Reference number(s)
4535-A

JURISDICTION SPECIFIC MEDICARE PART B

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

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.

A. Crohn's disease
B. Psoriatic arthritis
C. Rheumatoid arthritis
D. Ankylosing spondylitis
E. Plaque psoriasis
F. Ulcerative colitis
G. Reactive arthritis and inflammatory bowel disease
H. Hidradenitis suppurativa
I. Behcet's disease (also known as Behcet's Syndrome)
J. Chronic pulmonary sarcoidosis

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 in legible format, upon request, for all submissions:

A. The medical necessity for the use of the requested drug by clearly indicating the relevant clinical signs and symptoms related to the medical condition for which the drug is indicated
B. All prior treatment regimens and the member's response to therapy
C. For fistulizing Crohn's disease episodic retreatment, medical records substantiating that the member had a reduction in the clinical signs and symptoms of the disease after the initial treatment
D. For hidradenitis suppurativa, a listing of other differential diagnoses that have been ruled out and the history of failed antibiotic treatment prior to inception of infliximab treatment

E. For rheumatoid arthritis, documentation that the member is receiving the requested drug in combination with methotrexate, or that the member is intolerant to methotrexate, or that the member has a medical condition that contraindicates the use of methotrexate
F. For reactive arthritis and inflammatory bowel disease, if the member is unable to tolerate methotrexate or if methotrexate is contraindicated, documentation that clearly indicates the reason that the patient cannot take methotrexate
G. For maintenance therapy, documentation of the start date of the requested drug, the current status of the member, and the current response to therapy and current dosage
H. Documentation that services are performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

III. EXCLUSIONS

Coverage will not be provided when any of the following is met:
A. The member has class III or IV congestive heart failure
B. The member has untreated active or latent tuberculosis
C. 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])

IV. CRITERIA FOR APPROVAL

A. Crohn's disease (CD)

1. Authorization of 12 months may be granted for treatment of Crohn's disease in adult and pediatric members when all of the following are met:
   i. The member has moderately to severely active disease
   ii. The requested drug is being used to reduce the signs and symptoms of the disease and induce and maintain clinical remission
   iii. The member has had an inadequate response to conventional therapy (e.g., corticosteroids, aminosalicylates, and immunosuppressive agents)

2. 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.

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

B. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for treatment of psoriatic arthritis when both of the following are met:
   i. The member is currently receiving therapy with the requested drug
   ii. The member has responded to initial treatment as demonstrated by a reduction in signs and symptoms

C. Rheumatoid arthritis (RA)

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 all of the following are met:

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

D. Ankylosing spondylitis (AS)

1. Authorization of 12 months may be granted to reduce the signs and symptoms in a member with active ankylosing spondylitis when the member is not currently receiving therapy with the requested drug.

2. Authorization of 12 months may be granted for treatment of ankylosing spondylitis when both of the following are met:
   i. The member is currently receiving therapy with the requested drug
   ii. The member has responded to initial treatment as demonstrated by a reduction in signs and symptoms

E. Plaque psoriasis (PsO)

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

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

F. Ulcerative colitis (UC)

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 all of the following are met:

1. The disease is moderately to severely active
2. The member has had an inadequate response to conventional therapy such as aminosalicylates, corticosteroids, or immunosuppressants, unless the member is unable to tolerate these drugs

G. Reactive arthritis and inflammatory bowel disease

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 are met:

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

3. The member has failed or is intolerant to sulfasalazine

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

I. Behcet's Disease (Behcet's Syndrome)
Authorization of 12 months may be granted for treatment of Behcet's Disease (also known as Behcet's Syndrome) when all of the following are met:
1. The member has had an inadequate response to initial therapy
2. 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)

J. Chronic pulmonary sarcoidosis
Authorization of 12 months may be granted for treatment of chronic pulmonary sarcoidosis when all of the following are met:
1. The member remains symptomatic despite treatment for 3 or more months with steroids (10 mg per day or more)
2. The member remains symptomatic despite treatment for 3 or more months with immunosuppressants (such as azathioprine, cyclophosphamide, or methotrexate) OR the member has a contraindication or intolerance to one immunosuppressant (such as azathioprine, cyclophosphamide, or methotrexate)
3. The member is not/will not receive the requested drug in combination with either of the following:
   i. Biologic drugs (e.g., Enbrel [etanercept], Humira [adalimumab], Cimzia [certolizumab], Simponi [golimumab])
   ii. Janus kinase inhibitor (e.g., Xeljanz [tofacitinib])
4. The prescriber will consult the literature for proper dosing of the requested drug

V. DOSAGE AND ADMINISTRATION

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

VI. REFERENCES

1. INFLIXIMAB LCD (L35677) Version 29. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 19, 2022.
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, 2022.
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; March 2022.
6. Renflexis [package insert]. Jersey City, NJ. Organon LLC, Inc.; January 2022.
7. Infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.