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 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
   - 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 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 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 axial spondyloarthritis.

E. Psoriatic arthritis
Authorization of 24 months may be granted for treatment of 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 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. Graft versus host disease
Authorization of 24 months may be granted for the treatment of graft versus host disease.

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 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 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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