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.

ZTALMY (ganaxolone)
by Marinus Pharmaceuticals

AMVUTTRA (vutrisiran)
by Alnylam Pharmaceuticals

VIVJOA (oteseconazole)
by Mycovia Pharmaceuticals

ZYNTEGLO (betibeglogene autotemcel)
by Bluebird Bio

BYOOVIZ (ranibizumab-nuna)
by Biogen and Samsung Bioepis

CIMERLI (ranibizumab-eqrn)
by Coherus Biosciences

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ZTALMY (ganaxolone)
by Marinus Pharmaceuticals

On March 18th, 2022, the US Food and Drug Administration (FDA) approved Ztalmy (ganaxolone) for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD). CDD is a rare deficiency of the CDKL5 gene that causes seizures, followed by significant developmental delays. Ztalmy is an antiseizure agent resulting from the change in gamma-aminobutyric acid type A (GABA-A) receptor of the central nervous system. Ztalmy is a Schedule V Controlled Substance according to the Drug Enforcement Agency (DEA), meaning it has a potential to cause harm if misused. Ztalmy is the first CDD-specific therapy approved by the FDA.

AMVUTTRA (vutrisiran)
by Alnylam Pharmaceuticals

On June 13th, 2022, the US Food and Drug Administration (FDA) approved Amvuttra (vutrisiran) for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN). hATTR-PN is a disease caused by a buildup of amyloid deposits in the body that can result in nerve pain, muscle weakness, and negatively impact daily activities in affected individuals. Amvuttra is a small interfering RNA (siRNA) which helps reduce amyloid levels in the body. The approval of Amvuttra was based on the HELIOS-A study that found statistically significant improvements on polyneuropathy scales in patients treated with Amvuttra versus placebo. Amvuttra is the third FDA approved treatment for hATTR-PN following Onpattro and Tegsedi.

VIVJOA (oteseconazole)
by Mycovia Pharmaceuticals

On April 26th, 2022, the US Food and Drug Administration (FDA) approved Vivjoa (oteseconazole) to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC), or chronic yeast infection, in females with a history of RVVC who are NOT able to become pregnant. Vivjoa is an azole antifungal which inhibits fungal growth. Vivjoa is the first FDA approved medication for the treatment of RVVC. Currently, oral fluconazole is recommended for RVVC in clinical treatment guidelines from the CDC and Infectious Diseases Society of America (IDSA).

ZYNTEGLO (betibeglogene autotemcel)
by Bluebird Bio

On August 17th,2022, the US Food and Drug Administration (FDA) approved Bluebird bio's Zynteglo (betibeglogene autotemcel) for the treatment of β-thalassemia in adult and pediatric patients requiring regular red blood cell transfusions. Beta-thalassemia is caused by a change in the beta-globin gene, which causes the body to produce reduced or no beta-globin; requiring regular blood transfusions. ZYNTEGLO is an, one-time single dose intravenous, autologous hematopoietic stem cell-based gene therapy , intended to reduce the amount of blood transfusions required. The efficacy of ZYNTEGLO was evaluated in two ongoing Phase 3 open-label, single-arm, 24-month, multicenter studies in 41 patients aged 4 to 34 years with β-thalassemia; 89% of patients achieved transfusion independence. Zynteglo is produced using the patient's own stem cell, eliminating the need for donors.

BYOOVIZ (ranibizumab-nuna)
by Biogen and Samsung Bioepis

On September 17, 2021, the US Food and Drug Administration (FDA) approved Byooviz (ranibizumab-nuna); a vascular endothelial growth factor (VEGF) inhibitor produced by Biogen and Samsung Bioepis. Byooviz is an intravitreal therapy indicated or the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (MEfRVO), and myopic choroidal neovascularization (mCNV). Byooviz is a biosimilar to Lucentis produced by Roche/Genentech. Byooviz's approval was based on its safety and efficacy in comparison to Lucentis. Currently, Lucentis is the second most utilized VEGF inhibitor for ophthalmic conditions. However, a significant portion of VEGF ophthalmic use is from the off-label use of Avastin (bevacizumab), due to its lower cost. The launch of Byooviz, which costs 40% less than Lucentis, may provide another affordable option for providers and patients when it comes to ophthalmic conditions.

CIMERLI (ranibizumab-eqrn)
by Coherus Biosciences

On August 2, 2022,the US Food and Drug Administration (FDA) approved Coherus Biosciences Cimerli (ranibizumab-eqrn), for the treatment of diabetic macular edema ("DME"), diabetic retinopathy ("DR"), macular edema following retinal vein occlusion ("RVO"), myopic choroidal neovascularization ("mCNV"), and neovascular (wet) age-related macular degeneration ("AMD"). Cimerli is the second approved biosimilar of Lucentis, however, it is the only which is interchangeable to Lucentis. The FDA granted Cimerli approval based on the results of COLUMBUS-AMD trial, which evaluate the safety and efficacy of Cimerli compared with Lucentis. At launch, Cimerli costs 30% less than the cost of its reference product. Thus, making it another affordable therapy option in terms of ophthalmic conditions.