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.

A. FDA-Approved Indications[1]
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.

B. Compendial Uses[28]
Immune checkpoint inhibitor-related toxicity – inflammatory arthritis

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

Crohn's disease (CD), Rheumatoid arthritis (RA), Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), plaque psoriasis (PsO), and immune checkpoint inhibitor-related toxicity
For continuation requests: Chart notes or medical record documentation supporting benefit of therapy.

III. CRITERIA FOR INITIAL APPROVAL

A. Crohn's disease (CD)[1]
Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

B. Rheumatoid arthritis (RA)[1]
Authorization of 12 months may be granted for treatment of moderately to severely active rheumatoid arthritis.

C. Psoriatic arthritis (PsA)[1]
Authorization of 12 months may be granted for the treatment of active psoriatic arthritis.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1]
Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.

E. Plaque psoriasis (PsO)[1]
Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis.

F. Immune checkpoint inhibitor-related toxicity[28]
Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has severe immunotherapy-related inflammatory arthritis.

IV. CONTINUATION OF THERAPY

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

All indications
Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Cimzia.
B. Cimzia is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy.

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.
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4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.
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8. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis.* 2005;64(Suppl II):ii14–ii17.
9. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.

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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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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.
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27. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Gastroenterology (GI) – Inflammatory Bowel Disease (IBD). April/May 2023.
28. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 10, 2023.

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Revised:	ST 08/2021 (derm/GI annual), SP 08/2021 (rheum annual), CNg/SP 08/2022 (derm/GI/rheum annual), CNg 12/2022 (per ext review added pregnancy to contraindication to MTX in RA; added axial disease in PsA continuation), CNg 01/2023 (removed active dx from PsA COT to align with SGM), CNg 01/2023 (added CTE/MRE/US option in COT for CD), CNg 05/2023 (added intestinal US to CD COT per ext review), KS/MG 08/2023 (derm/GI-IBD/rheum annual-added immune checkpoint compendial use, removed step from RA initial criteria, removed specific requirements from COT for all indications), LP 09/2023 (2024 Updates)
Reviewed:	CDPR / DNC 05/2021, SNG 08/2021, APN 08/2022, SKY 12/2022, APN 01/2023, APN 08/2023, AN 10/2023
External Review:	Dermatology: 10/2021, 10/2022, 10/2023 Rheumatology: 10/2021, 11/2022, 11/2023 Gastroenterology: 11/2021, 12/2022, 05/2023, 09/2023