UMPQUA HEALTH

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Biosimilars: Frequently Asked Questions

What is a biosimilar?

A biosimilar is a biologic medication that is highly similar to an FDA-approved biologic product (known as the reference product) and has no clinically meaningful differences in safety, purity, or effectiveness.

Like all biologics, biosimilars are derived from living organisms and undergo rigorous FDA review before approval.

Examples include:

Reference Product	Biosimilar
Stelara® (ustekinumab)	Otulfi® (ustekinumab-aauz)
Humira® (adalimumab)	Hulio® (adalimumab-fkjp)
Lantus® (insulin glargine)	Semglee® (insulin glargine-yfgn)

The FDA requires biosimilars to demonstrate that they:

- Are highly similar to the reference product
- Have no clinically meaningful differences in safety or effectiveness
- Deliver the same expected clinical outcomes
- Meet the same standards for quality, manufacturing, and purity

Are biosimilars the same as generic drugs?

Not exactly. Generic drugs are exact chemical copies of brand-name medications. Because biologics are large, complex molecules produced from living cells, they cannot be replicated identically.

Instead, biosimilars are highly similar versions of biologic medications that have been shown to provide the same clinical benefit and safety profile as the reference product.

Biosimilars and reference products:

- Are used for the same approved indications

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- Are administered in the same way
- Are available in the same strengths and dosage forms
- Have comparable safety and effectiveness
- Have similar side effect profiles

What is an interchangeable biosimilar?

An interchangeable biosimilar is a biosimilar that meets additional FDA requirements demonstrating that patients can expect the same clinical result as the reference product, including when switching between products.

Depending on state law, pharmacists may substitute an FDA-designated interchangeable biosimilar for the reference product without obtaining a new prescription from the prescriber.

Not all biosimilars have received interchangeable designation; however, all FDA-approved biosimilars have been demonstrated to be as safe and effective as their reference products.

When is it appropriate to use a biosimilar?

Biosimilars may be used in:

- Patients who are new to biologic therapy (treatment-naïve)
- Patients currently receiving the reference product when a clinically appropriate switch is made

Multiple studies and real-world experience have demonstrated that switching from a reference biologic to a biosimilar does not result in meaningful differences in clinical outcomes, safety, or immunogenicity.

Why does UHA support biosimilar utilization?

Biosimilars provide the same expected clinical outcomes as their reference products while helping reduce healthcare costs. Increased use of biosimilars allows healthcare resources to be directed toward expanding access to care and other member services.

UHA may designate preferred biosimilars on its formulary based on clinical evidence, safety, and cost-effectiveness.

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Where can I find additional information?

The FDA Purple Book contains information on all FDA-approved biologic and biosimilar products, including interchangeability status:

FDA Purple Book: https://purplebooksearch.fda.gov/

Additional FDA Resource:

- https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

Questions?

For questions regarding UHA formulary preferences, prior authorization requirements, or biosimilar coverage, please contact:

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