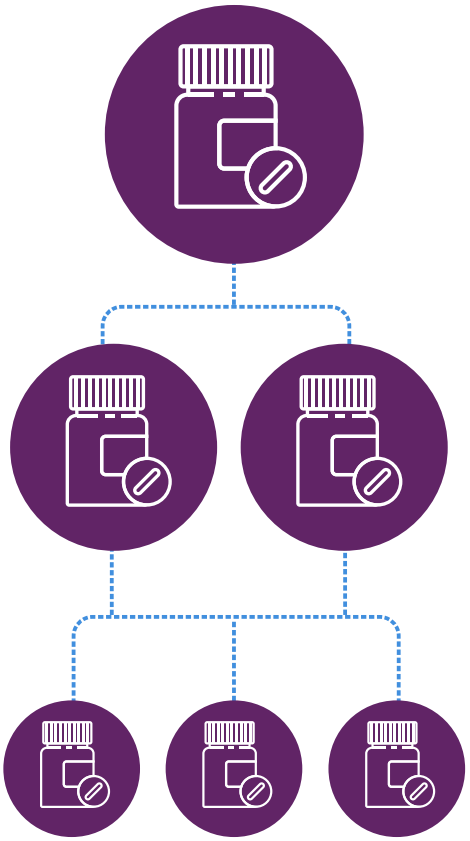
AN ENDOCRINE SOCIETY PATIENT RESOURCE

INTERCHANGEABLE BIOSIMILARS: WHAT TO KNOW IF YOU'RE ASKED TO SWITCH

If the costs of prescription drugs concern you, you should know about interchangeable biosimilars. This term refers to certain newer versions of brand-name biologic medications (biopharmaceuticals). They work just as well as brand name products, but cost less for drug companies to develop; which can lead to a cost saving at the pharmacy.

3 CATEGORIES OF MEDICATIONS

Biopharmaceuticals are the fastest-growing group of medications in the United States today. Here are the broad categories of what this medication includes, and how interchangeable biosimilars fit in.



BIOPHARMACEUTICALS

- Medications from living sources, such as animal cells, bacteria, or yeast
- Types include insulin, vaccines, and monoclonal antibodies
- FDA requires extensive research including full-scale clinical trials
- Data must show that the medication is safe and effective

BIOSIMILARS

- New medical product that is an identical copy of the original biopharmaceutical or brand-name
- There are no clinically meaningful differences between the two products
- FDA requires detailed lab studies comparing the products; studies in people may be needed as well
- Data must show that the biosimilar is as safe and effective as the original

INTERCHANGEABLE BIOSIMILARS

- Medication that contain the same amount of active ingredients and meets additional requirements
- A pharmacist can substitute them for the original medications, if state law allows
- FDA may ask for studies in which people switch back and forth between the interchangeable product and the original
- Data must show that this does not decrease safety or effectiveness

Visit endocrine.org/patients for more information.

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BIOSIMILARS VS. GENERICS

Interchangeable biosimilars are more complex than generic drugs, but also have a lot in common. Both can be substituted for brand name medications; they increase choice; and they save patients money.

	INTERCHANGEABLE BIOSIMILAR	GENERIC DRUG
Name	Chemical name of the original brand-name drug plus a four-letter suffix	Same chemical name as the original brand-name drug
Structure	Large molecule with a complex structure	Small molecule with a simple structure
Manufacturing process	Complicated process using living cells or microorganisms	Simpler process using chemicals
Structural comparison	Highly similar to the original drug	Identical to the original drug
Clinical comparison	No clinically meaningful differences from the original drug	Equivalent to the original drug, biologically and therapeutically

HOW THE SUBSTITUTION PROCESS WORKS

1. Your health care provider prescribes a brand-name biopharmaceutical to help manage conditions such as diabetes, rheumatoid arthritis and Crohn's disease.
2. Your pharmacist substitutes an interchangeable biosimilar. Switching is quick and convenient. For example, an interchangeable insulin called Semglee may be substituted for brand-name Lantus.
3. You receive the interchangeable biosimilar instead of the brand-name product. The out-of-pocket costs may be lower, and you can expect treatment results to be the same.

QUESTIONS TO ASK YOUR PROVIDER

- Why are you prescribing this medication for me?
- My prescription is hard to afford. Do you have any suggestions?
- When and how should I take the medication?
- What side effects may occur? How can I prevent or manage them?

QUESTIONS TO ASK YOUR PHARMACIST

- Does my insurance cover this medication? What will my out-of-pocket costs be?
- Is there an interchangeable (or generic) version?
- Are there other options for lowering what I pay?
- Would you please go over with me again how to use my medication correctly?

Learn more about biosimilar insulin › YouTube

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