Kroger Prescription Plans

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.

800.917.4926
www.kpp-rx.com

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.

Exkivity (mobocertinib)
by Takeda

Lybalvi (olanzapine/samidorphan)
by Alkermes

Tivdak (tisotumab)
by Seagen/Genmab

Livmarli (maralixibat)
by Mirum

Qulipta (atogepant)
by AbbVie

Skytrofa (lonapegsomatropin)
by Ascendis Pharma

Scemblix (asciminib)
by Novartis

Besremi (ropeginterferon)
by PharmaEssentia

For more information regarding these products or if you have any questions regarding our innovative clinical solutions and what KPP is doing to control drug costs, please contact:

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

Exkivity (mobocertinib)

by Takeda

On September 15, 2021, the U.S. Food and Drug Administration (FDA) approved Exkivity (mobocertinib) for the treatment of adult patients with locally advanced or metastatic non–small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. Exkivity represents the first-in-class oral tyrosine kinase inhibitor (TKI) specific to EGFR exon 20 insertion mutations. Approval was based on results of a 3-part, open-label, Phase 1/2 dose-escalation/expansion and extension trial (NCT02716116) with 7 cohorts which demonstrated a confirmed overall response rate (ORR) of 28%. The approval of Exkivity adds the second approved product on the market for this indication.

Lybalvi (olanzapine/samidorphan)

by Alkermes

On May 28, 2021, the U.S. Food and Drug Administration (FDA) approved Alkermes' Lybalvi (olanzapine and samidorphan) for the treatment of schizophrenia in adults and for the treatment of bipolar I disorder in adults as (1) a maintenance monotherapy or (2) for the acute treatment of manic or mixed episodes and as an adjunct to lithium or valproate. Lybalvi is a single-tablet containing both olanzapine while mitigating olanzapine-associated weight gain through the addition of samidorphan, an opioid antagonist. Clinical trials demonstrated non-inferiority of Lybalvi when compared to olanzapine alone for the treatment of psychiatric conditions. Providers will need to be especially cautious of patient selection with this product as mental health and opioid use disorder often go hand in hand. Use of Lybalvi in a chronic opioid patient may precipitate opioid withdrawal symptoms. In addition, not every patient on olanzapine experiences weight gain; therefore, payers should ensure that weight gain is a concern before approving use of this product. Well written prior authorization guidelines should help ease this concern.

Tivdak (tisotumab)

by Seagen/Genmab

On September 20, 2021, the U.S. Food and Drug Administration (FDA) granted accelerated approval for Tivdak (tisotumab vedotin-tftv) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Cervical cancer continues to be the third most common gynecologic cancer in the United States. Tivdak is the first tissue factor (TF)–directed antibody-drug conjugate (ADC) approved for this condition and works by binding to tissue factor on target cells ultimately causing cell death. Tivdak is expected to compete with Merck's Keytruda (pembrolizumab) in this space.

Livmarli (maralixibat)

by Mirum

On September 29, 2021, the U.S. Food and Drug Administration (FDA) approved Livmarli (maralixibat) for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older. Alagille syndrome is a rare genetic condition typically associated with a reduction of bile flow or cholestasis. Most patients with ALGS experience intractable pruritis that has historically been treated off-label with a variety of prescription medications. Livmarli is also currently being studied in two other rare pediatric liver diseases: progressive familial intrahepatic cholestasis (PFIC) and biliary atresia. In this space, Livmarli will compete directly with Alberio's Bylvay, which is approved for PFIC – another condition which causes similar intractable pruritis. Although patients will be relieved to have options which lead to a reduction in severe itching long-term clinical data still needs to be conducted to determine any effect on liver-related outcomes.

Qulipta (atogepant)

by AbbVie

On September 28, 2021, the U.S. Food and Drug Administration (FDA) approved AbbVie's Qulipta (atogepant) for the preventive treatment of episodic migraine in adults. Qulipta joins the anti-migraine space as the second oral CGRP inhibitor to be approved for the preventive treatment of episodic migraine, following Nurtec ODT (rimegepant). Nurtec ODT was originally approved for the acute treatment of migraine and later expanded its label for the preventive treatment of migraine in mid-2021. In this space Qulipta will compete directly with injectable CGRPs such as Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Ajovy (fremanezumab-vfrm), and Vyepti (eptinezumab-jjmr). We expect this drug class to continue to see additional products brought to market which can be used for both acute and preventive treatment.

Skytrofa (lonapegsomatropin)

by Ascendis Pharma

On August 25, 2021, the U.S. Food and Drug Administration (FDA) approved Skytrofa (lonapegsomatropin-tcgd) for the treatment of pediatric patients 1 year of age and older who weigh at least 11.5 kg (25.4 lb) and have growth failure due to inadequate secretion of endogenous growth hormone (GH). Skytrofa joins the growth hormone space as the first FDA-approved sustained-release somatropin (growth hormone) product. Clinical trial data shows non-inferiority to other somatropin products. We expect ease of use, particularly in pediatric patients who are needle averse, to be the largest market differentiator for this product.

Scemblix (asciminib)

by Novartis

On October 29, 2021, the U.S. Food and Drug Administration (FDA) approved Scemblix (asciminib) for the treatment of chronic myeloid leukemia (CML) in two indications: for the treatment of adult patients with Philadelphia chromosome–positive CML in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors (TKIs), and for the treatment of adult patients with Ph+ CML-CP with the T315I mutation. Scemblix joins Iclusig as the only other CML product which can be used to treat Ph+ CML-CP with the T315I mutation. Head to head trials are not yet available to determine if one product is superior to the other.

Besremi (ropeginterferon)

by PharmaEssentia

On November 12, 2021, the U.S. Food and Drug Administration (FDA) approved Besremi (ropeginterferon alfa-2b-njft) to treat adults with polycythemia vera (PV), a rare blood disease that causes an increase in hematocrit levels. Besremi is a monopegylated, long-acting interferon, which imparts its cellular effects in the bone marrow. Existing therapeutic options for patients with PV include hydroxyurea, busulfan, long-acting interferon, and Jakafi (ruxolitinib). Hydroxyurea is typically reserved for first-line treatment and comes at a significant cost reduction as compared to other options.