Scott&White HEALTH PLAN
PART OF BAYLOR SCOTT & WHITE HEALTH

FirstCare HEALTH PLANS
PART OF BAYLOR SCOTT & WHITE HEALTH

MEDICAL COVERAGE POLICY

SERVICE: Infliximab Products

Policy Number:	**239**
Effective Date:	**04/01/2021**
Last Review:	**02/25/2021**
Next Review Date:	**02/25/2022**

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Infliximab Biosimilar Products

PRIOR AUTHORIZATION: Renflexis™, Remicade® do NOT require prior authorization. All other infliximab biosimilar products require prior authorization.

POLICY: For ALL products except Medicare and Medicaid, Renflexis™ (infliximab-abda) and Remicade® (infliximab) are the preferred infliximab products for SWHP. SWHP may find it medically necessary to use an infliximab biosimilar product instead of Renflexis™ or Remicade® when the following criteria are met IN ADDITION TO medical policy #215 Medications Covered Under Medical Insurance Policy:

1. **One** of the following:
   - **Both** of the following:
     - History of a trial of at least 14 weeks of preferred agents resulting in minimal clinical response to therapy and residual disease activity.
     - Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with a nonpreferred infliximab biosimilar product, than experienced with preferred agents.

   OR
   - **Both** of the following:
     - History of intolerance or adverse event to preferred agents.
     - Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with a nonpreferred infliximab biosimilar product.

AND

2. **All** of the following:
   - Patient has NOT had a loss of a favorable response after established maintenance therapy with preferred agents
   - Patient has NOT developed neutralizing antibodies to any infliximab product that has led to an attenuation of efficacy of therapy.
   - Patient has not previously been stable on a preferred agent and switched to a nonpreferred infliximab biosimilar product.

OVERVIEW:

Infliximab is a genetically engineered chimeric human/mouse monoclonal antibody (cA2) against tumor necrosis factor alfa (TNF-alfa), a key mediator of mucosal inflammation. Increased levels of

TNF-alfa are found in the intestinal mucosa and stool of patients with active Crohn's disease and in the joints of rheumatoid arthritis patients. Elevated TNF-alfa concentrations are also involved in ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. TNF-alfa activity is neutralized by cA2 antibody binding to the soluble and transmembrane forms which blocks the binding of TNF-alfa with its receptors. Activities inhibited by anti-TNF-alfa antibodies include induction of interleukins, enhancement of leukocyte migration, and expression of adhesion molecules. In vitro studies have demonstrated that cells expressing transmembrane TNF-alfa bound by infliximab are lysed by complement or effector cells. In animal models, antibodies to TNF-alfa were shown to prevent or reduce inflammation.1

Avsola™ (infliximab-axxq), Inflectra™ (infliximab-dyyb), Ixifi™ (infliximab-qbtx) Renflexis™ (infliximab-abda) are biosimilar* to Remicade® (infliximab). Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	
CPT Not Covered:	
ICD10 codes:	
ICD10 Not covered:	
HCPCS	J1745 – Injection, infliximab, excludes biosimilar, 10 mg Q5103 – Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg Q5104 – Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg Q5109 - Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg Q5121 - Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg

CMS: Medicare does not have an NCD that specifically addresses biosimilar infliximab. LCDs do not exist at this time.

Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

POLICY HISTORY:

Status	Date	Action
New	06/13/2017	New policy
Update	08/21/2017	Added Renflexis (infliximab-adba)
Update	03/06/2018	Updated policy to add Renflexis as a co-preferred agent; updated HCPCS codes
Update	03/28/2019	Code update. PA update
Review	02/27/2020	Clarified language
Review	02/25/2021	Clarified language, added Avsola

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Remicade [prescribing information]. Horsham, PA: Janssen Biotech Inc.; November 2015.
2. Inflectra [prescribing information]. Lake Forest, IL: Hospira; February 2016.
3. Park W, Hrycaj P, Jeka S, et al. A randomised, double-blind, multicentre, parallel-group, prospective study comparing the pharmacokinetics, safety, and efficacy of CT-P13 and innovator infliximab in patients with ankylosing spondylitis: the PLANETAS study. Ann Rheum Dis. 2013 Oct;72(10):1605-12.
4. Gecse KB, Lovász BD, Farkas K et al. Efficacy and Safety of the Biosimilar Infliximab CT-P13 Treatment in Inflammatory Bowel Diseases: A Prospective, Multicentre, Nationwide Cohort. J Crohns Colitis. 2016 Feb;10(2):133-40.
5. Ruiz-Argüello MB, Maguregui A, Ruiz Del Agua A, et al. Antibodies to infliximab in Remicade-treated rheumatic patients show identical reactivity towards biosimilars. Ann Rheum Dis. 2016 Sep;75(9):1693-6.
6. Renflexis [prescribing information]. Whitehouse Station, NJ: Merck & Co.; April 2017.