brand name Piqray for treatment, in combination with fulvestrant, of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced, or metastatic breast cancer
Select Alternative Therapies	Prior to the approval of Vijoice, the only treatment options for PROS were surgery or interventional radiology.

CUVRIOR (TRIENTINE TETRAHYDROCHLORIDE), *PO*, GMP-ORPHAN

Indication	Treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine
Approval Date	4/28/2022
Clinical Overview	Wilson's disease is a rare genetic disorder that results in copper accumulation in the liver, brain, and corneas of the eye. Wilson's disease has a worldwide prevalence of 1:30,000 live births and accounts for about 5% of patients with acute liver failure who are referred for emergency transplantation.
Select Alternative Therapies	Cuprimine (penicillamine) PO, Depen (penicillamine) PO, Syprine (trientine hydrochloride) PO

CAMZYOS (MAVACAMTEN) , *PO*, MYOKARDIA INC.

Indication	Treatment of adults with symptomatic New York Heart Association class II–III obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms
Approval Date	4/28/2022
Clinical Overview	Hypertrophic cardiomyopathy (HCM) is the most common genetic cardiovascular disorder and affects an estimated 1 in 500 individuals worldwide. However, only about 1 in 3200 people in the United States are diagnosed with HCM and experience symptoms. About two-thirds of patients with HCM are diagnosed with obstructive HCM (oHCM). Patients with symptomatic oHCM are at high risk of progressive disease, which can lead to atrial fibrillation, stroke, and death due to arrhythmias.
Considerations	Available through a Risk Evaluation and Mitigation Strategy (REMS) program
Select Alternative Therapies	Currently, there are no other FDA-approved medications that specifically treat oHCM, but medications including beta blockers, calcium channel blockers, anti-arrhythmic drugs, heart failure drugs, and anticoagulants, are used to ease symptoms and prevent complications. Septal reduction procedures can have substantial benefit.

AMVUTTRA (VUTRISIRAN), *SC*, ALNYLAM PHARMACEUTICALS

Indication	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
Approval Date	6/13/2022
Clinical Overview	Hereditary transthyretin-mediated amyloidosis (hATTR) is a rare and progressive inherited disorder where amyloid fibrils accumulate in the body. In the polyneuropathy of hATTR (hATTR-PN), amyloid fibrils are deposited in the peripheral nerves, causing pain, muscle weakness, and autonomic dysfunction. It is estimated that less than 3000 U.S. patients are currently diagnosed with hATTR-PN.
Considerations	Healthcare Administered
Select Alternative Therapies:	Onpattro (patisiran) IV, Tegsedi (inotersen) SC

IGALMI (DEXMEDETOMIDINE), *SL*, BIOXCEL THERAPEUTICS

Indication	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults
Approval Date	4/6/2022
Clinical Overview	Schizophrenia and Bipolar disorder are mental health conditions affecting an estimated 1.5 million (<1%) and 7 million (2.8%) individuals in the United States, respectively. Both conditions share the overlapping symptom of agitation, which can include excessive motor and/or verbal activity, uncooperativeness, irritability, heightened responsiveness to stimuli, threatening gestures, and assault (verbal and/or physical). Up to 25% of people with schizophrenia or bipolar disorder experience agitation.
Considerations	Healthcare Administered
Select Alternative Therapies	Treatment of an acute agitation episode usually consists of verbal calming techniques, physical restraints, antipsychotics, and/or benzodiazepines; Precedex (dexmedetomidine) IV

VIVJOA (OTESECONAZOLE), *PO*, MYCOVIA PHARMACEUTICALS

Indication	Reduce the incidence of recurrent vulvovaginal candidiasis in females with a history of RVVC who are not of reproductive potential
Approval Date	4/26/2022
Clinical Overview	Vulvovaginal candidiasis (VVC) is associated with significant genital discomfort, reduced sexual pleasure, psychological distress, and loss of productivity. Recurrent VVC (RVVC) is defined as three or more episodes of symptomatic VVC within a year. Approximately 70% of women worldwide experience VVC, and an estimated 5% experience RVVC.
Considerations	Qualified Infectious Disease Product • Fast Track Designation
Select Alternative Therapies	Vivjoa is the first and only FDA-approved medication for RVVC. Off-label fluconazole is the standard of care for RVVC with an induction dose followed by a maintenance regimen.

VOQUEZNA DUAL PAK (AMOXICILLIN; VONOPRAZAN), *PO*, PHATHOM PHARMACEUTICALS

Indication	Treatment of H. pylori infection in adults
Approval Date	5/3/2022
Clinical Overview	H. pylori infection is one of the most common bacterial infections worldwide and has an estimated prevalence of about 35% in the United States. Most people who are infected with H. pylori will be asymptomatic and will not develop complications. However, in some people infected with H. pylori, it can lead to complications such as peptic ulcer disease and gastric cancer.
Considerations	Also available as Voquezna Triple Pak (amoxicillin; clarithromycin; vonoprazan)
Select Alternative Therapies	Standard of care includes an acid suppressive agent, such as a proton pump inhibitor (PPI) used in combination with antibiotic therapy

VOQUEZNA TRIPLE PAK, (AMOXICILLIN; CLARITHROMYCIN; VONOPRAZAN), *PO*, PHATHOM PHARMACEUTICALS

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Considerations	Also available as Voquezna Dual Pak (amoxicillin; vonoprazan)
Select Alternative Therapies	Standard of care includes an acid suppressive agent, such as a proton pump inhibitor (PPI) used in combination with antibiotic therapy

MOUNJARO (TIRZEPATIDE), *SC*, ELI LILLY

Indication	Adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes (T2D)
Approval Date	5/13/2022
Clinical Overview	Diabetes is a chronic, progressive, metabolic disorder characterized by persistently high blood glucose (hyperglycemia) due to inadequate levels of insulin in the body. T2D is one of the most common metabolic disorders and is classified by the presence of insulin resistance and β-cell dysfunction. Diabetes can often lead to long-term complications and failure of various organs. More than 37 million people in the United States currently have diabetes. T2D accounts for 90% of the total diabetes cases.
Considerations	Lilly is also pursuing a weight loss indication for Mounjaro • Mounjaro is the first FDA-approved dual GIP/GLP-1 agonist
Select Alternative Therapies	Trulicity (dulaglutide) SC, Rybelsus (semaglutide) PO, Ozempic (semaglutide) SC, Victoza (liraglutide) SC

VTAMA (TAPINAROF), *TOP*, DERMAVANT

Indication	Treatment of mild, moderate, or severe plaque psoriasis in adults
Approval Date	5/24/2022
Clinical Overview	Psoriasis affects an estimated 8 million Americans. Psoriasis can start at any age. In younger patients, psoriasis symptoms often start between the ages of 15 and 25. In adults, peak onset of psoriasis is between ages 30 and 39 and between ages 50 and 69. Plaque psoriasis is the most common of the 5 types of psoriasis, affecting 80%-90% of those with psoriasis. Definitions of “moderate-to-severe” plaque psoriasis vary, but generally consist of psoriasis that affects at least 3% of a patient’s body surface; produces lesions that have significant redness, thickness, and scale; or significantly reduces quality of life.
Select Alternative Therapies	Zoryve (roflumilast), Dovonex (calcipotriene), Tazorac (tazarotene), Taclonex (calcipotriene/betamethasone diproprionate), Duobrii (Halobetasol proprionate/tazarotene) topical

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
YESCARTA *axicabtagene ciloleucel*	Gilead	IV	B-cell lymphoma	4/1/2022
XIGDUO XR *dapagliflozin; metformin*	AstraZeneca	PO	Chronic kidney disease	4/11/2022
ALYMSYS *bevacizumab-maly*	Amneal	IV	Cancer	4/13/2022
glycopyrrolate	Fresenius	IM; IV	Anesthesia; Peptic ulcer	4/21/2022
EPSOLAY *benzoyl peroxide*	Sol-Gel Technologies	TOP	Rosacea	4/22/2022
VEKLURY *remdesivir*	Gilead	IV	COVID-19 (pediatrics)	4/25/2022
ULTOMIRIS *ravulizumab-cwvz*	Alexion Pharmaceuticals	IV	Myasthenia Gravis	4/27/2022
QELBREE *viloxazine*	Supernus Pharmaceuticals	PO	Attention deficit hyperactivity disorder (adults)	4/29/2022
RINVOQ *upadacitinib*	AbbVie	PO	Ankylosing spondylitis	4/29/2022
ERMEZA *levothyroxine*	Mylan	PO	Differentiated thyroid cancer; hypothyroidism	4/29/2022
OLUMIANT *baricitinib*	Eli Lilly	PO	COVID-19	5/10/2022
RADICAVA ORS *edaravone*	Mitsubishi Tanabe	PO	Amyotrophic lateral sclerosis	5/12/2022
TPOXX IV *tecovirimat*	SIGA Technologies	IV	Smallpox	5/18/2022
DUPIXENT *dupilumab*	Genzyme	SC	Eosinophilic esophagitis	5/20/2022
TYVASO DPI *treprostinil*	United Therapeutics Corporation	INH	Pulmonary arterial hypertension; pulmonary hypertension associated with interstitial lung disease	5/23/2022

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
FYLNETRA *pegfilgrastim-pbbk*	Adello Biologics	SC	Cancer patients receiving myelosuppressive chemotherapy	5/26/2022
EVRYSDI *risdiplam*	Genentech	PO	Spinal muscular atrophy	5/27/2022
KYMRIAH *tisagenlecleucel-T*	Novartis	IV	Follicular lymphoma	5/27/2022
OPDIVO *nivolumab*	Bristol-Myers Squibb	IV	Esophageal cancer	5/27/2022
YERVOY *ipilimumab*	Bristol-Myers Squibb	IV	Esophageal cancer	5/27/2022
RIABNI *rituximab-arrx*	AbbVie	IV	Rheumatoid arthritis	6/3/2022
PRIORIX *MMR live vaccine*	GSK	SC	Measles, mumps, rubella	6/3/2022
CELLCEPT *mycophenolate mofetil*	Genentech	IV; PO	Prophylaxis of organ rejection (pediatrics)	6/6/2022
DUPIXENT *dupilumab*	Genzyme	SC	Atopic dermatitis (pediatrics)	6/7/2022
OLUMIANT *baricitinib*	Eli Lilly	PO	Alopecia areata	6/13/2022
IMCIVREE *setmelanotide acetate*	Ipsen	SC	Bardet-Biedl syndrome	6/16/2022
SKYRIZI IV *risankizumab-rzaa*	AbbVie	IV	Crohn's disease	6/16/2022
VAXNEUVANCE *pneumococcal 15-valent conjugate vaccine*	Ligand Pharmaceuticals	IM	Pneumococcal disease	6/17/2022
TAFINLAR *dabrafenib mesylate*	Novartis	PO	Solid tumors	6/22/2022
MEKINIST *trametinib dimethyl sulfoxide*	GSK	PO	Solid tumors	6/22/2022

ADDITIONAL BRAND APPROVALS

BRAND *(GENERIC)*	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	FDA APPROVAL DATE
BREYANZI *lisocabtagene maraleucel*	Juno Therapeutics	IV	B-cell lymphoma	6/24/2022
QSYMIA *phentermine*	Vivus	PO	Chronic weight management	6/24/2022
drospirenone	Exeltis	PO	Pregnancy prevention	6/29/2022
VENBYSI XR *venlafaxine besylate*	Almatica Pharma	PO	Generalized anxiety disorder; major depressive disorder	6/29/2022

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
KRYSTEXXA *pegloticase*	Horizon Pharma	IV	Chronic gout	Pending (07/07/2022)
BGB-A317 *tislelizumab*	BeiGene; Novartis	IV	Esophageal cancer	Pending (07/12/2022)
REGN-COV2 *casirivimab; imdevimab*	Regeneron	SC	COVID-19	Pending (07/13/2022)
ET-104 *zonisamide*	Azurity Pharmaceuticals; Eton Pharmaceuticals	PO	Partial onset seizures in epilepsy	Pending (07/18/2022)
OPZELURA *ruxolitinib phosphate*	Incyte	TOP	Vitiligo	Pending (07/18/2022)
ARQ-151 *roflumilast*	Arcutis Biotherapeutics	TOP	Plaque psoriasis	Pending (07/29/2022)
CIMERLI *ranibizumab*	bioeq; Coherus BioSciences; Formycon; Polpharma; Santo Holding; Swiss Pharma International AG	IVT	Wet age-related macular degeneration	Pending (08/02/2022)
BIORPHEN VIAL *phenylephrine hydrochloride*	Eton Pharmaceuticals; Sintetica	IV	Treatment of hypotension resulting from anesthesia	Pending (08/04/2022)
NUPLAZID *pimavanserin tartrate*	Acadia Pharmaceuticals	PO	Psychosis associated with Alzheimer's disease	Pending (08/04/2022)
MYFEMBREE *estradiol; norethindrone acetate; relugolix*	Myovant Sciences; Pfizer; Roivant; Takeda	PO	Endometriosis	Pending (08/06/2022)
BETI-CEL *betibeglogene autotemcel*	bluebird bio	IV	Beta thalassemia	Pending (08/19/2022)
AT2221 *miglustat*	Amicus Therapeutics	PO	Pompe disease (Glycogen storage disease type II)	Pending (08/29/2022)
SB5 HC *adalimumab*	Organon; Samsung Bioepis	INJ	Juvenile idiopathic arthritis; Ulcerative colitis; Rheumatoid arthritis; Psoriatic arthritis; Ankylosing spondylitis; Crohn's disease; Plaque psoriasis	Pending (08/2022)
TX05 *trastuzumab*	Tanvex	INJ	HER2-positive breast cancer	Pending (08/2022)
STELARA SC *Ustekinumab*	Janssen	SC	Psoriatic arthritis	Pending (08/2022)

PRODUCTS IN THE PIPELINE

PIPELINE NAME *(GENERIC)*	COMPANY	ROUTE	INDICATION	FDA APPROVAL DATE
DAXI *daxibotulinumtoxinA*	Revance	IM	Glabellar frown lines	Pending (09/08/2022)
ROLONTIS *eflapegrastim*	Hanmi Pharmaceutical; Spectrum Therapeutics	SC	Cancer patients receiving myelosuppressive chemotherapy	Pending (09/09/2022)
BMS-986165 *deucravacitinib*	Bristol-Myers Squibb	PO	Plaque psoriasis	Pending (09/10/2022)
OBE2109 *linzagolix*	Kissei; ObsEva	PO	Uterine fibroids	Pending (09/13/2022)
LENTI-D *elivaldogene autotemcel*	bluebird bio	IV	Adrenoleukodystrophy	Pending (09/16/2022)
HTX-019 *aprepitant*	Heron Therapeutics	IV	Postoperative nausea and vomiting (PONV)	Pending (09/17/2022)
LIBTAYO IV *cemiplimab-rwlc*	Regeneron; Sanofi	IV	Non-small cell lung cancer (NSCLC)	Pending (09/19/2022)
AMX0035 *tauroursodeoxycholic acid; sodium phenylbutyrate*	Amylyx Pharmaceuticals	PO	Lou Gehrig's disease (amyotrophic lateral sclerosis (ALS)	Pending (09/29/2022)
MYRCLUDEX B *bulevirtide*	Gilead; MYR Pharmaceuticals	SC	Hepatitis D	Pending (3Q 2022)
IMFINZI *durvalumab*	AstraZeneca; MedImmune	IV	Biliary tract cancer	Pending (3Q 2022)
ENHERTU *fam-trastuzumab deruxtecan-nxki*	AstraZeneca; Daiichi Sankyo	IV	Non-small cell lung cancer (NSCLC)	Pending (3Q 2022)
TAS-120 *futibatinib*	Taiho Pharma	PO	Biliary tract cancer	Pending (09/30/2022)