

STANDARD MEDICARE PART B MANAGEMENT

CIMZIA (certolizumab pegol)

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.

FDA-Approved Indications¹

- A. Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- B. Treatment of adults with moderately to severely active rheumatoid arthritis.
- C. Treatment of adult patients with active psoriatic arthritis.
- D. Treatment of adults with active ankylosing spondylitis.
- E. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- F. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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. Crohn's disease
For continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.
- B. Rheumatoid arthritis (RA)
 - 1. For initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
 - 2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- C. Psoriatic arthritis (PsA), ankylosing spondylitis (AS) and active axial spondyloarthritis
For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- D. Plaque psoriasis

For continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected or improvement in signs and symptoms.

III. CRITERIA FOR INITIAL APPROVAL

A. Crohn's Disease

Authorization of 12 months may be granted for the treatment of moderately to severely active Crohn's disease.

B. Rheumatoid Arthritis

Authorization of 12 months may be granted for the treatment of moderately to severely active rheumatoid arthritis when any of the following criteria are met:

1. The member has previously received treatment with a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. The member has had an inadequate response to methotrexate or there is a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment).

C. Psoriatic Arthritis

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

D. Ankylosing Spondylitis and Axial Spondyloarthritis

Authorization of 12 months may be granted for the treatment of active ankylosing spondylitis and active axial spondyloarthritis.

E. Plaque Psoriasis

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis.

IV. CONTINUATION OF THERAPY

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

A. Crohn's disease

Authorization for 12 months may be granted for moderately to severely active Crohn's disease when all of the following criteria are met:

1. The member is currently receiving therapy with Cimzia.
2. The member is receiving benefit from therapy. Benefit is defined as one of the following:
 - i. Member has achieved or maintained remission.
 - ii. Member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - a. Abdominal pain or tenderness
 - b. Diarrhea
 - c. Body weight
 - d. Abdominal mass
 - e. Hematocrit
 - f. Endoscopic appearance of the mucosa
 - g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

B. Rheumatoid Arthritis

Authorization for 12 months may be granted for moderately to severely active rheumatoid arthritis when all of the following criteria are met:

1. The member is currently receiving therapy with Cimzia
2. The member is receiving benefit from therapy. Benefit is defined as the member has achieved or maintained a positive clinical response as evidenced by disease activity improvement from baseline in tender joint count, swollen joint count, pain, or disability.

C. Psoriatic Arthritis

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

1. The member is currently receiving therapy with Cimzia
2. The member is receiving benefit from therapy. Benefit is defined as the member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - i. Number of swollen joints
 - ii. Number of tender joints
 - iii. Dactylitis
 - iv. Enthesitis
 - v. Skin and/or nail involvement

D. Ankylosing Spondylitis and Axial Spondyloarthritis

Authorization for 12 months may be granted for active ankylosing spondylitis or active axial spondyloarthritis when all of the following criteria are met:

1. The member is currently receiving therapy with Cimzia
2. The member is receiving benefit from therapy. Benefit is defined as the member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
 - i. Functional status
 - ii. Total spinal pain
 - iii. Inflammation (e.g. morning stiffness)

E. Plaque Psoriasis

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

1. The member is currently receiving therapy with Cimzia.
2. The member has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:
 - i. Reduction in body surface areas (BSA) affected from baseline
 - ii. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, brining, cracking, pain)

V. REFERENCES

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