U.S. Department of Veterans Affairs
Veterans Health Administration
PBM Academic Detailing Services

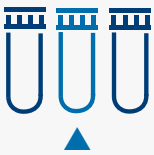
PROVIDER GUIDE

Biologics and Biosimilars

FDA-approved biosimilars offer equivalent efficacy and safety to FDA-approved biologics (reference product), often at a reduced cost.

What are biologics?

Biologics (also called biological products) include a **wide range of products** such as vaccines, monoclonal antibodies, blood components, allergenics, gene therapy, tissues, and proteins.



Biologics are medicines that generally come from **living organisms,** which can include animal cells and microorganisms, such as yeast and bacteria.

They are used to treat a variety of diseases and conditions, such as **cancer, kidney diseases,** and **autoimmune diseases.**

What are biosimilars?

A biosimilar is a biologic that is **highly similar** to another biologic that's already FDA-approved, called a reference product. Biosimilars have **no clinically meaningful differences** from their reference product in terms of **safety, purity, and potency.**

Biosimilars have the same:

Route of administration to patients

Potential side effects

Strength and dosage form

This image was taken from: https://www.fda.gov/media/161628/download?attachment

Fast Facts

1. Biosimilars are safe and effective biological medications for treatment many different illnesses.
2. Biosimilars are not the same as generics. Active ingredients of generics are generally smaller, simpler, molecules that are more straightforward to copy. Biologics generally cannot be copied exactly, because they usually contain a mix of slight variations of a protein, and this mix is never the same in each dose or batch of biologics. (Overview for Health Care Professionals | FDA)
3. All FDA-approved biologics undergo a rigorous evaluation to ensure their safety, effectiveness, and quality. A proposed biosimilar is compared to and evaluated against a reference product to verify that the biosimilar has no clinically meaningful differences in terms of safety and effectiveness. (Overview of Biosimilar Products)
4. Some examples of medications that have an approved biosimilar include:
   - ▶ Adalimumab ▶ Bevacizumab ▶ Epoetin alfa ▶ Filgrastim ▶ Infliximab
   - ▶ Pegfilgrastim ▶ Ranibizumab ▶ Rituximab ▶ Trastuzumab ▶ Ustekinumab

As with generic medications, biosimilars can reduce drug costs without compromising health outcomes.

Biosimilars in VA

Current VA MedSAFE data indicates that biosimilar use in VA is **safe**; no signals have been found to indicate that utilization of biosimilars is problematic. Should a signal arise for any agent in the future, long-standing methods are in place to apprise the field and stop or limit product use.

The VA Center for **Medication Safety (VA MedSAFE)** conducts robust surveillance of biosimilars within the VA population as part of a Comprehensive Biosimilar Surveillance Program.

- VA MedSAFE monitors utilization (including diagnosis) and safety via **Rapid Cycle Analysis** using VA's integrated databases. Safety outcomes, identified via ICD-10 codes, for all biosimilars used in VA are tracked over time using an incident user cohort.
- VA MedSAFE assesses reasons for switchbacks to originator from a biosimilar as needed and further **assesses any unexpected safety signals** if they arise in close to real time through extensive chart review.
- VA MedSAFE will also implement effectiveness monitoring for many biosimilars in close to real time through Rapid Cycle Analysis and for certain products as a full-study cohort analysis.
- VA MedSAFE continues to track voluntary/spontaneous reporting of **Adverse Drug Events (ADEs)** utilizing the VA Adverse Drug Event Reporting System (VA ADERS) which provides ad hoc reports and will be made available as part of the Biosimilar Dashboard.

  - *It is important for staff to accurately document adverse drug reactions and allergies using VA ADERS to ensure the data being evaluated is as accurate and comprehensive as possible.*

- VA MedSAFE's Biosimilar Dashboard will be used to track utilization, switching and voluntary ADE **reporting of all biosimilar agents** in close to real time at national, VISN and facility levels.

The VA contracted biologic/biosimilar medication is preferred for all new starts and existing patients.

Please Note:

▶ Biosimilars may be utilized prior to national contract award when doing so is cost-effective and supply is adequate – multiple switches should be avoided unless contract pricing or availability warrants a change.

▶ When switches occur, they should be phased in with appropriate patient and provider education.

▶ **Strong clinical justification** (e.g., allergies to excipients, documented failure, or intolerance to preferred medication) **will be required** for non-contracted medication non-formulary requests and will be considered on a case-by-case basis.

▶ It's important to consider clinical evidence and recognize issues like diminished response or immunogenicity that may occur with any biologic during treatment.

? DID YOU KNOW

VA contracts for medications include both a cost and quantity guarantee.

Resources developed by the U.S. Food and Drug Administration (FDA) for additional information

Healthcare staff	Patients
• What is a Biosimilar?	• Biosimilar Basics
• Overview of Biosimilar Products	• Biosimilars: What Patients Need To Know (Handout)
• Biosimilars Info Sheet	• Biosimilar Medications: What Patients Need To Know (video)

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