# Cimzia (certolizumab)
**Effective January 1, 2021**

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☑ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☑ Quantity Limit</th>
<th>☐ Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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<tr>
<td>Specialty Limitations</td>
<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy.</td>
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## 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:
- 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 AllWays Health Partners 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 (RA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to at least 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. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Psoriatic Arthritis (PsA)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Note: DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs.

Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
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. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Moderate to Severe Plaque Psoriasis
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to ONE conventional therapy (see appendix B)
      i. topical agent
      ii. phototherapy
      iii. systemic agent
   b. Contraindication to ALL conventional therapies:
      i. topical agents
      ii. phototherapy
      iii. systemic agents
   c. 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. Prescriber provides clinical rationale for use of Cimzia over Humira or Enbrel

Moderate to Severe Crohn’s Disease
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Appropriate dosing
3. Prescriber provides clinical rationale for use of Cimzia over Humira
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:

<table>
<thead>
<tr>
<th>Cimzia Prefill Syringe Kit</th>
<th>2 kits (4 syringes) per 28 days</th>
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<tbody>
<tr>
<td>Cimzia Starter Kit</td>
<td>6 syringes per 28 days</td>
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**Appendix A**

<table>
<thead>
<tr>
<th>Dosing</th>
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| 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), non-radiographic axial spondyloarthritis (nr-axSpA) & moderate to severe plaque psoriasis (PsO):  
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 |

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

<table>
<thead>
<tr>
<th>Conventional Treatment Lines</th>
<th>Agents Used</th>
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<tbody>
<tr>
<td>Topical Agents</td>
<td>emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors</td>
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<tr>
<td>Systemic Agents</td>
<td>Traditional DMARDs: methotrexate, apremilast, acitretin,</td>
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<tr>
<td>Phototherapy</td>
<td>ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)</td>
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**References**
1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; June 2018.


**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)

**Disclaimer**

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

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