CHOOSE CIMZIA®
(certolizumab pegol)

FOR YOUR PATIENTS WITH pJIA

A clinical overview of CIMZIA for the management of polyarticular juvenile idiopathic arthritis (pJIA)

INDICATION

CIMZIA is a tumor necrosis factor (TNF) blocker indicated for treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with CIMZIA, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens (such as Legionella or Listeria). Patients should be closely monitored for the signs and symptoms of infection during and after treatment with CIMZIA. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member.

Please see additional Important Safety Information on page 9.

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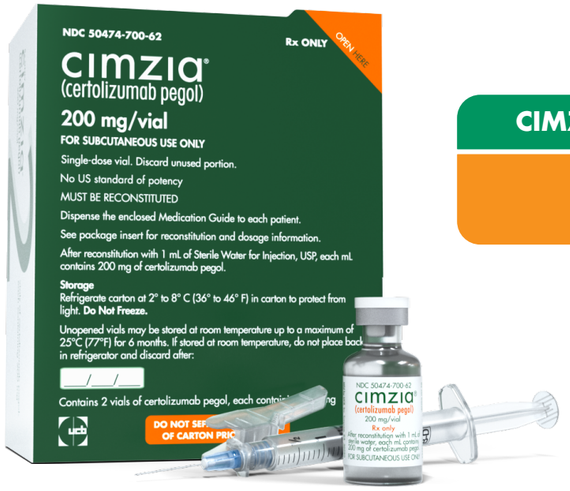
Dosing and Administration for pJIA

CIMZIA® (certolizumab pegol) offers a flexible treatment experience for patients with pJIA[1]

CIMZIA lyophilized powder for reconstitution (CIMZIA LYO) is supplied as a sterile, white, lyophilized powder in a single-dose vial for subcutaneous use, packaged with all components required for reconstitution and injection by a healthcare professional.



CIMZIA Lyophilized Powder for Reconstitution

2 x 200 mg vials
NDC Number: 50474-700-62

The recommended dosage of CIMZIA for patients with pJIA is based on body weight[1]

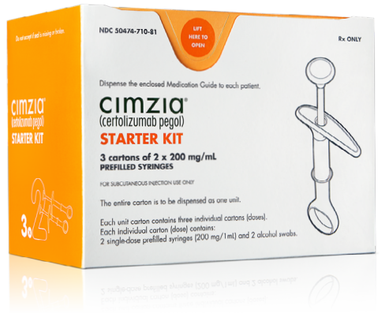
Total Body Weight	Loading Dose	Maintenance Dosing
10 kg (22 lb) to less than 20 kg (44 lb)	**100 mg** Weeks 0, 2, 4	**50 mg** Every other week
20 kg (44 lb) to less than 40 kg (88 lb)	**200 mg** Weeks 0, 2, 4	**100 mg** Every other week
Greater than or equal to 40 kg (88 lb)	**400 mg** Weeks 0, 2, 4	**200 mg** Every other week

There is no dosage form for CIMZIA that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a healthcare professional using the vial kit.

Each vial is for one-time use only. **Discard any remaining solution.**

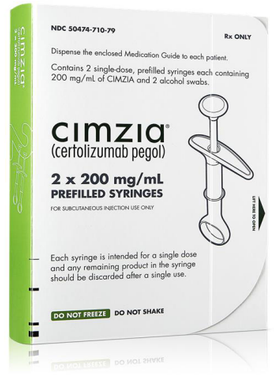
The CIMZIA Prefilled Syringe (PFS) may be appropriate for patients:

- Who are 40 kg or over
- Who are able to self-inject and are appropriately trained, or have access to a trained caregiver



Prefilled Syringe Starter Kit

6 x 200 mg/mL prefilled syringes
NDC Number: 50474-710-81



Prefilled Syringe Kit

2 x 200 mg/mL prefilled syringes
NDC Number: 50474-710-79

IMPORTANT SAFETY INFORMATION

Patients treated with CIMZIA are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g., corticosteroids or methotrexate) may be at a greater risk of infection.

Please see additional Important Safety Information on page 9.
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PASCAL Study Design

Study design[2]

The PASCAL trial was a Phase 3, multicenter, open-label study designed to evaluate the pharmacokinetics, safety, and efficacy of CIMZIA in children and adolescents with moderately to severely active polyarticular-course juvenile idiopathic arthritis (pJIA).

POPULATION

- 193 patients*
- Ages 2 – 17 years
- Active pJIA (≥5 joints) at screening and baseline

STUDY DURATION

Initial to Maintenance (Weeks 0 – 48)

PRIMARY ENDPOINTS:

- Plasma concentration of CIMZIA and number of participants with anti-certolizumab antibodies at Weeks 16 and 48
- Number of participants with serious TEAEs and TEAEs leading to withdrawal

*193 patients were included and 105 received the recommended dose.

Eligible patients:

- Onset of signs and symptoms consistent with JIA diagnosis† with initiation of JIA treatment for ≥6 months prior to baseline and inadequate response or intolerance to ≥1 disease-modifying antirheumatic drug (nonbiologic or biologic)
- Received prior JIA therapies for ≥6 months with inadequate disease control or worsening symptoms
- In patients receiving MTX, stable MTX for ≥3 total months of therapy prior to screening
- If using glucocorticoids, the dose must have been stable for ≥7 days prior to baseline (10 mg or 0.2 mg/kg prednisone per day, at maximum)

Dosing schedule:

- Patients were stratified into 3 body-weight categories
- CIMZIA was administered every 2 weeks for the first 3 doses, followed by either every 2 weeks or every 4 weeks thereafter

Weight category (2 years of age and older)	Loading dose	Maintenance dose (beginning at Week 6)
10 kg (22 lb) to less than 20 kg (44 lb)	100 mg at Weeks 0, 2, and 4	50 mg every 2 weeks
20 kg (44 lb) to less than 40 kg (88 lb)	200 mg at Weeks 0, 2, and 4	100 mg every 2 weeks
Greater than or equal to 40 kg (88 lb)	400 mg at Weeks 0, 2, and 4	200 mg every 2 weeks

Follow-up: Treatment continued until completion or discontinuation, with a 12-week safety follow-up period

Study period: March 2012 – April 2024

†JIA diagnosed according to International League of Associations for Rheumatology Classification of JIA, 2001.

IMPORTANT SAFETY INFORMATION

Treatment with TNF blockers, including CIMZIA, may rarely result in new onset or exacerbation of clinical symptoms and/or radiographic evidence of central or peripheral nervous system demyelinating disease, as well as the development of a lupus-like syndrome.

Baseline patient characteristics[1,2]

The study enrolled 193* children and adolescents with active pJIA, predominantly female and spanning ages 2–17 years.

CHARACTERISTIC	Weight Group 10–<20 kg	Weight Group 20–<40 kg	Weight Group ≥40 kg	Total / Overall
Number of baseline participants (n)	18	63	112	193
Age, mean (years)	5.4	9.1	14.5	11.9
SEX, %				
Female	61.1	68.3	67.9	67.4
Male	38.9	31.7	32.1	32.6
RACE / ETHNICITY, %				
American Indian / Alaska Native	0	1.6	3.6	2.6
Asian	0	3.2	2.7	2.6
Black or African American	0	0	5.4	3.1
White	94.4	84.1	75.9	80.3
Other / Mixed	5.6	11.1	12.5	11.4
Hispanic or Latino, %	55.6	28.6	24.1	28.5
Not Hispanic or Latino, %	44.4	71.4	75.9	71.5

*193 patients were included and 105 received the recommended dose.

Patients had 1 of the following types of juvenile idiopathic arthritis:

JIA SUBTYPE	Percent of Patients
Polyarthritis, rheumatoid factor–positive	20.0%
Polyarthritis, rheumatoid factor–negative	44.8%
Extended oligoarthritis	13.3%
Juvenile psoriatic arthritis	4.8%
Enthesitis-related arthritis	19.0%

IMPORTANT SAFETY INFORMATION

Cases of lymphoma and other malignancies have been observed among patients receiving TNF blockers, including children, adolescents, and young adults. Acute and chronic cases of leukemia have also been reported. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA. Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-antagonists, including CIMZIA. Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

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PASCAL Study Results

Primary endpoints:

- **CIMZIA plasma concentrations:**
  At Week 16, observed concentrations were lower for the reduced CIMZIA dose group compared with the original CIMZIA dose group. CIMZIA concentrations were generally stable after Week 12.[2,3]

- **Anti-CIMZIA antibodies:**
  Approximately 80% of patients in both the original and reduced-dose groups developed anti-CIMZIA antibodies by Weeks 16 and 48. There was no apparent impact on effectiveness or safety.[2]

- **Serious treatment-emergent adverse events (TEAEs) and treatment discontinuations:**
  No new safety signals were identified.[2,3]

Secondary endpoints:

- Efficacy was assessed as secondary endpoints through Week 24 and was generally consistent with responses in patients with rheumatoid arthritis.[1]

Treatment-Emergent Adverse Events (TEAEs)* and Adverse Reactions (ARs)† Related to CIMZIA (N=193)[3]

	TREATMENT-EMERGENT ADVERSE EVENTS	DRUG-RELATED ADVERSE REACTIONS
Adverse Events (AEs)	95.3% (184/193)	48.7% (94/193)
Most common AEs		
Nasopharyngitis	27.5% (53/193)	-
Upper respiratory tract infection	24.9% (48/193)	6.2% (12/193)
Headache	20.2% (39/193)	5.2% (10/193)
Injection site pain	-	8.8% (17/193)
Worsening idiopathic juvenile arthritis	-	7.3% (14/193)
Serious AEs	23.8% (46/193)	5.2 (10/193)
Most common serious AEs		
Pneumonia	1% (2/193)	1% (2/193)
Anemia	1.6% (3/193)	-
AEs leading to permanent discontinuation	12.4% (24/193)	5.7% (11/193)
AEs leading to death‡	-	1% (2/193)

- Exposure duration, mean (years) + 4.3; total participant-years at risk, years=849.8

*Treatment-emergent adverse events (TEAEs) are defined as any adverse event that started or worsened after the first CIMZIA dose.
†Adverse reactions (ARs) are defined as any TEAE related to CIMZIA.
‡Two deaths reported, one due to septic shock and tuberculosis liver, and another due to anemia and disseminated tuberculosis, were related to CIMZIA per investigator assessment.

Safety review:

- Overall, the incidence of serious infection TEAEs and opportunistic infections (including tuberculosis) were in line with the known safety profile of CIMZIA. In addition, no TEAEs of malignancies (including lymphoma), major adverse cardiovascular events, demyelinating-like disorders, lupus or lupus-like TEAEs, serious bleeding events, or serious skin reactions were reported.

IMPORTANT SAFETY INFORMATION

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers.

Anaphylaxis or serious allergic reactions may occur. Some of these reactions occurred after the first administration of CIMZIA. Hypersensitivity reactions have been reported rarely following CIMZIA administration. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex that may cause an allergic reaction in individuals sensitive to latex.

IMPORTANT SAFETY INFORMATION

Use of TNF blockers, including CIMZIA, has been associated with reactivation of hepatitis B virus in patients who are chronic carriers of the virus. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal.

Please see additional Important Safety Information on page 9.
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Coding for pJIA

Diagnosis coding*†

The following list provides ICD-10-CM codes that may relate to the use of CIMZIA in pJIA patients.

ICD-10-CM code	ICD-10-CM code description
M08.9#	Juvenile Arthritis, descriptors vary

Other relevant codes

The following codes may be relevant when filing claims for CIMZIA in pJIA patients

Note for the JZ modifier for single-use containers: If no drug was discarded, the JZ modifier should be used. If any of the drug was not used, the JW modifier should be used.

Drug/biologic codes

Code Type	Code	Definition
HCPCS	J0717	Certolizumab pegol, 1 mg
HCPCS Modifier‡	J0717-JW J0717-JZ	Drug amount discarded/not administered to any patient No drug was discarded
NDC Codes *Lyophilized powder for reconstitution*	50474-0700-62	CIMZIA Kit: 2 × 200 mg lyophilized powder vials
NDC 5010 Electronic Transition Codes	N4 50474-0700-62 UN1	CIMZIA Kit: 2 × 200 mg lyophilized powder vials
NDC Codes *Prefilled syringes*§¶	50474-0710-81 50474-0710-79	CIMZIA Starter Kit: 6 × 200 mg/mL prefilled syringes CIMZIA Kit: 2 × 200 mg/mL prefilled syringes

Note: There is no dosage form for CIMZIA that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a healthcare professional using the vial kit.

Drug administration codes

Code Type	Code	Definition
CPT	96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
CPT	96401	Chemotherapy administration; subcutaneous or intramuscular

Please contact your payers individually for specific guidance regarding their approved administration codes for CIMZIA.

Revenue codes||

Code Type	Code	Definition
Revenue	0636	Drugs requiring detailed coding
Revenue	0330	Radiology - therapeutic
Revenue	0331	Radiology - therapeutic; chemotherapy - injected

*The number sign (#) is a placeholder. Please consult the ICD-10 code book for the digits related to each specific diagnosis within the general category listed.

†The Centers for Medicare & Medicaid Services (CMS) advises reporting specific diagnosis codes as supported by available medical record documentation and clinical knowledge of the patient's health condition at the time of that visit. In the absence of sufficient clinical information to support a specific code (for example, a diagnosis is not yet confirmed), it is acceptable to report the appropriate unspecified code. CMS advises against selecting a specific code that is not documented by the medical record or conducting unnecessary diagnostic testing in order to determine a more specific code.

‡Not all plans require the HCPCS JW and JZ modifiers. Check with your state Medicaid and commercial payers for their specific requirements.

§UnitedHealthcare® requires inclusion of the NDC for all medical claims on commercial and Medicare Advantage plans.

¶After proper training in subcutaneous injection technique, a patient may self-inject with the CIMZIA prefilled syringe if a physician determines that it is appropriate.

||For hospital setting.

Important Safety Information

IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

CIMZIA is contraindicated in patients with a history of hypersensitivity reaction to certolizumab pegol or to any of the excipients. Reactions have included angioedema, anaphylaxis, serum sickness, and urticaria.

SERIOUS INFECTIONS

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue CIMZIA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before CIMZIA use and during therapy. Initiate treatment for latent TB prior to CIMZIA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with CIMZIA prior to initiating therapy in the following patients: with chronic or recurrent infection; who have been exposed to TB; with a history of opportunistic infection; who resided in or traveled in regions where mycoses are endemic; with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start CIMZIA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member.

- Consider the risks and benefits of CIMZIA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among CIMZIA-treated patients compared to control patients.
- In CIMZIA clinical trials, there was an approximately 2-fold higher rate of lymphoma than expected in the general U.S. population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk of lymphoma than the general population.
- Malignancies, some fatal, have been reported among children, adolescents, and young adults being treated with TNF blockers. Approximately half of the cases were lymphoma, while the rest were other types of malignancies, including rare types associated with immunosuppression and malignancies not usually seen in this patient population.
- Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including CIMZIA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis, and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treating with CIMZIA in these patient types.
- Cases of acute and chronic leukemia were reported with TNF blocker use.

HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) have been reported with TNF blockers. Exercise caution and monitor carefully.

HYPERSENSITIVITY

- Angioedema, anaphylaxis, dyspnea, hypotension, rash, serum sickness, and urticaria have been reported following CIMZIA administration. If a serious allergic reaction occurs, stop CIMZIA and institute appropriate therapy. The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex that may cause an allergic reaction in individuals sensitive to latex.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Test patients for HBV infection before initiating treatment with CIMZIA.
- Exercise caution in patients who are carriers of HBV and monitor them before and during CIMZIA treatment.
- Discontinue CIMZIA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming CIMZIA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including CIMZIA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, seizure disorder, optic neuritis, peripheral neuropathy, and Guillain-Barré syndrome.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with CIMZIA.
- Consider stopping CIMZIA if significant hematologic abnormalities occur.

DRUG INTERACTIONS

- Do not use CIMZIA in combination with other biological DMARDs.

AUTOIMMUNITY

- Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Avoid use of live vaccines during or immediately prior to initiating CIMZIA. Update immunizations in agreement with current immunization guidelines prior to initiating CIMZIA therapy.

ADVERSE REACTIONS

- The most common adverse reactions in CIMZIA clinical trials (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

Click here to see the full Prescribing Information for CIMZIA.

References: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc. **2.** Pediatric Arthritis Study of Certolizumab Pegol (PASCAL). ClinicalTrials.gov Identifier: NCT01550003. https://www.clinicaltrials.gov/study/NCT01550003?term=CERTOLIZUMAB%20PEGOL&rank=3#study-overview. Updated October 23, 2024. Accessed November 6, 2025. **3.** Data on file. UCB, Inc., Smyrna, GA.

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