Mass General Brigham
Health Plan

Cimzia (certolizumab pegol)
Effective 07/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker indicated for:

- Moderately to severely active rheumatoid arthritis (RA) in adults
- Moderate to severe Plaque Psoriasis (PsO)
- Active psoriatic arthritis (PsA) in adults
- Active ankylosing spondylitis (AS) in adults
- Axial spondyloarthritis, nonradiographic with objective signs of inflammation in adults
- Moderately to severely active Crohn's disease (CD) in adults
- Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all the following diagnosis-specific criteria are met:

Moderately to severely active rheumatoid arthritis (RA)

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)
2. The member has a minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine

Moderate to severe plaque psoriasis (PsO)

1. Diagnosis of moderate to severe plaque psoriasis (PsO)

2. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
3. Member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        i. Corticosteroids (e.g., betamethasone, clobetasol)
        ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        iii. Tazarotene
        iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        v. Anthralin
        vi. Coal tar
    b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)

1. Diagnosis of active psoriatic arthritis (PsA)
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Active ankylosing spondylitis (AS)

1. Diagnosis of active ankylosing spondylitis
2. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.

Non-radiographic Axial Spondyloarthritis

1. The member has a diagnosis of active non-radiographic axial spondyloarthritis
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease but without definitive radiographic evidence of structural damage on sacroiliac joints)
3. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.

Moderately to severely active Crohn's disease (CD)

1. Diagnosis of moderately to severely active Crohn's disease (CD)
2. ONE of the following:
    a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
        i. 6-mercaptopurine
        ii. Azathioprine
        iii. Corticosteroids (e.g., prednisone)
        iv. Methotrexate
    b. Disease severity warrants systemic biologic as first-line therapy

Polyarticular juvenile idiopathic arthritis (pJIA)

1. Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)
2. The member has a minimum duration of 6-week trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Leflunomide
    b. Methotrexate

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be granted when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Cimzia 200 mg/mL syringe	2 syringes per 28 days
Cimzia 200 mg/mL vial	2 vials per 28 days

References

1. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896–904.
2. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; September 2024.
3. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis.* 2005;64(Suppl II):ii14–ii17.
4. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
5. Landewe R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis.* 2014;73(1):39-47.
6. Lebwohl M, Blauvelt A, Paul C, et al. Certolizumab pegol for the treatment of chronic plaque psoriasis: results through 48 weeks of a phase 3, multicenter, randomized, double-blind, etanercept- and placebo-controlled study (CIMPACT). *J Am Acad Dermatol*. 2018;79(2):266-276
7. Menter A, Korman NJ, Elmets CA, et al. 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. *J Am Acad Dermatol.* 2011;65(1):137-174.
8. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. [Published online ahead of print May 8, 2014]. *Clin Rheumatol*. 2014.
9. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
10. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis.* 2017*;0*:1-18.
11. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.

12. 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.
13. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis*. Arthritis Rheumatol.* 2015: 10.1002/art.39298. [Epub ahead of print].

Review History

11/24/08 – Reviewed
01/05/09 – Implemented
02/22/10 – Reviewed
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
02/24/14 – Updated
02/23/15 – Updated
02/22/16 – Reviewed
02/27/17 – Adopted SGM & PD
02/26/18 – Updated
06/19/19 – Reviewed
11/20/19 – Added Rinvoq as a trial for RA and Skyrizi for PS
11/01/2020 – Reviewed; Updated for 2021 strategy to be implemented 1/1/2021.
05/19/2021 – Reviewed and Updated for May P&T; Removed Skyrizi as a previous treatment failure for the diagnosis psoriatic arthritis. Effective 08/01/2021.
03/16/2022 – Reviewed and Updated for March P&T; Added Rinvoq and Skyrizi as preferred trial for PsA under pharmacy benefit. Updated Inflectra as preferred agent for Medical benefit. Effective 05/01/2022
09/21/2022 – Reviewed and Updated for Sept P&T; Added Rinvoq as preferred agent under pharmacy benefit for diagnosis of ankylosing spondylitis, Added Skyrizi as preferred agent under pharmacy benefit for diagnosis of Crohn's Disease. Effective 11/1/22.
07/12/2023 – Reviewed and Updated for July P&T; added Rinvoq as a preferred agent for Crohn's disease. Effective 8/1/23
11/15/2023- Reviewed and Updated for Nov P&T; removed Medical vs. Pharmacy benefit preferred agents as Cimzia is a preferred agent. Removed Appendix. Removed TB requirement. RA – included sulfasalazine, methotrexate and leflunamide as additional conventional therapies. PsO – changed BSA requirement from 5% to 3%. Updated topical therapies. PsA – removed conventional therapies. Included examples of disease. Ankylosing spondylitis and non-radiographic axial spondylarthritis were separated out. CD – additional conventional therapies added. Effective 1/1/2024
10/9/2024 – Reviewed and updated at October P&T. Added criteria for pJIA. Clarified diagnosis of nr-axSpA is "active" to be aligned with FDA-approved package labeling. Effective 1/1/2025.
05/14/2025 – Reviewed and updated at May P&T. Updated criteria for Crohn's disease to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/01/2025.