Clinical Policy: Certolizumab (Cimzia)

Reference Number: PA.CP.PHAR.247
Effective Date: 01/18
Last Review Date: 08/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Certolizumab (Cimzia®) is a tumor necrosis factor (TNF) blocker.

FDA Approved Indication(s)
Cimzia is indicated for:

- Reducing signs and symptoms of Crohn's disease (CD) 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 (RA).
- Treatment of adult patients with active psoriatic arthritis (PsA).
- Treatment of adults with active ankylosing spondylitis (AS).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Cimzia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Crohn's Disease (must meet all)**:**

1. Diagnosis of CD and (a or b):
   a. Member is identified as moderate/high risk based on one of the following:
      i. Age at initial diagnosis < 30 years;
      ii. Extensive anatomic involvement (e.g., ileocecal disease, continuous ileocolonic disease, small bowel disease);
      iii. Perianal and/or severe rectal disease;
      iv. Deep ulcers;
      v. Prior surgical resection;
      vi. Stricturing and/or penetrating disease;
   b. Member has failed both of the following, unless contraindicated or clinically significant adverse effects are experienced (i and ii):
      i. An immunomodulator (e.g., azathioprine, mercaptopurine, methotrexate (MTX) used for ≥ 3 months;
      ii. Adalimumab *(Humira is preferred)* used for ≥ 3 consecutive months;
      **Prior authorization is required for adalimumab*
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 18 years;

4. Tuberculosis (TB) test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
5. Dose does not exceed 400 mg subcutaneously at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

B. Rheumatoid Arthritis (must meet all)**:**

1. Diagnosis of RA per American College of Rheumatology (ACR) criteria (refer to *Appendix B*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Failure of MTX for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
   b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or hydroxychloroquine for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred),* each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed 400 mg subcutaneously at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

C. Psoriatic Arthritis(must meet all)**:**

1. Diagnosis of active PsA
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. For Axial Disease
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs or
      ii. A documented contraindication or intolerance to NSAIDs
   b. For Peripheral Disease:
      i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs AND
      ii. A documented history of therapeutic failure of a three (3) or more month trial of methotrexate OR an alternate DEMARD OR
      iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate DMARD.

5. IFailure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed 400 mg subcutaneously at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

D. Ankylosing Spondylitis (must meet all)**:**

1. Diagnosis of active AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effect are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. TB test within the past 12 months is negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed 400 mg subcutaneously at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed 400 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACPA: anti-citrullinated protein antibody
AS: ankylosing spondylitis
CRP: serum C-reactive protein
DMARD: disease modifying antirheumatic drug
ESR: erythrocyte sedimentation rate
FDA: Food and Drug Administration
MTX: methotrexate
NSAID: non-steroidal anti-inflammatory drug
PsA: psoriatic arthritis
RA: rheumatoid arthritis
TB: tuberculosis
TNF: tumor necrosis factor

Appendix B: The 2010 ACR Classification Criteria for RA

Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

A	**Joint involvement**	Score
	1 large joint	0
	2-10 large joints	1
	1-3 small joints (with or without involvement of large joints)	2
	4-10 small joints (with or without involvement of large joints)	3
	> 10 joints (at least one small joint)	5
B	**Serology (at least one test result is needed for classification)**	
	Negative rheumatoid factor (RF) *and* negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF *or* low positive ACPA. * *Low: < 3 x upper limit of normal*	2
	High positive RF *or* high positive ACPA. * *High: ≥ 3 x upper limit of normal*	3
C	**Acute phase reactants (at least one test result is needed for classification)**	
	Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR)	0
	Abnormal CRP or normal ESR	1
D	**Duration of symptoms**	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix C: Definition of MTX or Disease modifying antirheumatic drug (DMARD) Failure

In RA, failure of MTX or DMARD is defined as ≤ 50% decrease in swollen joint count,

≤ 50% decrease in tender joint count, and ≤ 50% decrease in ESR, or ≤ 50% decrease in CRP.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	• 400 mg at 0, 2, and 4 weeks, then 400 mg every 4 weeks thereafter.	400 mg every 4 weeks
PsA, RA, AS	• 400 mg at 0, 2, and 4 weeks, then 200 mg every other week • Alternative maintenance dosing: 400 mg every 4 weeks	200 mg every other week or 400 mg every 4 weeks

VI. Product Availability

For Injection: 200 mg lyophilized powder for reconstitution in a single-use vial, with 1 mL of sterile water for injection
Injection: 200 mg/mL solution in a single-use prefilled syringe

VII. References

1. Cimzia Prescribing Information. Smyrna, GA: UCB, Inc.; January2017. Available at http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf. Accessed August 07, 2017.
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3. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. Ann Rheum Dis. 2014; 73: 492-509.
4. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res. 2012; 64(5): 625-639.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011; 65(1):137-174.
6. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58(5):826-850.
7. Ward MM, 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 & Rheumatology, 2015. DOI 10.1002/ART.39298.
8. Braun J, van den berg R, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Am Rheu Dis. 2011: 70; 896- 904.

9. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705.
10. Singh JA. Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care and Research. 2015; 1-25. DOI 10.1002/acr.22783
11. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative, Arthritis Rheum , 2010, vol. 62 (pg. 2569 - 81).

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

Reviews, Revisions, and Approvals	Date	Approval Date