Mass General Brigham
Health Plan

Targeted Immunomodulators
Cimzia (certolizumab) Vial
Effective 01/06/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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		
Notes	Cimzia Vial is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

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

- 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
- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA)
- Treatment of adults with moderate to severe plaque psoriasis (PsO)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan 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 if the member meets ALL following criteria and documentation has been submitted

Moderate to severe rheumatoid arthritis

1. Diagnosis of moderate to severe rheumatoid arthritis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication

3. Clinical rationale for use instead of Cimzia prefilled syringe
4. Appropriate dosing

Psoriatic arthritis (PsA)

1. Diagnosis of psoriatic arthritis
2. Clinical rationale for use instead of Cimzia prefilled syringe
3. Appropriate dosing

Ankylosing spondylitis

1. Diagnosis of ankylosing spondylitis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Clinical rational for use instead of Cimzia prefilled syringe
4. Appropriate dosing

Non-radiographic axial spondyloarthritis

1. Diagnosis of non-radiographic axial spondyloarthritis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Clinical rationale for use instead of Cimzia prefilled syringe
4. Appropriate dosing

Moderate to severe plaque psoriasis

1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies
        i. topical agent (emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors)
        ii. phototherapy (ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB))
        iii. systemic agent (Traditional DMARDs: methotrexate, apremilast, acitretin)
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Clinical rationale for use instead of Cimzia prefilled syringe
4. Appropriate dosing

Moderate to severe Crohn's disease

1. Diagnosis of moderate to severe Crohn's disease
2. Appropriate dosing
3. Clinical rationale for use instead of Cimzia prefilled syringe
4. **For a diagnosis of fistulizing Crohn's disease**, an inadequate response, adverse reaction or contraindication to Avsola (infliximab-axxq), Remicade (infliximab), Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda) should be documented.

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy and positive response to therapy.

Limitations

1. Initial approvals will be granted for:
    a. Plaque Psoriasis: 3 months
    b. All other diagnosis: 6 months
2. Reauthorizations will be for 12 months.
3. New members currently stable on Cimzia can be approved without documentation of failed trials with the conventional therapies if they have a documented history of hospitalization for one of the above immune conditions.

References

1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; June 2018.
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. Sandborn WJ, Feagan BG, Stoinov S, et al. Certolizumab pegol for the treatment of Crohn's disease. N Engl J Med 2007; 357:228.
4. 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.
5. 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.
6. 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.
7. Mariette X, Förger F, Abraham B, et al. Lack of placental transfer of certolizumab pegol during pregnancy: results from CRIB, a prospective, postmarketing, pharmacokinetic study. Ann Rheum Dis 2018; 77:228.
8. 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.
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.

Review History

11/24/2008 – Reviewed
01/05/2009 – Effective
02/22/2010 – Reviewed
02/28/2011 – Reviewed
02/27/2012 – Reviewed

02/25/2013 – Reviewed
02/24/2014 – Reviewed and revised
02/23/2015 – Reviewed and revised
02/22/2016 – Reviewed
02/27/2017 – Reviewed and revised (adopted SGM & Step) in P&T Meeting
11/20/2017 – Reviewed and revised (adopted MH RS)
02/20/2019 – Reviewed in P&T Meeting
03/18/2020 – Review and Updated P&T Mtg (removed inadequate response to Enbrel AND Humira to match MH) (effective 6/1/20)
11/05/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
01/11/2023 – Reviewed and updated for Jan P&T. Matched MH criteria. Appropriate diagnosis was replaced with a specific indication throughout. Added a noted in all indications to bypass required biologic trials if a provider documents that Cimzia is preferred because the member is pregnant, breastfeeding or planning to become pregnant. Removed clinical rationale for use of Cimzia over Humira or Enbrel for non-axial radiographic axial spondyloarthritis. Added criteria requiring a trial of Avsola, Remicade, Inflectra, or Renflexis for fistulizing Crohn's disease. Effective 3/1/23.
06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB. 06/30/23
12/11/24 – Reviewed and updated for P&T. Formatting updates. Added criteria requesting clinical rationale of vial over prefilled syringe. Effective 1/6/25