



**Helping you feel  
confident about  
your treatment  
is our first priority.**

SOME ANSWERS TO YOUR  
QUESTIONS ABOUT BIOLOGICS  
AND BIOSIMILARS ARE HERE.



# Biosimilars are designed to work the same way in the body as the original biologic product.

## What are biologic medicines?

Before getting into biosimilars, it helps to know about medications called biologics. Biologics are large, complex molecules. Doctors use biologic medications to treat certain serious conditions.

## Why are these medicines called biologics?

A lot of medicines that you pick up at your local drugstore are made of fairly simple molecules.

Medicines can generally be classified as small molecules or large molecules. Small molecules are made up of chemical structures and made with a chemical process.

Biologics are large, complex molecules. Large molecules are bigger in size and made up of protein structures through living organisms such as bacteria and yeast.

## What are biosimilar medicines?

A biosimilar is a biologic product that is highly similar to an existing reference product approved by the FDA, thus, the name biosimilar. The already approved biologic is known as the originator biologic product.

## How does a biosimilar compare to the original biologic product?

Quite well. A biosimilar must show that it is highly similar to the originator biologic product in safety, purity, and potency (efficacy).

A biosimilar must also demonstrate that it has no clinically meaningful differences in effectiveness and safety from the originator biologic product. A biosimilar generally has the same dosage as the originator biologic, and it's taken the same way.

## Are biosimilars like generic medicines?

Some may view biosimilars as generic medicines because they are both similar versions of an original product. However, biosimilars are not like generic medicines because generic medicines are drugs made from chemical structures and biosimilars are made from living organisms.



*Since the FDA passed the Biologics Price Competition and Innovation Act, biosimilars saved the US health care system over \$37 billion and have the potential to save an estimated \$104 billion from 2020-2024.*

## BIOSIMILARS ARE RIGOROUSLY TESTED. THEN THEY MUST BE APPROVED BY THE FDA.

The FDA requires a biosimilar to be tested to demonstrate that it is similar to the original biologic in several ways:

*Biosimilars must be shown to have no clinically meaningful differences in safety, purity, and potency (efficacy) compared to the originator product.*

*A biosimilar must show it's designed to work in the body in the same way as the originator biologic product.*

*A biosimilar is developed in a way that helps ensure that it is similar in structure to the originator biologic product.*

## If a biosimilar is similar to the originator biologic product, why do we need a biosimilar?

Good question. Biosimilars offer doctors and patients more treatment options. Biosimilars may help create competitive pricing for biologics, potentially helping more people get access to biologic medicines. They may also help reduce costs in the health care system.

# Biologics and biosimilars often have many similarities. Hence, the term biosimilar.

- Biosimilars must show they have no clinically meaningful differences in safety, purity, and potency compared to the biologic.
- Biosimilars are rigorously tested. Then they must be approved by the FDA.
- Biosimilars help more people gain access to biologic medicines.
- Have questions about biosimilars? Talk to your doctor.



**SCAN THIS  
QR CODE  
TO WATCH A  
VIDEO ABOUT  
BIOSIMILARS**