

Medical Biosimilar Products

Policy: PHARM-M030

Origination Date: 08/18/2021

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Current Effective Date: 01/01/2022

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.

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-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 1 st Line | Non-preferred 1 st Line | Non-preferred 2 nd Line |
|----------------------|--|--|--|
| infliximab | Renflexis [®] | | Inflectra [®] , Remicade [®] |
| rituximab | Ruxience [®] | Truxima [®] | Rituxan [®] |
| bevacizumab | Mvasi [™] , Zirabev [™] | | Avastin [®] |
| trastuzumab | Kanjinti [™] , Trazimera [™] | Ogivri [®] | Herceptin [®] , Herzuma [®] |
| filgrastim | Nivestym [®] | Granix [®] , Zarxio [®] | Neupogen [®] |
| pegfilgrastim | Nyvepria [™] | Fulphila [®] , Udenyca [®] , Ziextenzo [®] | 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. Drug Specific Criteria:

- A. Nivestym® and Nyvepria™ do not require prior authorization

3. 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. Medicare Advantage
- B. Commercial
- C. MHC

2. University of Utah Health Plans

- A. Healthy U
- B. Healthy U Integrated

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 sever 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 (Epoegen®) 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, Baranauskaite 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 |
|-------------|--|
| 08/18/2021 | Policy created. |
| 08/18/2021 | Policy reviewed and approved by P&T Committee Policy effective 01.01.2022 |

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