MVP Health Care Medical Policy

Medicare Part B: Infliximab

Type of Policy: **Drug/Medical Therapy**
Prior Approval Date: **10/01/2024**
Approval Date: **11/01/2025**
Effective Date: **01/01/2026**
Related Policies: **Experimental or Investigational Procedures, Risankizumab, Ustekinumab, Secukinumab**

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Codes Requiring Prior Authorization (covered under the medical benefit)
J1745 Injection, infliximab, 10 mg (Remicade®/Infliximab)
Q5103 Injection, infliximab, 10mg (Inflectra)
Q5104 Injection, infliximab, 10mg (Renflexis)
Q5121 Infliximab, 10mg (Avsola)

Overview/Summary of Evidence
Infliximab (Remicade®/Infliximab, Inflectra, Avsola, Renflexis), bind specifically to human tumor necrosis factor alpha (TNF-α). TNF-α is a pro-inflammatory cytokine that is important in the induction of other inflammatory cytokines that initiate and maintain the tissue inflammatory response. Inhibiting the binding of TNFα to its receptors prevents the release of the pro-inflammatory cytokines that are involved in the body's immune and inflammatory responses. Patients who receive infliximab are at increased risk for developing *serious infection* that may result in hospitalization and/or death. Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.

- Must be ordered by or with consult from an appropriate specialist: rheumatologist/immunologist/dermatologist/ gastroenterologist/colorectal surgeon
- Initial approval for all indications will be for six months, continuation up to one year will require documentation of improved member status.

A. Ankylosing Spondylitis

For the treatment of active moderate to severe **ankylosing spondylitis** the following criteria must be met:

- Chart notes documenting failure of at least one trial of NSAIDS at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**
- Chart notes documenting significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, and morning stiffness duration **AND**
- Chart notes documenting an insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where the Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

B. Crohn's Disease

For the treatment of active moderate to severe **Crohn's disease** confirmed by endoscopy (or capsule endoscopy when appropriate) the following criteria must be met:

- If member is <18 years old, Pediatric Crohn's disease requests will be reviewed on a case-by-case basis **OR**

- Documented failure or inadequate response to a 12-week trial of adalimumab **OR**

- Rationale, accompanied by documentation, identifying why the member or caregiver is unable to self-administer adalimumab.

- If adalimumab is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. <u>Plaque Psoriasis</u>

For the treatment of active **plaque psoriasis** ALL the following criteria must be met:

- The medication must be ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
    - Crucial body areas (e.g. hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected OR
    - At least 10% of the body surface area (BSA) is affected OR
    - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g. UVB, PUVA) OR
        - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. <u>Psoriatic Arthritis</u>

For the treatment of moderate to severe active **psoriatic arthritis** the following criteria must be met**:**

- Member has a diagnosis of moderate to severe psoriatic arthritis as indicated by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart.

- Chart notes documenting at least one NSAID at the maximum tolerated dose, unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

- Chart notes documenting a failure to respond to an adequate trial (at least 3 months of which 2 months is at standard target dose) of at least one of the following DMARDs: leflunomide, sulfasalazine, or methotrexate.

    - Members with pure axial manifestations do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)
    - If a trial of methotrexate is not appropriate due to alcohol use and both leflunomide and sulfasalazine are not clinically appropriate, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have

the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. Rheumatoid Arthritis

- Member has a diagnosis of active moderate to severe adult **rheumatoid arthritis** as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living **AND**
- Chart notes documenting a failure to respond to one or more nonbiologic disease modifying anti-rheumatic drugs (DMARDs), one of which includes a three-month trial of maximally tolerated dose of methotrexate.
    - Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
    - If the member has a contraindication or significant intolerance to methotrexate
        - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND**
        - Documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Must be given in combination with methotrexate unless the member has an acute, aggressive, very rapidly progressive intense inflammatory symmetrical arthritis disease as defined by their rheumatologist OR the member has a significant intolerance or contraindication to methotrexate, as indicated above.

Initial approval will be for 6 months

Extension requests will be approved for up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. <u>Ulcerative Colitis</u>

For the treatment of active moderate to severe **Ulcerative Colitis** ALL the following criteria must be met:

- Chart notes are provided documenting an inadequate response to or an intolerance to conventional therapy (i.e.:, anti-inflammatory aminosalicylates [e.g. Mesalamine (5-ASA), sulfasalazine], 6-mercaptopurine, and azathioprine).
    - If conventional therapy is not appropriate, rationale for medical necessity of infliximab must be provided (i.e., contraindication, disease severity) and will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.
- Pediatric Ulcerative Colitis requests will be reviewed on a case-by-case basis in accordance with current American College of Gastroenterology (ACG) guidelines.

Initial approval for all indications will be for 6 months

Extension requests will be approved up to 12 months if the member has a continued benefit to therapy. Extension requests where Infliximab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

G. Refractory granulomatosis with polyangiitis (Wegener's granulomatosis)

- Infliximab requests for refractory granulomatosis with polyangiitis (Wegener's granulomatosis) in combination with corticosteroids will be reviewed on a case-by-case basis

H. Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

• Member has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Member has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

- Continuation of therapy is not a covered benefit

Approval will be covered for infliximab 5mg/kg up to a maximum of 2 doses only within one month.

Exclusions

Infliximab will not be considered medically necessary in the following members:

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Members with a known hypersensitivity to murine proteins
- Members with heart failure (NYHA III/IV) at doses greater than 5mg/kg
- Infliximab in combination therapy with TNF blockers, other biologics, or interleukin-1 inhibitor.

References

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2. Avsola (infliximab) injection. Prescribing Information. Thousand Oaks, CA: Amgen Inc.; September 2021.
3. Joseph Feuerstein, Kim Isaacs et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. January 2020. Volume 158; Issue 5: p1450-1461. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis - Gastroenterology (gastrojournal.org) Accessed September 27, 2021.
4. Joseph D. Feuerstein, Edith Y. Ho et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. June 2021. Volume 160; Issue 7: p2696-2508. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease - Gastroenterology (gastrojournal.org).

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6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Journal of Psoriasis and Psoriatic Arthritis*. 2019;4(1):31-58. doi:10.1177/2475530318812244

7. Article - Billing and Coding: Infliximab and biosimilars (A52423). (Revised 08/01/2024). Cms.gov.

8. LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). (Revised 08/01/2024). Cms.gov.