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.

Duvyzat (givinostat)
by *Italfarmaco Therapeutics, LLC*

Vafseo (vadadustat)
by *Akebia Therapeutics, Inc*

Ohtuvayre (ensifentrine)
by *Verona Pharma, Inc*

Sofdra (sofpironium)
by *Botanix SB, Inc*

800.917.4926

www.kpp-rx.com

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

Duvyzat (givinostat)
by *Italfarmaco Therapeutics, LLC*

On March 21, 2024, the United States Food and Drug Administration (FDA) approved Duvyzat for the treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older. The approval of this product represents the first non-steroidal treatment option in this patient population for all generic variants of the disease. Typically affecting male patients only, DMD is a rare, progressive, and life-limiting neuromuscular condition fairly rare in nature, affecting about 15,000 patients in the United States. Given its limited presentation in the US, payers are unlikely to experience significant claims volume for this product.

Vafseo (vadadustat)
by *Akebia Therapeutics, Inc*

On March 27, 2024, the United States Food and Drug Administration (FDA) approved Vafseo for the treatment of anemia due to chronic kidney disease (CKD) in adults receiving dialysis for at least 3 months. Vafseo now shares the market with competitor Jesduvroq which was approved in early February 2023, and will compete directly for market share. Both product's labeling includes a Boxed Warning for increased risk of thrombotic vascular events, including MACE. Akebia recently announced a wholesale acquisition cost (WAC) of $15,500/year amidst the expectation that Vafseo will be approved for non-dialysis patients in the near future.

Ohtuvayre (ensifentrine)
by *Verona Pharma, Inc*

On June 26, 2024, the United States Food and Drug Administration (FDA) approved Ohtuvayre for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. Joining a crowded market with several treatment options, Ohtuvayre has the distinction of being the first product to work via a dual, PDE3 and PDE4 inhibition pathway. Clinically, this translates into the fact that Ohtuvayre will offer both airway opening and anti-inflammatory effects in the same medication. Verona is currently investigating the potential use of this product in other conditions such as asthma and cystic fibrosis. Due to a relatively high price point as compared to alternatives on the market, payers may wish to consider prior authorization criteria which prioritizes using Ohtuvayre as an add-on therapy in patients uncontrolled on existing products.

Sofdra (sofpironium)
by *Botanix SB, Inc*

On June 18, 2024, the United States Food and Drug Administration (FDA) approved Sofdra for the treatment of primary axillary hyperhidrosis (aHH) in patients 9 years of age and older. Axillary hyperhidrosis affects roughly 10 million patients in the United States and is defined by excessive underarm sweating. Although not harmful in and of itself, excessive underarm sweating can have significant psychological consequences in patient's lives due to embarrassment from clothes which always appear sweaty, or which may be malodorous. Up until recently, Botox had been the front-runner for this condition, as well as other products such as Qbrexza and Drysol. Sofdra offers a more patient palatable option to Botox – topical application of a gel instead of subcutaneous injections. The WAC for Sofdra is roughly $12,000/year; therefore, payers are encouraged to utilize prior authorization to ensure other more cost-effective options have already been utilized.
