

Biosimilars: Non-Medical Switching and Transitioning

Synopsis

As more biosimilars launch in the United States and achieve greater availability on formularies, many patients find themselves with increased access to safe, effective, and lower-cost biosimilars. Patients should understand that biosimilars are fully vetted through a vigorous, lengthy FDA review process, and offer the same clinical benefits and effectiveness of the originator biologic. If a patient's treatment plan includes biosimilars, they can be fully confident that the therapeutic outcome on a biosimilar will be the exact same as the originator biologic, supported by FDA reviews, academic studies, and guidelines from health care networks and physician societies.



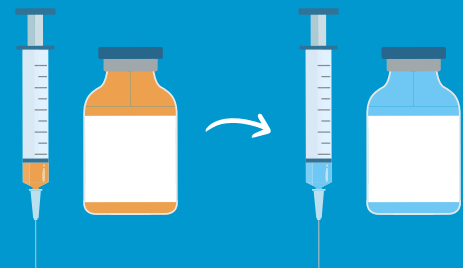
'Non-Medical Switching' and 'Transitioning': An Explanation for Patients

"Transitioning" describes a transition from an originator biologic to a biosimilar, as the transition from an originator adalimumab biologic to a biosimilar adalimumab biologic will yield no difference in clinical outcome or therapeutic benefit for patients. They are both adalimumabs.

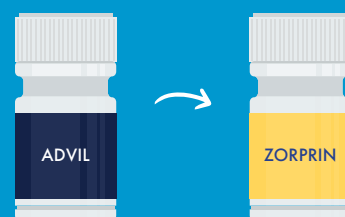
The phrase "transitioning" is appropriate when switching from a reference biologic and biosimilar because there are no quality or ethical issues raised and no change in treatment. Both products are licensed by the FDA to the same rigorous quality standards, thus making this change a transition from one equal product to another.

The term "non-medical switching" is inherently negative when applied to biosimilars because it suggests that a reference biologic and biosimilar may be clinically different or that the change between products may be unethical.

For example, moving a patient from reference biologic Lantus (Insulin glargine) to biosimilar Semglee (Insulin glargine) would be a transition.



For example, moving a patient from Advil (ibuprofen) to a Zorprin (high-dose aspirin) regimen would be a non-medical switch.





The Biosimilars Forum Supports an Open and Competitive Biosimilars Market that Provides Patient and Provider Choice

The Biosimilars Forum supports policies to expedite formulary access to biosimilars with reduced administrative burden. A health care provider can prescribe a biosimilar just like they prescribe the reference product. Biosimilars are approved to have no clinically meaningful differences from the reference product. This means there is no clinically meaningful difference in either structure or therapeutic outcome between the two products.

The Biosimilars Forum supports safe and effective biosimilars being included on all formularies, giving all parties involved the choice of medicine and access to a competitive, savings-driven marketplace.

The Biosimilars Forum fully supports patient and provider choice and defers completely to the discretion of a doctor and patient's best judgment.



What are Biosimilars?

Biosimilars are safe and effective biologic medicines that demonstrate clinical similarity its reference biologic, supported through vigorous, years-long clinical trials.¹

Biosimilars treat:

- ✓ Cancer
- ✓ Kidney Disease
- ✓ Diabetes
- ✓ Psoriasis
- ✓ Arthritis
- ✓ Crohn's Disease
- ✓ Ulcerative Colitis
- ✓ Macular Degeneration
- ✓ Macular Edema



Biosimilars - Demonstrated Safety and Effectiveness Through Vigorous Clinical Data

The FDA monitors the safety and effectiveness of all biosimilar medications after their approval.² This is to ensure that there is no difference in ongoing outcome between reference biologics and corresponding, FDA-approved biosimilars.



Biosimilars are proven to be highly similar in both structure and function to their reference products and the FDA has explicitly found them to have no clinically meaningful differences.³



Healthcare providers can prescribe biosimilars just like they would prescribe a reference product.⁴



Patients and healthcare providers can be fully confident in the safety and effectiveness of biosimilar products, just as they would for the original reference product.



Biosimilars are made with the same types of natural sources as the original biologic they were compared to – and thus provide the same treatment benefits.⁵



1 Biosimilars Basics. Biosimilars Forum. Published March, 2022. Accessed August 2022. <https://biosimilarsforum.org/wp-content/uploads/02-Biosimilars-Basics.pdf>.

2 Biosimilars Basics. Biosimilars Forum. Published March, 2022. Accessed August 2022. <https://biosimilarsforum.org/wp-content/uploads/02-Biosimilars-Basics.pdf>.

3 Biosimilar Development, Review, and Approval. U.S. Food and Drug Administration (FDA). Published October 10, 2017. Accessed August 2022. <https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval#:~:text=A%20biosimilar%20is%20highly%20similar,existing%20FDA%20approved%20reference%20product.>

4 Biosimilar and Interchangeable Biologics: More Treatment Choices. U.S. Food and Drug Administration (FDA). Published October 12, 2021. Accessed August 2022. <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>.

5 Biosimilar and Interchangeable Biologics: More Treatment Choices. U.S. Food and Drug Administration (FDA). Published October 12, 2021. Accessed August 2022. <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>.



The National Comprehensive Cancer Network Guidelines Endorse Transitioning

The National Comprehensive Cancer Network (NCCN) is an alliance of 32 cancer centers in the United States, **considered** “the gold standard for clinical direction and policy in cancer management.”⁶



Within NCCN guidelines, they **support** the transitioning of reference products to biosimilars, as this is deemed clinically appropriate.⁷



For example, **NCCN encourages this for a number of cancer treatments**, including biosimilars for breast (trastuzumab) and gastric (bevacizumab) cancers.⁸



The Body of Research Finds No Difference in Outcome Between Biosimilars and their Reference Biologics and Between Biosimilars to the Same Reference Product

A review conducted in 2018 counted 90 clinical trials and real-world observational studies in 14 indications that cumulatively enrolled over 14,000 patients or healthy individuals. The publication concludes that “the risk of immunogenicity-related safety concerns or diminished efficacy is unchanged after switching from a reference biologic to a biosimilar medicine.”⁹



Another review published in 2020 identified 178 clinical trials and real-world observational studies that cumulatively enrolled approximately 21,000 patients or healthy individuals. The review concluded that “the available switching data do not indicate that switching from a reference product to a biosimilar is associated with any major efficacy, safety, or immunogenicity issues.”¹⁰



Biosimilars have already been used extensively in the U.S. and Europe, with over 2 billion patient days of experience to date.¹¹ No biosimilar approved in the U.S. or Europe has been withdrawn or suspended for reasons of safety or efficacy. Health authorities have concluded that the monitoring systems for safety concerns “have not identified any relevant difference in the nature, severity or frequency of adverse events between biosimilar medicines and their reference medicines.”¹²



About Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.

For more information on the Biosimilars Forum’s work to increase access to lower-cost biosimilars, visit www.biosimilarsforum.org.

6 New NCCN Guidelines Analyze Evidence for Cancer Type Found Almost Exclusively in Children. Published February 17, 2021. Accessed August 2022. <https://www.nccn.org/home/news/NewsDetails?NewsId=2605#:~:text=NCCN%20Guidelines%20are%20considered%20the,for%20any%20area%20of%20medicine>.

7 NCCN Chemotherapy Order Templates. Published May 20, 2021. Accessed August 2022. https://www.nccn.org/docs/default-source/clinical/order-templates/appendix-h-biosimilars.pdf?sfvrsn=cd742243_2.

8 NCCN Guidelines. n.d. Accessed August 2022. https://www.nccn.org/guidelines/category_1.

9 Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes. Published March 2018. Accessed August 2022. <https://pubmed.ncbi.nlm.nih.gov/29500555/>.

10 The Efficacy, Safety, and Immunogenicity of Switching Between Reference Biopharmaceuticals and Biosimilars: A Systematic Review. Published October 2020. Accessed August 2022. <https://pubmed.ncbi.nlm.nih.gov/32236956/>.

11 Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Published Oct 2021. <https://doi.org/10.1007/s40265-021-01601-2> (Accessed August 2023)

12 Biosimilar Information Guide for Healthcare Professionals. Published Oct 2019. https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf (Accessed August 2019)