

SPECIALTY GUIDELINE 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

1. 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.
2. Treatment of adults with moderately to severely active rheumatoid arthritis.
3. Treatment of adult patients with active psoriatic arthritis.
4. Treatment of adults with active ankylosing spondylitis.
5. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
6. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Rheumatoid arthritis (RA)
 1. For initial requests:
 - i. 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.
 - ii. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
 2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- B. Psoriatic arthritis (PsA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- C. Ankylosing spondylitis (AS) and active axial spondyloarthritis:
 1. 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. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Crohn's disease

1. Initial requests
 - i. 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.
 - ii. Chart notes or medical record documentation supporting diagnosis of fistulizing Crohn's disease (if applicable)
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E. Plaque psoriasis

1. Initial requests:
 - i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
 - ii. 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. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

III. CRITERIA FOR INITIAL APPROVAL

A. Moderately to severely active rheumatoid arthritis (RA)^{1,3-5, 21-23}

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
 - i. Member meets either of the following criteria:
 - a. Member has been tested for either of the following biomarkers and the test was positive:
 1. Rheumatoid Factor (RF)
 2. Anti-cyclic citrullinated peptide (anti-CCP)
 - b. Member has been tested for ALL of the following biomarkers:
 1. RF
 2. Anti-CCP
 3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
 - ii. Member meets either of the following criteria:
 - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
 - b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Active psoriatic arthritis (PsA)^{1,6-9,18}

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

C. Active ankylosing spondylitis (AS) and active axial spondyloarthritis^{1,2,10-12}

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis or active axial spondyloarthritis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis or active axial spondyloarthritis when any of the following criteria is met:

- i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Moderately to severely active Crohn's disease (CD)^{1,13,14,16}

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Crohn's disease.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active CD when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).
3. Authorization of 12 months may be granted for the treatment of fistulizing CD.

E. Moderate to severe plaque psoriasis (PsO)^{1,6,15,19,20}

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members when any of the following criteria is met:
 - i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - ii. At least 10% of the body surface area (BSA) is affected.
 - iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
 - a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix C).

IV. CONTINUATION OF THERAPY

A. Moderately to severely active rheumatoid arthritis (RA)^{1,3-5,21-23}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

B. Active psoriatic arthritis (PsA)^{1,6-9,18}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain 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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement

C. Ankylosing spondylitis (AS) and active axial spondyloarthritis^{1,2,10-12}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain a positive clinical response with the requested medication 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:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g. morning stiffness)

D. Moderately to severely active Crohn's disease^{1,13,14,16}

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.
2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain 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. Abdominal pain or tenderness
 - ii. Diarrhea
 - iii. Body weight
 - iv. Abdominal mass
 - v. Hematocrit
 - vi. Endoscopic appearance of the mucosa
 - vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

E. Moderate to severe plaque psoriasis (PsO)^{1,6,15,19,20}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain 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:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

V. OTHER^{1,17}

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB, and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who

work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use the requested medication concomitantly with any other biologic DMARD or targeted synthetic DMARD.

VI. DOSAGE AND ADMINISTRATION

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

VII. APPENDICES

Appendix A: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
 - a. Oral budesonide
 - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
 - a. Prednisone, methylprednisolone intravenously (IV)
 - b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternative: methotrexate IM or SC

Appendix C: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

VIII. REFERENCES

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