Reference number(s)
4703-A

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 Indications

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 (CD)
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 axial spondyloarthritis (axSpA)
For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Plaque psoriasis (PsO)
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 (CD)
Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

B. Rheumatoid arthritis (RA)
Authorization of 12 months may be granted for treatment of moderately to severely active rheumatoid arthritis when any of the following criteria is met:
1. The member has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. The member has had an inadequate response to methotrexate.
3. The member has a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment, pregnancy or currently planning pregnancy).

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

D. Ankylosing spondylitis (AS) and axial spondyloarthritis (axSpA)
Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active axial spondyloarthritis.

E. Plaque psoriasis (PsO)
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 (CD)
Authorization for 12 months may be granted for moderately to severely active Crohn's disease when both 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. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

B. Rheumatoid arthritis (RA)

Authorization for 12 months may be granted for moderately to severely active rheumatoid arthritis when both 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 (PsA)

Authorization for 12 months may be granted for psoriatic arthritis when both 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. Axial disease
   vi. Skin and/or nail involvement

D. Ankylosing spondylitis (AS) and axial spondyloarthritis (axSpA)

Authorization for 12 months may be granted for active ankylosing spondylitis or active axial spondyloarthritis when both 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 (PsO)

Authorization of 12 months may be granted for moderate to severe plaque psoriasis when both 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 either of the following is met:
   i. Reduction in body surface area (BSA) affected from baseline
   ii. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Cimzia.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis.
4. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update
5. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.
6. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis.
7. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions.
8. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2019 update.
9. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021.
10. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis.
11. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis.
12. An evidence-based systematic review on medical therapies for inflammatory bowel disease.
13. ACG Clinical Guideline: Management of Crohn's Disease in Adults.
14. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics.
15. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.
16. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients.
17. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies.
18. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative
19. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease.
20. Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures.
21. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Cimzia are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; December 2022.
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
3. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79(6):685-699. Doi:10.1136/annrheumdis-2019-216655.
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12. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613. Doi:10.1002/art.41042.
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14. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol.* 2018;113:481-517.
15. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
16. Utilization Management (UM) Criteria Review CVS Caremark P&T Subgroup. Gastroenterology – IBD Agents – UM Criteria. December 2018.
17. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on August 9, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
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