DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Cimzia Drug Quantity Management Policy – Per Days
- Cimzia® (certolizumab pegol subcutaneous injection [lyophilized powder or solution] – UCB)

REVIEW DATE: 01/03/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.
- **Non-radiographic axial spondyloarthritis**, in patients with objective signs of inflammation.
- **Plaque psoriasis**, for the treatment of adults with moderately to severely active disease 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 (400 mg every 4 weeks may also be considered).
- **Crohn's Disease:** 400 mg initially and at Week 2 and Week 4. If response occurs, follow with 400 mg once every 4 weeks.
- **Non-Radiographic Axial Spondyloarthritis**: 400 mg initially and at Week 2 and Week 4, followed by 200 mg once every 2 weeks or 400 mg every 4 weeks.
- **Plaque Psoriasis:** 400 mg once every other week. For some patients (with body weight ≤ 90 kg), may consider 400 mg initially and at Week 2 and Week 4, followed by 200 mg once every other week.
- **Psoriatic Arthritis**: 400 mg initially and at Week 2 and Week 4, followed by 200 mg once every other week. For maintenance dosing, 400 mg every 4 weeks may be considered
- **Rheumatoid Arthritis:** 400 mg initially and at Week 2 and Week 4, followed by 200 mg once every other week. For maintenance dosing, 400 mg once every 4 weeks 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 of 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.

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.

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)	2 vials per 28 days	6 vials per 84 days
	200 mg prefilled syringes (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	6 syringes per 365 days

Inflammatory Conditions – Cimzia Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Cimzia 200 mg prefilled syringes or vials

1. If the patient is requesting Cimzia for the treatment of plaque psoriasis, approve a quantity of 4 prefilled syringes or vials per 28 days at retail or 12 prefilled 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 prefilled syringes or vials at retail or 10 prefilled syringes or vials at home delivery.

Cimzia 200 mg prefilled syringe Starter Kit

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 one starter pack (6 prefilled syringes) at retail or home delivery.

REFERENCES

1. Cimzia® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; December 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	12/15/2022
Annual Revision	No criteria changes.	01/03/2024