U.S. FOOD & DRUG ADMINISTRATION

Biosimilars: What Patients with Diabetes Need to Know

Biosimilars are a type of biologic medication that is safe and effective for treating diabetes and many other chronic and severe conditions, including:

- Chronic skin and bowel diseases
- Arthritis
- Kidney conditions
- Some cancers

What are biologic medications?

Most biologics, including insulin, are made from living sources, such as animal cells and microorganisms like bacteria or yeast, including insulin. Because they come from living sources and have natural differences, biologics are more complicated to produce than drugs made from chemicals. Drugs made from chemicals, such as aspirin, can easily be copied.

Has insulin always been a biologic?

Although insulin is made in living cells, it was historically regulated as a drug made from chemicals. Insulin and other drugs that meet the criteria for a biologic medication are now regulated as biologics. This does not change the ingredients of insulin or how you obtain medication at the pharmacy.

The regulation of insulin as a biologic will allow multiple companies to make biosimilar versions of "brand name" insulins, similar to how generics are versions of brand name drugs.

A biosimilar is very similar, but not identical, to an original biologic (also known as a reference product) already approved by FDA. Studies have shown that there are no differences in the safety and effectiveness of biosimilars and the original biologics. Compared with original biologics, biosimilars:

- Provide the same benefits when treating disease
- Are given at the same strength and dosage
- Cause no new or worsening side effects

FDA has approved many biosimilars and expects to approve more in the future. For more information about individual biosimilars, including insulin, and the conditions they treat, please visit **https://purplebooksearch.fda.gov.**

For more information on biosimilars, visit

www.FDA.gov/biosimilars

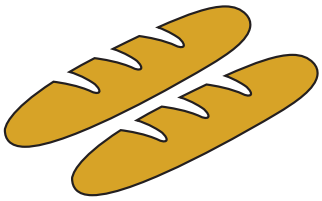
and talk to your doctor to learn more.

Why aren't biosimilars identical to the original biologics?

Because all biologics are made from living sources, it is normal for there to be minor differences between batches of the same medication. This means that biologics cannot be copied exactly, and that is why biosimilars are not identical to the original biologic.

FDA carefully reviews the differences in the original biologic and the biosimilar to ensure that biosimilars are safe and effective, just as the original biologics are.

All biologic medications, including biosimilars, are similar to loaves of bread made using the same recipe. No one loaf is an exact copy of another, but all are the same type of bread. The same is true for biologics, because they are made from a mix of ingredients that include living sources, so they are not exact copies but provide the same treatment benefits.



Biosimilars may be available at a lower cost than the original biologics are. Similar to generic drugs, biosimilars cost less because manufacturers use existing research that led to the development of the original biologics. The lower cost is not a reflection of the effectiveness of biosimilars. Because of the lower cost, these medications may be covered by more insurance companies and offer additional treatment options for patients.

How will this change affect an insulin prescription for me or a person I care for?

The regulation of insulin as a biologic will have no impact on your ability to fill current prescriptions through a pharmacist. The physical appearance of the insulin and how you administer it will also stay the same. There may be small changes to the labeling on the packaging and vial over time.

The most noticeable change is that patients can be prescribed a variety of new insulin treatment options once they are available, possibly at lower cost, depending on your insurance coverage.

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Biosimilars are safe and effective. As it does with all medication approvals, FDA takes a number of steps to ensure that all biosimilars, including insulin, are ready for patient use. Patients and health care providers can rely on a biosimilar to be as safe and effective as the original biologic. FDA takes the same precautions to ensure the safety and effectiveness of biosimilars as it does for all medications.

Before approving a biosimilar, FDA:

- Carefully reviews data, studies, and tests to decide whether a biosimilar meets FDA's high standards for approval
- Ensures that manufacturers show that there are no differences in side effects and that the side effects of the biosimilar are not more frequent or more severe than those of the original biologic

After approval, FDA:

- Checks the quality of the biosimilar during the production process
- Reviews reports from patients and health care providers on safety and effectiveness

As with all treatment decisions, patients should talk to their doctors and check other trusted sources of information related to their specific condition to learn more about biosimilar treatment options.

Biosimilars are a growing field of life-changing treatment options for a range of conditions. FDA is committed to educating patients and caregivers about biosimilars so they understand all potential treatment options. More detailed information on the approval process and published studies are also available for doctors and patients on the FDA website, **www.fda.gov/biosimilars.**

Analogy Alternative for Biosimilars/Biologics

All biologic medications, including biosimilars, are like oranges: No one orange can be an exact copy of another, because it came from a living organism, but they are all oranges. The same is true for biologics and biosimilars. They are made from living sources and are not exact copies, but they provide the same treatment benefits.

For more information on biosimilars, visit

www.FDA.gov/biosimilars

and talk to your doctor to learn more.