### Overview

Cimzia (certolizumab) is a tumor necrosis factor (TNF) blocker indicated for:

1. 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
2. Treatment of adults with moderately to severely active rheumatoid arthritis
3. Treatment of adult patients with active psoriatic arthritis
4. Treatment of adults with active ankylosing spondylitis

### Coverage Guidelines

Rheumatoid arthritis (RA), Ankylosing spondylitis (AS), Psoriatic arthritis (PsA)

Authorization may be granted for members when ALL the following criteria are met:

1. Member has a diagnosis of RA or AS/PsA AND
2. Prescriber has provided documentation of ONE of the following*:
   a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, methotrexate, sulfasalazine)
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

   AND
3. Dosing is appropriate (see appendix A) AND
4. Member has had an inadequate response, adverse reaction, or contraindication to Enbrel AND Humira

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### Cimzia (certolizumab)

**Effective February 20, 2019**

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<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>☒ MassHealth</td>
<td>☒ Prior Authorization</td>
<td>☐ Commercial/Exchange</td>
<td>☐ Quantity Limit</td>
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<tr>
<td>☐ Medical Benefit (NLX)</td>
<td>☐ Step Therapy</td>
<td>☒ Pharmacy Benefit</td>
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**Specialty Limitations**

This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Contact Information**

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
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<tbody>
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<td>All Plans</td>
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<tr>
<th>Non-Specialty Medications</th>
<th>Phone: 877-433-7643</th>
<th>Fax: 866-255-7569</th>
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<tr>
<td>MassHealth</td>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
</tr>
<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<tr>
<th>Medical Specialty Medications (NLX)</th>
<th>Phone: 844-345-2803</th>
<th>Fax: 844-851-0882</th>
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<tr>
<td>All Plans</td>
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**Exceptions**

N/A
*DMARD trial is not required for members with active Ankylosing spondylitis or Psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs

Crohn’s Disease
Authorization may be granted for members when ALL the following criteria are met:
1. Member has a diagnosis of Crohn’s disease AND
2. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to ALL the following:
      i. Aminosalicylate
      ii. Corticosteroid
      iii. Immunomodulator (e.g., azathioprine, 6-mercaptopurine or methotrexate) *
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
   AND
3. Dosing is appropriate (see appendix) AND
4. Member has had an inadequate response, adverse reaction, or contraindication to Humira

* If a request documents severe disease, a trial of an oral immunomodulator may be bypassed.

If the request is for a diagnosis of fistulizing Crohn’s disease, an inadequate response, adverse reaction or contraindication to 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 indicating a positive response to therapy.

Limitations
1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

Appendix

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<tr>
<th>Dosing</th>
<th>Crohn’s disease:</th>
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<tr>
<td>Cimzia® (certolizumab pegol)</td>
<td>Initial: 400 mg SQ (as 2 SQ injections of 200 mg) once and then repeat at weeks 2 and 4, then every 4 weeks</td>
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<tr>
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<td>Ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis (moderate-severe): Initial: 400 mg SQ (as 2 SQ injections of 200 mg) once and then repeat at weeks 2 and 4</td>
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<td>Maintenance: 200 mg SQ once every 2 weeks or 400 mg (as 2 SQ injections of 200 mg) every 4 weeks</td>
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</table>
References

1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; June 2018.

Review History
11/24/08 – Reviewed
01/05/09 – Effective
02/22/10 – Reviewed
02/28/11 – Reviewed
02/27/12 – Reviewed
02/25/13 – Reviewed
02/24/14 – Reviewed and revised
02/23/15 – Reviewed and revised
02/22/16 – Reviewed
02/27/17 – Reviewed and revised (adopted SGM & Step) in P&T Meeting
11/20/17 – Reviewed and revised (adopted MH RS)
02/20/19 – Reviewed in P&T Meeting
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