



Are you on a biologic medication?

What you need to know about biosimilar treatment options.

The U.S. Food and Drug Administration (FDA) has approved many biologics (also called biological products), which are medications generally made from living sources like bacteria and yeast. Biologics treat many conditions like arthritis, diabetes, kidney conditions, cancer, macular degeneration, and chronic skin and bowel diseases, such as psoriasis, Crohn's disease, and ulcerative colitis.

But biologics are often expensive and can be unaffordable, especially for people using several medications. If you're currently using a biologic and you're concerned about cost, you and your health care provider may want to talk about switching to a biosimilar. A biosimilar is an FDA-approved biologic that is highly similar to and has no clinically meaningful differences from a biologic previously approved by FDA, which is sometimes described as the original biologic or reference product. Like generic drugs, biosimilars may save you money and are as safe and effective as the original biologic.

Some patients and health care providers might worry that biosimilars are not as safe or effective as the original biologic or that an interchangeable biosimilar is better than a biosimilar that is not an interchangeable biosimilar. Unwarranted concerns may discourage patients and their doctors from using or switching to a biosimilar, so it's important to find out the facts.

How is a biologic like other drugs?

FDA-approved biologics, like other drugs FDA approves, are safe and effective medications for treating many illnesses. However, biologics are usually made from living sources such as proteins, living cells, and microorganisms such as bacteria or yeast. They usually are more complex than other drugs, and more complicated to make.

What is a biosimilar?

A biosimilar is a biologic that is highly similar to an original biologic already approved by FDA. Both products are made from the same types of sources (such as living cells or microorganisms). Biosimilars also have no clinically meaningful differences from original biologic. This means biosimilars are as safe and effective as the original biologic for their approved uses.

Is a biosimilar the same as a generic?

Biosimilars and generics are a lot alike. For example, both are versions of FDA-approved medicines and both may offer patients more affordable treatment options. Both also go through a rigorous review process at FDA. Once FDA approves biosimilars and generics, patients and their doctors can be confident that they are just as safe and effective as the products they're compared to.

There are also some differences between biosimilars and generics. Generics can be easier to copy exactly because their active ingredients tend to be smaller and simpler. Meanwhile, biologics generally cannot be copied exactly, even between batches of the same brand, because their living sources can contain many slight variations. However, FDA requires biologic manufacturers, including biosimilar manufacturers, to carefully control and monitor for differences.

Should I be concerned if my doctor prescribes a biosimilar or wants to switch me from a reference product to a biosimilar?

No. FDA-approved biosimilars are as safe and effective as their original biologic and you can expect biosimilars to have the same benefits and risks as the original biologic. To be approved by FDA, companies show that patients on biosimilars don't have any new or worsening side effects as compared to patients on the original biologic.

Your doctor may prescribe or switch you to a biosimilar for any number of reasons, including because it may be less costly, or the biosimilar might be covered by your insurance company.

What is the difference between a biosimilar and an interchangeable biosimilar?

Biosimilars and interchangeable biosimilars both must meet FDA's requirements for showing that they are highly similar to and have no clinically meaningful differences from a biologic already approved by FDA. The difference is that an interchangeable biosimilar meets additional requirements related to the potential for "pharmacy level substitution." This means a pharmacy may substitute an interchangeable biosimilar for the reference product without consulting the prescribing doctor, depending on state pharmacy laws.

Should I wait for a biosimilar to be approved as "interchangeable" to use it?

No. Both biosimilars and interchangeable biosimilars meet the same high standard of biosimilarity for FDA approval and both are as safe and effective as the original biologic. Moreover, many biosimilar manufacturers do not seek "interchangeable" status because interchangeability is only relevant to pharmacy-level substitution, which depends on state pharmacy laws. Biosimilars and interchangeable biosimilars can both be used in place of the original biologic.

Will biosimilars cost less? Will my insurance cover it?

FDA does not have a direct role in drug pricing, but FDA's work does play a critical role in increasing access to safe and effective biologics and supporting a competitive marketplace for biologics. Biosimilars may improve patient access to medicines and lower health care costs.

Insurance coverage and reimbursement can affect patient and doctor adoption of biosimilars. In turn, such coverage and reimbursement can depend on many factors, such as insurance plans and formulary coverage. If you have insurance, check with your insurance provider to find out what's included in your plan. If you are covered by Medicare or Medicaid, check with the [Centers for Medicare & Medicaid Services](https://www.cms.gov) (<https://www.cms.gov>) and your plan provider.

For More Information

Visit www.fda.gov/biosimilars and talk to your doctor about available treatment options and potential risks and benefits.

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Contact the [FDA Bad Ad program](https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program) (<https://www.fda.gov/drugs/office-prescription-drug-promotion/bad-ad-program>) and [FTC](https://www.ftc.gov/complaint) (<https://www.ftc.gov/complaint>) to report false or misleading prescription drug advertising, including advertising for biological products. You can also report false or misleading non-prescription or other health product or service advertising to [FTC](https://www.ftc.gov/complaint) (<https://www.ftc.gov/complaint>).

Additional Advice

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