

Health Plans Should Prioritize Biosimilars



Biosimilar vs Interchangeable is not relevant for formulary regulations. The distinction is only meaningful at the pharmacy counter and is not an indication of superior quality.

Biosimilars

FDA-Approval

- Highly similar to the reference product and does not have clinically meaningful differences

Administration

- Prescribed and administered by a physician or other health care provider

Interchangeable Biosimilars

FDA-Approval

- Biosimilar
- Per FDA's requirements, may have undergone additional studies about the effects of switching between biosimilar and reference

Administration

- Typically dispensed by a pharmacist
- Subject to state law, a pharmacist may substitute an interchangeable biosimilar instead of the reference without the prescribing physician's approval

Interchangeable biologics aren't superior versions of biosimilars



Both undergo same testing and are held to the same FDA scientific standard for approval



Interchangeability designation doesn't mean it's a better product – it simply dictates how the product can be dispensed.



"Interchangeable" doesn't mean the drug was changed or improved.



"Interchangeable" means the manufacturer provided additional data to allow for pharmacy-level switching of that drug.



Interchangeable biologics are **not** a separate class of medicine.