Cimzia (certolizumab pegol)
Effective January 1, 2020

Plan Benefits
☐ 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

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)
1. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:

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

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
a. Member has experienced an inadequate response or intolerance to ALL preferred products (Enbrel, Humira and Rinvoq).
b. Member has a contraindication to Enbrel, Humira and Rinvoq, and meets one of the following:
   • 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).
   • Member has an intolerance or contraindication to methotrexate (see Appendix).

**Moderate to severe plaque psoriasis**
A. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

B. Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
   a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid these products.
   b. 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.
   c. Member meets any of the following criteria:
      i. Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
         o 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
         o 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
         o 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
         o 2 systemic agents
      ii. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy and systemic agents). See Appendix.
      iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy

**Active psoriatic arthritis (PsA)**
1. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

2. Authorization may be granted for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
   a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara).
   b. Member has a contraindication to all of the preferred agents AND meets one of the following:
      o Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
      o 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 axial spondyloarthritis**
1. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
2. Authorization may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when both of the following criteria is met:
   a. One of the following:
      i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over the past four weeks.
      ii. Member has an intolerance or contraindication to two or more NSAIDs.
   AND
   b. For members with ankylosing spondylitis, member has had a documented inadequate response or intolerable adverse event with ALL of the preferred products: Humira, Enbrel and Cosentyx or member has a documented clinical reason to avoid these products.

Moderately to severely active Crohn's disease (CD)
1. Authorization may be granted for members who are currently receiving treatment with Cimzia, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
2. Authorization may be granted for treatment of moderately to severely active CD when the member has an inadequate response, intolerance or contraindication to BOTH of the following:
   a. Humira (adalimumab)
   b. At least ONE conventional therapy option (see Appendix B).

Continuation of Therapy
Reauthorization may be granted for all members (including new 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. Approvals 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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cimzia Starter Kit</td>
<td>2 Kits (4 syringes) per 28 days</td>
</tr>
<tr>
<td>Cimzia Prefilled Kit 200mg/ml</td>
<td>3 kits (6 syringes) per 28 days</td>
</tr>
</tbody>
</table>

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
1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; April 2019.

**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 Rinoq as a trial for RA and Skyrizi for PS

**Disclaimer**
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.