infliximab

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration
Home Infusion Administration
Infusion Center Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: a monoclonal antibody with affinity for human tumor necrosis factor (TNF)
HCPCS:
J1745:Injection, infliximab, excludes biosimilar, 10 mg
Q5103:Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104:Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5121:Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
How Supplied:

- 100 mg (single use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Ankylosing Spondylitis
- Crohn's Disease
- Fistulizing Crohn's Disease
- Graft Versus Host Disease
- Immunotherapy-Related Toxicities Secondary to Immune-Checkpoint Inhibitor Therapy
- Plaque Psoriasis
- Psoriatic Arthritis
- Rheumatoid Arthritis
- Ulcerative Colitis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a

preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating on infliximab or is being re-initiated on infliximab after at least 6 months off therapy.. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on infliximab based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on infliximab based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Ankylosing Spondylitis
Meets medical necessity if all the following are met:
Initial

1. Prescribed by or in consultation with a rheumatologist
2. ONE of the following:
   a. For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy, or
   b. For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI), or
   c. Patient unable to use NSAIDs due to history of GI bleed or ulcer
3. Not being used in combination with other targeted immunomodulators

4. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra

Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Up to 5 mg/kg IV weeks 0, 2, and 6. Maintenance every 6 weeks thereafter.

Requests for doses greater than 5 mg/kg for induction or maintenance are not covered. Efficacy with greater than 5mg/kg or increased frequency of administration has not been demonstrated.

Coverage Period:
Initial: 3 induction doses then maintenance for a total of 1 year
Reauthorization: yearly

ICD-10:
M45.0-M45.9

Crohn's Disease
Meets medical necessity if all the following are met:

Initial

1. Disease is moderate to severe
2. Age is consistent with the FDA-approved indication
3. ***Effective 2/1/2026 and after*** Prescribed by or in consultation with a gastroenterologist
4. Not being used in combination with other targeted immunomodulators
5. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra
6. Infliximab is dosed according to the FDA labeled dosing/compendia support

Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators
3. Infliximab is dosed according to the FDA labeled dosing/compendia support

Covered Doses:
Up to 5 mg/kg IV infusion for induction therapy at 0, 2, 6, followed by 5 mg/kg for maintenance therapy every 8 weeks

Dose Escalation-Adults:
Dose or frequency increases may be covered if ALL of the following conditions met:

1. Only for adults
2. Only after the first 3 induction doses (at wks 0, 2 & 6) and at least one maintenance dose of 5 mg/kg every 8 weeks (week 14)
3. The member has not responded to therapy or is experiencing flares
4. The total dose should not exceed 10 mg/kg over an eight-week period

Coverage Period:
Initial: 3 induction doses and maintenance for a total of 1 year
Reauthorization: yearly

ICD-10:
K50.00-K50.119, K50.80-K50.919

Fistulizing Crohn's Disease
Meets medical necessity if all the following are met:
Initial

1. Fistulizing disease
2. ***Effective 2/1/2026 and after*** Prescribed by or in consultation with a gastroenterologist
3. Not being used in combination with other targeted immunomodulators
4. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra
5. Infliximab is dosed according to the FDA labeled dosing/compendia support

Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators
3. Infliximab is dosed according to the FDA labeled dosing/compendia support

Covered Doses:
Up to 5 mg/kg IV infusion for induction therapy at 0, 2, 6, followed by 5 mg/kg for maintenance therapy every 8 weeks.

Dose Escalation-Adults:
Dose or frequency increases may be covered if ALL of the following conditions met

1. Only for adults
2. Only after the first 3 induction doses (at wks 0, 2 & 6) and at least one maintenance dose of 5 mg/kg every 8 weeks (week 14)
3. The member has not responded to therapy or is experiencing flares
4. The total dose should not exceed 10 mg/kg over an eight-week period

Coverage Period:

Initial: 3 induction doses then maintenance for total of 1 year
Reauthorization: yearly

ICD-10:
K50.013, K50.113, K50.313, K50.813, K50.913

Graft Versus Host Disease
Meets medical necessity if all the following are met:
Initial

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)
2. Not being used in combination with other targeted immunomodulators
3. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra

Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators

Covered Doses:
Up to 10 mg/kg IV once weekly

Coverage Period:
Initial: one year
Reauthorization: one year

ICD-10:
D89.12, D89.810, D89.813, T86.09

Immunotherapy-Related Toxicities Secondary to Immune-Checkpoint Inhibitor Therapy
Meets medical necessity if all the following are met:

1. Treatment for ONE of the following immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy:
   a. Moderate or severe diarrhea or colitis refractory to corticosteroids
   b. Severe pneumonitis refractory to methylprednisolone
   c. Severe acute renal failure/elevated serum creatinine refractory to corticosteroids
   d. Severe uveitis refractory to high-dose corticosteroids
   e. Severe myocarditis, pericarditis, arrhythmias, impaired ventricular function, or conduction abnormalities refractory to pulse-dose methylprednisolone
   f. Severe inflammatory arthritis refractory to high-dose corticosteroids
   g. Moderate or severe myalgias or myositis refractory to corticosteroids

2. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra

Covered Doses:
Up to 5 mg/kg IV weeks 0, 2, and 6

Coverage Period:
Cover up to 3 doses

ICD-10:
K52.1, J70.2, J70.4, N17.8, N17.9, I30.8, I30.9, I40.8, I40.9, I44.0, I44.1-I44.3, I44.30, I44.39, I47.0, I45.0, I45.10, I45.19, I45.2-I45.6, I45.81, I45.89, I45.9, I49.9, R19.7, M06.4, M60.80, M60.811, M60.812, M60.819, M60.821, M60.822, M60.829, M60.831, M60.832, M60.839, M60.841, M60.842, M60.849, M60.851, M60.852, M60.859, M60.861, M60.862, M60.869, M60.871, M60.872, M60.879, M60.88, M60.89, M60.9, M79.1

Plaque Psoriasis
Meets medical necessity if all the following are met:
Initial:

1. Disease is moderate to severe
2. Age ≥ 18 years of age
3. Prescribed by or in consultation by a dermatologist or rheumatologist
4. ONE of the following:
   a. Baseline PASI score is 10 or more prior to starting biological therapy
   b. Baseline BSA (body surface area) affected is 3% or more prior to starting biological therapy
   c. Sensitive area is involved (i.e., groin, face, etc.)
   d. Disease is otherwise debilitating
5. Inadequate response, intolerable side effect, or contraindication to ONE of the following:
   a. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane)
   b. PUVA or UVB treatment
6. Not being used in combination with another targeted biologic
7. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra

Reauthorization:

1. Not being used in combination with other targeted biologics
2. One of the following:
   a. Improvement in PASI score from baseline
   b. Improvement in BSA from baseline
   c. Decrease in sensitive area disease severity

d. Decrease in debilitating disease severity

Covered Doses:
Induction: Up to 5 mg/kg IV weeks 0, 2, and 6
Maintenance: As frequently as every 8 weeks after induction dosing

Requests for dose greater than 5 mg/kg for induction or maintenance are not covered. Efficacy with greater than 5 mg/kg or increased frequency of administration has not been demonstrated.

Coverage Period:
Initial: 24 weeks
Reauthorization: yearly

ICD-10:
L40.0-L40.9

Psoriatic Arthritis
Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response to one or more disease modifying anti-rheumatic drug (DMARD - *see section 5*), or patient has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used
3. Not being used in combination with other targeted immunomodulators
4. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra

Reauthorization

1. Patient is responding to therapy (e.g. improvement in symptoms)
2. Not being used in combination with other targeted immunomodulators

Covered Doses:
5 mg/kg IV weeks 0, 2, and 6. Maintenance every 8 weeks thereafter.

Requests for dose greater than 5 mg/kg for the induction or maintenance of psoriatic arthritis are not covered. Efficacy with greater than 5mg/kg or increased frequency of administration has not been demonstrated.

Coverage Period:
Initial: 3 induction doses then maintenance for total of 1 year
Reauthorization: yearly

ICD-10:
L40.50-L40.59

Rheumatoid Arthritis
Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to methotrexate
3. Not used in combination with another targeted immunomodulators
4. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra
5. Infliximab is dosed according to the FDA labeled dosing/compendia support

Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators
3. Infliximab is dosed according to the FDA labeled dosing/compendia support

Covered Doses:
Initial:
3 mg/kg I.V. followed with additional similar doses at 2 and 6 weeks after the initial infusion, then every 8 weeks thereafter.
Infliximab may be given in combination with methotrexate.

Dose Escalation:
Dose or frequency increases may be covered if ALL of the following conditions met:

- Only after the first 3 induction doses (at wks 0, 2 & 6) and at least one maintenance dose of 3 mg/kg every 8 weeks (week 14)
- The patient is not responding or experiencing flares
- The total dose should not exceed 10 mg/kg over an eight-week period

Coverage Period:
Initial: 3 induction doses then maintenance for total of 1 year
Reauthorization: yearly

ICD-10:
(X=0-9) M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

Ulcerative Colitis
Meets medical necessity if all the following are met:

Initial

1. Disease is moderate to severe
2. Age is consistent with the FDA-approved indication
3. ***Effective 2/1/2026 and after*** Prescribed by or in consultation with a gastroenterologist
4. Not being used in combination with other targeted immunomodulators

5. If request is for Remicade or Renflexis: Intolerable side effect with infliximab (Avsola and Inflectra) that is not expected with the requested drug, or contraindication to both Avsola and Inflectra
6. Infliximab is dosed according to the FDA labeled dosing/compendia support

Reauthorization
1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators
3. Infliximab is dosed according to the FDA labeled dosing/compendia support

Covered Doses:
Up to 5 mg/kg IV infusion for induction therapy at 0, 2, 6, followed by 5 mg/kg for maintenance therapy every 8 weeks

Dose Escalation-Adults:
Dose or frequency increases may be covered if ALL of the following conditions met:
- Only for adults
- Only after the first 3 induction doses (at wks 0, 2 & 6) and at least one maintenance dose of 5 mg/kg q 8 weeks (week 14)
- The member has not responded to therapy or is experiencing flares
- The total dose should not exceed 10 mg/kg over an eight-week period

Coverage Period:
Initial: 3 induction doses and maintenance for a total of 1 year
Reauthorization: yearly

ICD-10:
K51.0-K51.319, K51.5-K51.519, K51.80-K51.919

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Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- For Crohn's disease, Fistulizing Crohn's disease:
  - Effective 2/1/2026 and after: require use is prescribed by or in consultation with a gastroenterologist (Rationale: Ensure appropriate use)
  - Clarify reauthorization requirement for dosing, patient response, combination use of other agents. (Rationale: Ensure appropriate use)
- For Ulcerative colitis:
  - Effective 2/1/2026 and after: require use is prescribed by or in consultation with a gastroenterologist (Rationale: Ensure appropriate use)
  - Clarify initial authorization for dose Rationale: infliximab prescribing information and compendia support (Rationale: Ensure appropriate use)
- For Rheumatoid arthritis: clarify reauthorization requirement for dosing, patient response, combination use with other agents. (Rationale: Ensure appropriate use)
- Remove coverage for Hidradenitis Suppurativa. (Rationale: No longer compendia supported)

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee