Cimzia (certolizumab)
Effective February 20, 2019

Plan	☒ MassHealth ☐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:

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

Coverage Guidelines

Rheumatoid arthritis (RA), Ankylosing spondylitis (AS), Psoriatic arthritis (PsA)

Authorization may be granted for members when ALL the following criteria are met:

1. Member has a diagnosis of RA or AS/PsA **AND**
2. Prescriber has provided documentation of ONE of the following*:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
3. Dosing is appropriate (see appendix A) **AND**
4. Member has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira

**DMARD trial is not required for members with active Ankylosing spondylitis or Psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs*

Crohn's Disease

Authorization may be granted for members when ALL the following criteria are met:

1. Member has a diagnosis of Crohn's disease **AND**
2. Prescriber has provided documentation of ONE of the following:
    a. Inadequate response, adverse reaction, or contraindication to ALL the following:
        i. Aminosalicylate
        ii. Corticosteroid
        iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
3. Dosing is appropriate (see appendix) **AND**
4. Member has had an inadequate response, adverse reaction, or contraindication to Humira

** If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.*

If the request is for a diagnosis of fistulizing Crohn's disease, an inadequate response, adverse reaction or contraindication to Remicade®(infliximab), Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda) should be documented.

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 indicating a positive response to therapy.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

Appendix

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):** 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

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

11/24/08 – Reviewed
01/05/09 – Effective
02/22/10 – Reviewed
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
02/24/14 – Reviewed and revised
02/23/15 – Reviewed and revised
02/22/16 – Reviewed
02/27/17 – Reviewed and revised (adopted SGM & Step) in P&T Meeting
11/20/17 – Reviewed and revised (adopted MH RS)
02/20/19 – Reviewed in P&T Meeting

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