

Retail Biosimilar Products

Policy: PHARM-012

Origination Date: 11/27/2018

Reviewed/Revised Date: 05/18/2022

Next Review Date: 05/18/2023

Current Effective Date: 06/01/2022

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 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 1 st Line	Non-preferred 1 st Line	Non-preferred 2 nd 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:

1. Armuzzi A, Fiorino G, Variola A, et al. The PROSIT Cohort of Infliximab Biosimilar in IBD: A Prolonged Follow-up on the Effectiveness and Safety Across Italy. *Inflamm Bowel Dis*. 2018. DOI: 10.1093/ibd/izy264
2. Blackwell K, Gascon P, Krendyukov A, et al. Safety and efficacy of alternating treatment with Ep2006, a filgrastim biosimilar, and reference filgrastim: a phase III, randomize, double-blind clinical study in the prevention of severe neutropenia in patients with breast cancer receiving myelosuppressive chemotherapy. *Ann Oncol*. 2018; 29(1):244-249.
3. Blauvelt A, Lacour JP, Fowler JF, et al. Phase III randomized study of the proposed adalimumab biosimilar GP2017 in psoriasis: impact of multiple switches. *Br J Dermatol*. 2018; 179(3):623-631.

4. Cohen SB, Alonso-Ruiz A, Klimiuk PA, et al. Similar efficacy, safety and immunogenicity of adalimumab biosimilar BI 695501 and Humira reference product in patients with moderately to severely active rheumatoid arthritis: results from the phase III randomised VOLTAIRE-RA equivalence study. *Ann Rheum Dis.* 2018;77(6):914-921.
5. Glintborg B, Sorensen IJ, Loft AG, et al. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. *Ann Rheum Dis.* 2017; 76(8):1426-1431.
6. Jorgensen KK, Olsen IC, Goll GL, et al. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomized, double-blind, non-inferiority trial. *Lancet.* 2017; 389(10086):2304-2316
7. Radin M, Sciascia S, Roccatello D, Cuadrado MJ. Infliximab Biosimilars in the Treatment of Inflammatory Bowel Diseases: A Systematic Review. *BioDrugs.* 2017; 31(1):37-49
8. Smolen JS, Choe JY, Prodanovic N, et al. Safety, immunogenicity and efficacy after switching from reference infliximab to biosimilar SB2 compared with continuing reference infliximab and SB2 in patients with rheumatoid arthritis: results of a randomised, double-blind, phase III transition study. *Ann Rheum Dis.* 2017;77(2):234-240.
9. Strik AS, van de Vrie W, Bloemsaat-Minekus JPJ, et al. Serum concentrations after switching from originator infliximab to the biosimilar CT-P13 in patients with quiescent inflammatory bowel disease (SECURE): an open-label, multicenter, phase 4 non-inferiority trial. *Lancet Gastroenterol Hepatol.* 2018; 3(6):404-412.
10. Thadhani R, Guilatco R, Hymes J, et al. Switching from Epoetin Alfa (Epoen®) to Epoetin Alfa-Epbx (Retacrit™) Using a Specified Dosing Algorithm: A Randomized, Non-Inferiority Study in Adults on Hemodialysis. *Am J Nephrol.* 2018; 48(3):214-224
11. Weinblatt ME, Baranaukaite A, Dokoupilova E, et al. Switching From Reference Adalimumab to SB5 (Adalimumab Biosimilar) in Patients With Rheumatoid Arthritis: Fifty-Two-Week Phase III Randomized Study Results. *Arthritis Rheumatol.* 2018;70(6):832-840.
12. Renflexis® [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp. Revised 02/2021. Accessed 08/2021.
13. Ruxience® [package insert]. New York, NY: Pfizer. Revised 05/2020. Accessed 08/2021.
14. Mvasi™ [package insert]. Thousand Oaks, CA: Amgen, Inc. Revised 04/2021. Accessed 08/2021.
15. Zirabev™ [package insert]. New York, NY: Pfizer. Revised 05/2021. Accessed 08/2021.
16. Kanjinti™ [package insert]. Thousand Oaks, CA: Amgen, Inc. Revised 10/2019. Accessed 08/2021.
17. Trazimera™ [package insert]. New York, NY: Pfizer. Revised 11/2020. Accessed 08/2021.
18. Nivestym® [package insert]. Lake Forest, IL: Hospira, Inc. Revised 04/2021. Accessed 08/2021.
19. Nyvepria™ [package insert]. Lake Forest, IL: Hospira, Inc. Revised 04/2021. Accessed 08/2021.

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

Disclaimer:

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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