

**Cimzia (certolizumab)**  
**Effective 06/30/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>			

### 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 the plan 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

**ALL** of the following:

1. Diagnosis of moderate to severe rheumatoid arthritis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **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. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel (e.g., member is pregnant, breastfeeding or planning to become pregnant)

### Psoriatic arthritis (PsA)

**ALL** of the following:

1. Diagnosis of psoriatic arthritis
2. Appropriate dosing
3. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel (e.g., member is pregnant, breastfeeding or planning to become pregnant)

### Ankylosing spondylitis

**ALL** of the following:

1. Diagnosis of ankylosing spondylitis
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. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel (e.g., member is pregnant, breastfeeding or planning to become pregnant)

### Non-radiographic axial spondyloarthritis

**ALL** of the following:

1. Diagnosis of non-radiographic axial spondyloarthritis
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)

### Moderate to severe plaque psoriasis

**ALL** of the following:

1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix B)
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent
  - b. 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. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel (e.g., member is pregnant, breastfeeding or planning to become pregnant)

### Moderate to severe Crohn's disease

**ALL** of the following:

1. Diagnosis of moderate to severe Crohn's disease



2. Appropriate dosing
3. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Cimzia over Humira (e.g., member is pregnant, breastfeeding or planning to become pregnant)
4. **For a diagnosis of fistulizing Crohn’s disease,** an inadequate response, adverse reaction or contraindication to Avsola® (infliximab-axxq), 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 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**

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

**Appendix B. Conventional Therapies for Plaque Psoriasis**

<b>Conventional Treatment Lines</b>	<b>Agents Used</b>
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.



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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.
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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

01/11/2023 – Reviewed and updated for Jan P&T. Matched MH criteria. Appropriate diagnosis was replaced with a specific indication throughout. Added a noted in all indications to bypass required biologic trials if a provider documents that Cimzia is preferred because the member is pregnant, breastfeeding or planning to become pregnant. Removed clinical rationale for use of Cimzia over Humira or Enbrel for non-axial radiographic axial spondyloarthritis. Added criteria requiring a trial of Avsola, Remicade, Inflectra, or Renflexis for fistulizing Crohn’s disease. Effective 3/1/23.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through MB.

06/30/23

