# Drug Coverage Policy

**Effective Date……..05/01/2026**
**Coverage Policy Number……IP0672**
**Policy Title…Cimzia Prior Authorization Policy**

# Inflammatory Conditions – Cimzia Prior Authorization Policy

- Cimzia® (certolizumab pegol subcutaneous injection [lyophilized powder or solution] – UCB)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## OVERVIEW

Cimzia, a tumor necrosis factor inhibitor (TNFi), is indicated for the following uses:[1]

- **Ankylosing spondylitis**, in adults with active disease.
- **Crohn's disease**, for reducing signs and symptoms and maintaining clinical responses in adults with moderate to severe active disease who have had an inadequate response to conventional therapy.
- **Juvenile idiopathic arthritis (JIA)**, for treatment of active polyarticular disease in patients ≥ 2 years of age.
- **Non-radiographic axial spondyloarthritis**, in adults with objective signs of inflammation.
- **Plaque psoriasis**, in adults with moderately to severely active disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease.
- **Rheumatoid arthritis**, in adults with moderately to severely active disease.

Cimzia may be used as monotherapy or in combination with conventional synthetic disease-modifying antirheumatic drugs (DMARDs).

### Dosing Information

Approved induction dosing is 400 mg given subcutaneously at Weeks 0, 2, and 4. For psoriasis, maintenance dosing is 400 mg given every 2 weeks. In JIA, a weight-based dose is given every 2 weeks. For other indications, maintenance dosing is generally given as 400 mg subcutaneously per 28-day period. This dose may be administered as a single 200 mg injection given once every 2 weeks or as two 200 mg doses (400 mg dose) given once every 4 weeks. Of note, if a patient who has rheumatoid arthritis is in remission, guidelines from the American College of Rheumatology (ACR) [2021] mention tapering (reducing the dose or dosing frequency) as an option for patients with rheumatoid arthritis who have been at target (low disease activity or remission) for at least 6 months prior to tapering.[6]

### Guidelines

TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- **Axial Spondyloarthritis and Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] TNFis are recommended for the initial biologic. In those who are secondary nonresponders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] and the American Gastroenterological Association (AGA) [2025] have guidelines for the management of CD in adults.[3,7] Both guidelines recommend upfront use of advanced therapies, rather than step-up therapy after failure of corticosteroids and/or immunomodulators. Advanced therapies recommended include TNF inhibitors, Entyvio® (vedolizumab IV infusion, SC injection), interleukin (IL)-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib extended-release tablets).
- **JIA:** There are guidelines from ACR and the Arthritis Foundation for the treatment of JIA (2021) which address oligoarthritis and temporomandibular joint (TMJ) arthritis.[8] For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD. In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids are recommended first-line. A biologic is a therapeutic option if there is an inadequate response or intolerance. Additionally, rapid escalation to a biologic ± conventional synthetic DMARD (methotrexate preferred) is often appropriate given the impact and destructive nature of TMJ arthritis. In these guidelines, there is not a preferred biologic that should be initiated for JIA. There are also guidelines from the ACR/Arthritis Foundation for the treatment of JIA (2019) specific to juvenile non-

systemic polyarthritis, sacroiliitis, and enthesitis.[9] TNFis are the biologics recommended for polyarthritis, sacroiliitis, and enthesitis. Biologics are recommended following other therapies (e.g., following DMARDs for active polyarthritis or following an NSAID for active JIA with sacroiliitis or enthesitis). However, there are situations where initial therapy with a biologic may be preferred over other conventional therapies (e.g., if there is involvement of high-risk joints such as the cervical spine, wrist, or hip; high disease activity; and/or those judged to be at high risk of disabling joint damage). TNFis may also be used as second- or third-line treatment for systemic JIA.[10]

- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatologists and National Psoriasis Foundation (2019) recommend TNFis as a monotherapy treatment option for adults with moderate to severe disease.[4] Based on extrapolation of data, Cimzia is likely to have class characteristics similar to the other TNFis.
- **Psoriatic Arthritis:** Guidelines from ACR (2018) generally recommend treatment with a TNFi over other therapies as initial treatment for patients who are treatment-naïve.[5]
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.[6]

## Coverage Policy

**POLICY STATEMENT**

Prior Authorization is required for benefit coverage of Cimzia. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of a patient treated with Cimzia as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cimzia to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**NOTE: This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Employer Plans: Standard/Performance, Value/Advantage, Total Savings Drug Lists (PSM001), Legacy Drug Lists (PSM017), or Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.**

**Cimzia is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, 7, or 8):**

**FDA-Approved Indications**

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR
   - **B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

**ii.** Patient meets at least ONE of the following (a or b):

**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

**Dosing.** Approve ONE of the following regimens (A, B, or C):

**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

---

**2. Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** The medication is prescribed by or in consultation with a gastroenterologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):

**i.** Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

**ii.** Patient meets at least ONE of the following (a or b):

**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.

**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

**Dosing.** Approve ONE of the following regimens (A, B, or C):

**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

---

**3. Juvenile Idiopathic Arthritis (JIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient is ≥ 2 years of age; AND
- **ii.** Patient meets ONE of the following conditions (a, b, c, or d):
  - **a)** Patient has tried one other systemic medication for this condition; OR
    Note: Examples of other systemic therapy for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.
  - **b)** Patient will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; OR
  - **c)** Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
    Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.
  - **d)** Patient has aggressive disease, as determined by the prescriber; AND
- **iii.** The medication is prescribed by or in consultation with a rheumatologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on therapy for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cimzia is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least ONE of the following (a or b):
  - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cimzia); OR
    Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
  - **b)** Compared with baseline (prior to initiating Cimzia), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

**Dosing.** Approve ONE of the following regimens (A, B, or C):
**A)** Patient weighs 10 kg to < 20 kg: 100 mg initially and at Week 2 and Week 4, then 50 mg once every 2 weeks; OR

**B)** Patient weighs 20 kg to < 40 kg: 200 mg initially and at Week 2 and Week 4, then 100 mg every 2 weeks; OR
**C)** Patient weighs ≥ 40 kg: 400 mg initially and at Week 2 and Week 4, then 200 mg once every 2 weeks.

---

**4. Non-Radiographic Axial Spondyloarthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
**i.** Patient is ≥ 18 years of age; AND
**ii.** Patient has objective signs of inflammation, defined as at least ONE of the following (a or b):
**a)** C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
**b)** Sacroiliitis reported on magnetic resonance imaging (MRI); AND
**iii.** The medication is prescribed by or in consultation with a rheumatologist; OR
**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
**i.** Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
**ii.** Patient meets at least ONE of the following (a or b):
**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

**Dosing.** Approve ONE of the following regimens (A, B, or C):
**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
**i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
**ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR
**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

---

**5. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
**A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
**i.** Patient is ≥ 18 years of age; AND
**ii.** Patient meets ONE of the following conditions (a or b):

**a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, or acitretin tablets. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (other than the requested drug), Otezla/Otezla XR (apremilast tablets/extended-release tablets), or Sotyktu (deucravacitinib tablets). A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis, Otezla/Otezla XR, or Sotyktu is not required to "step back" and try a traditional systemic agent for psoriasis.

**b)** According to the prescriber, the patient has a contraindication to methotrexate; AND

**iii.** The medication is prescribed by or in consultation with a dermatologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

**i.** Patient has been established on the requested drug for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

**ii.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area affected by psoriasis, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

**iii.** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

**Dosing.** Approve ONE of the following (A or B):

**A)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

---

**6. Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

a. Patient is ≥ 18 years of age; AND
b. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):

**i.** Patient has been established on the requested drug for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).

**ii.** Patient meets at least ONE of the following (a or b):

**a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA),

Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

**b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

**Dosing.** Approve ONE of the following regimens (A, B, or C):

**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

---

**7. Rheumatoid Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):

**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND
  Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial of at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on the requested drug for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least ONE of the following (a or b):
  - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
  - **b)** Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

**Dosing.** Approve ONE of the following regimens (A, B, or C):

**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

**Other Uses with Supportive Evidence**

---

**8. Spondyloarthritis, Other Subtypes.** Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Examples of other subtypes of spondyloarthritis include undifferentiated arthritis and reactive arthritis (Reiter's disease). For ankylosing spondylitis, psoriatic arthritis, or non-radiographic axial spondyloarthritis, refer to the respective criteria under FDA-approved indications.

**A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
- **iii.** Patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); AND
  Note: Examples include methotrexate, leflunomide, and sulfasalazine.
- **iv.** The medication is prescribed by or in consultation with a rheumatologist; OR

**B)** Patient is Currently Receiving Cimzia. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on the requested drug for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
- **ii.** Patients meets at least ONE of the following (a or b):
  - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
    Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
  - **b)** Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

**Dosing.** Approve ONE of the following regimens (A, B, or C):

**A)** For Initial Therapy, approve 400 mg as a subcutaneous injection followed by additional similar doses at 2 and 4 weeks after the first injection, then ONE of the following (i or ii):
- **i.** 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR
- **ii.** 200 mg administered subcutaneously not more frequently than once every 2 weeks; OR

**B)** For Initial or Continuation, approve 400 mg administered subcutaneously not more frequently than once every 4 weeks; OR

**C)** For Initial or Continuation, approve 200 mg administered subcutaneously not more frequently than once every 2 weeks.

**Conditions Not Covered**

**Cimzia for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

## Coding Information

**Note:** 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

| 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) |

## References


1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; September 2025.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
3. Lichtenstein G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2025 June;120(6):1225-1264.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123.
7. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.
8. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis,

temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
9. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
10. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013;65(10):2499-2512.

## Revision Details

| Summary of Changes | Effective Date | Review Date |
|---|---|---|
| New policy | 09/12/2024 | 11/01/2024 |
| Juvenile Idiopathic Arthritis: This newly approved condition was added to the policy. | 11/25/2024 | 01/01/2025 |
| No criteria changes<br><br>**Updated HCPCS Coding**<br>**Added** HCPCS J0717 | 04/03/2025 | 05/01/2025 |
| **Plaque Psoriasis:** For initial therapy, in the Note, a 3-month trial or prior intolerance to Otezla/Otezla XR (apremilast tablets/extended-release tablets) or Sotyktu (deucravacitinib tablets) was added as an exception to the requirement for a trial of one traditional systemic agent for psoriasis. For initial therapy, the requirement "patient has a contraindication to methotrexate, as determined by the prescriber" was modified to "according to the prescriber, the patient has a contraindication to methotrexate". In the Appendix, Otezla XR (apremilast extended-release tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecular Drugs. | 11/13/2025 | 01/01/2026 |
| **Crohn's Disease:** For initial therapy, the following options of approval were removed: The patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated; patient has tried one conventional systemic therapy for Crohn's disease along with the associated Note; patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). | 02/19/2026 | 03/15/2026 |
| No criteria changes. | 04/02/2026 | 05/01/2026 |

The policy effective date is in force until updated or retired.

## APPENDIX

| | Mechanism of Action | Examples of Indications* |
|---|---|---|
| **Biologics** | | |
| **Adalimumab SC Products** (Humira®, biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC |
| **Cimzia®** (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, JIA, nr-axSpA, PsO, PsA, RA |
| **Etanercept SC Products** (Enbrel®, biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA, RA |
| **Infliximab IV Products** (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| **Zymfentra®** (infliximab-dyyb SC injection) | Inhibition of TNF | CD, UC |
| **Simponi®, Simponi Aria®** (golimumab SC injection, golimumab IV infusion) | Inhibition of TNF | SC formulation: AS, PsA, RA, UC |
| | | IV formulation: AS, PJIA, PsA, RA |
| **Tocilizumab Products** (Actemra® IV, biosimilars; Actemra SC, biosimilars) | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA |
| | | IV formulation: PJIA, RA, SJIA |
| **Kevzara®** (sarilumab SC injection) | Inhibition of IL-6 | PJIA, RA |
| **Orencia®** (abatacept IV infusion, abatacept SC injection) | T-cell costimulation modulator | SC formulation: JIA, PSA, RA |
| | | IV formulation: JIA, PsA, RA |
| **Rituximab IV Products** (Rituxan®, biosimilars) | CD20-directed cytolytic antibody | RA |
| **Kineret®** (anakinra SC injection) | Inhibition of IL-1 | JIA^, RA |
| **Omvoh®** (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | CD, UC |
| **Ustekinumab Products** (Stelara® IV, biosimilars, Stelara SC, biosimilars) | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC |
| | | IV formulation: CD, UC |
| **Siliq®** (brodalumab SC injection) | Inhibition of IL-17 | PsO |
| **Cosentyx®** (secukinumab SC injection; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
| | | IV formulation: AS, nr-axSpA, PsA |
| **Taltz®** (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| **Bimzelx®** (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F | AS, nr-axSpA, PsA, PsO |
| **Ilumya®** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |
| **Skyrizi®** (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC |
| | | IV formulation: CD, UC |
| **Tremfya®** (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: CD, PsA, PsO, UC |
| | | IV formulation: CD, UC |
| **Entyvio®** (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |
| **Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs** | | |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Otezla XR™** (apremilast extended-release tablets) | Inhibition of PDE4 | PsO, PsA |
| **Cibinqo™** (abrocitinib tablets) | Inhibition of JAK pathways | AD |

| | | |
|---|---|---|
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | RA, AA |
| **Litfulo®** (ritlecitinib capsules) | Inhibition of JAK pathways | AA |
| **Leqselvi®** (deuruxolitinib tablets) | Inhibition of JAK pathways | AA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, UC |
| **Rinvoq® LQ** (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |
| **Sotyktu®** (deucravacitinib tablets) | Inhibition of TYK2 | PsO, PsA |
| **Xeljanz®** (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |
| **Zeposia®** (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |
| **Velsipity®** (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.