

## Biosimilar Drug Use Criteria

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### Guideline for Use:

1. Does the requested biologic agent have an FDA approved biosimilar that is commercially available?
  - a. If yes, go to #2
  - b. If no, does not apply. Please see appropriate Drug Use Criteria for requested biologic agent.
2. Is the requested agent less costly than an FDA-approved biosimilar that is clinically appropriate?
  - a. If yes, approve request if all other criteria are met per specific brand drug use criteria guidelines.
  - b. If no, request change to the least costly biosimilar agent available.

**Purpose:** To promote the safe, effective, and cost-conscious use of biologic therapies by ensuring that FDA-approved biosimilars are utilized when clinically appropriate. Biosimilars provide equivalent therapeutic outcomes to their reference products while offering significant cost savings. This policy supports Advanced Health's commitment to evidence-based care, formulary stewardship, and sustainable healthcare resource management, without compromising quality of care or patient access.

**Rationale:** Biosimilars are biological products licensed by the FDA that are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference biologic. Minor differences in inactive components are permitted. A biosimilar may only be approved for indications and uses also approved for the reference product. Healthcare providers should consult product labeling for approved indications and routes of administration.

Interchangeable biosimilars, which meet additional FDA standards, may be substituted at the pharmacy level where state law allows.

Members are required to use the least costly option (biosimilar or reference product) that is clinically appropriate and approved for the member's indication.

### **References:**

1. Oregon Health Authority. Oregon Administrative Rule (OAR) 410-120-0250(3).
2. Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria.
3. U.S. Food and Drug Administration (FDA). Biosimilar Product Regulatory Review and Approval. Available at: <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>. Accessed April 2025.
4. U.S. Food and Drug Administration. Purple Book Database of Licensed Biological Products. Available at: <https://purplebooksearch.fda.gov/>. Accessed April 2025.