# ISSUE BRIEF: Ensure Coverage of Cost-Effective Biosimilar Medicines

**States can encourage the use of biosimilar medicines by addressing payer and provider barriers**

As of July 2025, the Food & Drug Administration (FDA) has approved 84 biosimilars, 67 of which are now available to patients for 21 reference products.[1] Biosimilar medicines offer patients a lower-cost alternative to brand biologics that are among the most expensive prescription drugs on the market. As a result, patients can now achieve significant savings and access to care. States could consider steps to facilitate improved patient access to these lower cost and lifesaving medicines.

**Biosimilar medicines are highly similar with no clinical meaningful difference from brand reference products**

Low-cost generics help patients more easily afford their medicine and properly adhere to their treatment plan. This results in lower out-of-pocket costs for patients and lower spending for the health care system overall.

- To obtain approval, the FDA requires a full data package proving the same chemical structure, therapeutic effect and safety as the brand-name reference product.[2]
- Prior to launch, the FDA must follow the same rigorous standards to approve the biosimilar for safe and effective use as it did for the brand-name reference product.

**Biosimilars are reducing patient costs and significantly increasing access to life-saving treatments**

- Biosimilar medicines treat conditions such as cancers, autoimmune diseases, and macular degeneration.
- Biosimilar competition lowers prices. Biosimilars average sales prices (ASP) three years post-launch are approximately 40 percent less than their comparable brand price at the time of biosimilar launch. And biosimilar competition is causing brands to cut their prices – by more than one-third lower since biosimilar market entry.
- Since the first biosimilar was introduced in 2015, biosimilars have saved patients and the health care system a total of $56.2 billion.
- Patients have received more than 3.3 billion days of therapy from biosimilars. Most importantly, patients have benefited from increased access to care through more than 460 million days of patient therapy that otherwise would not have been provided.[3]

[1] https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
[2] https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
[3] https://accessiblemeds.org/resources/blog/2025-savings-report

**For cancer patients, biosimilar medicines have already increased patient access and lowered spending**

- Biosimilars used to treat cancers are a prime example of biosimilar competition's ability to reduce spending – generating more than $26.6 billion in savings to date.[4]
- Moreover, biosimilars cut the growth rate in oncology spending by nearly half.

**States can encourage the use of lower-cost biosimilars through formulary coverage**

- While the early results are positive, the biosimilars market is not homogenous. Market adoption varies and this can limit the amount of savings achieved.
- Adoption of biosimilars is affected by education and misinformation; provider incentives; and health plan and pharmacy benefit manager (PBM) formulary decisions.
- Policymakers should encourage adoption of lower-cost biosimilars to ensure that the market functions optimally for all biosimilars and not just a few. For example, states should ensure that health plans cover new biosimilars with lower patient cost-sharing and without utilization management that is more restrictive than that placed on the brand.

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[4] https://accessiblemeds.org/resources/blog/2025-savings-report