

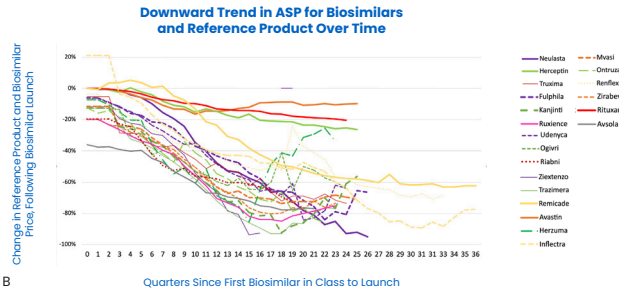
Development and Adoption of Biosimilars for a Stronger Healthcare System

A policy environment that promotes competition is key to sustainable healthcare systems and cost savings

The introduction of new biosimilars promotes a competitive marketplace that helps reduce healthcare costs and expand treatment options for U.S. patients.

- Since 2015, **more than 60 biosimilars** have been launched in the U.S., with **more on the way**ⁱ
- Biosimilar ASPs have **decreased 15% to 19% annually***, with some products having **decreased more than 90% in total** after biosimilars launchⁱⁱ
- Originator (reference) product ASPs have **decreased 1.6% to 18% annually**ⁱⁱⁱ

*Based on the compound annual growth rate (CAGR) relative to Average Sales Price (ASP) at launch, biosimilar and reference products covered under Medicare Part B



Beginning in 2015, biosimilars have been used in 3.3 billion days of patient therapy,^{iv} generating an estimated \$56 billion in healthcare system savings through 2024.^v

A stable, predictable policy environment is essential for continued biosimilar investment and long-term marketplace sustainability in the U.S.

Protect biosimilar development with focused changes that simplify the Inflation Reduction Act (IRA)

- **Simplify the process for application of a delay in price setting for reference products when a biosimilar is highly likely to launch (i.e., biosimilar pause)** and automatically grant a 2-year delay to allow for launches
- **Provide a more reliable path for manufacturers** by using the U.S. Food & Drug Administration (FDA) standard of entry into interstate commerce to define a marketed biosimilar product
- **Remove reference product Maximum Fair Prices (MFPs) promptly** when a biosimilar is marketed



Without needed modifications, the conditions of the IRA will result in **fewer potential treatment options for patients and less competition within the marketplace.**

Preserve science-based regulatory standards

- **Maintain the FDA's flexibility** to apply a scientifically appropriate framework to demonstrate interchangeability of a biosimilar product – this remains important as biosimilars to more complex therapies are developed



There is **no evidence that the current interchangeability standard is a barrier to access.**

Maintain mechanisms for a competitive marketplace

- **Reform pharmacy benefit manager (PBM) practices** to support formulary competition that passes cost savings on to patients
- Under current conditions, biosimilar uptake can be limited by PBM actions that may concentrate savings within intermediaries



If left unchecked, existing PBM practices can even result in **higher biosimilar medicine costs** for patients.

For more information about biosimilars and Amgen's commitment, visit our [Value of Biosimilars webpage](#).

ⁱ U.S. Food & Drug Administration. FDA-Approved Biosimilar products. Updated Dec. 22, 2025. Retrieved from <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>.

ⁱⁱ CMS ASP Pricing Files by quarter. Sept. 2025.

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^{iv} Association for Accessible Medicines. 2025 U.S. Generic and Biosimilar Medicines Savings Report. Sept. 2025.

Retrieved from <https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf>.

^v IQVIA National Prescription Audit, December 2024; IQVIA Institute, June 2025.