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.

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.

Spevigo (spesolimab)
by Boehringer Ingelheim

Xenpozyme (olupidase alfa)
by Sanofi/Genzyme

Skysona (elivaldogene autotemcel)
by Bluebird Bio

Sotyktu (deucravacitinib)
by Bristol Myers Squibb

Relyvrio (sodium phenylbutyrate/taurursodiol)
by Amylyz Pharmaceuticals

Imjudo (tremelimumab)
by AstraZeneca

Lytgobi (futibatinib)
by Taiho Oncology

Tecvayli (teclitamab)
by Janssen

Tzield (teplizumab)
by ProventionBio

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Spevigo (spesolimab)
by Boehringer Ingelheim

On September 1, 2022, Boehringer Ingelheim's (BI's) Spevigo (spesolimab-sbzo) became the first drug to receive FDA approval for the treatment of generalized pustular psoriasis (GPP). GPP is an extremely rare form of psoriasis with very limited epidemiological data; it has been said to account for less than 1% of all psoriasis cases worldwide. It is characterized by recurrent episodes of sterile pustule formation in the skin, which can be accompanied by fever and systemic inflammation that is a highly unpredictable. Spevigo is a humanized antibody that inhibits the interleukin-36 receptor (IL-36R), which is believed to play a role in the pathogenesis of many autoimmune diseases, including GPP. The approval of Spevigo was based on data from the EFFISAYLI-1 trial, which evaluated the safety and efficacy of 900 mg intravenous (IV) spesolimab versus placebo for the treatment of acute GPP flares. The primary efficacy endpoint was a pustulation score of 0 on the Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) after 1 week. At the end of 1 week, 54% of patients in the spesolimab group met the primary endpoint versus 6% in the placebo group.

Xenpozyme (olupidase alfa)
by Sanofi/Genzyme

On August 31, 2022, the U.S. Food and Drug Administration (FDA) approved Xenpozyme (olipudase alfa) as the first disease-specific therapy indicated for the treatment of non–central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. ASMD is a rare, progressive genetic disorder that results from a deficiency of the enzyme acid sphingomyelinase (ASM). Since ASMD is such a rare disorder, there are currently fewer than 120 people diagnosed within the United States with majority of them being pediatric patients. Xenpozyme is an enzyme replacement therapy that works by reducing sphingomyelin accumulation in the liver, spleen, and lung. The approval was based on positive data from the ASCEND and ASCEND-Peds clinical trials, which demonstrated that Xenpozyme improved lung function and platelet count, and reduced spleen and liver volumes.

Skysona (elivaldogene autotemcel)
by Bluebird Bio

On September 16, 2022, the U.S. Food and Drug Administration (FDA) granted approval for Skysona (elivaldogene autotemcel) to slow the progression of neurologic dysfunction in boys 4–17 years of age with early, active cerebral adrenoleukodystrophy (CALD). CALD is a rare genetic condition that primarily affects young males and is caused by a mutation in the ABCD1 gene, located on the X chromosome. The disease causes progressive, irreversible neurologic decline, leading to a vegetative state or death within a few years without treatment. The approval of Skysona was based on data from the Phase 2/3 Starbeam (ALD-102) and the Phase 3 ALD-104 clinical trials. In the studies, patients who received Skysona had an estimated 72% likelihood of major functional disability (MFD)–free survival versus untreated patients from a natural history study had an estimated 43% likelihood of MFD-free survival.

Sotyktu (deucravacitinib)
by Bristol Myers Squibb

On September 9, 2022, the U.S. Food and Drug Administration (FDA) approved Sotyktu (deucravacitinib) oral tablets for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. Sotyktu is the first tyrosine kinase 2 (TYK2) inhibitor to be FDA-approved. TYK2 inhibitors are members of the same family of proteins as Janus kinases (JAK inhibitors) and play a role in the cellular JAK/signal transducer and activator of transcription (STAT) cytokine signaling pathway. The approval of Sotyktu was based on two Phase 3 trials (POETYK-PSO-1 and POETYK-PSO-2) to evaluate its safety and efficacy versus Otezla, Sotyktu's main competitor. In both trials, Sotyktu demonstrated superior efficacy to Otezla.

Relyvrio (sodium phenylbutyrate/taurursodiol)
by Amylyz Pharmaceuticals

On September 29, 2022, the U.S. Food and Drug Administration (FDA) approved Relyvrio (sodium phenylbutyrate/taurursodiol) oral suspension for the treatment of amyotrophic lateral sclerosis (ALS) in adults. ALS is a rare, fatal, progressive neurodegenerative disorder that affects upper and lower motor neurons. A loss of motor neurons in the brain and spinal cord initially leads to focal weakness, with muscle weakness spreading over time. Relyvrio is an oral, fixed-dose combination therapy that targets endoplasmic reticulum stress and mitochondrial dysfunction. The approval of Relyvrio was based on data from the Phase 2 CENTAUR trial and the CENTAUR open-label extension (OLE) study. The primary efficacy outcome measure for the CENTAUR trial was the rate of decline in the Revised ALS Functional Rating Scale (ALSFRS-R) total score. After 24 weeks, patients treated with Relyvrio scored on average 2.32 points higher on the ALSFRS-R than the placebo group. In the CENTAUR-OLE study, the median survival was 23.5 months for the Relyvrio group versus 18.7 months for the placebo group, a 4.8-month difference.

Imjudo (tremelimumab)
by AstraZeneca

On October 24, 2022, the U.S. Food and Drug Administration (FDA) approved Imjudo (tremelimumab-actl) in combination with Imfinzi (durvalumab) for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC). Imjudo is the second anti–cytotoxic T-lymphocyte–associated antigen 4 (CTLA-4) antibody to be approved in the United States. Imjudo blocks the activity of CTLA-4, contributing to T-cell activation, priming the immune response to cancer and fostering cancer cell death.

The approval of Imjudo in combination with Imfinzi in uHCC is based on final results from the Phase 3 HIMALAYA trial, which compared Imfinzi monotherapy and the single tremelimumab, regular-interval durvalumab (STRIDE) regimen versus Bayer's Nexavar (sorafenib), a standard-of-care (SOC) multikinase inhibitor. Overall, patients receiving the STRIDE regimen experienced a 22% reduction in the risk of death versus Nexavar monotherapy. The Imjudo/Imfinzi combination was approved for administration according to the STRIDE regimen, which includes a single dose of Imjudo 300 mg plus Imfinzi 1500 mg, followed by Imfinzi every 4 weeks. The Imjudo/Imfinzi combination is expected to be added to the NCCN Guidelines in the near future.

Lytgobi (futibatinib)
by Taiho Oncology

Lytgobi was granted approval by FDA On September 30, 2022, for the treatment of adult patients with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma (iCCA); in which the patients are harboring (FGFR2) gene fusions or other rearrangements. CCA is a rare type of cancer that forms in the epithelial cells of the bile ducts. About 8000 U.S. patients are diagnosed with CCA annually, and of those diagnosed with CCA, about 20% have iCCA. FGFR2 gene rearrangements occur in approximately 10% to 16% of those patients with iCCA. Lytgobi is an oral small-molecule kinase inhibitor of FGFR1–4 receptors Its mechanism of action is to covalently bind to FGFR2 and inhibits the signaling pathway. The approval of Lytgobi was based on FOENIX-CCA2 trial, in which the primary endpoint of the trial was objective response rate, with a major secondary endpoint being disease control rate. The study showed an objective response rate of 42%, and disease control rate of 82.5% with Lytgobi treatment, with 74% of responses lasting at least 6 months.

Tecvayli (teclitamab)
by Janssen

On October 25, 2022, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Tecvayli (teclistamab-cqyv) for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMA), and an anti-CD38 monoclonal antibody (mAb). Tecvayli is available as an "off-the-shelf" T cell–redirecting, bispecific antibody that targets both B-cell maturation antigen (BCMA) and (CD3). The approval of Tecvayli was based on results the MajesTEC-1 study, which evaluated efficacy in 110 patients who had previously received at least three prior therapies and had not received prior BCMA-targeting therapy. In the study, Tecvayli demonstrated an overall response rate of 61.8%. There is some speculation that patients who need therapy sooner may rely on the "off-the-shelf" products. The number of patients with multiple myeloma who are on a CAR-T waiting list is reported to be higher than the number of slots available. Therefore, Tecvayli may serve as an alternative treatment option for patients with limited access to, require urgent care, or those who are ineligible for a CAR-T therapy.

Tzield (teplizumab)
by ProventionBio

On November 17, 2022, the FDA approved Tzield as the first and only treatment indicated to delay the onset of stage 3 type 1 diabetes (T1D) in adults and pediatric patients 8 years of age and older with stage 2 T1D. Tzield works to delay the onset of Stage 3 T1D by binding to CD3 cells (cell antigen present on T lymphocytes), to deactivate the immune cells that attack insulin producing cells. It is administered as an IV infusion once daily for 14 days. In a pivotal Phase 2 trial (TN-10), Tzield was compared to placebo in patients with a high risk of developing T1D and looked for the delay of T1D in Stage 2 patients. The primary efficacy endpoint was the time to development of Stage 3 T1D diagnosis which showed a median time to diagnosis of 50 months in the Tzield group versus 25 months in the placebo group. Stage 3 T1D was diagnosed in (45%) of the TZIELD-treated patients and in (72%) of the placebo-treated patients. With a median follow-up time of 51 months, therapy with TZIELD resulted in a statistically significant delay in the development of Stage 3 T1D.