



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.

800.917.4926

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Winrevair (sotatercept-csrk)
by Merck and Co

Ojemda (tovorafenib)
by Day One Biopharmaceuticals

Tryvio (aprocitentan)
by Idorsia

Xolremdi (mavorixafor)
by X4 Pharmaceuticals

Rezdiffra (resmetirom)
by Madrigal Pharmaceuticals

Voydeya (danicopan)
by Alexion Pharmaceuticals



Nelson Aragon, Pharm.D.
Clinical Formulary Manager
nelson.aragon@krogerhealth.com

Winrevair (sotatercept-csrk)
by Merck and Co

On March 26, 2024, the United States Food and Drug Administration (FDA) approved Winrevair, a subcutaneous activin signaling inhibitor, indicated for use in adults with pulmonary arterial hypertension (PAH). Winrevair is the first activin signaling inhibitor to be approved by the FDA for PAH. While there are other preferred options available on the market indicated for PAH, Winrevair may offer benefit as added therapy for patients inadequately controlled on initial treatment. Exposure to Winrevair is expected to be limited as PAH is only diagnosed in an estimated 40,000 to 50,000 patients in the United States and uptake by prescribers may be slow.

Ojemda (tovorafenib)
by Day one Biopharmaceuticals

On April 23, 2024, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Day One Biopharmaceuticals' Ojemda, an oral type II RAF kinase inhibitor, for patients 6 months of age and older with relapsed or refractory (R/R) pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. Ojemda is the first FDA-approved systemic therapy for pLGG with BRAF rearrangements, including fusions, and is the second agent approved for BRAF V600-mutated pLGG. Payers are likely to have limited exposure to Ojemda as there are only an estimated 1,100 diagnosed cases of BRAF-mutated pLGG annually in the United States. Guidance on the preferred systemic treatment for BRAF-mutated pLGG is expected in the near future as additional trials are completed.

Tryvio (aprocitentan)
by Idorsia

On March 19, 2024, the U.S. Food and Drug Administration (FDA) approved Idorsia's Tryvio (aprocitentan), an oral endothelin receptor antagonist for the treatment of resistant high blood pressure in combination with other blood pressure medications. This is the first oral antihypertensive drug approved in over 30 years that targets the endothelin pathway. Despite the common diagnosis of high blood pressure, payers should expect to see Tryvio appear further down as 4th or 5th line in therapy.

Xolremdi (mavorixafor)
by X4 Pharmaceuticals

On April 26, 2024, the U.S. Food and Drug Administration (FDA) approved X4 Pharmaceutical's Xolremdi, a selective CXCR4 chemokine receptor 4 (CXCR4) antagonist for the treatment of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome in patients 12 years of age and older. This is the first FDA-approved medication indicated for WHIM syndrome as it addresses the underlying cause of the disease. However, WHIM syndrome is currently estimated to only have about 1,000 cases in the United States, so payers can expect to have very limited exposure to Xolremdi.

Rezdiffra (resmetirom)
by Madrigal Pharmaceuticals

On March 14, 2024, the U.S. Food and Drug Administration (FDA) approved Madrigal Pharmaceutical's Rezdiffra (resmetirom), an oral, thyroid receptor-beta agonist indicated for noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to severe fibrosis. Rezdiffra is the first FDA-approved treatment for NASH with moderate to severe fibrosis, a condition where many other molecules have failed to show benefit. Payers should expect somewhat limited exposure, as only 1.5-6.5% of the U.S. population has NASH, but as Madrigal Pharmaceuticals seeks to gain expanded indications for Rezdiffra in nonalcoholic fatty liver disease (NAFLD), this drug may become more popular. NAFLD is estimated to affect up to 25% of the U.S. population.
