Kroger Prescription Plans

2023 New-to-Market Drugs

KPP Key Insights

Every year the Federal Drug Administration (FDA) receives countless numbers of applications for the approval of new medications as well as the approval of current medications with new indications. It is through careful research and consideration that they approve these medications for use among the patients in the United States.

Over the last couple of years these applications and approvals have continued to increase year-to-year. In 2023, the FDA approved a total of 72 novel drugs. This newsletter was written to highlight ten drugs approved by the FDA in 2023 with potential to make an impact on client drug spend.

Briumvi (ublituximab-xiiy)
by TG Therapeutics

Leqembi (lecanemab-irmb)
by Eisai Inc.

Vowst (fecal microbiota spores)
by Aimmune Therapeutics

Veozah (fezolinetant)
by Astellas Pharma

Paxlovid (nirmatrelvir/ritonavir)
by Pfizer

Roctavian (valoctogene-roxaparvovec-rvox)
by BioMarin Pharmaceutical

Beyfortus (nirsevimab-alip)
by Sanofi

Zurzuvae (zuranolone)
by Biogen

Xphozah (tenapanor)
by Ardelyx

Zepbound (tirzepatide)
by Eli Lilly

References

Paxlovid for the Treatment of Mild to Moderate COVID-19. IPD Analytics. Accessed December 11, 2023.
Beyfortus for the Prevention of RSV LRTD in Infants. IPD Analytics. Accessed December 11, 2023.
Zurzuvae for the Treatment of Postpartum Depression in Adults. IPD Analytics. Accessed December 11, 2023.
Zepbound for Chronic Weight Managment. IPD Analytics. Accessed December 11, 2023.
Leqembi for Treatment of Alzheimer'a Disease. IPD Analytics. Accessed December 11, 2023.
New Drug Review: Roctavian for Treatment of Severe Hemophilia A. IPD Analytics. Accessed December 11,2023.
Veozah for Treatment of Hot Flashes Caused by Menopause. IPD Analytics. Accessed December 11, 2023.. Briumvi for Treatment of Relapsing Forms of Multiple Sclerosis. IPD Analytics. Accessed December 11, 2023.
Vowst for Prevention of Recurrent CDI. IPD Analytics. Accessed December 11, 2023.
Xphyozah for Treatment of Hyperphosphatemia. IPD Analytics. Accessed December 11, 2023.

800.917.4926
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Briumvi (ublituximab-xiiy)
by TG Therapeutics

Approved on December 28, 2022 by the FDA, however, did not come to market until the first quarter of 2023. Briumvi is approved for the treatment of adults with relapsing forms of multiple sclerosis (RMS) including those with clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease. Dosing: administered as a 1-hour intravenous infusion which is dosed once every 24 weeks after an initial round of 2 infusions that are administered 2 weeks apart. Briumvi is the third antiCD20 inhibitor approved for MS and is significantly less costly than its counterparts.

Key Insights: Due to the route of administration, Briumvi is expected to increase spend on the medical benefit. Limited impact expected on pharmacy benefit.

Leqembi (lecanemab-irmb)
by Eisai Inc.

Approved January 6, 2023 by the FDA for the treatment of Alzheimer's Disease (AD). An accelerated approval was granted to Leqembi, an anti-amyloid beta protofibril antibody. Treatment should be initiated in patients with mild cognitive impairment or mild dementia stages of AD. Patients should also have a confirmed presence of anti- amyloid beta pathology prior to treatment. Second FDA approved anti-amyloid beta monoclonal antibody for the treatment of AD. No box warnings or REMS program, however, a warning does exist for amyloid-related imaging abnormalities (ARIA) with MRI recommendations for monitoring for signs and symptoms.

Key Insights: Due to patient population mix, expected utilization of Leqembi is in the Medicare demographic. Limited impact to commercial plans.

Vowst (fecal microbiota spores)
by Aimmune Therapeutics

Approved April 26, 2023 by the FDA to aid in the prevention of Clostridioides difficile infection (CDI) for those 18 years or older following antibacterial treatment for recurrent CDI (rCDI). Vowst is an encapsulated Firmicutes bacterial spore suspension manufactured from human fecal matter sourced by qualified volunteers. First oral , microbiota-based therapeutic approved for rCDI. Dosing: 4 capsules once daily for 3 days. Adverse effects include abdominal distention, fatigue, constipation, chills, and diarrhea.

Key Insights: Payers can expect some increased utilization on pharmacy benefit.

Veozah (fezolinetant)
by Astellas Pharma

Approved on May 12, 2023 by the FDA, Veozah is an oral, non-hormonal therapy for the treatment of moderate to severe vasomotor symptoms (VMS), or hot flashes, associated with menopause. Veozah binds to neurokinin (NK) 3 receptors and blocks them from binding to neurokinin B. Through this mechanism the thermoregulatory neuronal activity in the hypothalamus is regulated. The gold standard for the VMS is menopausal hormonal treatment, however, a large population of women are not candidates for this form of treatment, due to underlying or past medical conditions. These women would include those with a history or elevated risk of estrogen-dependent cancers, those with coronary artery disease, and history of stroke or venous thromboembolism.

Key Insights: Payers can expect some increased utilization on pharmacy benefit due to novel mechanism and large target population

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Paxlovid (nirmatrelvir/ritonavir)
by Pfizer

Approved on May 25, 2023 by the FDA for the treatment of mild to severe COVID-19 infections in adults that are at high-risk for progression of severe infection, including hospitalization or death. Paxlovid was granted emergency use authorization (EUA) in December 2021 for use in pediatric and adult patients (ages 12 and older and weighed more than 40kg) and is the first approval for an oral COVID-19 treatment. Paxlovid is made of nirmatrelvir, a main protease inhibitor of SARS-CoV-2, as well as, ritonavir, a cytochrome P4503A (CYP3A) inhibitor that aids in the slowing of nirmatrelvir. Dosing: Two (2) 300mg tablets of nirmatrelvir and one (1) tablet of 100mg ritonavir taken together twice daily for 5 days. Box Warning: Significant Interactions due to use of ritonavir, a strong CYP3A4 inhibitor, as a component of treatment.

Key Insights: Payers can expect continued utilization. Government subsidies for Paxlovid have been suspended, likely increasing drug spend.

Roctavian (valoctogene-roxaparvovec-rvox)
by BioMarin Pharmaceutical

Approved on June 29, 2023 by the FDA as the first gene therapy for the treatment of adults with severe hemophilia A without antibodies to adeno-associated virus serotype 5 (AAV5) as detected by FDA-approved test. Consist of a viral vector carrying the F8 gene that encodes FVIII. Roctavian is administered intravenously as a one-time dose and is not intended for administration for women. Intended to be a one-time, alternative treatment to chronic prophylaxis treatments currently on the market. Most common adverse effects: mild changes to liver function, headache, nausea, vomiting, fatigue, abdominal pain, and infusion-related reactions.
Key Insights: Due to the route of administration and monitoring, Roctavian is expected to increase spend on the medical benefit. Limited impact expected on pharmacy benefit.

Beyfortus (nirsevimab-alip)
by Sanofi

Approved on July 17, 2023 by the FDA for the prevention of respiratory syncytial virus (RSV), a lower respiratory tract disease (LRTD) in newborns and infants born during or entering RSV season and for children up to 24 months of age who are vulnerable to severe RSV. 1-3% of children under 12 months are hospitalized in the US each year due to RSV disease. Beyfortus can help as it is a long acting monoclonal antibody administered as a single intramuscular injection prior to or during RSV season and is recommended for all infants less than 8 months old born during or start of RSV season.
Key Insights: Due to expanded target population, expect increases in utilization and cost across all healthcare coverage.

Zurzuvae (zuranolone)
by Biogen

Approved on August 4, 2023 by the FDA to treat postpartum depression (PPD) in adults. This is the first oral PPD medication approved by the FDA. Zurzuvae is a neuroactive steroid that acts a positive allosteric modulator of gamma-aminobutyric acid type A (GABAA) receptors. Dosing: Take one (1) 50mg tablet daily for 14 days Box Warning: Can impact one's ability to drive and can impair ability to perform other activities due to CNS depressive effects and advises against such activities for 12 hours post dose.
Key Insights: Payers can expect utilization on pharmacy benefit due to novel mechanism and route of administration.

Xphozah (tenapanor)
by Ardelyx

Approved October 17, 2023 by the FDA for the reduction of serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as an add-on therapy for those who have an inadequate response to phosphate binders (PBs) or intolerant to any dose of PB therapy. Xphozah is the first and only phosphate absorption inhibitor to be approved for CKD and works on lowering serum phosphorus levels by being a sodium/hydrogen exchanger (NHE3) inhibitor, which results in decreased phosphorus absorption. Although dialysis itself removes phosphorus, often patients need to take additional PBs to reach phosphorus levels of <5.5mg/dL. It is estimated that 50-85% of patients on dialysis and PBs cannot maintain target levels of phosphorus.
Key Insights: Due to patient population mix, expected utilization of Xphozah is in the Medicare demographic. Limited impact to commercial plans.

Zepbound (tirzepatide)
by Eli Lilly

Approved on November 8, 2023 by the FDA for chronic weight management for adults with a body mass index (BMI) of 30kg/m2 or above OR 27kg/m2 or above with at least one weight related condition (high blood pressure, type 2 diabetes, or high cholesterol). Approved for use in addition to reduced-calorie diet and increased activity level. Zepbound is the sixth FDA approved drug for chronic weight management, however, first in it's category to combine both GLP-1 agonism and a physiological regulator of appetite and caloric intake. Eli Lilly is offering a copay savings program making out-of-pocket costs less than $550 for those who are commercially insured without coverage of Zepbound. Physician's will now be challenged to decide which medication to use for chronic weight management with options of both Wegovy, which provides weight loss and cardiovascular benefit, or Zepbound, which proves to have a higher degree of weight loss, but unknown cardiovascular benefit.
Key Insights: Expect increases in utilization for pharmacy benefit plans with coverage for weight loss products.