Reference number
1979-A

STANDARD MEDICARE PART B MANAGEMENT

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

POLICY

I. INDICATIONS

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

A. REMICADE

1. FDA-Approved Indications
   - i. Crohn's disease
     - a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
     - b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   - ii. Pediatric Crohn's disease
     Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
   - iii. Ulcerative colitis
     Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   - iv. Pediatric ulcerative colitis
     Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy
   - v. Rheumatoid arthritis in combination with methotrexate
     Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease
   - vi. Ankylosing spondylitis
     Reducing signs and symptoms in patients with active disease
   - vii. Psoriatic arthritis
     Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function
   - viii. Plaque Psoriasis

Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
   i. Adult onset Still's disease
   ii. Arthritis/arthropathy in Crohn's disease
   iii. Axial spondyloarthritis
   iv. Behcet's disease
   v. Gastrointestinal tract transplantation organ rejection
   vi. Giant cell arteritis
   vii. Graft versus host disease
   viii. Granulomatosis with polyangiitis
   ix. Hidradenitis suppurativa
   x. Juvenile idiopathic arthritis
   xi. Kawasaki disease
   xii. Necrobiosis lipoidica diabeticorum
   xiii. Pyoderma gangrenosum
   xiv. Rheumatoid arthritis as monotherapy
   xv. Severe, refractory SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome
   xvi. Sarcoidosis
   xvii. Subcorneal pustular dermatosis
   xviii. Synovitis
   xix. Takayasu's arteritis
   xx. Uveitis
   xxi. Immune checkpoint inhibitor toxicity

B. AVSOLA

1. FDA-Approved Indications
   i. Crohn's disease
      a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
      b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   ii. Pediatric Crohn's disease
   Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   iii. Ulcerative colitis
   Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   iv. Pediatric ulcerative colitis
   Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   v. Rheumatoid arthritis in combination with methotrexate
   Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease

vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease
vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function
viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
Same as Remicade. See Section I.A.2.

C. INFLECTRA

1. FDA-Approved Indications
i. Crohn's disease
a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
ii. Pediatric Crohn's disease
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
iii. Ulcerative colitis
Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
iv. Pediatric ulcerative colitis
Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
v. Rheumatoid arthritis in combination with methotrexate
Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease
vi. Ankylosing spondylitis
Reducing signs and symptoms in patients with active disease
vii. Psoriatic arthritis
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function
viii. Plaque Psoriasis
Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
Same as Remicade. See Section I.A.2.

D. RENFLEXIS

1. FDA-Approved Indications
   i. Crohn's disease
      a. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
      b. Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
   ii. Pediatric Crohn's disease
      Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   iii. Ulcerative colitis
      Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   iv. Pediatric ulcerative colitis
      Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy
   v. Rheumatoid arthritis in combination with methotrexate
      Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease
   vi. Ankylosing spondylitis
      Reducing signs and symptoms in patients with active disease
   vii. Psoriatic arthritis
      Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function
   viii. Plaque Psoriasis
      Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Compendial Uses
   Same as Remicade. See Section I.A.2.

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. CRITERIA FOR INITIAL APPROVAL

A. Crohn's disease
Authorization of 24 months may be granted for treatment of Crohn's disease.

B. Ulcerative colitis
Authorization of 24 months may be granted for treatment of moderately to severely active ulcerative colitis.

C. Rheumatoid arthritis

Authorization of 24 months may be granted for treatment of rheumatoid arthritis when any of the following criteria are met:

i. The member has previously received any other biologic disease-modifying anti-rheumatic drug (DMARD) (e.g., Humira) or targeted synthetic DMARD (e.g., Xeljanz) indicated for rheumatoid arthritis.
ii. The member had an inadequate response to methotrexate or there is a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment).

D. Ankylosing spondylitis and axial spondyloarthritis
Authorization of 24 months may be granted for treatment of active ankylosing spondylitis and active axial spondyloarthritis.

E. Psoriatic arthritis
Authorization of 24 months may be granted for treatment of active psoriatic arthritis.

F. Plaque psoriasis
Authorization of 24 months may be granted for treatment of plaque psoriasis.

G. Adult onset Still's disease
Authorization of 24 months may be granted for the treatment of active adult onset Still's disease.

H. Arthritis/arthropathy in Crohn's disease
Authorization of 24 months may be granted for the treatment of arthritis or arthropathy in a member with Crohn's disease.

I. Behcet's disease
Authorization of 24 months may be granted for the treatment of Behcet's disease.

J. Gastrointestinal tract transplantation organ rejection
Authorization of 24 months may be granted for the treatment of gastrointestinal tract transplantation organ rejection.

K. Giant cell arteritis
Authorization of 24 months may be granted for the treatment of giant cell arteritis.

L. Acute graft versus host disease
Authorization of 24 months may be granted for the treatment of acute graft versus host disease when either of the following criteria is met:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

M. Granulomatosis with polyangiitis (Wegener's granulomatosis)
Authorization of 24 months may be granted for the treatment of granulomatosis with polyangiitis.

N. Hidradenitis suppurativa
Authorization of 24 months may be granted for the treatment of hidradenitis suppurativa.

O. Juvenile idiopathic arthritis
Authorization of 24 months may be granted for the treatment of active juvenile idiopathic arthritis.

P. Kawasaki disease

Authorization of 24 months may be granted for the treatment of Kawasaki disease.

Q. Necrobiosis lipoidica diabeticorum
Authorization of 24 months may be granted for the treatment of necrobiosis lipoidica diabeticorum.

R. Pyoderma gangrenosum
Authorization of 24 months may be granted for the treatment of pyoderma gangrenosum.

S. SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome
Authorization of 24 months may be granted for the treatment of SAPHO syndrome.

T. Sarcoidosis
Authorization of 24 months may be granted for the treatment of sarcoidosis.

U. Subcorneal pustular dermatosis
Authorization of 24 months may be granted for the treatment of subcorneal pustular dermatosis.

V. Synovitis
Authorization of 24 months may be granted for the treatment of synovitis.

W. Takayasu's disease
Authorization of 24 months may be granted for the treatment of Takayasu's disease.

X. Uveitis
Authorization of 24 months may be granted for the treatment of uveitis.

Y. Immune Checkpoint Inhibitor Toxicity
Authorization of 1 month may be granted for the treatment of immune checkpoint inhibitor toxicity.

III. CONTINUATION OF THERAPY

A. Immune Checkpoint Inhibitor Toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. All other indications
All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 24 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Avsola, Remicade, Inflectra, or Renflexis.
2. The requested medication is being used to treat an indication enumerated in Section II.
3. The member is receiving benefit from therapy.

IV. REFERENCES

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