Cimzia (certolizumab pegol)
Effective 11/01/2022

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)

Authorization may be granted for members new to the plan 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 Inflectra 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 new to the plan 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 Inflectra
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 new to the plan 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 Inflectra and Simponi Aria
3. If requesting under the ***Pharmacy Benefit***: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, Humira, Otezla, Stelara, Rinvoq, and Skyrizi
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 new to the plan 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 Inflectra and Simponi Aria
    b. If requesting under the ***Pharmacy Benefit***: the member has had intolerance, inadequate response, or contraindication to Cosentyx, Enbrel, Rinvoq, 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 new to the plan 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, Inflectra and Stelara IV 130mg
3. If requesting under the ***Pharmacy Benefit***: the member has had intolerance, inadequate response, or contraindication to Humira, Skyrizi 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

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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.

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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.
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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].
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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.
05/19/2021 – Reviewed and Updated for May P&T; Removed Skyrizi as a previous treatment failure for the diagnosis psoriatic arthritis. Effective 08/01/2021.

03/16/2022 – Reviewed and Updated for March P&T; Added Rinvoq and Skyrizi as preferred trial for PsA under pharmacy benefit. Updated Inflectra as preferred agent for Medical benefit. Effective 05/01/2022
09/21/2022 – Reviewed and Updated for Sept P&T; Added Rinvoq as preferred agent under pharmacy benefit for diagnosis of ankylosing spondylitis, Added Skyrizi as preferred agent under pharmacy benefit for diagnosis of Crohn's Disease. Effective 11/01/2022

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