Retail Biosimilar Products

Policy: PHARM-CHIP-012

Origination Date: 07/01/2024

Reviewed/Revised Date: 05/27/2025

Next Review Date: 05/27/2026

Current Effective Date: 06/01/2025

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations for Healthy U CHIP. Refer to the "Policy" and "Lines of Business" section for more information.
3. Services requiring prior-authorization may not be covered, if the prior-authorization is not obtained.
4. This Pharmacy Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Purpose

To define the conditions under which biosimilar products may be covered under the retail pharmacy benefit.

Note: For Medical Biosimilar Products see Pharmacy Policy PHARM-CHIP-M030

Medications

1. Preferred agents must have clinical documentation of an adequate trial and failure or contraindication/intolerance before a request for a non-preferred medication may be considered.
2. Non-Preferred medications will be considered if FDA labeling is only for the originator Brand Product.
3. See online formulary and/or drug specific policies for details.

Policy/Coverage

1. **Prior Authorization Criteria**
    A. Biosimilar products may be considered medically necessary if the following criteria are met:
        i. The product is approved by the FDA as a biosimilar to the reference product.
        ii. The member meets criteria for the biosimilar or reference product according to the respective disease state.

iii. The biosimilar is cost effective compared to the reference product, in which case it will be preferred over the reference product. If the biosimilar is not considered cost effective compared to the reference product, a trial and failure of or intolerance to the reference product must be documented.
iv. The Health Plan reserves the right to require whichever biosimilar is most cost effective.

2. Dosage

A. Dosing must be in accordance with US Food and Drug Administration (FDA) approved package insert.
   i. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for any dose outside of the Food and Drug (FDA) package insert listed in this policy. For a list of Health Plan-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Lines of Business

1. University of Utah Health Plans

A. Healthy U CHIP

References:

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Date	Review, Revisions, Approvals
07/01/2024	Healthy U CHIP specific policy created. Separated out from PHARM-HU-012
01/30/2025	Annual review of policy complete. Removed medication table – see drug specific polices for preferred/non-preferred medications.
05/27/2025	Policy reviewed and approved by the P&T Committee via e-vote. Policy effective 06.01.2025