



Eliminate Threats to Coverage of Lower-Cost Biosimilar Medicines

States should reject proposals based on false and misleading information about biosimilars, safe and effective alternatives to high-cost brand medicines.

- Despite the proven benefits of biosimilars, there is a targeted effort in several states to disseminate false and misleading information about the safety and efficacy of biosimilars. The goal of these tactics is to extend the brand/reference product's control of the market.
- These monopolistic behaviors prevent competition, thereby stifling biosimilar adoption, which limits patient access to more affordable life-saving treatments.

Biosimilar medications are highly similar to, with no clinical meaningful difference from, their reference products.

- Biosimilar medicines are safe, effective, and less-costly biologic medicines that are approved by the U.S. Food and Drug Administration (FDA) as highly similar to a previously approved brand biological medicine.
- Biosimilars are subject to a rigorous FDA review and approval process and have scientifically comparable quality, safety, and efficacy to their brand product.

Biosimilar competition drives prices down, delivering savings to patients and increasing access to care.

- Like generic drugs, biosimilars are a proven tool to lowering drug prices.
- To date, the average sales price (ASP) of biosimilars is more than 40 percent less than what the brand price was at the time the biosimilar first launched. And biosimilar competition is also forcing brand biologics to reduce their price – by more than one-third lower since biosimilar market entry.
- In 2023 alone, biosimilars provided \$12.4 billion in savings nationwide. And since the first biosimilars became available in 2015, biosimilars have generated more than \$36 billion in savings.
- To date, biosimilars have been used in 2.7 billion days of patient therapy with no clinically meaningful differences in safety or efficacy. . Importantly, they have also expanded patient access to care – resulting in more than 495 million days of patient therapy that would not have occurred if no biosimilar was available.

State legislation involving a health plan's ability to manage prescription benefit design has been used to limit biosimilar competition in primarily two ways.

- One type of legislation limits a plan's ability to add new biosimilars to their product offering in the middle of the plan year, often referred to as "mid-year switching." This process already exists and is widely used when new generic medications enter the market.
- The other type of legislation limits a plan's ability to require that healthcare providers use a certain, often lower-cost but equally effective, medication before trying another, known as "step therapy".
- It is commonly accepted that health plans do and should use such tools to encourage patient use of lower-cost generics and biosimilars.
- However, these laws have been drafted to prevent plans from encouraging use of lower-cost biosimilars, thereby reducing patient access to savings.
- Both types of bills allow for plans to use mid-year switching or step therapy for generics. But because of misinformation about biosimilars and "interchangeable" biosimilars, the proposals inappropriately disallow the use of these common tools to encourage use of lower-cost biosimilars.

The distinction between biosimilars and "interchangeable" biosimilars applies to the practice of pharmacy and is not relevant to health plan design.

- An interchangeable biologic is a product that satisfies the requirements for biosimilarity along with additional regulatory requirements to show that the risk of a pharmacist switching a patient between an interchangeable and brand product without physician approval is not greater than the risk of using the brand product without such switching.
- The FDA has made clear that the interchangeable designation is a product attribute, **not** an indication of superior quality.¹
- FDA undertakes a rigorous and thorough evaluation to ensure that all products, including biosimilar and interchangeable products, meet the Agency's high standards for approval.
- An interchangeable designation is only relevant at the pharmacy counter in the context of state pharmacy substitution laws governing a pharmacist's ability to dispense a generic or biosimilar when the patient's doctor prescribes the brand product.
- Because many biosimilars are dispensed and administered by a health care provider, the interchangeable designation is often irrelevant.
- Legislation aimed at changing formulary plans and design should not make a distinction between those biosimilars with versus those without an interchangeable designation.
- Like generic drugs, biosimilars should be exempted from legislation limiting mid-year switching and step therapy. Otherwise, patients will be forced to continue with the more expensive reference products when less costly, but equally safe and effective biosimilar alternatives are available.

¹ "Biosimilars improve patient access to quality medicines" US FDA Infographic. <https://www.fda.gov/media/161628/download>