

Biosimilar Products

Policy PHARM-012

Origination Date: 11/27/2018

Reviewed/Revised Date: 05/20/2020

Next Review Date: 05/20/2021

Current Effective Date: 06/01/2020

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.

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	Preferred 2nd Line	Non-preferred
infliximab	Renflexis		Inflectra, Remicade
rituximab	Ruxience	Truxima	Rituxan
bevacizumab	Mvasi, Zirabev		Avastin
trastuzumab	Kanjinti, Trazimera	Ogivri	Herceptin, Herzuma

Policy/Coverage

1. Prior Authorization

- 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.

Lines of Business

1. University of Utah Health Plans

- A. Healthy U
- B. Commercial Groups
- C. Individual Exchange

2. Mountain Health Co-Op

- A. Commercial Groups
- B. Individual Exchange

3. Medicare Advantage

- A. Advantage U

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, 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.

Revision Date	Revision
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

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