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, 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.

- Qfitlia
- Vykat XR
- Vanrafia
- Avmapki/Fakzynja Co-Pack
- Rapiblyk (landiolol)
- Emrelis
- Encelto
- Zevtera
- Imaavy

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Qfitlia

Sanofi's Qfitlia enters the hemophilia market as a broad-use treatment option for both hemophilia A and B, with or without inhibitors. Qfitlia differs from the competition in that It's dosed subcutaneously just once every two months—dramatically reducing treatment burden compared to existing options. For plans, this could lead to improved adherence and potentially lower administration costs. However, it enters an already crowded SC prophylaxis market, competing directly with Hemlibra, Hympavzi, and Alhemo. Its unique broad-label indication may drive formulary placement pressure, especially in hemophilia B where fewer options exist.

Implications:

- May consolidate therapy options across A/B and inhibitor status
- Potentially offsets factor replacement costs
- Could be leveraged as a preferred option with proper contracting

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Vykat XR

Vykat XR is the **first** FDA-approved treatment for hyperphagia in Prader-Willi syndrome (PWS)—a rare disease with intense caregiver burden and high behavioral management costs. Though pricing is high, demand will likely be significant due to the absence of effective alternatives and the severe impact on quality of life and safety. Plans should anticipate strong advocacy for coverage.

Implications:

- High unmet need supports premium pricing
- Likely strong uptake despite niche indication
- Consider prior authorization and adherence monitoring strategies

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Vanrafia

Vanrafia joins a small but growing class of treatments for IgA nephropathy (IgAN), aimed at slowing disease progression in high-risk patients. While clinical benefit must still be confirmed, it follows the path of Filspari and will likely require specialty-tier management and prior authorization. Due to its narrow target and high cost, plans should be cautious with initial access.

Implications:

- Specialty tier placement with tight utilization controls
- Medical exception requests likely to increase
- Competitive pressure on Filspari if outcomes data matures

Avmapki/Fakzynja Co-Pack

This co-pack of kinase inhibitors targets a small subset of patients with KRAS-mutated low-grade serous ovarian cancer (LGSOC)—a hard-to-treat cancer with limited prior options. Despite the narrow indication, costs will be high, and use will be closely monitored. Appropriate for high-control management (PA + quantity limits).

Implications:

- Rare, mutation-specific population limits volume but drives high cost per patient
- Strong biomarker requirement supports targeted use
- Co-packaging may create reimbursement complexity

Rapiblyk (landiolol)

Rapiblyk enters a highly genericized market for supraventricular tachycardia (SVT), including AFib and atrial flutter. It offers ultra-short-acting IV control and may find use in inpatient settings needing rapid rate control. But with ample lower-cost alternatives available (e.g., esmolol, diltiazem), formulary uptake may be limited unless a clear clinical advantage is shown.

Implications:

- Minimal outpatient relevance
- Consider restricted hospital use or non-formulary status unless proven benefit over generics
- May see use in specific cardiac procedural settings

Emrelis

Emrelis is a new antibody-drug conjugate targeting high c-Met overexpression in NSCLC. This biomarker-driven therapy addresses a small subset (12.5%) of a large cancer population and comes with a high annual price tag ($580K). With no direct competitors in this biomarker-defined group, payer leverage is low for now. However, strong biomarker gating should control volume.

Implications:

- Strong cost-control needed: PA based on biomarker test results
- Specialty pharmacy-only access may limit disruption
- Future competitors may drive price negotiations

Encelto

Encelto is the first treatment for MacTel type 2, delivered via a surgically implanted device that continuously releases gene therapy directly to the eye. It's an ultra-specialized solution, with pricing projected at $300K–$500K per eye. Due to its novel mechanism, expect limited initial utilization but high one-time cost per patient.

Implications:

- High upfront cost with uncertain long-term benefit
- Surgical implant requirement may restrict to centers of excellence
- Medical benefit billing pathway likely

Zevtera

Zevtera is an IV antibiotic with activity against MRSA **and** gram-negative pathogens—potentially reducing the need for multi-drug regimens in complicated infections like bacteremia, pneumonia, and skin infections. It's positioned to compete with generics (e.g., vancomycin + cefepime), but its broad coverage could make it attractive for empiric use in select patients.

Implications:

- Useful for hospital formularies needing broad empiric therapy
- May offset combo antibiotic use in mixed infections
- Watch for stewardship protocols and resistance profiles

Imaavy

Imaavy is the first FcRn blocker approved for **both** adult and pediatric patients (≥12) with generalized myasthenia gravis (gMG) who are antibody-positive. Competes directly with Vyvgart and Rystiggo in adults, but has a first-mover advantage in pediatrics. High acquisition cost and potential overlap with complement inhibitors make formulary placement and step therapy critical.

Implications:

- Potentially displaces complement inhibitors in pediatric gMG
- Consideration for pediatric coverage where competitors have no label
- Step therapy or biomarker-based PA recommended
