Retail Biosimilar Products

Policy: PHARM-012

Origination Date: 11/27/2018

Reviewed/Revised Date: 12/19/2022

Next Review Date: 12/19/2023

Current Effective Date: 01/01/2023

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations for all members and clients of University of Utah Health Insurance Plans. Refer to the "Policy" and "Lines of Business" section for more information.
3. 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-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.

Product	Preferred 1st Line	Non-preferred 1st Line	Non-preferred 2nd Line
infliximab	Renflexis®, Inflectra®	n/a	Remicade®
rituximab	Ruxience®	Truxima®	Rituxan®
bevacizumab	Mvasi™, Zirabev™		Avastin®
trastuzumab	Kanjinti™, Trazimera™	Ogivri®	Herceptin®, Herzuma®

Product	No Prior Authorization Required	Prior Authorization Required	Not Covered
filgrastim	Granix®, Nivestym®, Zarxio®	N/A	Neupogen®
pegfilgrastim	Fulphila®, Nyvepria™ Udenyca®, Ziextenzo®	N/A	Neulasta®, Neulasta® Onpro

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.
        ii. Accurate member information is necessary for the Health Plan to approve the requested dose and frequency. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Health Plan for a new approval based on those changes as part of the precertification process. The Health Plan reserves the right to conduct post-payment review and audit procedures for any submitted claims.

Lines of Business

1. **University of Utah Health Insurance Plans**
    A. Commercial
    B. MHC

References:

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Date	**Review, Revisions, Approvals**
11/27/2018	Policy created.
03/20/2019	Policy reviewed and approved by P&T Committee
05/14/2020	Added: The Health Plan reserves the right to require whichever biosimilar is most cost effective.
05/20/2020	Added: preferred/non-preferred products voted on by the committee. Policy reviewed and approved by P&T Committee Policy effective 06.01.2020
01/27/2021	Updated Lines of Business
03/30/2021	Policy reviewed for annual review.
04/19/2021	Policy reviewed and approved by P&T Committee Policy effective 05.01.2021
08/11/2021	Added: 1. Preferred medications for filgrastim and pegfilgrastim - Nivestym® and Nyvepria™ do not require prior authorization 2. Must use FDA-approved dosing
08/18/2021	Policy reviewed and approved by P&T Committee Policy effective 01.01.2022
01/01/2022	Removed University of Utah Health Plans (Healthy U, Healthy U Integrated) from Lines of Business to create Healthy U specific policy.
05/10/2022	Updated GCSFs: biosimilars are preferred with no PA; originator is not covered

05/18/2022	Policy reviewed and approved by P&T Committee Policy effective 06.01.2022
12/13/2022	Moved Inflectra from non-preferred to first line co-preferred with Renflexis
12/19/2022	Policy reviewed and approved by the P&T Committee via e-vote. Policy effective 01.01.2023