Medical Biosimilar Products

Policy: PHARM-HU-M030

Origination Date: 01/01/2022

Reviewed/Revised Date: 05/18/2022

Next Review Date: 05/18/2023

Current Effective Date: 08/01/2022

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 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 medical benefit.

Note: For Retail Biosimilar Products see Pharmacy Policy PHARM-HU-012

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®, 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®	Neupogen®	Nivestym®, Zarxio®

pegfilgrastim	Fulphila®, Neulasta®, Neulasta® Onpro, Udenyca®	Nyvepria™, Ziextenzo®	N/A

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 Plans**
    A. Healthy U
    B. Healthy U Integrated

References:

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Date	Review, Revisions, Approvals
01/01/2022	Healthy U specific policy created. Separated out from PHARM-M030
05/11/2022	Updated preferred GCSFs products
05/18/2022	Policy reviewed and approved by the P&T Committee. Policy effective 08.01.2022