Kroger Prescription Plans

Q2 Recent Drug Developments and Product Approvals

At Kroger Prescription Plans (KPP), we understand that staying ahead of drug development and market launch is key to successful drug spend management. By analyzing how future drug approvals will change the prescribing landscape, clients and payers can more easily anticipate future drug spend and take appropriate steps to ensure drug costs don't spiral out of control.

On a quarterly basis, KPP researches and analyzes new drug approvals with the goal of predicting how these products will disrupt the clinical status quo.

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With the help of our in-house Pharmacy and Therapeutics committee, and our wholly owned specialty pharmacy, Kroger Specialty Pharmacy (KSP), our goal is to provide best-in-class clinical analytics for our clients. Our clinical team has summarized the key products that have recently come to market or are anticipated to launch in the coming months.

Livtencity (maribavir) by Takeda

Apretude (cabotegravir) by ViiV Healthcare

Vyvgart (efgartigimod alfa-fcab) by Argenz BV

Tezspire (tezepelumab-ekko) by AstraZeneca and Amgen

Adbry (tralokinumab-ldrm) by LEO Pharma

Vabysmo (faricimab-svoa) by Roche/Genentech

Cibinqo (abrocitinib) by Pfizer

For more information regarding these products or if you have any questions regarding our innovative clinical solutions and what KPP is doing to control drug costs, please contact:

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Livtencity (maribavir)
by Takeda

The U.S. Food and Drug Administration (FDA) recently approved Livtencity (maribavir) to treat patients 12 years of age and older (and weighing at least 35 kilograms) with cytomegalovirus (CMV) infection that is resistant to available antiviral treatment after hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). Livtencity is the first drug approved to treat CMV in this capacity. The Centers for Disease Control and Prevention (CDC) estimates that nearly one in three children in the United States have been exposed to the virus by 5 years of age, and more than half of the U.S. population has been exposed to the virus by 40 years of age. Although most patients are asymptomatic CMV disease can be life-threatening in those who are immunocompromised. In SOT recipients, CMV infection may result in loss of the transplanted organ in up to 25% of cases. Livtencity is not FDA-approved in patients with human immunodeficiency virus (HIV) or other nontransplant populations, nor is it approved for prophylaxis of CMV infection.

Apretude (cabotegravir) by ViiV Healthcare

On December 20, 2021, the FDA approved Apretude (cabotegravir extended-release injectable suspension) for the pre-exposure prophylaxis (PrEP) of HIV infection in at-risk adults and adolescents weighing at least 35 kg. Like Truvada and Descovy, Apretude has a black box warning indicating patients must have a negative HIV-1 test prior to initiating therapy for PrEP. A negative HIV-1 test is also required before each subsequent dose. The CDC states that PrEP use has increased for HIV prevention in the United States. Preliminary data show that in 2020, about one-quarter of the 1.2 million people for whom PrEP was recommended received medication, compared to only about 3% in 2015. Medication adherence is vitally important in PrEP use, and many patients at risk for acquiring HIV are noncompliant with daily medications.

Vyvgart (efgartigimod alfa-fcab)
by Argenx BV

In December 2021, the FDA approved Vyvgart (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adults positive for anti-acetylcholine receptor (AChR) antibodies representing about 85% of the total gMG population. Generalized myasthenia gravis is a chronic autoimmune, neuromuscular disease that causes muscle weakness and fatigue. Unfortunately, there is no cure for gMG, with symptoms progressing over time. Vyvgart is a first-in-class human immunoglobulin G1 (IgG1) antibody fragment. The annual wholesale acquisition cost (WAC) of Vyvgart will vary based on patient weight and an individualized dosing frequency. The estimated annualized cost for an 80-kg patient receiving six treatment cycles per year is close to $285,000.

Tezspire (tezepelumab-ekko) by AstraZeneca and Amgen

On December 17, 2021, the FDA approved Tezspire (tezepelumab-ekko) for the add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma. Tezspire is a first-in-class monoclonal antibody that blocks the action of thymic stromal lymphopoietin (TSLP), an epithelial cytokine that acts at the top of the inflammatory

cascade implicated in the pathogenesis of asthma. Tezspire is the only biologic approved for severe asthma without concern for phenotype or biomarker limitation. Tezspire is administered subcutaneously every four weeks and is intended to be administered by a healthcare provider. Tezspire joins a competitive market class, with five other biologics already approved to treat severe asthma. Tezspire is the first biologic agent to demonstrate a clinically significant reduction in asthma exacerbations in patients with low blood eosinophil levels. Experts note that the the initial uptake of Tezspire is likely to be focused on the non-eosinophilic severe asthma population due to an unmet need in this space.

Adbry (tralokinumab-idrm) by LEO Pharma

On December 27, 2021, the FDA approved Adbry (tralokinumab-ldrm) for the treatment of moderate to severe atopic dermatitis (AD) in adults ≥18 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry is the first biologic approved that directly inhibits interleukin (IL)-13 and the second biologic approved in the AD category. Dupixent (dupilumab), which binds to the IL-4 receptor alpha (IL-4Rα) subunit and inhibits IL-4 and IL-13 signaling, was approved for AD in early 2017. Adbry will compete directly with Dupixent; however, it is possible that Adbry will have difficulty overtaking Dupixent's market share given Dupixent's first-to-market status and broad commercial coverage.

Vabysmo (faricimab-svoa) by Roche/Genetech

In January 2022, the FDA approved (faricimab-svoa) for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). Vabysmo is the first bispecific antibody approved for ophthalmic use. Vabysmo is the second Genentech product approved for AMD in the recent past; Susvimo (ranibizumab), an ocular implant, was approved in October 2021. For patients who can be maintained on an every-16-week injection schedule, Vabysmo represents a cost-effective treatment option. Lucentis biosimilars are expected in late 2022 with Eylea biosimilars coming in 2024. Multiple competitors are expected to launch versions for both products.

Cibinqo (abrocitinib) by Pfizer

On January 14, 2022, the FDA approved Cibinqo (abrocitinib), an oral once-daily Janus kinase 1 (JAK1) inhibitor, for the treatment of adults ≥18 years of age with refractory, moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Cibinqo's labeling shares the same risks as other JAK inhibitors on the market. Cibinqo and Rinvoq, which was also approved for AD on January 14, 2022, represent the first oral JAK inhibitors approved by the FDA for this indication. These agents will help fill an unmet need for further chronic therapy options in patients who fail or are not candidates for biologics. Two strengths of Cibinqo were approved: 100 mg and 200 mg, with the 200-mg dose reserved for patients who do not respond to the lower dose after 12 weeks. It likely that Pfizer will seek approval in a lower age population to compete with Rinvoq's approval to treat patients as young as 12 years of age.