

Tyruko finally debuts on the U.S. market after a long wait

Market Event Summary

Sandoz's natalizumab biosimilar, Tyruko, enters the U.S. market

Background

Sandoz **launched** Tyruko (natalizumab-sztn), **the first and only FDA-approved** biosimilar for relapsing forms of multiple sclerosis, in the United States in **November 2025**, following its initial launch in European markets by Polpharma and Sandoz in February 2024.

Tyruko is an intravenous injection indicated for adults with relapsing forms of MS, including clinically isolated syndrome (CIS), relapsing-remitting MS (RR-MS), and active secondary progressive disease (SP-MS), as well as Crohn's disease.

Tyruko's U.S. launch faced nearly two years of delay due to multiple prerequisites:

FDA approval for JCV antibody assay: Launch was postponed until approval of an assay critical for monitoring PML risk—a rare, potentially fatal brain infection. To ensure patient safety, Sandoz partnered with Labcorp to develop and validate a lab-developed test for anti-JCV antibodies. Labcorp will provide testing at no cost to eligible patients, with Sandoz covering all expenses.

Implementation of the REMS program: Similar to Tysabri, Tyruko requires an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) program to manage PML risk. This program includes prescriber certification, patient education, and regular monitoring. Establishing this infrastructure was a prerequisite for entry.

Logistical readiness: Administrative tasks such as securing the HCPCS code, setting up distribution channels, and finalizing pricing strategies were necessary to integrate Tyruko into the U.S. healthcare system.



Clarivate's takeaways



Clarivate expects slow yet steady uptake of Tyruko

- Clarivate's research highlights that neurologists have a strong preference for Tysabri due to its proven long-term efficacy and Biogen's robust risk mitigation support, but its high cost limits use. Key opinion leaders are increasingly interested in lower-cost biosimilars, signaling a gradual shift toward more cost-effective options.
- We expect Tyruko's initial use will be limited because prescriber familiarity remains a key driver of uptake. However, its first-to-market advantage and U.S. prescribers' trust in the Sandoz brand position it well for growth. Clarivate forecasts Tyruko to capture approximately 40% patient shares in the U.S. and European markets by 2033.



Commercial potential in the multiple sclerosis market

- Only one biosimilar is available across the U.S. and European MS markets. We expect biosimilars of Tysabri to experience a modest uptake supported by the reference brand's strong safety and tolerability record—key factors influencing prescribing decisions.
- The small but significant risk of PML limits the eligible patient pool, making this segment less attractive for many manufacturers. As a result, few companies are expected to pursue Tysabri biosimilars. In 2033, the natalizumab biosimilars market is projected to reach **\$500 million in the U.S.** and **\$80 million** in Europe, with **major -market biosimilar penetration estimated at 34%**.

About the author



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