MEDICAL COVERAGE POLICY	
SERVICE:	**Infliximab Products**
Policy Number:	**239**
Effective Date:	**11/01/2024**
Last Review:	**08/12/2024**
Next Review:	**08/12/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Infliximab Products

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

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use medical policy #215 Medications Covered Under Medical Insurance Policy.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Renflexis™ (infliximab-abda), Remicade® (infliximab), and unbranded infliximab are the preferred infliximab products for BSWHP.

BSWHP may find it medically necessary to use an infliximab biosimilar product instead of Renflexis™, Remicade®, or unbranded infliximab when the following criteria are met **IN ADDITION TO** medical policy #215 Medications Covered Under Medical Insurance Policy:

1) **One** of the following:
   a) **Both** of the following:
      i) History of a trial of at least 14 weeks of preferred agents resulting in minimal clinical response to therapy and residual disease activity; **AND**
      ii) 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
   b) **Both** of the following:
      i) History of intolerance or adverse event to preferred agents; **AND**
      ii) 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:

a) Patient has NOT had a loss of a favorable response after established maintenance therapy with preferred agents; **AND**
b) Patient has NOT developed neutralizing antibodies to any infliximab product that has led to an attenuation of efficacy of therapy; **AND**
c) Patient has not previously been stable on a preferred agent and switched to a nonpreferred infliximab biosimilar product.

BACKGROUND:

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.

Avsola™ (infliximab-axxq), Inflectra™ (infliximab-dyyb), Ixifi™ (infliximab-qbtx), and Renflexis™ (infliximab-abda) are biosimilar to Remicade® (infliximab) and unbranded 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: *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:	
HCPCS Codes:	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
ICD10 codes:	
ICD10 Not covered:	

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
Review	02/24/2022	No changes
Review	02/23/2023	Added unbranded infliximab to policy
Update	09/28/2023	Updated Medicaid instructions.
Update	08/12/2024	Applied new format and layout

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications 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 BSWHP 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.

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.