Policy	PHARM-MM-012
Origination Date	01/01/2022
Reviewed/Revised Date	05/27/2025
Next Review Date	05/27/2026
Current Effective Date	06/01/2025
Line of Business	Healthy U, Health Choice Utah

Biosimilars- Retail

Purpose

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

Note: For Medical Biosimilar Products see PHARM-MM-M030 Biosimilars- Medical

Definitions

1. N/A

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.

Note: N/A

Prior Authorization Criteria

1. Biosimilar products may be considered medically necessary if the following criteria are met:
    a. The product is approved by the FDA as a biosimilar to the reference product.
    b. The member meets criteria for the biosimilar or reference product according to the respective disease state.
    c. 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.
    d. The Health Plan reserves the right to require whichever biosimilar is most cost effective.

Drug Specific Criteria

1. N/A

Re-Authorization Criteria

1. N/A

Dosage

1. Dosing must be in accordance with US Food and Drug Administration (FDA) approved package insert.
    a. 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.

Exclusions/Contraindications

1. N/A

Approval Duration

1. Initial Authorization
    a. N/A
2. Re-Authorization
    a. N/A

Appendix/Table

1. N/A

References

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Review, Revisions, Approval History	
Date	Change/Approval Information
01/01/2022	Healthy U specific policy created. Separated out from PHARM-012
05/11/2022	Updated GCSFs: biosimilars are preferred with no PA; originator is non-preferred requires PA
05/18/2022	Policy reviewed and approved by the P&T Committee. Policy effective 06.01.2022
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
07/31/2025	Clerical update: title update
01/13/2026	Clerical update: formatted to new template. Updated policy number to PHARM-MM-012 to apply to both Healthy U and Health Choice lines of business.

Disclaimer
1. The plan reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final. The plan also revises and updates Pharmacy Coverage Policies annually, or more frequently if new evidence becomes available that suggests needed revisions. Policies are subject to change in accordance with Federal and State notice requirements.
2. Services requiring prior-authorization may not be covered, if the prior-authorization is not obtained.
3. This Pharmacy Coverage Policy does not guarantee coverage or payment of the service. The Plan may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive.
4. 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.
5. Pharmacy Coverage Policies have been developed for determining coverage for plan benefits and when published are available to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a member's benefit document and in coordination with the member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs.