



**Cimzia (certolizumab pegol)
Effective January 15, 2020**

| | | | |
|------------------------------|---|---------------------|---|
| Plan | <input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> 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)

Authorization may be granted for members new to AllWays Health Partners 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. If requesting under the **Medical Benefit**: the member has experienced an intolerance, inadequate response or contraindication to Remicade and Simponi Aria
3. If requesting under the **Pharmacy Benefit**: the member has experienced intolerance, inadequate response or contraindication Enbrel, Humira and Rinvoq
4. The member meets ONE of the following:
 - a. The 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).
 - b. The member has an intolerance or contraindication to methotrexate (see Appendix).

Moderate to severe plaque psoriasis (PsO)

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.

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. If requesting under the **Medical Benefit**: the member has had intolerance, inadequate response, or contraindication to Ilumya and Remicade
3. If requesting under the **Pharmacy Benefit**: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, Humira, Otezla, Skyrizi, and Stelara
4. 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.
5. Member meets any of the following criteria:
 - a. Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
 - i. 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
 - ii. 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
 - iii. 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
 - iv. 2 systemic agents
 - b. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix.
 - c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy

Active psoriatic arthritis (PsA)

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.

OR

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. If requesting under the **Medical Benefit**: the member has had intolerance, inadequate response, or contraindication to Remicade and Simponi Aria
3. If requesting under the **Pharmacy Benefit**: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, Humira, Otezla, Skyrizi, and Stelara
4. Member meets one of the following:
 - a. Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
 - b. 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/or axial spondyloarthritis

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

OR

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of active ankylosing spondylitis and/or axial spondyloarthritis
 - a. If requesting under the **Medical Benefit**: the member has had intolerance, inadequate response, or contraindication to Remicade and Simponi Aria
 - b. If requesting under the **Pharmacy Benefit**: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, and Humira
2. One of the following:
 - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over the past four weeks.
 - b. Member has an intolerance or contraindication to two or more NSAIDs.

Moderately to severely active Crohn’s disease (CD)

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.

OR

Authorization may be granted when the following criteria are met:

1. The member has a diagnosis of severely active Crohn’s disease (CD)
2. If requesting under the **Medical Benefit**: the member has had intolerance, inadequate response, or contraindication to Entyvio, Remicade and Stelara IV 130mg
3. If requesting under the **Pharmacy Benefit**: the member has had intolerance, inadequate response, or contraindication to Humira and Stelara
4. The member has had intolerance, inadequate response, or contraindication to at least ONE conventional therapy option (see Appendix B)

Continuation of Therapy

Reauthorization may be granted for all 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. Initial approvals and reauthorizations 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
11/01/2020 – Reviewed; Updated for 2021 strategy to be implemented 1/1/2021.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.