Policy Title:	Cimzia (certolizumab pegol)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	09/18/2019, 12/11/2019		
Revision Date:	09/18/2019, 12/11/2019		

Purpose: To support safe, effective and appropriate use of Cimzia (certolizumab pegol)

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Cimzia (certolizumab pegol) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Cimzia (certolizumab pegol) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- 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); AND

Moderately to severely active rheumatoid arthritis (RA)

- Authorization may be granted for members who have previously received Cimzia or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis and dose is within FDA guidelines; OR
- Authorization may be granted for treatment of moderately to severely active RA and dose is within FDA guidelines when any of the following criteria is met:
    - 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); OR
    - Member has an intolerance or contraindication to methotrexate (see Appendix A).

Active psoriatic arthritis (PsA)

- Authorization may be granted for treatment of active psoriatic arthritis (PsA) and dose is within FDA guidelines

Active ankylosing spondylitis (AS) and axial spondyloarthritis

- Authorization may be granted for members who have previously received Cimzia or any other biologic DMARD indicated for active ankylosing spondylitis and dose is within FDA guidelines; OR
- Authorization may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when dose is within FDA guidelines and any of the following criteria is met:
    - Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs); OR
    - Member has an intolerance or contraindication to two or more NSAIDs

Moderately to severely active Crohn's disease (CD)

- Authorization may be granted for members who have previously received Cimzia or any other biologic indicated for the treatment of Crohn's disease and dose is within FDA guidelines; OR
- Authorization may be granted for treatment of moderately to severely active CD when the member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B) and dose is within FDA guidelines

Moderate to severe plaque psoriasis (PsO)

- Authorization may be granted for members who have previously received Cimzia, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis and dose is within FDA guidelines; OR
- Authorization may be granted for treatment of moderate to severe plaque psoriasis when the dose is within FDA guidelines and all of the following criteria are met:
    - At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; AND
    - Member meets any of the following criteria:
        - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or a pharmacologic treatment with methotrexate, cyclosporine or acitretin; OR
        - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix C); OR
        - Member has severe psoriasis that warrants a biologic DMARD as first-line therapy

Continuation of Therapy Criteria:

- Authorization of 6 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response within FDA dosing guidelines after at least 3 months of therapy with Cimzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Coverage durations:

- Initial coverage: 6 months

- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dosing	Maximum Dosing (1 billable unit = 1 mg)
Rheumatoid Arthritis	Loading: 400 mg, subcutaneously, at weeks 0, 2 and 4; then Maintenance: 200 mg subcutaneously, every other week, thereafter (or 400 mg every 4 weeks)	Loading Dose: 400 billable units on weeks 0, 2 and 4 Maintenance Dose: 400 billable units every 4 weeks
Crohn's Disease	Loading: 400 mg, subcutaneously, at weeks 0, 2 and 4; then Maintenance: 400 mg, subcutaneously, every 4 weeks, thereafter	Loading Dose: 400 billable units on weeks 0, 2 and 4 Maintenance Dose: 400 billable units every 4 weeks
Psoriatic Arthritis	Loading: 400 mg, subcutaneously, at weeks 0, 2 and 4; then Maintenance: 200 mg, subcutaneously, every other week, thereafter (or 400 mg every 4 weeks)	Loading Dose: 400 billable units on weeks 0, 2 and 4 Maintenance Dose: 400 billable units every 4 weeks
Plaque Psoriasis	400 mg (given as 2 subcutaneous injections of 200 mg each) every other week Optional alternate dosing for patients with body weight ≤ 90 kg Loading: 400 mg (given as 2 subcutaneous injections of 200 mg each) at Weeks 0, 2 and 4 Maintenance: 200 mg every other week thereafter	400 billable units every other week
Ankylosing Spondylitis	Loading: 400 mg, subcutaneously, at weeks 0, 2 and 4; then Maintenance 200 mg, subcutaneously, every other week, thereafter (or 400 mg every 4 weeks	Loading Dose: 400 billable units on weeks 0, 2 and 4 Maintenance Dose: 400 billable units every 4 weeks

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
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
   b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
   a. Prednisone, methylprednisolone intravenously (IV)
   b. Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
   a. Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: methotrexate IM or SC

Appendix C: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J0717	Injection, certolizumab pegol, 1 mg

References:

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12. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2015: 10.1002/art.39298. [Epub ahead of print].
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