Kroger Prescription Plans

Q4 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.

Zavzpret (zavegepant)
by Biohaven and Pfizer

Inpefa (Sotagliflozin)
by Lexicon Pharmaceuticals

Miebo (perfluorohexyloctane)
by Novaliq and Bausch + Lamb

Roctavian (valoctocogene roxaparvovec)
by BioMarin

***Vanflyta* (quizartinib)**
by Ambit Biosciences and Daiichi Sankyo

Xdemvy (lotilaner)
by Tarsus Pharmaceuticals

Ngenla (somatrogon-ghla)
by OPKO Health and Pfizer

***Brenzavvy* (bexagliflozin)**
by TheracosBio

Akeega (abiraterone acetate and niraparib)
by Janssen

***Litfulo* (ritlecitinib)**
by Pfizer

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Zavzpret (zavegepant)
by Biohaven and Pfizer

On March 10, 2023, the U.S. Food and Drug Administration (FDA) approved Zavzpret (zavegepant), the first calcitonin gene-related peptide (CGRP) inhibitor available as a nasal spray, for the acute treatment of migraine with or without aura in adults. Due to multiple products being approved for acute migraine treatment, including generic triptans, payers should consider step therapy, prior authorization, and quantity limits to manage utilization and costs.

Inpefa (sotagliflozin)
by Lexicon Pharmaceuticals

On May 26, 2023, the FDA approved Inpefa (sotagliflozin) to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HHF), and urgent heart failure (HF) visits in adults with HF or type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and other CV risk factors. With Inpefa having only a heart failure indication currently, an unclear mechanistic advantage over therapeutic alternatives, and anticipated similar cost, payers will likely maintain the formulary status of currently available sodium-glucose cotransporter type 2 (SGLT2) inhibitors. If adding to formulary, consider a prior authorization to ensure appropriate use.

Miebo (perfluorohexyloctane)
by Novaliq and Bausch + Lamb

On May 18, 2023, the FDA approved Miebo (perfluorohexyloctane) ophthalmic solution; formerly known as NOV03), for the treatment of the signs and symptoms of dry eye disease (DED). Miebo is now commercially available at a wholesale acquisition cost (WAC) of $771 per 5 mL bottle. The cost of Miebo is slightly higher than other brand dry eye products, which range in price from $500 to $700 (WAC) per month, and significantly higher than generic Restasis versions, which are now around $200 per month.

Roctavian (valoctocogene roxaparvovec-rvox)
by BioMarin

On June 29, 2023, the FDA approved Roctavian (valoctocogene roxaparvovec-rvox), the first gene therapy for the treatment of adults with severe hemophilia A (congenital Factor VIII [FVIII] deficiency with FVIII activity <1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5), as detected by an FDA-approved test. Roctavian is administered intravenously (IV) as a one-time dose and has an anticipated a WAC of $2.9 million. Due to its high cost, payers should implement prior authorization to reserve use for patient populations most likely to benefit from this treatment.

Vanflyta (valoctocogene roxaparvovec)
by BioMarin

On July 20, 2023, the FDA approved Vanflyta (quizartinib) in combination with cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adults with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)–positive as detected by an FDA approved test. The use of pharmacy management tools to ensure appropriate use of Vanflyta is recommended.

Xdemvy (lotilaner)
by Tarsus Pharmaceuticals

On July 24, 2023, the FDA approved Xdemvy (lotilaner ophthalmic solution) 0.25% for the treatment of Demodex blepharitis (DB), a common eyelid condition that affects approximately 25 million patients in the US. The anti-parasitic topical ophthalmic solution Xdemvy is the first treatment approved by the FDA for DB. The agent has a WAC of $1,850 per 6-week treatment course, but some patients may eventually require retreatment. Tarsus is planning to offer copay assistance to ensure that eligible patients pay no more than $100 per treatment course. A prior authorization is recommended to ensure use in the appropriate patient population, as well as quantity limits to ensure appropriate duration of therapy.

Ngenla (somatrogon-ghla)
by Opko Health and Pfizer

On June 27, 2023, the FDA approved Ngenla (somatrogon-ghla), a once-weekly human growth hormone (hGH) analog indicated for the treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH). Ngenla has an annual WAC of about $99,600 for a child weighing 35 kg. It will compete with daily somatropin products, of which several are available at a lower cost than the once-weekly products.

Brenzavvy (bexagliflozin)
by TheracosBio

On January 20, 2023, the FDA approved Brenzavvy (bexagliflozin), an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, for use as an adjunct treatment with diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). Payers can manage Brenzavvy in the same way as other SGLT2 inhibitors, and should consider step therapy with metformin to ensure appropriate use. Payers will likely maintain the current formulary positioning of previously approved SGLT2 inhibitors, as Brenzavvy is expected to struggle to gain market share as the fifth SGLT2 inhibitor approved for T2DM and due to the anticipated generic availability of Farxiga starting in 2025.

Akeega (abiraterone acetate and niraparib)
by Janssen

On August 11, 2023, the FDA approved the fixed-dose combination of niraparib and abiraterone acetate (Akeega) with prednisone, for adult patients with deleterious or suspected deleterious BRCA-mutation (BRCAm) positive metastatic castration-resistant prostate cancer (mCRPC). This is the first and only dual-action tablet combining a PARPi (polymerase inhibitor), niraparib, with the androgen deprivation therapy (ARDT) abiraterone, and the third “two-drug” combination approved for treatment of mCRPC. Payer preference in this space is likely for Akeega and for Lynparza plus abiraterone if the patient has BRCAm mCRPC (10%–15% of mCRPC cases). Payers may require step therapy prior to coverage of Talzenna and Xtandi, which can be reserved for patients who may not be able to tolerate the other two regimens.

Litfulo (ritlecitinib)
by Pfizer

On June 23, 2023, the FDA approved Litfulo (ritlecitinib) as a once daily oral treatment for severe alopecia areata (AA) in individuals 12 years of age and older. Litfulo is the first drug approved for children 12 years of age and older with severe AA and the second drug approved for the treatment of AA overall, after Eli Lilly/Incyte’s Olumiant (baricitinib). Many payers consider AA to be a cosmetic condition and do not consider its treatment medically necessary. For payers that do cover AA treatments, a prior authorization is recommended with either Litfulo or Olumiant as a preferred product for AA treatment