Reference number(s)
3938-A

JURISDICTION SPECIFIC MEDICARE PART B

INFLIXIMAB PRODUCTS
REMICADE (infliximab)
AVSOLA (infliximab-axxq)
INFLECTRA (infliximab-dyyb)
RENFLEXIS (infliximab-abda)

POLICY

I. 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 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. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Crohn's disease
B. Ulcerative colitis
C. Rheumatoid arthritis
D. Ankylosing spondylitis
E. Psoriatic arthritis
F. Plaque psoriasis
G. Behcet's disease
H. Pyoderma gangrenosum
I. Sarcoidosis
J. Immune-related colitis
K. Adult onset Still's disease
L. Acute graft versus host disease
M. Granulomatosis with polyangiitis
N. Hidradenitis suppurativa
O. Juvenile idiopathic arthritis
P. Synovitis and tenosynovitis
Q. Takayasu's disease
R. Uveitis
S. Management of immune checkpoint inhibitor-related toxicities
T. Bone marrow transplant
U. Wegener's granulomatosis
V. Churg-Strauss
W. Toxic gastroenteritis and colitis
X. Atrioventricular block
Y. Fascicular block
Z. Pre-excitation syndrome
AA. Long QT syndrome

BB. Ventricular tachycardia

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.
C. The basis for each diagnosis and that the diagnosis was made in accordance with recognized standards such as guidelines published by the American College of Rheumatology (ACR)
D. Height and weight when needed to determine appropriate dosing
E. Evaluation for latent tuberculosis infection through medical evaluation and TB skin test (PPD). Treatment of latent tuberculosis infection should be initiated prior to therapy with infliximab.
F. Documentation of disease specific relevant symptoms and signs which are both being treated and being followed to assess for response to treatment.
G. Documentation of inadequate response (includes lack of efficacy, adverse effects prohibiting further use of the drug or medical contraindications) to a 3 month trial of appropriately dosed and disease specific conventional (non-biologic) therapy.
H. For treatment of Crohn's disease, documentation of the presence and severity of abdominal pain, diarrhea, extra-intestinal manifestations, enterocutaneous and/or rectovaginal fistulae. For continuation of therapy requests, the medical record substantiates that the patient had a reduction in the clinical signs and symptoms of the disease after the initial treatment.
I. For plaque psoriasis, documentation supports that the condition is chronic, severe, extensive or disabling (e.g., body surface area (BSA) affected, Psoriasis Area Severity Index (PASI) score, Psoriasis Disability Index (PDI) score, and/or results from other psoriasis assessment tools).
J. For rheumatoid arthritis, the documentation indicates the patient is also receiving methotrexate or there is a reason the member cannot take methotrexate. For continuation of therapy requests, the medical record must include evidence of at least 20% improvement in tender joint count and at least 20% improvement in swollen joint count.

III. CRITERIA FOR APPROVAL

A. Crohn's disease

1. 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.

2. Authorization of 12 months may be granted for treatment of Crohn's disease when both of the following criteria are met:
   i. The member is currently receiving therapy with the requested drug.
   ii. The member has experienced a reduction in the clinical signs and symptoms of the disease after initial treatment.

B. Ulcerative colitis

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

C. Rheumatoid arthritis

1. Authorization of up to 30 weeks may be granted for treatment of rheumatoid arthritis when both of the following criteria are met:
   i. The member is new to therapy or has received less than 30 weeks of therapy with the requested product.
   ii. The member is currently receiving methotrexate or the patient cannot take methotrexate.

2. Authorization of 12 months may be granted for treatment of rheumatoid arthritis when all of the following criteria are met:
   i. The member has received at least 30 weeks of treatment with the requested drug.
   ii. The member has experienced at least 20% improvement in tender joint count and 20% improvement in swollen joint count.
   iii. The member is receiving methotrexate or the member cannot take methotrexate.

D. Ankylosing spondylitis

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

E. Psoriatic arthritis

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

F. Plaque Psoriasis

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

1. The disease is chronic, severe, extensive or disabling as evidenced by one of the following assessment tools:
   i. Percent body surface area (BSA) affected
   ii. Psoriasis Area Severity Index (PASI) score
   iii. Psoriasis Disability Index (PDI) score
   iv. Result from other psoriasis assessment tool(s)
2. The member will be monitored for non-melanoma skin cancers, especially if the patient has had prolonged phototherapy treatment.
3. The member will be closely monitored and have regular follow-up visits with a physician.

G. Behcet's Disease

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

1. 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).
2. The member did not experience an adequate response to initial therapy

H. Pyoderma Gangrenosum

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

I. Sarcoidosis

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.

J. Immune-Related Colitis
Authorization of 1 month may be granted for treatment of severe immune related colitis when both of the following criteria are met:
1. The disease did not respond promptly (within 1 week) to therapy with high-dose steroids.
2. The request is for a single dose of infliximab.

K. **Adult Onset Still's Disease**
Authorization of 12 months may be granted for treatment of adult onset Still's disease.

L. Acute Graft Versus Host Disease
Authorization of 12 months may be granted for treatment of acute graft versus host disease, including acute on chronic graft versus host disease.

M. Granulomatosis with Polyangiitis
Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis.

N. Hidradenitis Suppurativa
Authorization of 12 months may be granted for treatment of hidradenitis suppurativa.

O. Juvenile Idiopathic Arthritis
Authorization of 12 months may be granted for treatment of juvenile idiopathic arthritis.

P. Synovitis and Tenosynovitis
Authorization of 12 months may be granted for treatment of synovitis and tenosynovitis.

Q. Takayasu's Disease
Authorization of 12 months may be granted for treatment of Takayasu's disease.

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

S. Immune Checkpoint Inhibitor-Related Toxicities
Authorization of 12 months may be granted for management of immune checkpoint inhibitor-related toxicities.

T. All Other Indications
Authorization of 12 months may be granted for treatment of all other approvable indications listed in section I of this document.

IV. DOSAGE AND ADMINISTRATION

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

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 17, 2021.

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9. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed June 17, 2021.