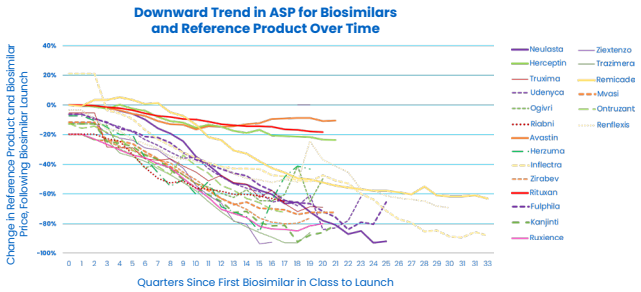
Development and Adoption of Biosimilars for a Stronger Healthcare System

An environment that promotes competition is key to a sustainable marketplace and cost savings

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

- Since 2015, **more than 40 biosimilars** have been launched in the US, with **more on the way**[i]
- Biosimilar ASPs have **decreased 11% to 24% annually***, with some products having **decreased more than 80% in total** after biosimilars launch
- Originator (reference) product ASPs have **decreased 1.8% to 36% annually**[ii]

*Based on 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 2.7 billion days of patient therapy, **generating an estimated $36 billion in healthcare system savings.**[iii]

Fostering a long-term, sustainable marketplace with biosimilars requires focused policies.

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 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 program or product

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

Maintain mechanims for a competitive marketplace

- **Reform pharmacy benefit manager (PBM) practices** to support cost savings being passed on to patients
- Under current conditions, biosimilar uptake can be limited by PBM actions that favor higher-list price biologics in formulary coverage

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] US Food and Drug Administration. FDA-Approved Biosimilar products. Updated Jan. 6 2025. Retrieved from https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
[ii] CMS ASP Pricing Files by quarter. Dec. 2024.
[iii] Association for Accessible Medicines. 2024 US Generic and Biosimilar Medicines Savings Report, Pages 29-30. September 2024. Retrieved from: https://accessiblemeds.org/sites/default/files/2024-09/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf