Cimzia (certolizumab)  
Effective 06/01/20

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<th>☑ MassHealth</th>
<th>☑ Prior Authorization</th>
<th>☑ Pharmacy Benefit</th>
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**Specialty Limitations**
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Contact Information**

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<tr>
<th>Specialty Medications</th>
<th>All Plans</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
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<tr>
<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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**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:
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
5. Treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA)
6. Treatment of adults with moderate to severe plaque psoriasis (PsO)

**Coverage Guidelines**
Rheumatoid arthritis (RA), Ankylosing spondylitis (AS), Psoriatic arthritis (PsA), & non-radiographic axial spondyloarthritis (nr-axSpA)
Authorization may be granted for members when ALL the following criteria are met:
1. Member has a diagnosis of RA or AS/PsA or nr-axSpA
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
3. Dosing is appropriate (see appendix A)
Plaque Psoriasis
1. Member has a diagnosis of PsO
2. Prescriber has provided documentation of ONE of the following*:
   a. Inadequate response, adverse reaction, or contraindication to at least TWO conventional therapies in any one of the following combinations (combinations DO NOT have to be used concurrently):
      i. 1 topical agent + 1 systemic agent
      ii. 1 topical agent + 1 phototherapy (required for diagnosis of guttate psoriasis)
      iii. 1 systemic agent + 1 phototherapy
      iv. 2 systemic agents
   b. Contraindication to ALL conventional therapies
      i. Topical agents
      ii. Phototherapy
      iii. Systemic agents
   c. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis
3. Dosing is appropriate (see appendix A)

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
2. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response, adverse reaction, or contraindication to ALL the following:
      iv. Aminosalicylate
      v. Corticosteroid
      vi. 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
3. Dosing is appropriate (see appendix A)
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 A**

| Dosing | **Crohn’s disease:**<br>Initial: 400 mg SQ (as 2 SQ injections of 200 mg) once and then repeat at weeks 2 and 4, then every 4 weeks<br>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<br>Maintenance: 200 mg SQ once every 2 weeks or 400 mg (as 2 SQ injections of 200 mg) every 4 weeks |
| Cimzia® (certolizumab pegol) | |

**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
02/23/2014 – 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
03/17/2020 – Review and Updated P&T Mtg (removed inadequate response to Enbrel AND Humira to match MH) (effective 6/1/20)

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