Cimzia (certolizumab)
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

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 AllWays Health Partners 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 (RA)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to at least ONE

traditional DMARD (See Appendix B) 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. Dosing is appropriate
4. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Psoriatic Arthritis (PsA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Note: DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs

Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Appropriate dosing (see appendix A)
4. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Moderate to Severe Plaque Psoriasis
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B)
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Contraindication to **ALL** conventional therapies:
        i. topical agents
        ii. phototherapy
        iii. systemic agents
    c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing
4. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Moderate to Severe Crohn's Disease
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Cimzia over Humira

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.

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. The following quantity limits apply:

Cimzia Prefill Syringe Kit	2 kits (4 syringes) per 28 days
Cimzia Starter Kit	6 syringes per 28 days

Appendix A

Dosing	
Cimzia® (certolizumab pegol)	**Crohn's disease:** Initial: 400 mg SQ (as 2 SQ injections of 200 mg) once and then repeat at weeks 2 and 4, then every 4 weeks **Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis (moderate-severe), non-radiographic axial spondyloarthritis (nr-axSpA) & moderate to severe plaque psoriasis (PsO):** Initial: 400 mg SQ (as 2 SQ injections of 200 mg) once and then repeat at weeks 2 and 4 Maintenance: 200 mg SQ once every 2 weeks or 400 mg (as 2 SQ injections of 200 mg) every 4 weeks

Appendix B. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

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

Disclaimer

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