

QUESTIONS YOU MAY HAVE ABOUT IBD AND BIOSIMILARS

When it comes to inflammatory bowel disease (IBD) and biosimilars, many people have questions and concerns. Why does my health care provider want to switch me to a biosimilar? Are there any advantages to using a biosimilar instead of a biologic? Will my treatment routine stay the same?

These frequently asked questions are meant to give you clear answers and to help you talk to your health care provider about your choices.

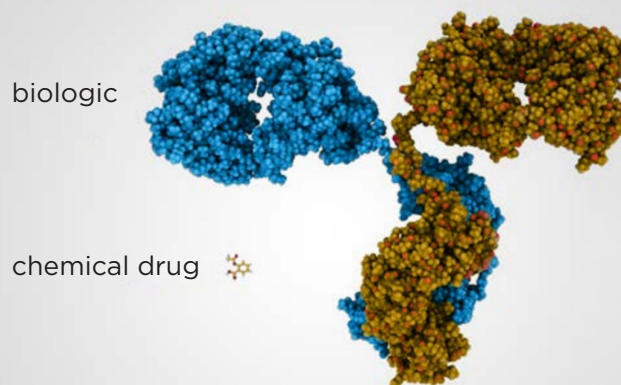
Key Terms and Concepts

QUESTION:

What is a biologic?

ANSWER:

The medicines most people know are made from chemicals. Biologics are different. Biologics are large, complex compounds derived from living organisms. Insulin is an example of a biologic medicine. Because they are complex, biologics cost a lot of money and are hard to make.



QUESTION:

What is a biosimilar?

ANSWER:

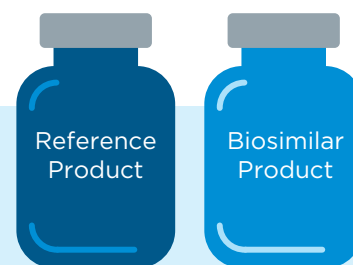
Biosimilars are prescription biologic medicines that are highly similar to an already approved biologic medicine. You might hear a biologic called a “reference product” or “reference biologic.” There are minor differences between a biosimilar and its reference biologic due to the complex nature of these agents and how they are made. But, biosimilars act like their reference biologics, with no big differences in effectiveness, safety, or treatment routine.

QUESTION:

Are biosimilars the same as generic versions of biologic medicines?

ANSWER:

No. The active ingredients in generic medicines are chemically the same as in brand name medicines. Biologic medications cannot be exactly copied because they are made from living sources. For that reason, biosimilars are similar—but NOT identical—to their reference biologic. That’s why a biosimilar is not a “generic” biologic.



QUESTION:

Are biosimilars as safe and effective as biologics?

ANSWER:

Yes. The U.S. Food and Drug Administration (FDA) requires biosimilars to meet rigorous approval standards to make sure that they are as safe and effective as their reference biologic. These standards were set up through the Biologics Price Competition and Innovation Act (BPCI Act) of 2009. The act was passed to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs.

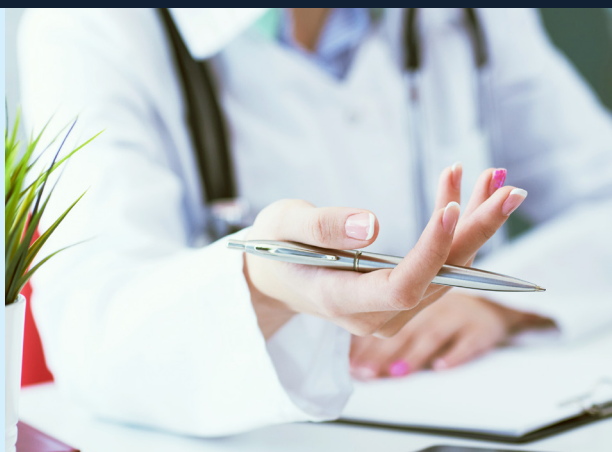
Biosimilars and Me

QUESTION:

Why should I start a biosimilar?

ANSWER:

Your doctor may prescribe a biosimilar for IBD if other medicines have not managed your symptoms or make your disease go into remission. For many patients with IBD, a biologic or biosimilar makes a big difference in quality of life, greatly improving disease symptoms. Because biosimilars are highly similar to a reference biologic, there is no need to try a biologic first before trying or switching to a biosimilar.



QUESTION:

I am taking a biologic that works for me. Why should I switch to a biosimilar?

ANSWER:

Switching to a biosimilar means access to an effective medication at a potentially lower cost. You should expect no difference with a biosimilar than the biologic you are using. Biosimilars are just as safe and effective as their reference biologic, whether you start treatment with them or switch to them later.

To approve a biosimilar, the FDA compares safety data for patients treated with the reference product who switched to a biosimilar. The FDA also carefully reviews studies, checks the quality of medicine while it's being made, and reviews patient safety reports received after the biosimilar has been approved.

QUESTION:

Can a pharmacist substitute a biosimilar for my biologic medicine without letting my health care provider or me know?

ANSWER:

It largely depends on state laws. If a biosimilar is granted "interchangeability" status, individual state laws may allow a pharmacist to substitute an interchangeable biosimilar for the reference product without talking to the health care provider who prescribed the original medicine. But, the FDA has not yet granted interchangeability of any biosimilar for treating IBD in the U.S., making these substitutions unlikely.



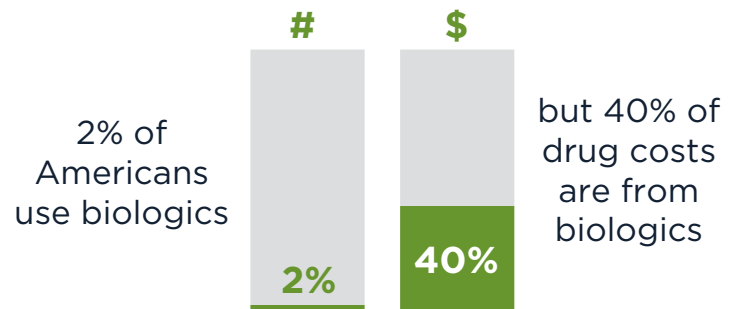
QUESTION:

Will a biosimilar save me money?

ANSWER:

Biosimilars often cost less than biologics. Biologics are costly: While fewer than 2% of Americans use them, they represent about 40% of all prescription drug spending.

Whether they save you money directly will depend largely on your health plan. Some patients receive financial assistance or drug discounts from the companies that make a biologic. Companies that make biosimilars also offer patient assistance if the medicines are too costly for someone to pay for on their own.



QUESTION:

What biosimilars are available for treating IBD in the U.S.?

ANSWER:

At this time, there are five biologic medicines approved for treating IBD in the U.S.; only two—adalimumab and infliximab—have biosimilars available:

Adalimumab Biosimilars

- Abrilada (adalimumab-afzb)
- Cyltezo (BI 695501) (adalimumab-adbm)
- Hadlima (SB5) (adalimumab-bwwd)
- Amgevita (adalimumab-atto)
- Hyrimoz (adalimumab-adaz)

Infliximab Biosimilars

- Ixifi (infliximab-qbtx)
- Renflexis (infliximab-abda)
- Inflectra (CT-P13) (infliximab-dyyb)