

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, 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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Voquezna (vonoprazan) by Phathom Pharmaceuticals

Sohonos (palovarotene) by Ipsen

Jesduvroq (daprodustat) by GSK

Aphexda (motixafortide) by BioLineRx Ltd

Bimzelx (bimekizumab) by UCB

Ojjaara (momelotinib) by Sierra Oncology GSK

Velsipity (etrasimod) *by* Pfizer

Zurzuvae (zuranolone)
by Biogen and Sage Therapeutics



Nelson Aragon, Pharm.D.

Clinical Formulary Manager
nelson.aragon@krogerhealth.com

Voquezna (vonoprazan) by Phathom Pharmaceuticals

On November 1, 2023, the FDA approved Voquezna, as a stand-alone treatment option for erosive esophagitis. Entering a crowded market with the proton pump inhibitors, Voquezna's unique mechanism of action translates into a faster onset of action, extended half-life, and lack of food timing concerns. However, given its high price tag and limited information on whether or not it is superior to proton pump inhibitors, many of which are available generically or over-the-counter, the true place in therapy remains to be seen.

Sohonos (palovarotene) by Ipsen

On February August 16, 2023, the FDA approved Sohonos for the treatment of heterotopic ossifications in adults and pediatric patients. The introduction of Sohonos represents the first FDA-approved treatment option for this condition. Although Sohonos does carry a steep price tag (~\$1M/year) there are an estimated 400 patients total in the United States with this condition; therefore, most payers will not see any utilization. Ipsen has partnered with CVS Health to be the sole supplier of this product.

Jesduvroq (daprodustat) by GSK

On February 1, 2023, the FDA approved Jesduvroq, the first hypoxia-inducible factor prolyl hydrolase inhibitor and first oral medication for the treatment of anemia caused by chronic kidney disease in patients who have been receiving dialysis for at least 4 weeks. Given Jesduvroq's daily administration does not align with three times weekly dialysis protocols, uptake will likely be limited to a small subset of patients who experience hypo-responsiveness to erythropoietin stimulating agents.

Aphexda (motixafortide) by BioLineRx Ltd

On September 8, 2023, the FDA approved Aphexda in combination with filgrastim for the mobilization of hematopoietic stem cells to the peripheral blood where they can be collected for autologous stem cell transplant in patients with Multiple Myeloma. Aphexda is the second hematopoietic stem cell mobilizing agent to be approved and will be competing with Mozobil (plerixafor) which was approved in 2008. Aphexda is similarly priced to brand Mozobil but is significantly more expensive than the available plerixafor generics which may limit its use.

Bimzelx (bimekizumab) by UCB

On October 18, 2023, the U.S. Food and Drug Administration (FDA) approved Bimzelx for the treatment of moderate to severe plaque psoriasis in adults who are eligible for systemic therapy or phototherapy. Bimzelx joins a competitive market in the moderate to severe plaque psoriasis treatment space with an estimated cost of about \$112,320 per year. Payers will likely maintain the current formulary positioning of other previously approved medications in its class due to its high cost and frequent monitoring.

Ojjaara (momelotinib) by Sierra Oncology GSK

On September 15, 2023 the U.S. Food and Drug Administration (FDA) approved Ojjaara for the treatment of intermediate or high-risk myelofibrosis, in adults with anemia. Ojjaara is the first to be FDA approved for patients with myelofibrosis specifically with anemia. Ojjaara is given orally with an average wholesaler acquisition cost of \$327,283 per year. Addition of prior authorization is recommended to ensure use in the appropriate patient population.

Velsipity (etrasimod) *by* Pfizer

On October 12, 2023, the U.S. Food and Drug Administration (FDA) approved Pfizer's Velsipity, an oral, once-daily, selective sphingosine-1-phosphate (S1P) receptor modulator for adults with moderately to severely active ulcerative colitis (UC). Due to Velsipity's pre-assessment requirements and stiff competition, especially considering upcoming Humira and Stelara biosimilars, prior authorization is recommended if Velsipity is added to formulary.

Zurzuvae (zuranolone)by Biogen and Sage Therapeutics

On August 4, 2023, the U.S. Food and Drug Administration (FDA) approved Biogen and Sage Therapeutics' Zurzuvae to treat postpartum depression (PPD) in adults. While Zurzuvae is the first and currently only approved oral treatment for PPD, many off label therapies may be appropriate at a significantly lower cost, such as SSRIs. Payers should consider prior authorization to reserve Zurzuvae for utilization only in appropriate patient populations.