CIMZIA® (certolizumab pegol)

CIMZIA Overview for Specialty Pharmacies

CIMZIA is indicated for:

- Reducing the 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 active **polyarticular juvenile idiopathic arthritis (pJIA)** in patients 2 years of age and older
- 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
- Treatment of adult patients with active **psoriatic arthritis (PsA)**
- Treatment of adult patients with active **ankylosing spondylitis (AS)**

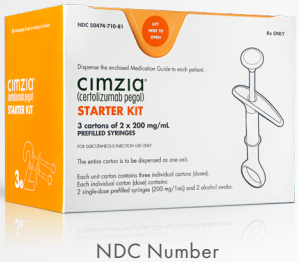
Important Safety Information

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 and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.

Recommended Dosing and Administration for Adult Patients*

MONTH 1
ALL INDICATIONS



NDC Number
50474-0710-81

Dispense 1 Kit (6 syringes)

400 mg
(2 injections x 200 mg/mL)
WEEKS 0, 2, 4
(DAYS 0, 14, 28)

MONTH 2 AND BEYOND
INDICATION-SPECIFIC

NDC Number:
50474-0710-79

CD
400 mg
(2 injections x 200 mg/mL)
EVERY 4 WEEKS

Dispense 1 Kit (2 syringes)

RA PsA AS NR axSpA
400 mg
(2 injections x 200 mg/mL)
EVERY 4 WEEKS
OR
200 mg
(1 injection x 200 mg/mL)
EVERY 2 WEEKS

Dispense 1 Kit (2 syringes)

PSO
400 mg
(2 injections x 200 mg/mL)
EVERY 2 WEEKS

ALTERNATE DOSING FOR PSO
For some patients (with body weight ≤90 kg), a dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at Weeks 2 and 4, followed by 200 mg every other week, may be considered.

Dispense 2 Kits (4 syringes)

*Please note: The above dosing does not represent the recommended dosing for pediatric patients with pJIA. Please refer to the full Prescribing Information for more details on dosing and administration for patients with pJIA.

Prefilled syringe designed for comfort and control in partnership with OXO GOOD GRIPS®

For subcutaneous administration in abdomen or thigh. Please see full Prescribing Information for additional dosing and administration information.

Reference: CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

NDC Number
50474-0700-62

Dosing shown above for At-Home Administration using CIMZIA prefilled syringe (PFS) formulation. Dosing would be the same for In-Office Injection using the CIMZIA lyophilized powder (LYO) formulation.

Important Safety Information

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.

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CIMZIA® (certolizumab pegol)

CIMZIA® (certolizumab pegol) Recommended Dosing and Administration*

Dosing shown below for polyarticular juvenile idiopathic arthritis (pJIA)

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

Total Body Weight	Initial Dosing	Vials used for Initial Dosing (Week 0, 2, and 4)	Maintenance Dosing	Vials used for Maintenance Dosing (every other week)
10 kg (22 lbs) to less than 20 kg (44 lbs)	100 mg initially and at Weeks 2 and 4	 1/2 of 200 mg vial	50 mg every other week	 1/4 of 200 mg vial
20 kg (44 lbs) to less than 40 kg (88 lbs)	200 mg initially and at Weeks 2 and 4	 1 x 200 mg vial	100 mg every other week	 1/2 of 200 mg vial
Greater than or equal to 40 kg (88 lbs)	400 mg initially and at Weeks 2 and 4	 2 x 200 mg vial	200 mg every other week	 1 x 200 mg vial

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

Note: If any drug amount is discarded or not administered to patient, a JW modifier may be required on claims billing for CIMZIA.

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.

*For subcutaneous administration in abdomen or thigh. Please see full Prescribing Information for additional dosing and administration information.

Reference: CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

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Specialty Pharmacies Can Help Eligible, Commercially Insured Patients Save on the Cost of CIMZIA® (certolizumab pegol) Throughout Treatment

- Specialty pharmacies can help enroll eligible patients in the CIMplicity® Savings* program by visiting **UCBSavings.com**. Patients must be enrolled prior to first dispense.
- Enrolled patients could pay **as little as $0 per dose** for their medication.
- Savings are only a part of the benefits offered to CIMZIA patients. Be sure to tell patients to register at **cimzia.com/cimplicity-program** to access the full suite of services and resources available through the CIMplicity® patient support program to help them successfully manage their condition.

Eligible patients can be enrolled in the CIMplicity Savings* program prior to first dispense in a few simple steps:

STEP 1:

Visit **UCBSavings.com** to begin process

STEP 2:

Complete all **patient eligibility questions as required.** Click **"Create Savings Card"** to download a unique patient CIMplicity® savings card

STEP 3:

Utilize information from CIMplicity® savings card (BIN, PCN) as the secondary insurance when processing the CIMZIA patient claim

Please note that card can be saved as a PDF to attach to patient file if desired.

Eligible, commercially insured patients with approved coverage may receive CIMZIA for as little as $0 per dose. View complete eligibility requirements and terms at **cimzia.com/cimplicity-program.*

Enrolled patients could pay as little as $0 per dose for their medication.

Eligibility Requirements

CIMplicity® Savings Program:

CIMplicity® Savings (the "Program") provides CIMZIA® (certolizumab pegol) Prefilled Syringe or Lyophilized Powder to eligible patients for as little as $0 per dose. Eligible patients must have commercial insurance coverage and a valid prescription for CIMZIA Prefilled Syringe or Lyophilized Powder consistent with FDA-approved product labeling. The Program is not valid (1) for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, or any other federal- or state-funded healthcare programs (including but not limited to any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), (2) where a patient's commercial insurance plan reimburses for the entire cost of the drug, (3) for uninsured or cash paying patients, (4) where the product is not covered by patient's insurance, or (5) where otherwise prohibited by law. Product shall be dispensed pursuant to Program rules and federal and state laws. The value of the Program is exclusively for the benefit of patients and is intended to be credited in full toward patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance and deductibles. Patient may not seek reimbursement for the value received from this Program from other parties, including any health insurance program or plan, government healthcare program, flexible spending account, or healthcare savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the U.S. and Puerto Rico. This Program is not health insurance. Proof of purchase may be required. This Program is not transferrable and cannot be combined with any other savings, free trial, or similar offer. UCB, Inc. reserves the right to amend or end this Program at any time without notice. Subject to the prior sentence, this Program expires at 11:59 p.m. on December 31. Patients that meet the above requirements may re-enroll in the Program each year.

CIMplicity Administration Savings Program for CIMZIA Lyophilized Powder for In-Office Injection:

The CIMplicity® Administration Savings Program (the "Program") provides eligible patients with reimbursement for in-office administration-related costs (subject to an annual cap) for CIMZIA® (certolizumab pegol) Lyophilized Powder, subject to submission of an Explanation of Benefits (EOB) form to CIMplicity. Eligible patients must have commercial insurance coverage and a valid prescription for CIMZIA Lyophilized Powder consistent with FDA-approved product labeling. The total patient out-of-pocket cost under the Program is dependent on the patient's health insurance plan. The Program assists with costs related to the administration of CIMZIA Lyophilized Powder only. The Program does not assist with the cost of other administrations, medications, procedures, or office visit fees. After reaching the maximum Program's benefit amounts, the patient will be responsible for all remaining out-of-pocket expenses. The Program's benefit amounts cannot exceed the patient's out-of-pocket expenses for administration of CIMZIA Lyophilized Powder. The Program is not valid (1) for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, or any other federal- or state-funded healthcare programs (including but not limited to any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), (2) where a patient's commercial insurance plan reimburses for the entire cost of the drug, (3) for uninsured or cash paying patients, (4) where the product is not covered by patient's insurance, or (5) where otherwise prohibited by law. Product shall be dispensed pursuant to Program rules and federal and state laws. The value of the Program is exclusively for the benefit of patients and is intended to be credited in full toward patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patient may not seek reimbursement for the value received from this Program from other parties, including any health insurance program or plan, government healthcare program, flexible spending account, or healthcare savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the U.S. and Puerto Rico. This Program is not health insurance. This Program is not transferrable and cannot be combined with any other savings, free trial, or similar offer. UCB, Inc. reserves the right to amend or end this Program at any time without notice. Subject to the prior sentence, this Program expires at 11:59 p.m. on December 31. Patients that meet the above requirements may reenroll in the Program.

CIMplicity® Nurse Navigator Support* Helps Keep Patients on Track

When patients start treatment with CIMZIA® (certolizumab pegol), they'll have access to **free on-call support from reliable CIMplicity Nurse Navigators**

Support services may include:

- Support in **understanding their medication**, including how CIMZIA works, dosing, and how to tell that it is working
- **Nutrition tracking** and lifestyle tips related to the patient's condition
- **Goal setting** to identify and manage expectations from treatment
- **Practical information** like injection training support (for PFS patients) and sharps disposal details

cimplicity®

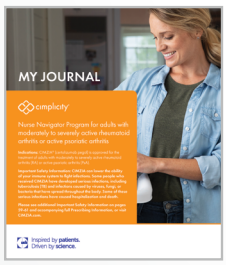
Help eligible patients understand the benefits of CIMplicity Nurse Navigator Support

- Our dedicated nurses can enroll patients in CIMplicity and for Nurse Navigator support over the phone. To talk to a nurse, patients can sign up at **cimzia.com/cimplicity-program** or call **1-844-822-6877**

Patients have access to **patient journals** available **based on their indication**

- CIMplicity Patient Journals contain helpful information and are designed for **patients to take notes**
- Patients can use their CIMplicity Patient Journal when meeting with their **healthcare professional**

CD



RA

PSO

NR axSpA

*Nurse Navigators do not provide medical advice and will refer patients to their healthcare professional for any treatment-related questions.

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CIMplicity® Syringe Disposal

CIMplicity Syringe Disposal helps protect children, waste workers, members of the community, and the environment

- Patients enrolled in the **CIMplicity support program** can receive a **free syringe disposal container**, also known as a sharps container
- Patients can visit **cimzia.com/cimplicity-program** to sign up for CIMplicity support services and syringe disposal
- Patients **should not throw away syringes and needles** in household trash
- The CIMplicity Syringe Disposal container is made **specifically to fit used CIMZIA syringes with attached needles**

Syringe Disposal Service Details

Once patients request a sharps container, they will receive a package in 7 to 10 business days

The package includes a sharps container, a return box with prepaid postage, and instructions to mail it back for safe disposal once it's full

For more information about safe disposal in your state, visit **www.fda.gov/safesharpsdisposal**

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CIMZIA Specialty Pharmacy Contact Quick Reference Guide

CIMplicity® Savings* Program

- Specialty Pharmacies can help enroll patients by visiting **UCBSavings.com**
- If you have any questions about the **CIMplicity Savings Program** call CIMplicity at 1-866-424-6942

CIMplicity Nurse Navigator** Support

- Specialty Pharmacies can let patients know about CIMplicity Nurse Navigator Support and direct patients to call **1-844-UCBNurse (1-844-822-6877)**

CIMplicity Syringe Disposal

- Patients enrolled in **CIMplicity** can receive a **free syringe disposal container**, also known as a sharps container
- Patients can request a **free syringe disposal container** through **CIMZIA.com**

Adverse Event Reporting

- Fax an Adverse Event Form or MedWatch Form 3500A to **1-800-619-5974** or send via email to **ds.us@ucb.com**

UCBCares®

- UCBCares can help with: UCB products and disease state information, product safety and quality issues, and financial assistance, including the **Patient Assistance Program**
- For additional questions and/or to request CIMZIA training demo kits, call **1-844-599-CARE (2273)**

*Eligible, commercially insured patients with approved coverage may receive CIMZIA for as little as $0 per dose. View complete eligibility requirements and terms at cimzia.com/cimplicity-program.

**Nurse Navigators do not provide medical advice and will refer patients to their healthcare professional for any treatment-related questions.

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CIMZIA® (certolizumab pegol)

IMPORTANT SAFETY INFORMATION

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%).

Please see full Prescribing Information attached and visit www.CIMZIAhcp.com.

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