Clinical Policy: Certolizumab (Cimzia)

Reference Number: IN.PHAR.247
Effective Date: 08.16
Last Review Date: 08.21
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. Axial Spondylitis (must meet all)**:**

1. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 12 months

B. Crohn's Disease (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Failure of a ≥ 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*);
2. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 12 months

C. Plaque Psoriasis (must meet all)**:**
1. Diagnosis of moderate-to-severe PsO
2. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of a ≥ 3 consecutive month trial of Taltz®, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Taltz*
4. Dose does not exceed 400 mg every 2 weeks.

Approval duration: 12 months

D. Psoriatic Arthritis (must meet all)**:**
Diagnosis of Psoriatic Arthritis
1. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 12 months

E. Rheumatoid Arthritis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 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;
2. Failure of at least TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Enbrel®, Kevzara®, Xeljanz®/Xeljanz XR®;
   **Prior authorization may be required for Enbrel, Kevzara, and Xeljanz/Xeljanz XR*

3. Dose does not exceed 400 mg at weeks 0, 2, and 4, followed by maintenance dose of 400 mg every 4 weeks.

Approval duration: 12 months

F. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Histoy of utilization of Cimzia for 90 days.
2. If request is for a dose increase, new dose does not exceed:
   a. For CD, RA, PsA, AS, nr-axSpA: 400 mg every 4 weeks;
   b. For PsO: 400 mg every 2 weeks.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

6-MP: 6-mercaptopurine
AS: ankylosing spondylitis
CD: Crohn's disease
CDAI: clinical disease activity index
DMARD: disease-modifying antirheumatic drug
FDA: Food and Drug Administration
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
NSAID: non-steroidal anti-inflammatory drug
PsA: psoriatic arthritis
PsO: plaque psoriasis
RA: rheumatoid arthritis
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
acitretin (Soriatane®)	**PsO** 25 or 50 mg PO QD	50 mg/day

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*** prednisone 40 mg PO QD for 2 weeks or IV 50 – 100 mg Q6H for 1 week budesonide (Entocort EC®) 6 – 9 mg PO QD	Various
Cuprimine® (d-penicillamine)	**RA*** Initial dose: 125 or 250 mg PO QD Maintenance dose: 500 – 750 mg/day PO QD	1,500 mg/day
cyclosporine (Sandimmune®, Neoral®)	**RA, PsO** 2.5 – 4 mg/kg/day PO divided BID	4 mg/kg/day
hydroxychloroquine (Plaquenil®)	**RA*** Initial dose: 400 – 600 mg/day PO QD Maintenance dose: 200 – 400 mg/day PO QD	600 mg/day
leflunomide (Arava®)	**RA** 100 mg PO QD for 3 days, then 20 mg PO QD	20 mg/day
6-mercaptopurine (Purixan®)	**CD*** 50 mg PO QD or 1 – 2 mg/kg/day PO	2 mg/kg/day
methotrexate (Rheumatrex®)	**CD*** 15 – 25 mg/week IM or SC **RA** 7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week **PsO** 10 to 25 mg/week, IM, IV or PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA** Varies	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)	**PsA, RA** 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Kevzara® (sarilumab)	**RA** 200 mg SC once every two weeks	**200 mg/2 weeks**
Otezla® (apremilast)	**PsA** Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID	60 mg/day
Simponi® (golimumab)	**PsA** 50 mg SC once monthly	50 mg/month
Simponi Aria® (golimumab)	**PsA** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg IV every 8 weeks	2 mg/kg every 8 weeks
Taltz® (ixekizumab)	**PsA** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks **PsO** Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12	80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Maintenance dose: 80 mg SC every 4 weeks	
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.
  - Cimzia should be discontinued if a patient develops a serious infection or sepsis.
  - Perform test for latent TB; if positive, start treatment for TB prior to starting Cimzia
  - Monitor all patients for active TB during treatment, even if initial latent TB test is negative
  - 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
- 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.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CD	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 400 mg SC every 4 weeks	400 mg every 4 weeks
RA, PsA, AS, nr-axSpA	Initial dose: 400 mg SC at 0, 2, and 4 weeks Maintenance dose: 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

V. Product Availability

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

VI. References

1. Cimzia Prescribing Information. Smyrna, GA: UCB, Inc.; September 2019. Available at: https://www.cimzia.com/. Accessed January 11, 2021.
2. 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.

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
Created for IN Medicaid PA Alignment	08.21	OMPP approved

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.