Drug Coverage Policy

Effective Date……02/15/2026
Coverage Policy Number…… DQM018
Policy Title……Cimzia Drug Quantity Management Policy – Per Days

Inflammatory Conditions – Cimzia Drug Quantity Management Policy – Per Days

- 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**, for the treatment of 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 patients with objective signs of inflammation.
- **Plaque psoriasis**, for the treatment of adults with moderate to severedisease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, for the treatment of adult patients with active disease.
- **Rheumatoid arthritis**, for the treatment of adults with moderately to severely active disease.

Dosing

Cimzia is administered by subcutaneous (SC) injection.[1] Injection sites should be rotated and injections should not be given into areas where the skin is tender, bruised, red or hard. When a 400 mg dose is needed, it should be given as two 200 mg SC injections at separate sites in the thigh or abdomen.

- **Ankylosing Spondylitis**: 400 mg initially and at Week 2 and Week 4, followed by 200 mg once every 2 weeks (Q2W) or 400 mg every 4 weeks (Q4W).
- **Crohn's Disease:** 400 mg initially and at Week 2 and Week 4. If response occurs, follow with 400 mg Q4W.
- **JIA:** Dosing for JIA is weight-based.
  - 10 kg to < 20 kg: 100 mg initially and at Week 2 and Week 4, followed by 50 mg Q2W.
  - 20 kg to < 40 kg: 200 mg initially and at Week 2 and Week 4, followed by 100 mg Q2W.
  - ≥ 40 kg: 400 mg initially and at Week 2 and Week 4, followed by 200 mg Q2W.
- **Non-Radiographic Axial Spondyloarthritis**: 400 mg initially and at Week 2 and Week 4, followed by 200 mg Q2W or 400 mg Q4W.
- **Plaque Psoriasis:** 400 mg Q2W. For some patients (with body weight ≤ 90 kg), may consider 400 mg initially and at Week 2 and Week 4, followed by 200 mg Q2W.
- **Psoriatic Arthritis**: 400 mg initially and at Week 2 and Week 4, followed by 200 mg Q2W. For maintenance dosing, 400 mg Q4W may be considered.
- **Rheumatoid Arthritis:** 400 mg initially and at Week 2 and Week 4, followed by 200 mg Q2W. For maintenance dosing, 400 mg Q4W may be considered.

Availability

Cimzia is available in cartons containing two **single-dose vials** along with other materials needed for administration, including sterile water diluent. Each vial contains 200 mg of certolizumab pegol lyophilized powder for reconstitution for SC administration. Contents of the carton should not be separated prior to use. Cimzia is also supplied in cartons containing one or two **single-dose prefilled syringes**. Each prefilled syringe contains 200 mg of certolizumab pegol solution for SC administration. Additionally, the **prefilled syringes are available in a Starter Kit.** Each Start Kit contains six 200 mg prefilled syringes (three sets of two syringes each), to provide sufficient drug supply for the three initial induction doses at the start of treatment. Initial

quantity limits provide a quantity sufficient for a 28-day supply of 400 mg every 4 weeks and one induction dose regimen per 365 days. Override criteria provide for additional quantities for patients receiving induction re-dosing or for patients requiring 400 mg every two weeks for the treatment of plaque psoriasis.

Coverage Policy

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Cimzia and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below. "One-time" overrides are provided for 30 days in duration. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Cimzia® (certolizumab pegol SC injection [lyophilized powder or solution])	200 mg vials (two vials per carton)	1 carton (2 vials) per 28 days	3 cartons (6 vials) per 84 days
	200 mg prefilled syringes (one or two syringes per carton)	2 syringes per 28 days	6 syringes per 84 days
	200 mg prefilled syringes in a Starter Kit (6 syringes per kit)	6 syringes per 365 days	

Exceptions to the quantity limits listed above are covered as medically necessary when ONE of the following criteria is met. Any other exception is considered not medically necessary.

CRITERIA

Cimzia 200 mg syringes or vials (NOT starter packages)

1. If the patient is requesting Cimzia for the treatment of plaque psoriasis, approve a quantity of 4 syringes or vials per 28 days at retail or 12 syringes or vials per 84 days at home delivery.

2. If the patient is initiating treatment with Cimzia or requires additional induction dosing, as verified by the absence of claims for Cimzia in the past 130 days, approve a one-time override for 6 syringes or vials at retail or 10 syringes or vials at home delivery.

Cimzia 200 mg syringes (Starter Kit of 6 syringes)

1. If the patient requires additional induction dosing, as verified by the absence of claims for Cimzia in the past 130 days, approve a one-time override for 6 syringes (one starter pack) at retail or home delivery.
   Note: The approval quantity should be the number of Cimzia 200 mg syringes (Starter Kit) the patient has received in the past 365 days plus 6 syringes at retail and home delivery.

References

1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; September 2025.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	02/15/2026

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