

KEYTRUDA Coverage Landscape

With subcutaneous KEYTRUDA, Merck seeks to build a moat around its pembrolizumab franchise

KEYTRUDA Qlex launched in late 2025 as the first subcutaneous pembrolizumab formulation, introducing an alternative to IV-infused KEYTRUDA. Administered by a healthcare professional in approximately 1-2 minutes, Qlex enables treatment delivery without the need for a traditional infusion chair. Compared with the 30-minute IV infusion, the formulation reduces administration time and supports more efficient utilization of site-of-care resources. Despite these operational differences, payer adoption remains selective, with IV KEYTRUDA continuing to maintain broader formulary positioning and medical benefit coverage as payers evaluate reimbursement pathways, benefit design, and site-of-care economics.

At the same time, multiple developers are advancing IV pembrolizumab biosimilars, with Samsung Bioepis, Celltrion, and Formycon emerging as leading potential competitors based on late-stage clinical progress. However, all current biosimilar programs are IV-administered, creating a potential market-access challenge as Merck drives greater utilization of its patented subcutaneous formulation.

As a result, biosimilar erosion in oncology is expected to be more gradual than in autoimmune markets such as HUMIRA, where rapid price-driven switching accelerated biosimilar uptake. Following the anticipated launch of pembrolizumab biosimilars, IV market erosion will be gradual, due to physician-led prescribing and buy-and-bill reimbursement incentives. If payer-led adoption of KEYTRUDA Qlex demonstrates comparable clinical outcomes at lower cost, driving broader formulary expansion could increasingly shift pembrolizumab treatment initiation to the subcutaneous formulation, reducing the addressable IV market and limiting long-term pembrolizumab biosimilar penetration.

Stay ahead of shifting coverage trends and emerging therapies with Clarivate's DRG Fingertip foundations [here](#).

Fingertip Coverage | Fingertip Restrictions | Fingertip Publisher | Fingertip PolicyTrack



Keytruda QLEX gains early coverage traction, but IV Keytruda continues to lead formulary positioning

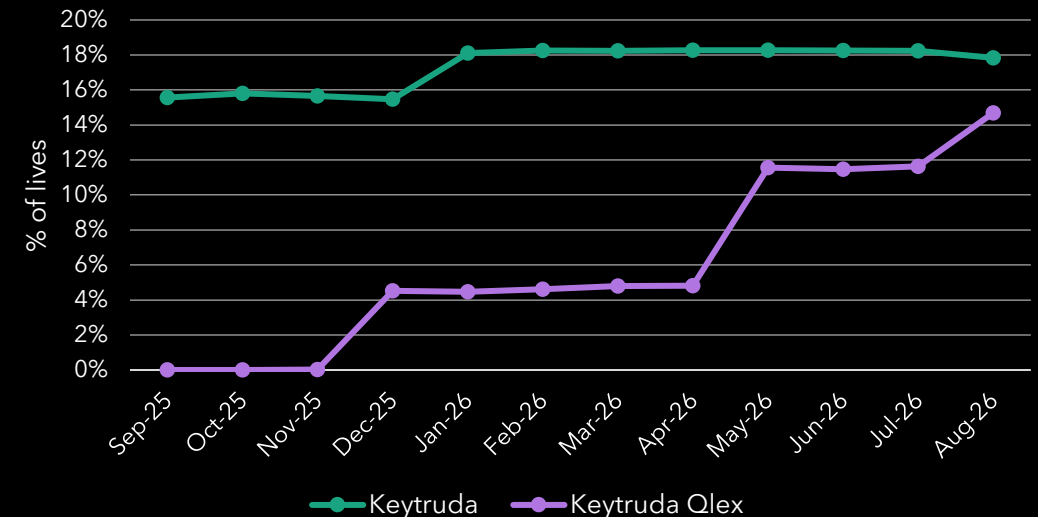


Figure 1. Percentage of preferred lives by pharmacy status

Key coverage and formulary trends

- KEYTRUDA Qlex coverage remains limited but is gradually expanding, with approximately 35% of covered lives gaining access through various tiers. Coverage is distributed across specialty and preferred tiers, with specialty-tier placement accounting for about 12% of covered lives and preferred formulary positioning representing approximately 15%.
- Adoption varies significantly by payer segment, with Medicaid emerging as the fastest adopter as preferred coverage for Qlex approaches parity with IV KEYTRUDA. This reflects Medicaid programs' focus on cost efficiency and the potential savings. Commercial and Medicare Advantage plans remain more cautious, relying primarily on specialty-tier placement and prior authorization, with preferred access concentrated in employer-sponsored plans and special needs plans.