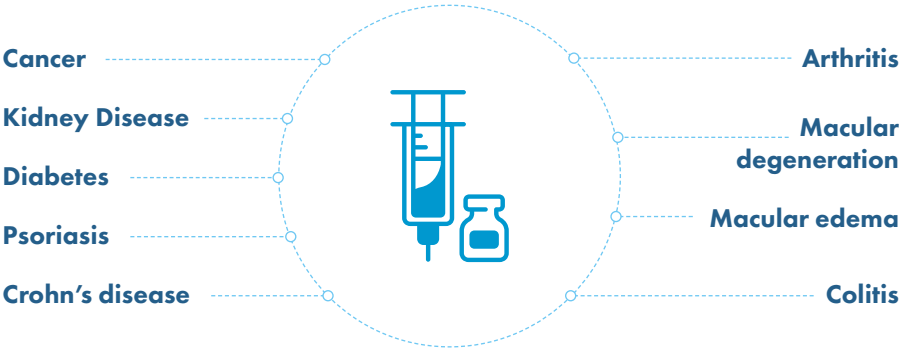
Biosimilars FORUM

Biosimilars Basics

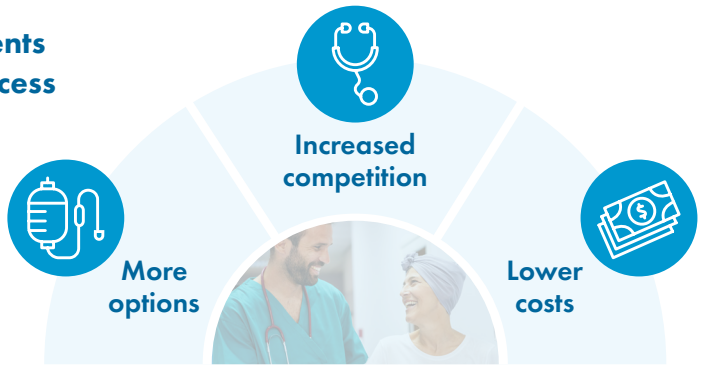
What is a Biosimilar?

A biosimilar is an FDA-approved biologic product that is approved based on the demonstration of a high degree of similarity to an FDA-approved reference biologic product; biosimilars must also show no clinically meaningful difference to the reference product in terms of safety and effectiveness.

Biosimilars are safe and effective biologic medications for treating many conditions, including



Biosimilars provide patients with more access to important treatments



Source: https://www.fda.gov/drugs/biosimilars/patient-materials

What is a Biologic?

Biologic (reference) drugs are medications made by using living organisms (such as yeast or animal cells) to produce complex proteins that are purified then administered to affect certain processes in the human body.

Biologics are the single largest driver of prescription drug spending—making up 40% of all drug spending but accounting for just 2% of prescriptions filled.

Biosimilars & Original Biologics Similarities

- **Same benefits**
- **Same strength and dosage**
- **Administered the same way**

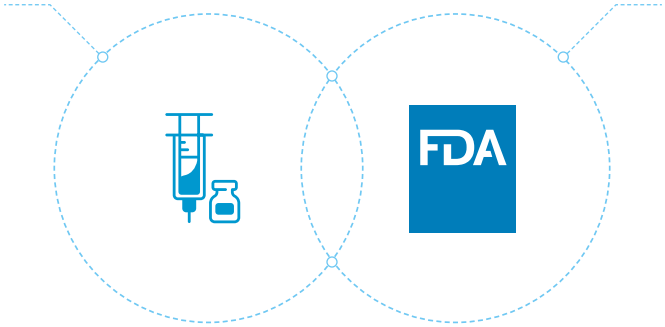
Source: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers

What Do Experts Say About Biosimilars?

Biosimilars are approved by FDA after a careful review of data, studies, and tests. A biosimilar is proven through a rigorous FDA approval pathway to be highly similar to the reference product. Patients can expect no clinically meaningful differences in safety, potency, and purity with a biosimilar vs the reference product.

Biosimilars were established by the FDA

- To provide more treatment options
- To increase patient access
- To lower healthcare costs
- To increase patient access and affordability



FDA monitors the safety and effectiveness of all medications after their approval

- Check for medication quality during production
- Review patient safety reports

Sources: https://www.fda.gov/drugs/biosimilars/patient-materials, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

How Do Biosimilars Lower Drug Costs?

Biosimilars cost on average 30 percent less than reference biologics, which account for 40 percent of all drug spending. Not only are biosimilars more affordable, but the competition they provide lowers the cost of the reference product as well.

Biosimilars could reduce drug costs by $133 billion over the next five years if their use rises.

Sources: https://www.fda.gov/drugs/biosimilars/patient-materials
https://biosimilarscouncil.org/resource/biosimilars-facts/

What is the Difference Between Generics and Biosimilars?

Biosimilars are not the same as generic drugs. Generic drugs are small molecules that are chemically synthesized and contain identical medicinal ingredients to their brand name reference products. Due to the size, complexity and natural variability of biologic drugs, and because biologic drugs are made in living cells rather than with chemicals, a biosimilar and its reference biologic drug can be shown to be similar, but not identical.

Source: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

The Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.