

Brush Up on Biosimilars

You'll see **more Rx's for biosimilars**...now that there are over 60 available in the US. And over 16 were approved in 2024 alone.

For example, there are now several biosimilars approved for ustekinumab (*Stelara*)...with ustekinumab-kfce (*Yesintek*) being the latest.

Keep in mind, biosimilars aren't generics. It's not possible to create an exact copy of the original reference product...since biologics contain larger, more complex molecules than most traditional drugs.

Biosimilars show NO clinically meaningful differences in safety, purity, and potency compared to the reference biologic.

Note that biosimilars may not have all the same indications as the reference product. This is mostly due to patent protection...NOT lack of effectiveness.

Use FDA's Purple Book as your guide to biosimilars, substitution options, and to check if biologics are interchangeable.

Both biosimilars and interchangeable biosimilars are as safe and effective as the reference product...one isn't better than another.

But an interchangeable biosimilar is a biosimilar that meets additional FDA requirements for switching.

And you can automatically substitute a biosimilar approved as interchangeable...if your state allows.

For example, in the Purple Book, look for boxes with matching colors to indicate the biosimilar is interchangeable with the reference biologic.

Insulin glargine (*Lantus*) is interchangeable with insulin glargine-aglr (*Rezvoglar*) or insulin glargine-yfgn (*Semglee*)...but not *Basaglar*.

Brush up on your state laws. Some require you to inform the patient or prescriber even when substituting an interchangeable biosimilar...a handful require contacting the prescriber BEFORE substituting.

Watch payer alert screens. Insurers often provide messaging about which product is covered...or if they prefer a different med altogether.

For instance, tocilizumab (*Actemra*) costs about \$1,170 for a 162 mg dose...versus about \$760 for the biosimilar tocilizumab-aazg (*Tyenne*).

Continue to request a new Rx when the biosimilars aren't interchangeable or a med switch is required.

Reassure patients that biosimilars are safe and effective. Point out that switching to a biosimilar from its reference product is likely no different than switching between different lots of the reference product.

Stay alert for mix-ups. Verify the trade name and FDA-designated 4-letter suffix...especially if you stock multiple biosimilars. For example, *Abrilada* is adalimumab-afzb...*Amjevita* is adalimumab-atto.

Be aware of differences between biosimilars. For instance, concentrations and stability vary between adalimumab products...and some may contain latex. Double-check labeling if needed.

Review our resource, Facts About Biosimilars, for more FAQs.

Key References:

Cite this document as follows: Article, Brush Up on Biosimilars, Pharmacist's Letter, January 2025

The content of this article is provided for educational and informational purposes only, and is not a substitute for the advice, opinion or diagnosis of a trained medical professional. If your organization is interested in an enterprise subscription, email sales@trchealthcare.com.

© 2025 Therapeutic Research Center (TRC). TRC and Pharmacist's Letter and the associated logo(s) are trademarks of Therapeutic Research Center. All Rights Reserved.

- FDA. Overview for Health Care Professionals. August 1, 2024. <https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals> (Accessed December 13, 2024).
- Humphreys S. Understanding interchangeable biosimilars at the federal and state levels. *Am J Manag Care*. 2023 Aug;29 (7 Spec No.):SP545-SP548.
- FDA. Purple Book. Database of licensed biological products. November 8, 2024. <https://purplebooksearch.fda.gov/> (Accessed December 13, 2024).
- Cohen HP, Bodenmueller W. Additional Data in Expanded Patient Populations and New Indications Support the Practice of Biosimilar-to-Biosimilar Switching. *BioDrugs*. 2024 May;38(3):331-339.
- Medication pricing by Elsevier, accessed Dec 2024.

Pharmacist's Letter. January 2025, No. 410101

Cite this document as follows: Article, Brush Up on Biosimilars, Pharmacist's Letter, January 2025

The content of this article is provided for educational and informational purposes only, and is not a substitute for the advice, opinion or diagnosis of a trained medical professional. If your organization is interested in an enterprise subscription, email sales@trchealthcare.com.

© 2025 Therapeutic Research Center (TRC). TRC and Pharmacist's Letter and the associated logo(s) are trademarks of Therapeutic Research Center. All Rights Reserved.