



Kroger
Prescription
Plans

Q2 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.

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Ogsiveo (nirogacestat)
by Springworks Therapeutics

Wainua (eplontersen)
by AstraZeneca/Ionis Pharmaceuticals

Agamree (vamorolone)
by Santhera Pharmaceuticals

Zilbrysq (zilucoplan)
by UCB

Fabhalta (iptacopan)
by Novartis



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Ogsiveo (nirogacestat)
by Springworks Therapeutics

On November 27, 2023, the U.S. Food and Drug Administration (FDA) approved SpringWorks Therapeutics' Ogsiveo (nirogacestat), an oral, selective gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors (DTs) who require systemic treatment. Although desmoid tumors are typically rare, this represents the first FDA-approved treatment for this type of tumor, and for SpringWorks Therapeutics. Payers should expect very limited exposure to this product as only 900-1400 new cases are diagnosed each year.

Wainua (eplontersen)
by AstraZeneca/Ionis Pharmaceuticals

On December 21, 2023, the U.S. Food and Drug Administration (FDA) approved AstraZeneca (AZ) and Ionis Pharmaceuticals' Wainua (eplontersen) for the treatment of adult patients with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN). Up until this point treatment has typically consisted of managing symptoms. Wainua will largely compete with Amvuttra, Onpattro, and Tegsedi; although, it offers the advantage of being self-administered without the need for routine lab work.

Agamree (vamorolone)
by Santhera Pharmaceuticals

On October 26, 2023, the U.S. Food and Drug Administration (FDA) approved Santhera Pharmaceuticals' Agamree (vamorolone), a corticosteroid for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. Given that corticosteroid therapy is the standard of care for DMD, payers are likely to prefer cheaper, generically available alternatives in most patients. It is anticipated that Agamree will not shift the current treatment patterns observed in DMD given the similarity in efficacy and side effect profile observed between all corticosteroids.

Zibrysq (zilucoplan)
by UCB

On October 17, 2023, the U.S. Food and Drug Administration (FDA) approved UCB's Zilbrysq (zilucoplan) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Although multiple therapies exist for the treatment of gMG (e.g. Soliris, Ultomiris) Zilbrysq represents the first self-administered once-daily targeted C5 complement inhibitor on the market. Currently there are no head-to-head trials with Soliris and Ultomiris; however, it is likely that providers will prefer this new product for younger patients who demand more convenient treatment strategies.

Fabhalta (iptacopan)
by Novartis

On December 5, 2023, the U.S. Food and Drug Administration (FDA) approved Novartis' Fabhalta (iptacopan), a complement factor B inhibitor, for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). The introduction of Fabhalta represents the first FDA-approved oral monotherapy for the treatment of this condition. Current therapies for PNH include Soliris, Ultomiris, and Empaveli. Given the rarity of this condition in the United States (up to 6000 total patients), payers are unlikely to see much, if any, utilization.
