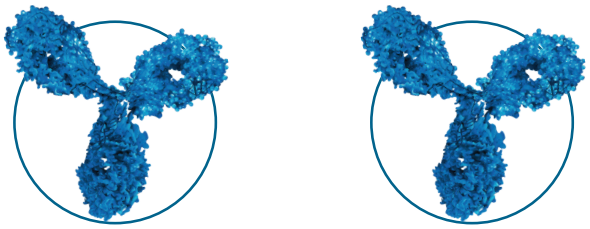
USING BIOSIMILARS IN CLINICAL PRACTICE

Therapeutic biosimilars are approved in many other countries, but are relatively new additions to some healthcare marketplaces.

The following information may answer some of the questions you have about prescribing a biosimilar.

IS RECEIVING A BIOSIMILAR THE SAME AS RECEIVING THE REFERENCE PRODUCT?

Physicians and their patients can expect a biosimilar to be highly similar to and have no clinically meaningful differences in safety, purity, and potency from the reference product when the products are used as intended.[1]



Reference Product | Biosimilar

CAN BIOSIMILARS BE USED FOR THE SAME INDICATIONS AS THE REFERENCE PRODUCT?

Biosimilars may be approved for all of the indications of the reference product or a subset of these indications.[1] Healthcare providers should review the prescribing information of the biosimilar to ensure it is being used for its approved indications.

References: 1. US Food and Drug Administration. Labeling for biosimilar products. *Guidance for Industry*. July 2018. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm493439.pdf. Accessed July 20, 2018. **2.** US Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product. *Guidance for Industry*. April 2015. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291128.pdf. Accessed June 25, 2018. **3.** US Food and Drug Administration. Considerations in demonstrating interchangeability with a reference product. *Draft Guidance for Industry*. January 2017. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537135.pdf. Accessed August 24, 2018.

CAN A BIOSIMILAR BE APPROVED FOR AN INDICATION FOR WHICH THE REFERENCE PRODUCT IS APPROVED, WITHOUT BEING STUDIED IN THAT INDICATION?

Yes, a biosimilar can be approved for an indication, even if it was not specifically studied for use in that indication. This concept is known as **extrapolation**. If the body of evidence supporting the biosimilar demonstrates biosimilarity in at least one of the reference product's indications, expanded approval for the reference product's other indications may be granted by the Food and Drug Administration (FDA). The FDA draws on available data, information, and scientific justification provided in the biosimilar application, in addition to the FDA's previous findings on the safety and efficacy of the reference product, to make a final determination on whether or not to extrapolate.[2]

CAN BIOSIMILARS BE SUBSTITUTED FOR REFERENCE PRODUCTS BY PHARMACISTS?

When supplemental data are submitted to the FDA, a biosimilar can be designated as interchangeable with the reference product.[3] Check your state's pharmacy laws to determine whether a biosimilar can be substituted for the reference product at the pharmacy.

WHERE CAN I FIND MORE INFORMATION ABOUT BIOSIMILAR PRODUCTS?

The FDA has a number of online resources available for healthcare professionals and patients interested in learning more about approved biological products:

- The FDA's "Purple Book" provides information about biologics, including both reference products and biosimilars
- For product-specific information, including a summary of the FDA review and approval, please visit Drugs@FDA or www.fda.gov/biosimilars

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