BIOSIMILARS COUNCIL
A DIVISION OF AAM

Biosimilar Interchangeability FAQs

Interchangeable biologics are biosimilars that are approved by the FDA to be substituted by a third party for the reference biologic. Patients can rely on the safety of these products just as they would the reference medicine. Here are answers to some common questions about these products.

What does interchangeability mean when it comes to biosimilars?

All biosimilars, whether they have an "interchangeable" designation or not, are rigorously tested and approved by the FDA and are certified to have "no clinically meaningful differences" from the original "reference" biologic.

Interchangeability is an additional designation, defined by statute, that simply means that the biosimilar "may be substituted for the reference product without first getting approval of the health care provider who prescribed the reference product." Seeking this additional designation is at the option of the manufacturer.

In other words, an "interchangeable" designation from the FDA has no bearing on the quality or clinical effectiveness of the biosimilar, it simply allows pharmacists to switch a patient, without the approval of a treating physician, from taking a more expensive biologic to a lower-cost biosimilar. Specific rules and regulations for how this occurs differ by state laws.

Are interchangeable biosimilars as safe and effective as reference biologics?

All biosimilars, including interchangeable biosimilars, undergo the same rigorous testing for safety and efficacy as brand-name biologics before receiving FDA approval, meaning patients can have confidence in taking them. To be classified "interchangeable," a biosimilar manufacturer choosing to seek this additional designation may supply additional data to ensure it can be switched by a pharmacist without consulting the prescribing physician without having adverse effects on patient treatment.

How are biosimilars tested for interchangeability?

A manufacturer must specifically seek an interchangeable designation, meaning that a lack of an interchangeable designation on a biosimilar product may simply indicate that the manufacturer did not seek the designation or that the additional data required has not yet been provided.

To achieve an interchangeable designation, manufacturers generally conduct studies in which patients alternate between the reference product and the interchangeable biosimilar and compare those patients to patients who are just being treated with the reference product. The results must show no decrease in effectiveness or increase in safety risk associated with switching.

According to the FDA, the additional data that manufacturers provide "helps FDA to determine the safety of pharmacy-level substitution, this does not mean that an interchangeable biosimilar is safer or more effective than other biosimilars."

Are there any risks associated with switching between a reference product and an interchangeable biosimilar?

To meet the FDA's requirements for interchangeability, a biosimilar must be as safe and effective as its reference product, and produce no meaningful difference in treatment, meaning there are no inherent risks in switching.

How do physicians and patients decide whether to use a reference product or an interchangeable biosimilar?

While specific requirements vary by state, generally pharmacists are required to notify physicians and patients if they intend to dispense an interchangeable biosimilar. Additionally, a physician can choose to prescribe an interchangeable product at the outset if they wish. Patients are not required to take an interchangeable biosimilar.