Reference number(s)
3938-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

Covered Uses

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.

The FDA-labeled indications and recognized compendia (off-label) uses are below[1-10]:

- Crohn's disease
- Ulcerative colitis
- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Plaque psoriasis
- Behcet's disease (also known as Behcet's syndrome)

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- Pyoderma gangrenosum
- Sarcoidosis
- Immune-related colitis
- Adult-onset Still's disease
- Acute graft versus host disease
- Hidradenitis suppurativa
- Juvenile idiopathic arthritis
- Synovitis and tenosynovitis
- Takayasu's arteritis
- Uveitis
- Immune checkpoint inhibitor-related toxicity
- Multisystem inflammatory syndrome in children (MIS-C)
- Arthritis in Crohn's disease
- Gastrointestinal tract transplantation organ rejection
- Kawasaki disease
- Necrobiosis lipoidica diabeticorum
- Polyarteritis nodosa
- Rheumatoid arthritis as monotherapy
- SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome
- Subcorneal pustular dermatosis
- Giant cell arteritis
- Microscopic colitis

Compendial Uses:

ICD-10 codes supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

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.

Coverage Criteria

Crohn's disease (CD)[2,4-8]

Authorization of 12 months may be granted for treatment of Crohn's disease when the member is not currently receiving therapy with the requested drug.

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

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- The member is currently receiving therapy with the requested drug.
- The member has experienced a reduction in the clinical signs and symptoms of the disease after initial treatment.

Ulcerative colitis (UC)[2,4-8]

Authorization of 12 months may be granted for treatment of ulcerative colitis.

Rheumatoid arthritis (RA)[2,4-8]

Authorization of up to 30 weeks may be granted for treatment of rheumatoid arthritis when both of the following criteria are met:

- The member is new to therapy or has received less than 30 weeks of therapy with the requested drug.
- The member meets one of the following:
    - Member is currently receiving methotrexate or the member cannot take methotrexate.
    - Member is currently receiving the requested drug as monotherapy.

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

- The member has received at least 30 weeks of treatment with the requested drug.
- The member has experienced at least 20% improvement in tender joint count and 20% improvement in swollen joint count.
- The member meets one of the following:
    - Member is currently receiving methotrexate or the member cannot take methotrexate.
    - Member is currently receiving the requested drug as monotherapy.

Ankylosing spondylitis (AS)[2,4-8]

Authorization of 12 months may be granted for treatment of ankylosing spondylitis.

Psoriatic arthritis (PsA)[4-8]

Authorization of 12 months may be granted for treatment of psoriatic arthritis.

Plaque psoriasis (PsO)[2,4-8]

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

- The disease is chronic, severe, extensive or disabling as evidenced by one of the following assessment tools:
    - Percent body surface area (BSA) affected

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  - Psoriasis Area Severity Index (PASI) score
  - Psoriasis Disability Index (PDI) score
  - Result from other psoriasis assessment tool(s)
- The member will be monitored for non-melanoma skin cancers, especially if the patient has had prolonged phototherapy treatment.
- The member will be closely monitored and have regular follow-up visits with a physician.

Behcet's Disease (Behcet's Syndrome)[1,2,10]

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 requested drug will be used to treat clinical manifestations 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).
- The member did not experience an adequate response to initial therapy.

Pyoderma gangrenosum[1,2,10]

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum with coexisting inflammatory bowel disease.

Sarcoidosis[1,2,10]

Authorization of 12 months may be granted for treatment of sarcoidosis when the disease is refractory to treatment with steroids and other standard drug regimens.

Immune-related colitis[1]

Authorization of 1 month may be granted for treatment of severe immune-related colitis when both of the following criteria are met:

- The disease did not respond promptly (within 1 week) to therapy with high-dose steroids.
- The request is for a single dose of infliximab.

Acute graft versus host disease[2,9,10]

Authorization of 12 months may be granted for treatment of acute graft versus host disease, including acute on chronic graft versus host disease.

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Uveitis[2,9,10]

Authorization of 12 months may be granted for treatment of uveitis including iridocyclitis, panuveitis, and sympathetic uveitis.

Immune checkpoint inhibitor-related toxicity[9]

Authorization of 12 months may be granted for management of immune checkpoint inhibitor-related toxicity.

Multisystem inflammatory syndrome in children (MIS-C)[2,10]

Authorization of 1 month may be granted for treatment of multisystem inflammatory syndrome in children (MIS-C) post severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection who have failed to respond to standard pharmacologic therapy.

Microscopic colitis[1]

Authorization of 12 months may be granted for treatment of microscopic colitis when the disease is refractory due to lack of response with standard pharmacologic therapy.

All other indications[2,4-10]

Authorization of 12 months may be granted for treatment of all other approvable indications listed in Section I of this document.

Dosage and Administration

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

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