Kroger Prescription Plans

Q3 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.

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.

DayBue (trofinetide)
by Acadia Pharmaceuticals

Filspari (sparsentan)
by Travere Therapeutics

Epkinly (epcoritamab)
by AbbVie and Genmab

Joenja (leniolisib)
by Pharming Healthcare

Lamzede (velmanase alfa)
by Chiesi

Omisirge (omidubicel)
by Gamida

Qalsody (tofersen)
by Biogen

Veozah (fezolinetant)
by Astella

Zynyz (retifanlimab)
by Incyte Corporation

Skyclarys (omaveloxolone)
by Reata Pharmaceuticals

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DayBue (trofinetide
by Acadia Pharmaceuticals

On March 10, 2023, the U.S. Food and Drug Administration (FDA) approved Daybue (trofinetide) for treatment of Rett syndrome (RTT) in patients 2 years of age and older. Daybue is administered orally or via a gastrostomy tube twice daily. Given the rarity of RTT it is unlikely that most payers will see claims for this product.

***Filspari* (sparsentan)**
by Travere Therapeutics

The U.S. Food and Drug Administration (FDA) granted accelerated approval for Filspari (sparsentan) on February 17, 2023, as the first non-immunosuppressive therapy approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for rapid disease progression. Safety and efficacy data suggests this agent is likely to be used later in the treatment lifecycle; therefore, prior authorization is recommended to ensure appropriate utilization.

Epkinly (epcoritamab)
by AbbVie and Genmab

On May 19, 2023, the U.S. Food and Drug Administration (FDA) approved Epkinly (epcoritamab-bysp) for the treatment of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL), following ≥2 lines of systemic therapies. Epkinly is likely to compete with Kymriah, Yescarta, and Breyanzi in the third line setting.

Joenja (leniolisib)
by Pharming Healthcare

On March 24, 2023, the U.S. Food and Drug Administration (FDA) approved Joenja (leniolisib) for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in patients 12 years of age and older. Given the rarity of this disease (less than 500 patients in the United States) it is unlikely most payers will see prescription claims for this product. The typical 30-day cost for Joenja is about $45,000.

Lamzede (velmanase alfa)
by Chiesi

The U.S. Food and Drug Administration (FDA) approved Lamzede (velmanase alfatycv) on February 16, 2023, as the first and only treatment of non–central nervous system manifestations of alpha-mannosidosis (AM) in adult and pediatric patients. AM is an ultra-rare, progressive lysosomal storage disorder indicated by a deficiency of the enzyme alpha-mannosidase. Similar to other rare diseases, most payers are unlikely to see pharmacy claims; although, the use of rare disease programs which offer a targeted clinical review is recommended. The estimated annual cost for Lamzede sits at around $1.2M.

Omisirge (omidubicel)
by Gamida

On April 17, 2023, the U.S. Food and Drug Administration (FDA) approved Omisirge (omidubicel-onlv to decrease the time to neutrophil recovery and infections in patients 12 years of age and older with blood cancers who plan to have umbilical cord blood transplantation (UCBT) following a myeloablative conditioning regimen. Omisirge is made from stem cells derived from umbilical cord blood (UCB) that are processed and cultured with nicotinamide. Omisirge is a one-time, patient-specific treatment which is administered in transplant centers around the country. Retail pharmacy claims are also unlikely for this product, especially considering its price of over $300,000 for a one-time treatment.

Qalsody (tofersen)
by Biogen

On April 25, 2023, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Qalsody (tofersen) to treat adult patients with amyotrophic lateral sclerosis (ALS) who have the superoxide dismutase 1 (SOD1) gene (SOD1-ALS) mutation. Qalsody represents the first FDA-approved therapy specifically for ALS patients who harbor a SOD1 mutation. Qalsody is administered via the intrathecal route and is unlikely to be seen in retail pharmacy claims. The estimated year treatment cost is $200,000.

Veozah (fezolinetant)
by Astella

On May 12, 2023, the U.S. Food and Drug Administration (FDA) approved Veozah (fezolinetant), an oral, nonhormonal therapy for the treatment of moderate to severe vasomotor symptoms (VMS), or hot flashes, accompanied with menopause. Hormone replacement therapy (HRT) continues to remain the gold standard in this patient population; however, Veozah may offer an alternative treatment option for woman who are not candidates for HRT (e.g., patients with a history of coronary artery disease). Payers can expect a price tag of $7,000 for a year's worth of therapy.

Zynyz (retifanlimab)
by Incyte Corporation

The U.S. Food and Drug Administration (FDA) granted accelerated approval to Zynyz (retifanlimab-dlwr) on March 22, 2023, for the treatment of adult patients who have metastatic or recurrent locally advanced Merkel cell carcinoma (MCC). MCC is an uncommon and aggressive type of skin cancer with an overall 5-year survival rate of around 14%. Zynyz is likely to compete with Keytruda, Opdivo, and Bavencio in this space.

Skyclarys (omaveloxolone)
by Reata Pharmaceuticals

On February 28, 2023, the U.S. Food and Drug Administration (FDA) approved Skyclarys (omaveloxolone; for the treatment of Friedreich's ataxia (FA or FRDA) in patients 16 years of age and older. Skyclarys represents the first approved therapy for this condition in the United States. An ultra-rare, inherited neurodegenerative disorder estimates point to around 4,000-6,000 patients with diagnosed FA in the United States, and about 15,000-22,000 around the world. The annual wholesale acquisition cost (WAC) of Skyclarys is $375,136.