

Clinical Policy: Certolizumab (Cimzia)

Reference Number: IL.PHAR.247

Effective Date: 1.1.20

Last Review Date: 3.4.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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)
- Treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] 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;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Medical justification supports inability to use immunomodulators (*see Appendix D*);

5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 400 mg 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 (*see Appendix E*);
2. Prescribed by or in consultation with a rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Documentation of one of the following baseline assessment scores (a or b):
 - a. Clinical disease activity index (CDAI) score (*see Appendix F*);
 - b. Routine assessment of patient index data 3 (RAPID3) score (*see Appendix G*);
7. Dose does not exceed 400 mg 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 PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

D. Axial Spondylitis (must meet all):

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;

3. Age \geq 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for \geq 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 6 months

E. Plaque Psoriasis (must meet all):

1. Diagnosis of PsO;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of cyclosporine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed 400 mg every 2 weeks.

Approval duration: 6 months

F. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.
;
3. Member meets one of the following (a or b):
 - a. For RA: member is responding positively to therapy as evidenced by one of the following (i or ii):
 - i. A decrease in CDAI (*see Appendix F*) or RAPID3 (*see Appendix G*) score from baseline;
 - ii. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
 - b. For all other indications: member is responding positively to therapy;
4. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
5. If request is for a dose increase, new dose does not exceed:
 - c. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks;
 - d. For PsO: 400 mg every 2 weeks.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.
- B.** Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia[®], Enbrel[®], Humira[®] and its biosimilars, Simponi[®], Avsola[™], Inflectra[™], Remicade[®], Renflexis[™]], interleukin agents [e.g., Arcalyst[®] (IL-1 blocker), Ilaris[®] (IL-1 blocker), Kineret[®] (IL-1RA), Actemra[®] (IL-6RA), Kevzara[®] (IL-6RA), Stelara[®] (IL-12/23 inhibitor), Cosentyx[®] (IL-17A inhibitor), Taltz[®] (IL-17A inhibitor), Siliq[™] (IL-17RA), Ilumya[™] (IL-23 inhibitor), Skyrizi[™] (IL-23 inhibitor), Tremfya[®] (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz[®]/Xeljanz[®] XR, Cibinqo[™], Olumiant[™], Rinvoq[™]], anti-CD20 monoclonal antibodies [Rituxan[®], Riabni[™], Ruxience[™], Truxima[®], Rituxan Hycela[®]], selective co-stimulation modulators [Orencia[®]], and integrin receptor antagonists [Entyvio[®]] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

- | | |
|---|--|
| 6-MP: 6-mercaptopurine | MTX: methotrexate |
| AS: ankylosing spondylitis | nr-axSpA: non-radiographic axial spondyloarthritis |
| CD: Crohn’s disease | NSAID: non-steroidal anti-inflammatory drug |
| CDAI: clinical disease activity index | PsA: psoriatic arthritis |
| DMARD: disease-modifying antirheumatic drug | PsO: plaque psoriasis |
| FDA: Food and Drug Administration | RA: rheumatoid arthritis |
| JAKi: Janus kinase inhibitors | RAPID3: routine assessment of patient index 3 |
| | TNF: tumor necrosis factor |

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine (Azasan [®] , Imuran [®])	RA 1 mg/kg/day PO QD or divided BID CD* 1.5 – 2 mg/kg/day PO	2.5 mg/kg/day
corticosteroids	CD*	Various

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>prednisone 40 mg – 60 mg PO QD for 1 to 2 weeks, then taper daily dose by 5 mg weekly until 20 mg PO QD, and then continue with 2.5 – 5 mg decrements weekly or IV 50 – 100 mg Q6H for 1 week</p> <p>budesonide (Entocort EC®) 6 – 9 mg PO QD</p>	
Cuprimine® (d-penicillamine)	<p>RA* <u>Initial dose:</u> 125 or 250 mg PO QD <u>Maintenance dose:</u> 500 – 750 mg/day PO QD</p>	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	<p>RA, PsO 2.5 – 4 mg/kg/day PO divided BID</p>	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	<p>RA* <u>Initial dose:</u> 400 – 600 mg/day PO QD <u>Maintenance dose:</u> 200 – 400 mg/day PO QD</p>	600 mg/day
leflunomide (Arava®)	<p>RA 100 mg PO QD for 3 days, then 20 mg PO QD</p>	20 mg/day
6-mercaptopurine (Purixan®)	<p>CD* 50 mg PO QD or 0.75 – 1.5 mg/kg/day PO</p>	2 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Rheumatrex®, Jylamvo®, Rheumatrex®)	<p>CD* 15 – 25 mg/week IM or SC</p> <p>RA 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week</p> <p>PsO 10 to 25 mg/week, IM, IV or PO or 2.5 mg PO Q12 hr for 3 doses/week</p>	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	<p>AS, nr-axSpA Varies</p>	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Pentasa [®] (mesalamine)	CD 1,000 mg PO QID	4 g/day
Ridaura [®] (auranofin)	RA 6 mg PO QD or 3 mg PO BID	9 mg/day (3 mg TID)
sulfasalazine (Azulfidine [®])	RA 2 g/day PO in divided doses	3 g/day
tacrolimus (Prograf [®])	CD* 0.27 mg/kg/day PO in divided doses or 0.15 – 0.29 mg/kg/day PO	N/A
Enbrel [®] (etanercept)	AS 50 mg SC once weekly PsA, RA 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira [®] (adalimumab)	AS, PsA, PsO 40 mg SC every other week CD <u>Initial dose:</u> 160 mg SC on Day 1, then 80 mg SC on Day 15 <u>Maintenance dose:</u> 40 mg SC every other week starting on Day 29 RA 40 mg SC every other week (may increase to once weekly)	AS, PsA, CD, PsO: 40 mg every other week RA: 40 mg/week
Xeljanz [®] (tofacitinib)	PsA, RA 5 mg PO BID	10 mg/day
Xeljanz XR [®] (tofacitinib extended-release)	PsA, RA 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):

- There is an increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
- Lymphoma and other malignancies have been observed.
- Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed.

Appendix D: General Information

- Definition of failure of MTX or DMARDs
 - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
 - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
 - Reduction in joint pain/swelling/tenderness
 - Improvement in ESR/CRP levels
 - Improvements in activities of daily living
- Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti-TNF agent. A two year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- The following may be considered for medical justification supporting inability to use an immunomodulator for Crohn's disease:
 - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
 - High-risk factors for intestinal complications may include:
 - Initial extensive ileal, ileocolonic, or proximal GI involvement
 - Initial extensive perianal/severe rectal disease
 - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
 - Deep ulcerations
 - Penetrating, stricturing or stenosis disease and/or phenotype
 - Intestinal obstruction or abscess
 - High risk factors for postoperative recurrence may include:
 - Less than 10 years duration between time of diagnosis and surgery
 - Disease location in the ileum and colon
 - Perianal fistula
 - Prior history of surgical resection
 - Use of corticosteroids prior to surgery
- According to the CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study (n = 17), there were no or minimal certolizumab pegol transfer from the maternal plasma to breast milk, with a relative infant dose of 0.15% of the maternal dose.
- TNF blockers:

Etanercept (Enbrel®), adalimumab (Humira®), adalimumab-atto (Amjevita™), infliximab (Remicade®) and infliximab biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

Appendix E: 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) <i>and</i> negative anti-citrullinated protein antibody (ACPA)	0
	Low positive RF <i>or</i> low positive ACPA <i>* Low: < 3 x upper limit of normal</i>	2
	High positive RF <i>or</i> high positive ACPA <i>* High: ≥ 3 x upper limit of normal</i>	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 abnormal ESR	1
D	Duration of symptoms	
	< 6 weeks	0
	≥ 6 weeks	1

Appendix F: Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

CDAI Score	Disease state interpretation
≤ 2.8	Remission
2.8 to ≤ 10	Low disease activity
10 to ≤ 22	Moderate disease activity
> 22	High disease activity

Appendix G: Routine Assessment of Patient Index Data 3 (RAPID3) Score

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

RAPID3 Score	Disease state interpretation
≤ 3	Remission
3.1 to 6	Low disease activity
6.1 to 12	Moderate disease activity
> 12	High disease activity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	<u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 400 mg SC every 4 weeks	400 mg every 4 weeks
RA, PsA, AS, nr-axSpA	<u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
PsO	400 mg SC every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg SC at 0, 2 and 4 weeks, followed by 200 mg SC every other week may be considered.	400 mg every other week

VI. Product Availability

- Single-use vial: 200 mg
- Single-use prefilled syringe: 200 mg/mL

VII. References

1. Cimzia Prescribing Information. Smyrna, GA: UCB, Inc.; December 2022. Available at http://www.cimzia.com/assets/pdf/Prescribing_Information.pdf. Accessed January 10, 2023.
2. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018; 113:481-517.
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. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;76:978-991. doi:10.1136/annrheumdis-2016-210770.
9. 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.
10. Sandborn WJ. Crohn’s Disease Evaluation and Treatment: Clinical Decision Tool. *Gastroenterology* 2014; 147: 702-705.
11. 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.
12. Clowse MEB, Forger F, Hwang C, et al. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicenter, pharmacokinetic study. *Ann Rheum Dis* 2017;76:1980-1896. doi:10.1136/annrheumdis-2017-211384.
13. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *American College of Rheumatology.* 2019; 71(1):5-32. doi: 10.1002/art.40726.
14. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023 Jan;82(1):19-34. doi: 10.1136/ard-2022-223296.

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	P&T Approval Date
New policy created, adapted CP.PHAR.247 Certolizumab (Cimzia) policy.	12.11.19	1.7.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review. For RA, added specific diagnostic criteria for definite RA, baseline CDAI score requirement, and decrease in CDAI score as positive response to therapy; references reviewed and updated. Added criteria for RAPID3 assessment for RA given limited in-person visits during COVID-19 pandemic, updated appendices.	4.12.2021	
2Q 2022 annual review: references reviewed	4.27.2022	
2Q 2023 annual review: for PsA and RA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; Template changes applied to other diagnoses/indications and continued therapy section; ; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; updated appendix A; references reviewed and updated.	4.19.23	
2Q 2024 Annual review: PsA and RA t/f criteria removed. References reviewed	3.4.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.