Kroger Prescription Plans

Q1 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, 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.

Yorvipath
by Ascendis Pharma

Ebglyss
by Eli Lilly

Aqneursa
by IntraBio

Miplyffa
by Zevra Therapeutics

Cobenfy
by Bristol Myers Squibbs (BMS)

Itovebi
by Roche/Genentech's

Hympavzi
by Pfizer

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Yorvipath
by Ascendis Pharmaa

On August 9, 2024, the U.S. Food and Drug Administration (FDA) approved Yorvipath (palopegteriparatide), a parathyroid hormone (PTH) analog indicated for the treatment of hypoparathyroidism (HP) in adults. HP is a rare endocrine disorder characterized by insufficient levels of PTH, resulting in low calcium and elevated phosphate levels in the blood that can cause a range of symptoms depending on the extent of the deficiency. Yorvipath is currently the only PTH analog approved for HP that is on the market. Yorvipath is self-administered once daily subcutaneous injection. Yorvipath utilizes transient conjugation technology for a longer half-life, which allows for a more gradual and sustained release of PTH over 24 hours. As of December 2024, Yorvipath is now commercially available in the United States. Given the high cost and specific treatment population of Yorvipath, payers will most likely utilize prior authorization criteria to ensure appropriate use.

Ebglyss
by Eli Lilly

On September 13, 2024, the U.S. Food and Drug Administration (FDA) approved Ebglyss (lebrikizumab-lbkz), an interleukin (IL)-13 inhibitor for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss is the third biologic FDA-approved to treat AD in addition to Dupixent and Adbry. Ebglyss appears similarly effective to Dupixent in clearing skin in AD, but more effective than Adbry, based on cross-trial comparisons. Ebglyss may struggle with gaining market share due to its similar efficacy and higher first-year cost versus Dupixent. In addition, Dupixent's established market presence, high prescriber preference and familiarity, broad preferred payer coverage, approval for younger AD patients, and multiple approved indications for other inflammatory conditions provide it with a significant competitive advantage. Due to its high cost, specific patient population, and potential for off-label use, payers may utilize Ebglyss through prior authorization, including step therapy with topical or off-label treatments and other preferred biologics.

Aqneursa
by IntraBio

On September 24, 2024, the U.S. Food and Drug Administration (FDA) approved Aqneursa (levacetylleucine) oral suspension granules for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg. Aqneursa is the second FDA-approved treatment for NPC, following Zevra Therapeutics' Miplyffa. Aqneursa is supplied as oral suspension granule packets that are given orally up to three times per day, with or without food. The recommended dose is based on body weight thresholds; therefore, price will vary significantly from patient to patient. With two FDA-approved therapies and one standard-of-care off-label treatment, questions regarding treatment sequencing and combination therapy will be top of mind for all stakeholders. Updates to guidelines and/or statements from clinical experts to help clarify these questions are unlikely until healthcare providers have had time to use the treatments in real-world settings. Payers will need to balance providing access to different MOAs while being conscious of the exceedingly high costs in this category. Payers should consider universal implementation of prior authorization to ensure an accurate diagnosis of NPC and careful consideration of formulary management strategies.

Miplyffa
by Zevra Therapeutics

On September 20, 2024, the U.S. Food and Drug Administration (FDA) approved Miplyffa for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. While Miplyffa was the first FDA-approved treatment for NPC, approval of IntraBio's Aqneursa, also for the treatment of NPC, followed just 4 days later. However, the drugs work by different mechanisms of action. Miplyffa is administered orally three times daily, with or without food, and is dosed based on patient body weight. With two FDA-approved therapies and one standard-of-care off-label treatment, questions regarding treatment sequencing and combination therapy will be top of mind for all stakeholders. Updates to guidelines and/or statements from clinical experts to help clarify these questions are unlikely until healthcare providers have had time to use the treatments in real-world settings. Payers will need to balance providing access to different MOAs while being conscious of the exceedingly high costs in this category. Payers should consider universal implementation of prior authorization to ensure an accurate diagnosis of NPC and careful consideration of formulary management strategies.

Cobenfy
by Bristol Myers Squibbs (BMS)

On September 26, 2024, the U.S. Food and Drug Administration (FDA) approved Cobenfy (xanomeline and trospium chloride), an oral first-in-class muscarinic agonist for the treatment of schizophrenia in adults. This drug introduces a novel mechanism of action by combining xanomeline, an M1/M4 muscarinic receptor agonist, with trospium chloride, a muscarinic receptor antagonist that offsets the peripheral effects of xanomeline and does not appreciably cross the blood-brain barrier. Unlike first- and second-generation antipsychotics (SGAs), which are associated with adverse events including extrapyramidal symptoms, weight gain, QTc prolongation, and an increased risk for diabetes, the Cobenfy Phase 3 studies consistently found no significant changes in weight, lipid levels, glucose, insulin, or alertness. Considering the availability of numerous generic SGAs, it is believed that most payers will manage Cobenfy similar to branded SGA antipsychotics used for the treatment of schizophrenia.

Itovebi
by Roche/Genentech's

On October 10, 2024, the U.S. Food and Drug Administration (FDA) approved Itovebi (inavolisib), in combination with Pfizer's Ibrance (palbociclib) and fulvestrant, for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer (mBC), as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy. Itovebi is a phosphatidylinositol 3-kinase (PI3K) inhibitor with activity predominantly against PI3Kα. When combined with Ibrance and fulvestrant, the Itovebi triplet becomes the first and only PI3Kα inhibitor-based treatment for patients with HR-positive/HER2-negative mBC with a PIK3CA mutation in the first-line setting. The use of management tools, such as prior authorization, is recommended due to the specific patient type, cancer stage, and the high cost of Itovebi. This will help ensure the appropriate utilization of the triplet regimen.

Hympavzi
by Pfizer

On October 11, 2024, the U.S. Food and Drug Administration (FDA) approved Hympavzi (marstacimab-hncq), a once-weekly subcutaneous injection for the treatment of adults and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without FVIII inhibitors, or hemophilia B (congenital factor IX deficiency) without FIX inhibitors. Hympavzi is the first anti-tissue factor pathway inhibitor approved for the treatment of hemophilia A or B. It is also the first non-factor and subcutaneous prophylactic therapy for people with hemophilia B and the first treatment administered as a prefilled, autoinjector pen for people with hemophilia A or B. It is recommended that payers place Hympavzi on prior authorization to ensure appropriate use. Payers may also consider step therapy with prophylactic treatments for patients with hemophilia A or B.
