Reference number(s)
4535-A

Jurisdiction Specific Medicare Part B infliximab products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Remicade	infliximab
Avsola	infliximab-axxq
Inflectra	infliximab-dyyb
Renflexis	infliximab-abda
infliximab (all brands)	infliximab

Indications

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Crohn's disease
- Psoriatic arthritis
- Rheumatoid arthritis
- Ankylosing spondylitis
- Plaque psoriasis
- Ulcerative colitis
- Reactive arthritis and inflammatory bowel disease
- Hidradenitis suppurativa
- Behcet's disease (also known as Behcet's Syndrome)
- Chronic pulmonary sarcoidosis

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided when any of the following is met:

- The member has class III or IV congestive heart failure
- The member has untreated active or latent tuberculosis
- The member is using/will use the requested medication in combination with other biologics such as Enbrel (etanercept), Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), or a Janus kinase inhibitor (e.g., Xeljanz [tofacitinib])

Coverage Criteria

Crohn's disease (CD)[1,2]

Authorization of 12 months may be granted for treatment of Crohn's disease in adult and pediatric members when all of the following criteria are met:

- The member has moderately to severely active disease
- The requested drug is being used to reduce the signs and symptoms of the disease and induce and maintain clinical remission
- The member has had an inadequate response to conventional therapy (e.g., corticosteroids, aminosalicylates, immunosuppressive agents)

Authorization of 12 months may be granted for treatment of fistulizing Crohn's disease to reduce the number of draining enterocutaneous and rectovaginal fistulas and maintain fistula closure in members who are new to therapy.

Authorization of 12 months may be granted for treatment of fistulizing Crohn's disease when both of the following criteria are met:

- The member is currently receiving therapy with the requested drug
- Medical records substantiate that the member has had a reduction in signs and symptoms of the disease after the initial treatment

Psoriatic arthritis (PsA)[1,2]

Authorization of 12 months may be granted for treatment of psoriatic arthritis to reduce the signs and symptoms of active arthritis, inhibit the progression of structural damage, and improve physical function in members who are new to therapy.

Authorization of 12 months may be granted for treatment of psoriatic arthritis when both of the following criteria are met:

- The member is currently receiving therapy with the requested drug

- The member has responded to initial treatment as demonstrated by a reduction in signs and symptoms after the initial treatment

Rheumatoid arthritis (RA)[1,2]

Authorization of 12 months may be granted for treatment of rheumatoid arthritis to reduce the signs and symptoms of the disease, inhibit the progression of structural damage, and improve physical function when both of the following criteria are met:

- The disease is moderately to severely active
- The requested drug will be used in combination with methotrexate or treatment with methotrexate is contraindicated

Ankylosing spondylitis (AS)[1,2]

Authorization of 12 months may be granted for treatment of ankylosing spondylitis to reduce the signs and symptoms in a member with active ankylosing spondylitis when the member is new to therapy.

Authorization of 12 months may be granted for treatment of ankylosing spondylitis when both of the following criteria are met:

- The member is currently receiving therapy with the requested drug
- The member has responded to initial treatment as demonstrated by a reduction in signs and symptoms after the initial treatment

Plaque psoriasis (PsO)[1,2]

Authorization of 12 months may be granted for treatment of adult members with plaque psoriasis when all of the following criteria are met:

- The disease is chronic and severe as evidenced by plaques covering at least 10% of the body surface
- The member meets one of the following:
    - The member has failed prior treatment with psoralen-ultraviolet A (UVA) or ultraviolet B (UVB) light therapy
    - The member is a candidate for systemic therapy when other conventional systemic therapies have failed (methotrexate, cyclosporine, Soriatane)
    - The member is a candidate for systemic therapy and has contraindications to psoralen-ultraviolet A (UVA) or ultraviolet B (UVB) light therapy and other conventional systemic therapies (methotrexate, cyclosporine, Soriatane)
- The member will be closely monitored and have regular follow-up visits with a physician

Ulcerative colitis (UC)[1,2]

Authorization of 12 months may be granted for treatment of ulcerative colitis to reduce the signs and symptoms, achieve clinical remission and mucosal healing, and eliminate corticosteroid use when both of the following criteria are met:

- The disease is moderately to severely active
- The member has had an inadequate response to conventional therapy (e.g., aminosalicylates, corticosteroids, immunosuppressants), unless the member is unable to tolerate these drugs

Reactive arthritis and inflammatory bowel disease[1,2]

Authorization of 12 months may be granted for treatment of reactive arthritis and inflammatory bowel disease (e.g., Reiter's syndrome) when all of the following criteria are met:

- The member has failed or is intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)
- The member has failed or is intolerant to methotrexate
- The member has failed or is intolerant to sulfasalazine

Hidradenitis suppurativa[1,2]

Authorization of 12 months may be granted for treatment of hidradenitis suppurativa in members with severe disease refractory to systemic antibiotics and surgical treatments.

Behcet's Disease (Behcet's Syndrome)[1,2]

Authorization of 12 months may be granted for treatment of Behcet's Disease (also known as Behcet's Syndrome) when both of the following criteria are met:

- The member has had an inadequate response to initial therapy
- The requested drug is being prescribed for the treatment of clinical manifestations of the disease such as severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement, and resistant cases of joint or mucocutaneous involvement (i.e., painful oral and genital ulcers)

Chronic pulmonary sarcoidosis[1,2]

Authorization of 12 months may be granted for treatment of chronic pulmonary sarcoidosis when all of the following criteria are met:

- The member remains symptomatic despite treatment for 3 or more months with steroids (10 mg per day or more)
- The member remains symptomatic despite treatment for 3 or more months with immunosuppressants (e.g., azathioprine, cyclophosphamide, methotrexate) OR the member

has a contraindication or intolerance to one immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate)
- The member is not/will not receive the requested drug in combination with either of the following:
    - Biologic disease-modifying anti-rheumatic drugs (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
    - Janus kinase inhibitors (e.g., Xeljanz [tofacitinib])
- The prescriber will consult the literature for proper dosing of the requested drug

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. INFLIXIMAB LCD (L35677) Version 30. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 19, 2024.
2. Billing and coding: Infliximab (A56432) Version R4. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 19, 2024.
3. Remicade [package insert]. Horsham, PA. Janssen Biotech, Inc.; October 2021.
4. Avsola [package insert]. Thousand Oaks, CA. Amgen, Inc; September 2021.
5. Inflectra [package insert]. New York, NY. Pfizer Inc; April 2023.
6. Renflexis [package insert]. Jersey City, NJ. Organon LLC, Inc.; December 2023.
7. Infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.

