Mass General Brigham
Health Plan

Cimzia (certolizumab pegol)
Effective 01/01/2024

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
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

1. Moderately to severely active rheumatoid arthritis (RA)
2. Moderate to severe Plaque Psoriasis (PsO)
3. Active psoriatic arthritis (PsA)
4. Active ankylosing spondylitis (AS)
5. Axial spondyloarthritis, nonradiographic
6. Moderately to severely active Crohn's disease (CD)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)
Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria is met:

1. The member has a diagnosis of moderate 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:
    i. Methotrexate
    ii. Leflunomide

iii. Sulfasalazine

Moderate to severe plaque psoriasis (PsO)
Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all the following criteria are met:

1. The member has a 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when the following criteria are met:

1. The member has a 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)
Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when the following criteria are met:

1. The member has a 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
Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of 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 imagine [MRI], indicative of imflammatory 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)

Authorization may be granted for members new to the plan who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of moderate to severely active Crohn's disease (CD)
2. ONE of the following:
    a. Frequent diarrhea and abdominal pain
    b. At least 10% weight loss
    c. Complications such as obstruction, fever, abdominal mass
    d. Abnormal lab values (e.g., C-reactive protein [CRP])
    e. CD Activity Index (CDAI) great than 220
3. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies
    a. 6-mercaptopurine
    b. Azathioprine
    c. Corticosteroids (e.g., prednisone)
    d. methotrexate

Continuation of Therapy

Reauthorizations for all diagnoses will be granted when 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:

Cimzia Starter Kit	2 Kits (4 syringes) per 28 days
Cimzia Prefilled Kit 200mg/ml	3 kits (6 syringes) per 28 days

References

1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April 2019.
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 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.

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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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].
13. 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.
14. 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

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