Cimzia (certolizumab pegol)
Effective January 1, 2020

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

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)

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

2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:

a. Member has experienced an inadequate response or intolerance to ALL preferred products (Enbrel, Humira and Rinvoq).
b. Member has a contraindication to Enbrel, Humira and Rinvoq, and meets one of the following:
    - Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
    - Member has an intolerance or contraindication to methotrexate (see Appendix).

Moderate to severe plaque psoriasis

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

B. Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
    a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid these products.
    b. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    c. Member meets any of the following criteria:
        i. Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
            - 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
            - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
            - 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
            - 2 systemic agents
        ii. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix.
        iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy

Active psoriatic arthritis (PsA)

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

2. Authorization may be granted for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
    a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara).
    b. Member has a contraindication to all of the preferred agents AND meets one of the following:
        - Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
        - Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis (AS) and axial spondyloarthritis

1. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
2. Authorization may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when both of the following criteria is met:
    a. One of the following:
        i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over the past four weeks.
        ii. Member has an intolerance or contraindication to two or more NSAIDs.

    AND

    b. For members with ankylosing spondylitis, member has had a documented inadequate response or intolerable adverse event with ALL of the preferred products: Humira, Enbrel and Cosentyx or member has a documented clinical reason to avoid these products.

Moderately to severely active Crohn's disease (CD)

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

2. Authorization may be granted for treatment of moderately to severely active CD when the member has an inadequate response, intolerance or contraindication to BOTH of the following:
    a. Humira (adalimumab)
    b. At least ONE conventional therapy option (see Appendix B).

Continuation of Therapy

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Cimzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
    a. Note: Members who have received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. 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

Appendices

Appendix A
Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding

3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B
Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
    a. Oral budesonide, oral mesalamine
2. Mild to moderate disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
    a. Prednisone, methylprednisolone intravenously (IV)
    b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission:
    a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission:
    a. Azathioprine, mercaptopurine
    b. Alternative: methotrexate IM

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

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