Biosimilar Market Trends

A decade after the first biosimilar approval, these medications are still gaining approval from the U.S. Food and Drug Administration (FDA) and entering the market each year. Biosimilars are the most cost-efficient type of biologic medication, and they are safe and effective for treating many illnesses. Not only do these drugs have the potential to offer significant savings to the health care system, but they also increase patient access to medications and specialty treatments that their insurance may not have previously covered.

With high price tags, access to biologics is not covered under all health care plans and may not be feasible for many individuals. Research by the Biosimilars Council suggests that populations with limited access to expensive specialty drugs such as biologics stand to benefit from the expansion of the biosimilar market.

This article explores biosimilar trends in 2025 and what employers can expect this year and beyond.

Biosimilar Overview

Specialty drugs, including biological drugs, are one of the fastest-growing categories of pharmacy spending. Biologics are medications that come from living organisms, such as sugars, proteins and DNA. Biologics treat a range of conditions, such as cancer, psoriasis, rheumatoid arthritis and inflammatory bowel diseases. Even though these drugs are effective at treating complex health conditions, they are expensive. According to a report published in the medical journal JAMA, biologics make up only 2% of prescriptions but account for 37% of net drug spending. However, biosimilars have the ability to be a deflationary force in an otherwise rising-cost health care industry.

Biosimilars are an emerging category of biologic medications. These treatments are similar to a reference drug, which is an existing biologic that the FDA previously approved. For a biosimilar to be approved, there must be no meaningful differences in safety and effectiveness from the original biologic. Compared with original biologics, biosimilars are lower-cost drugs that allow for greater access to more patients. New biosimilars are gaining FDA approval and entering the market each year. As of April 2025, 74 biosimilars are currently approved and have been frequently entering the market since the first one was approved in 2015.

In the past decade, $36 billion of biosimilar spending has saved $56 billion on original biologics. However, efforts to integrate biosimilars into the drug market have faced challenges in reaching widespread adoption, such as drug exclusivity rights, active patents, approval processes and success rates for developing biosimilars.

Biosimilar Trends to Watch

The total biologics industry is projected to expand. Industry projections show that the market size is expected to grow from a current spend of around $450 billion to almost $850 billion over the next decade. As biosimilar acceptance and uptake increase, here are some of the latest biosimilar trends to monitor this year:

- **Cost savings**—Biosimilars have the potential to reduce health care costs significantly. Prices for biosimilars are often around 50% lower than their respective brand-name biologics. The biosimilar market is poised for significant expansion. The next five years are expected to increase savings to $181 billion, more than four times the savings over the past five years. This cost reduction is crucial for health care systems and patients struggling with the high price tags associated with biologic treatments.
- **Approvals**—The number of biosimilars approved each year has been steadily increasing. In 2024, the FDA approved 19 new biosimilar drugs, compared to five in the preceding year. In fact, 2024 had the most biosimilar approvals in a single year. The momentum continues; as of April 2025, 10 biosimilars have been approved so far this year. This trend is expected to continue, with predictions indicating that at least 10 new biosimilars will be approved annually over the next five years.
- **Regulatory challenges**—Although there's been movement, rollout to date has been slower for these medications than initially predicted by industry experts. The approval process for biosimilars is lengthy and requires extensive analytical, preclinical and clinical data to demonstrate their similarity to the reference product. This complexity continues to delay market entry and increase development costs.
- **Manufacturing hurdles**—Besides regulatory barriers, biosimilars face additional rollout challenges. Biosimilars are large, complex molecules produced by living cells, making it challenging to create an exact replica of the reference product. Variability in the manufacturing process can affect biosimilars' structure and clinical behavior.
- **Lapsing patents**—The IQVIA Institute for Human Data Science reports that 90% of the 118 biologics will lose their exclusivity in the next decade. Even when a biosimilar is approved, the matching biologic must lose

exclusivity rights before the biosimilar can be marketed. These exclusivity rights last for 12 years. With most biologics coming off patents and about to lose exclusivity, this could make it possible for new biosimilars to finally reach the market. However, many of the biologics coming off patent still don't have a matching approved biosimilar.

- **Health care system adoption**—While FDA approval can lead to access to biosimilars, market adoption adds an additional step before reaching the hands of pharmacy benefit managers (PBMs). PBMs have recently begun to include biosimilars in preferred drug formularies but may resist positioning biosimilars on the formulary and instead choose more expensive brand names. Also, prescribing providers may be slowing adoption due to efficacy concerns. Doctors or patients may be hesitant to switch prescriptions and disrupt treatment. Altogether, this has hindered the widespread use of biosimilars.

Conclusion

As the potential for biosimilars continues to grow, employers should monitor how these drug alternatives will impact their health care plans, coverage and formularies. However, employers should also be aware of the challenges in new biosimilar rollout and understand why its movement is taking years to gain traction.