



CIMZIA[®] (certolizumab pegol) In-Office Injection Process Guide



CIMZIA is indicated for:

- CD** Reducing 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
- RA** Treatment of adults with moderately to severely active **RHEUMATOID ARTHRITIS (RA)**
- PsA** Treatment of adult patients with active **PSORIATIC ARTHRITIS (PsA)**
- AS** Treatment of adults with active **ANKYLOSING SPONDYLITIS (AS)**
- NR axSpA** Treatment of adults with active **NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA)** with objective signs of inflammation
- PSO** Treatment of adult patients with moderate-to-severe **PLAQUE PSORIASIS (PSO)** who are candidates for systemic therapy or phototherapy

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. CIMZIA is not indicated for use in pediatric patients.

Please see additional Important Safety Information on the back cover. Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.

CIMZIA® (certolizumab pegol) IN-OFFICE INJECTION YOUR STEP-BY-STEP GUIDE

Keep this Guide on hand for easy reference



Preparing to Use CIMZIA® (certolizumab pegol) In-Office Injection for the First Time

- ✓ Contact a Group Purchasing Organization (GPO) to obtain contracted pricing for the CIMZIA Lyophilized Powder for reconstitution. You will need to join a GPO to access the CIMZIA GPO Contract Price.
NDC: 50474-0700-62¹
- ✓ Purchase Cimzia In-Office Injection (IOI) directly from a Wholesaler or Specialty Distributor. Provide your GPO contract number to the Wholesaler or Specialty Distributor when purchasing Cimzia IOI.
- ✓ Check the CIMZIA In-Office Injection fee schedules for each of the payers you see within your practice (commercial payers, Medicare, Medicaid, etc.)
HCPCS code: J0717²

Contact

**Your UCB Field Reimbursement Manager
(FRM) for additional information or assistance**

NAME

PHONE

EMAIL

References: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc. 2. American Medical Association. *HCPCS Level II 2018 Professional*. United States; American Medical Association; 2018.

The information contained in this guide is for educational purposes only. It is intended to assist healthcare professionals in understanding the reimbursement process for CIMZIA when appropriately prescribed or administered. Any determination regarding if and how to seek reimbursement should be made by the appropriate members of the physician office and in consideration of the specific patient. Although payers generally reimburse for CIMZIA, it is the plan details that dictate coverage of the individual patient's healthcare.

The information contained in this guide represents no statement, promise, or guarantee by UCB concerning reimbursement of CIMZIA and injection services and UCB does not recommend or endorse the use of any particular diagnosis or procedure code. Importantly, payer coverage, reimbursement codes, and payment are subject to continual change; information contained in this guide is current as of August 2020.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



CIMZIA® (certolizumab pegol) Indications¹



Reducing 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 adult patients with active psoriatic arthritis (PsA)



Treatment of adults with active ankylosing spondylitis (AS)



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

Get Started

Once a clinical decision has been made to prescribe CIMZIA In-Office Injection as the appropriate choice, use this resource to get your patient's treatment journey started.



Reference: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

Important Safety Information

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.

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.

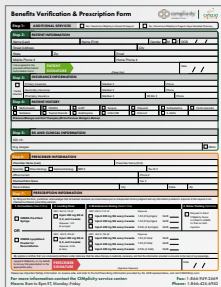
The needle shield inside the removable cap of the CIMZIA prefilled syringe contains a derivative of natural rubber latex which may cause an allergic reaction in individuals sensitive to latex.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



CIMZIA® (certolizumab pegol) In-Office Injection: Steps to Treatment



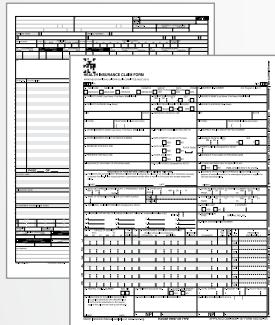
Step 1: Determining a Patient's Coverage

- Complete benefits investigation through CIMplicity®*
– **Have patient sign CIMplicity form**
- Review benefits to confirm coverage for CIMZIA In-Office Injection
- Discuss treatment and coverage with patient



Step 2: Purchasing and Administration

- Schedule patient for in-office injection
- Order CIMZIA through wholesaler or specialty distributor
- Trained healthcare professional administers CIMZIA to patient



Step 3: Coding and Billing

- Document CIMZIA administration within patient medical records
- Submit insurance claims based on payer guidance



Step 4: Supporting Patients

- Provide educational resources to the patient
- Provide appropriate affordability assistance to the patient

*The CIMplicity program is provided as a service of UCB and is intended to support the appropriate use of CIMZIA. The CIMplicity program may be amended or canceled at any time without notice. Eligibility and restrictions apply.

Reference: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

Please see Important Safety Information on the back cover.

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STEP 1 | DETERMINING A PATIENT'S COVERAGE

CIMZIA® (certolizumab pegol) In-Office Injection Is Covered Under the Medical Benefit

- The Medical Benefit typically covers healthcare practitioner (HCP)-administered drugs and services purchased by a physician, infusion center, outpatient clinic or hospital¹
- Reimbursement is typically based on negotiated fee schedules*

How the Medical Benefit Works Under Different Payers

	Medicare Part B	Medicare Advantage	Commercial
Patient Deductible	Patient pays 100% annual deductible before insurance begins to pay.	Patient pays 100% annual deductible before insurance begins to pay.	Patient pays 100% annual deductible before insurance begins to pay.
After Deductible Is Met, Patient's Financial Responsibility	Co-insurance is 20% of the Medicare allowable. A Medicare supplement (Medigap) or commercial secondary plan may apply to decrease out-of-pocket drug costs to \$0.	Co-insurance or co-pay varies by payer. A Medicare supplement (Medigap) may NOT be purchased by patients.	Co-insurance or co-pay varies by payer. A secondary insurance may apply which could decrease out-of-pocket drug costs to \$0.
Patient's Financial Responsibility Once Out-of-Pocket Maximum Is Met	There is no out-of-pocket max.	Patients will have low or no out-of-pocket cost.	Patients will have low or no out-of-pocket cost.
Eligibility for Co-Pay Assistance	NO	NO	YES
Drug Reimbursement	106% of quarterly ASP [†]	Varies by payer. Fee schedule is negotiated between provider/payer.	Varies by payer. Fee schedule is negotiated between provider/payer.
Administration Reimbursement[‡]	Fee Schedule available at https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx	Varies by payer. Fee schedule is negotiated between provider/payer.	Varies by payer. Fee schedule is negotiated between provider/payer.

*Commercial Payer fee schedules are often negotiated between each provider and payer. Medicare fee schedules are determined by the Centers for Medicare & Medicaid Services (CMS). Medicaid fee schedules are determined by each state's Department of Medicaid.

[†]The payment limit is 106% of average sales price (ASP). This does not include sequestration. Medicare fee-for-service claims with dates of service or dates of discharge on or after April 1, 2013, incur a 2% reduction in Medicare payment. The claims payment adjustment is applied to claims after determining co-insurance, any applicable deductible, and any applicable Medicare secondary payment adjustments.²

[‡]Recognized Administration Specific Codes are 96372 and 96401; however, specific coverage and payment vary by payer.

References: 1. Pharmacy benefit vs. medical benefit. Inside Edge Consulting website. <http://www.insideedgeconsulting.com/views-news/pharmacy-benefit-vs-medical-benefit>. Accessed August 3, 2020. 2. CMS Medicare FFS Provider e-News. Centers for Medicare and Medicaid Services website. <https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf>. Published March 8, 2013. Accessed August 3, 2020.

Important Safety Information

Other serious side effects have been reported with CIMZIA including heart failure, anaphylaxis or serious allergic reactions, hepatitis B reactivation, nervous system disorders, blood problems, and certain immune reactions (including a lupus-like syndrome). It is not recommended to administer CIMZIA with other biologic DMARDs due to an increased risk of infections. In pre-marketing controlled trials of all patient populations combined, the most common adverse reactions (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 1 | DETERMINING A PATIENT'S COVERAGE

Verifying Patient Benefits

If your practice utilizes CIMplicity® for help coordinating insurance verification, please complete the patient enrollment form and CIMZIA® (certolizumab pegol) Prescription Form to investigate benefits and/or send the prescription to a specialty pharmacy.

- These services include benefits investigation and prior authorization to help address insurance questions about CIMZIA
- Your UCB Field Reimbursement Manager (FRM) or Clinical Account Specialist (CAS) can assist your practice in the enrollment process for your patients using simplicitycares.com or via fax

Benefits Verification & Prescription Form

Step 1: ADDITIONAL SERVICES ☐ Yes, I Would Like CIMplicity to Provide PA Support ☐ Yes, I Would Like CIMplicity to Triage to Payer Mandated Pharmacy

Step 2: PATIENT INFORMATION

Name (Last) _____ Name (First) _____ Gender ☐ M ☐ F DOB / /

Street Address _____ City _____

State _____ Zip _____ Email _____

Mobile Phone # _____ Home Phone # _____

I have agreed to the provided HIPAA Patient Authorization Form **PATIENT SIGNATURE** _____ Date / /

Step 3: INSURANCE INFORMATION

☐ Primary Insurance Member # _____ Phone _____

☐ Secondary Insurance Member # _____ Phone _____

☐ Pharmacy Insurance Member # _____ RX Bin # _____ Phone _____

Step 4: PATIENT HISTORY

☐ Methotrexate ☐ NSAIDs ☐ 6-MP ☐ Surgery ☐ Plaquenil ☐ Sulfasalazine ☐ Corticosteroids

☐ Soriatane ☐ Topical Steroids ☐ Azathioprine ☐ UVA/UVB ☐ Entocort ☐ 5-ASA's

Previous Biologic and Oral Therapies (Write Previous Biologics Below): _____

Step 5: RX AND CLINICAL INFORMATION

ICD-10: _____

Drug Allergies: _____ ☐ NKDA

Step 6: PRESCRIBER INFORMATION

Prescriber Name (Last) _____ Prescriber Name (First) _____

Specialty ☐ Rheumatology ☐ Gastroenterology NPI # _____ Tax ID # _____

Step 7: PRESCRIPTION INFORMATION

By filling out this form, practitioner acknowledges that formulation decisions are made based upon an independent clinical judgment and any information provided in response to this request is not intended to influence prescribing decision.

1. Formulation (Select One)	2. Loading Dose	3. Maintenance Dosing (Select One)	4. Nurse Training (Optional)
<input type="checkbox"/> CIMZIA Pre-Filled Syringe	NDC: 50474-710-81 <input type="checkbox"/> Inject 400 mg SQ at 0, 2, and 4 weeks Dispense: 1 Kit (6 syringes)	NDC: 50474-710-79 <input type="checkbox"/> Inject 200 mg SQ every 2 weeks 1 Kit (2 Syringes) Refill _____ <input type="checkbox"/> Inject 400 mg SQ every 4 weeks 1 Kit (2 Syringes) Refill _____ <input type="checkbox"/> Inject 400 mg SQ every 2 weeks 2 Kits (4 Syringes) Refill _____	<input type="checkbox"/> Request to Send CIMplicity Nurse to Patient's HOME to Train on Self-Injection.
OR <input checked="" type="checkbox"/> CIMZIA Lyophilized Powder for Reconstitution	NDC: 50474-700-62 <input type="checkbox"/> Inject 400 mg SQ at 0, 2, and 4 weeks Dispense: 3 Kits (6 Vials)	NDC: 50474-700-62 <input type="checkbox"/> Inject 200 mg SQ every 2 weeks 1 Kit (2 Vials) Refill _____ <input type="checkbox"/> Inject 400 mg SQ every 4 weeks 1 Kit (2 Vials) Refill _____ <input type="checkbox"/> Inject 400 mg SQ every 2 weeks 2 Kits (4 Vials) Refill _____	

I appoint CIMplicity, on my behalf, to convey this prescription to the appropriate party **PRESCRIBER SIGNATURE** _____ Date / /

Please see Important Safety Information on reverse side, and refer to the full Prescribing Information provided by the UCB representative, and visit CIMZIAhcp.com.

For more information contact the CIMplicity service center: **Fax: 1-866-949-2469**
Hours: 8am to 8pm ET, Monday-Friday **Phone: 1-866-424-6942**



Complete patient enrollment online at simplicitycares.com

OR



Fax a completed CIMplicity® Enrollment Form to 1-866-949-2469



Please see additional Important Safety Information on the back cover.
Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.





STEP 1 | DETERMINING A PATIENT'S COVERAGE

Reviewing Benefits

Start by reviewing the Verification of Benefits*

Once CIMplicity® investigates your patient's benefits, your practice will receive an overview of your patient's benefits and coverage for CIMZIA® (certolizumab pegol) In-Office Injection. The examples on this page show a patient's coverage for treatment with CIMZIA In-Office Injection under a commercial plan's Medical Benefit.

*Patient benefits and coverage may vary based on Payer benefit design.

CIMZIA® (certolizumab pegol)

LYOPHILIZED POWDER VERIFICATION OF BENEFITS - SECONDARY

Secondary Insurance Verification Results

Case ID: New/Reverification: Patient: DOB: MRN: Diagnosis Code: Physician: Office Contact: Office Phone: Prior Biologics/History:	Payer Name: Payer Phone: Plan Name: Plan Type: Policy Number:	Site of Care: Payer Suggested Coding: Payer Call Reference #: Payer Contact: BV Completed:
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CIMZIA® (certolizumab pegol)

LYOPHILIZED POWDER VERIFICATION OF BENEFITS - PRIMARY

Primary Insurance Verification Results

Case ID: New/Reverification: Patient: DOB: MRN: Diagnosis Code: Physician: Office Contact: Office Phone: Prior Biologics/History:	Payer Name: Payer Phone: Plan Name: Plan Type: Policy Number: Group: Policy Effective Date: Policy Expiration Date: Policy Renewal Date:	Site of Care: Payer Suggested Coding: Payer Call Reference #: Payer Contact: BV Completed: PBM: PBM Program: Savings Card Eligible**:
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COVERAGE FOR CIMZIA® LYOPHILIZED POWDER - PRIMARY

Physician Purchase (Buy & Bill)	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	PA/Pre-Cert Required?
Ind. Deductible:	Office Visit Co-Pay:	Office Visit Co-Ins.:	PA/Pre-Cert Required?	
Fam. Deductible:	Ind. Deductible Met:	Fam. Deductible Met:	OOP Max:	
Step Edit:				
Assignment of Benefits (AOB)	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	PA/Pre-Cert Required?
Preferred SP:	SP Phone:	SP Phone:	SP Fax:	
Pharmacy Benefit for Lyophilized Powder	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	PA/Pre-Cert Required?
Ind. Deductible:	Ind. Deductible Met:	Fam. Deductible Met:	OOP Max:	
Fam. Deductible:	Benefit Cap Met:	OOP Max Met:		
Step Edit:				
Additional Information:				

****NOT A GUARANTEE OF PATIENT insurance coverage for CIMZIA®.** Insurance coverage for CIMZIA® is available in Puerto Rico, or where not be submitted to any public pay amount is \$15,000 per calendar year.

Disclaimer: THIS VERIFICATION OF informational purposes only and r or endorse the use of any particular physician's diagnosis of the individual offices are responsible for the acc intended only for confidential use.

Please refer to the full Prescribing by the UCB representatives, and for more information, contact the CIMZIA® service center
Hours: 8:00 AM to 8:00 PM ET, Monday through Friday
Phone: 1-866-4CIMZIA (1-866-424-6124)
USP-C23018-0120

****NOT A GUARANTEE OF PATIENT SAVINGS CARD ELIGIBILITY.** The CIMplicity Savings Card is available to individuals with commercial prescription insurance coverage for CIMZIA®. Not valid for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, similar federal or state-funded programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), or where otherwise prohibited by law. Product dispensed pursuant to program rules and federal and state laws. Claims should not be submitted to any public payer (i.e., Medicare, Medicaid, Medicaid, Medicaid, TRICARE, VA, and DoD) for reimbursement. The maximum annual benefit amount is \$15,000 per calendar year. The parties reserve the right to amend or end this program at any time without notice.

Disclaimer: THIS VERIFICATION OF BENEFITS IS NOT A GUARANTEE OF COVERAGE OR PAYMENT. The benefit information contained herein is provided for informational purposes only and represents no statement, promise or guarantee concerning reimbursement of CIMZIA®, and UCB does not recommend or endorse the use of any particular diagnosis or procedure code. It is the physician's responsibility to determine the appropriate codes based on the physician's diagnosis of the individual patient and the procedures performed. Payer coverage is subject to change without notice. Physicians and their offices are responsible for the accuracy of any claims, invoices and related documentation submitted to payers. The content of this communication is intended only for confidential use of the person(s) to whom it is addressed above.

Please refer to the full Prescribing Information, including boxed warning regarding serious infections, including tuberculosis and lymphoma, provided by the UCB representatives, and visit CIMZIAhpc.com.

For more information, contact the CIMplicity® service center
Hours: 8:00 AM to 8:00 PM ET, Monday through Friday Fax: 1-866-949-2469
Phone: 1-866-4CIMZIA (1-866-424-6124) Website: www.cimzia.com

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Preparing patients for their financial responsibility

Use the information in the Verification of Benefits Notification when you:

- Explain co-pay/co-insurance requirements for the medication and the office visit, and annual deductible, if applicable
- Assist patients in obtaining a CIMZIA Savings Card for In-Office-Injection if eligible†
- Discuss collection of out-of-pocket costs

Disclaimer: The Verification Form example shown is for illustrative purposes only. Patient benefits and coverage may vary based on Payer benefit design.

†See page 22 for additional Co-Pay Savings Program terms and conditions.

Please see Important Safety Information on the back cover.



Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhpc.com.



STEP 1 | DETERMINING A PATIENT'S COVERAGE

A CIMZIA® (certolizumab pegol)

LYOPHILIZED POWDER VERIFICATION OF BENEFITS - PRIMARY

Primary Insurance Verification Results			
Case ID:	Payer Name:	Site of Care:	
New/Reverification:	Payer Phone:	Payer Suggested Coding:	
Patient:	Plan Name:	Payer Call Reference #:	
DOB: B	Plan Type: C	Payer Contact: D	
MRN:	Policy Number:	BV Completed:	
Diagnosis Code:	Group:	PBM:	
Physician:	Policy Effective Date:	PBM Phone:	
Office Contact:	Policy Expiration Date:	Savings Card Eligible**:	
Office Phone:	Policy Renewal Date:		
Prior Biologics/History:			

E **COVERAGE FOR CIMZIA® LYOPHILIZED POWDER - PRIMARY**

COVERAGE FOR CIMZIA® LYOPHILIZED POWDER - PRIMARY				
Physician Purchase (Buy & Bill)	<input type="checkbox"/> In-Network	<input type="checkbox"/> Out-of-Network		
	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	
	Office Visit Co-Pay:	Office Visit Co-Ins:	PA/Pre-Cert Required?	
Ind. Deductible:	Ind. Deductible Met:	OOP Max:		
Fam. Deductible:	Fam. Deductible Met:	OOP Max Met:		
Step Edit:				
Assignment of Benefits (AOB)	Please note: All financial medical coverage information for Physician Buy & Bill benefits (above) applies to Assignment of Benefits with the exception of copay/coinsurance for CIMZIA®, which is listed below.			
	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	PA/Pre-Cert Required?
	Preferred SP:	SP Phone:	SP Fax:	
Pharmacy Benefit for Lyophilized Powder	Coverage for CIMZIA® Available?	Co-Pay for CIMZIA®:	Co-Ins. For CIMZIA®:	PA/Pre-Cert Required?
	Preferred SP:	SP Phone:	SP Fax:	
	Ind. Deductible:	Ind. Deductible Met:	OOP Max:	
Fam. Deductible:	Fam. Deductible Met:	OOP Max Met:		
Benefit Cap:	Benefit Cap Met:			
Step Edit:				
Additional Information:				

****NOT A GUARANTEE OF PATIENT SAVINGS CARD ELIGIBILITY:** The Cimlicity Savings Card is available to individuals with commercial prescription insurance coverage for CIMZIA®. Not valid for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, similar federal or state-funded programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), or where otherwise prohibited by law. Product dispensed pursuant to program rules and federal and state laws. Claims should not be submitted to any public payor (i.e., Medicare, Medicaid, Medigap, TRICARE, VA, and DoD) for reimbursement. The maximum annual benefit amount is \$15,000 per calendar year. The parties reserve the right to amend or end this program at any time without notice.

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Please refer to the full Prescribing Information, including boxed warning regarding serious infections, including tuberculosis and lymphoma, provided by the UCB representatives, and visit CIMZIAhcp.com.

For more information, contact the Cimlicity® service center
Hours: 8:00 AM to 8:00 PM ET, Monday through Friday Fax: 1-866-949-2469
Phone: 1-866-4CIMZIA (1-866-424-6942) Website: www.cimzia.com

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USP-C20518-0125

STEP 1 | DETERMINING A PATIENT'S COVERAGE

CIMZIA® (certolizumab pegol) In-Office Injection Verification of Benefits

Review the Verification of Benefits for a detailed outline of your patient's coverage.

A Formulation (lyophilized powder for in-office injection or prefilled syringe)

B Patient Information

- CIMplicity® ID
- Patient Name
- Date of Birth (DOB)
- Diagnosis Code
- Prior History
- CIMZIA J Code
- Medical Record Number (MRN)

C Plan Information

- Payer Name
- Plan Name
- Plan Type
- Effective Dates

D Payer Contact Information

- Co-pay Assistance Eligibility
- BV Delivered-Benefit Verification Delivered
- Prior Biologics/History
- Billable CPT® Codes
- Specific Case-related Information
- CIMplicity Case Manager Contact Information

E Medical Benefits

- Coverage for CIMZIA
- Drug Co-pay/Co-insurance
- Office Visit Co-pay/Co-insurance
- Deductible Information
- Out-of-Pocket (OOP) Information
- OOP Max
- Prior Authorization Requirement
- Step Edit Requirements

F Assignment of Benefits Coverage

- Coverage for CIMZIA
- Drug Co-pay/Co-insurance
- Prior Authorization Information
- Specialty Pharmacy Provider Information

G Pharmacy Benefits

- Coverage for CIMZIA (LYO Under Pharmacy Benefit)
- Drug Co-pay/Co-insurance
- Prior Authorization Requirement
- Prior Authorization Information
- Specialty Pharmacy Provider Information
- Deductible Information
- OOP Information
- Step Edit Requirements

STEP 2 | PURCHASING AND ADMINISTRATION

To Obtain Pricing for CIMZIA® (certolizumab pegol): Contact one of these Group Purchasing Organization (GPO) Partners

CIMZIA is made available through a number of GPO partners. **You must join a GPO to access the CIMZIA GPO contract price.** Confirm you have a GPO membership agreement in place prior to purchasing*

GPO Partner	Web site	Contact Number
Cardinal Vitalsource™	www.vitalsourcegpo.com	877.453.3972
Cornerstone Partners™	www.cornerstonepartnersgpo.com	800.768.2002
CuraScript® Matrix	www.curascripts.com/matrix-GPO	877.599.7748
HealthTrustSM Group	www.healthtrustpg.com	888.222.1172
IntalereSM	www.intalere.com	877.711.5600
IPN (International Physician Group through Besse Medical)	www.ipnonline.com	877.728.3476
MHA™	www.mhainc.com	800.642.3020
McKesson Specialty Health, OnMark	www.mckessonspecialtyhealth.com	855.477.9800
McKesson PACT	www.mckesson.com/pharmacies/pharmaceutical-ordering-and-packaging/pharmaceutical-group-purchasing-organizations	866-329-0113 (for retail pharmacies) 800-571-2889 (for health system or alternate site pharmacies)
Premier	www.premierinc.com	877.777.1552
ROi (Resource Optimization & Innovation)	www.roiscs.com	314.364.6400
Unity		833.726.8766
Vizient®	www.vizientinc.com	866.600.0618

*This list is subject to change without notice.

Please see Important Safety Information on the back cover.
Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 2 | PURCHASING AND ADMINISTRATION

To Purchase CIMZIA® (certolizumab pegol): Purchase from either a Specialty Distributor or a Wholesaler

Please provide your GPO contract number to the Wholesaler or Specialty Distributor when purchasing CIMZIA In-Office Injection

Wholesaler or Specialty Distributor	Contact Number
Besse® Medical/AmerisourceBergen Specialty Group	877.728.3476
Cardinal Health™	866.300.3838
CuraScript	877.599.7748
Health Coalition, Inc.	800.456.7283
Henry Schein®	800.772.4346
McKesson Specialty Health	855.477.9800
Metro® Medical	800.768.2002
Oncology® Supply/AmerisourceBergen Specialty Group	800.633.7555



Purchasing Checklist

- ☒ Contact the GPO to become a member and receive the CIMZIA contract price
- ☒ Provide the Specialty Distributor or Wholesaler with your GPO contract number when ordering CIMZIA
- ☒ Wholesaler or Specialty Distributor ships medication to your office
- ☒ Pay Wholesaler or Specialty Distributor for your CIMZIA order directly



REMEMBER

- Medication orders should be based on appointment calendar:
 - Schedule delivery close to patient injection dates
 - Work with your Specialty Distributor to establish lead times for product orders
 - Confirm order requirements with wholesaler

STEP 2 | PURCHASING AND ADMINISTRATION

CIMZIA® (certolizumab pegol) In-Office Injection Dosing in RA, PsA, AS, nr-axSpA, PSO and CD¹


Subcutaneous anti-TNF therapy with an approved loading dose. See below for the recommended dosing schedule for lyophilized powder for reconstitution.

CIMZIA Recommended Dosing and Administration*

After initial dosing is complete, please talk with your patient about which maintenance dose should be taken.

MONTH 1

ALL INDICATIONS



NDC 50474-0700-62
Dispense 3 Kits (6 syringes)

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



MONTH 2 AND BEYOND

INDICATION-SPECIFIC

CD

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

NDC 50474-0700-62
Dispense 1 Kit (2 syringes)

RA
PsA
AS
NR axSpA

400 mg
(2 injections x 200 mg/mL) **OR** **200 mg**
(1 injection x 200 mg/mL)
EVERY 4 WEEKS **EVERY 2 WEEKS**

NDC 50474-0700-62
Dispense 1 Kit (2 syringes)

PSO

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

NDC 50474-0700-62
Dispense 2 Kits (4 syringes)

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.

**Dosing shown with lyophilized powder formulation.
Dosing would be the same with prefilled syringe.**

*For subcutaneous administration in abdomen or thigh. Please see section 2 of full Prescribing Information for additional dosing and administration information.

Reference: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

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 which may cause an allergic reaction in individuals sensitive to latex.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 2 | PURCHASING AND ADMINISTRATION

CIMZIA® (certolizumab pegol) In-Office Injection Kit

Every 400 mg In-Office Injection Kit contains 2 inner cartons.

Each carton contains:

- 1 Vial of CIMZIA (200 mg)
- 1 Vial of sterile water for injection (1 mL)
- 1 Single-dose plastic syringe
- 4 Alcohol swabs
- 2 Reconstitution safety needles
- 1 Dosing safety needle

All-in-one packaging for CIMZIA In-Office Injection includes all the supplies necessary for reconstitution and administration.



2 Storage Options for CIMZIA In-Office Injection¹



Room Temperature

- Unopened CIMZIA vials can be stored at room temperature for up to six months, but not exceeding the original expiration date
- Room temperature up to a maximum of 25°C (77°F)
- Do not place back in refrigerator
- Write the new expiration date in the space provided on the kit itself
- **CIMZIA lyophilized powder vials stored at room temperature are immediately ready to be reconstituted**

AND/OR



Refrigerated

- Refrigerate kit between 2° and 8°C (36° to 46°F)
- Note the expiration date on the kit
- Remember to bring CIMZIA lyophilized powder vials to room temperature before reconstituting (may take up to 30 minutes)

Reference: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 2 | PURCHASING AND ADMINISTRATION

Preparation and Administration Process¹

Preparation

If stored at room temperature

- Unopened vials may be stored at room temperature* for 6 months, but not exceeding the original expiration date
- Room temperature up to a maximum of 25°C (77°F)
- Once committed to room temperature, do not place back in refrigerator
- CIMZIA® (certolizumab pegol) In-Office Injection vials stored at room temperature are immediately ready to be reconstituted
- Use appropriate aseptic technique when preparing and administering CIMZIA.

If stored in the refrigerator

- Refrigerate carton between 2° to 8°C (36° to 46°F). Do not freeze
- Remove CIMZIA from the refrigerator and allow the vial(s) to sit at room temperature for 30 minutes before reconstituting. Do not warm the vial in any other way
- Use appropriate aseptic technique when preparing and administering CIMZIA

Reconstitution

1. **Add 1 mL of Sterile Water for Injection, USP**, per vial. Use the 20-gauge needle provided. The Sterile Water for Injection should be directed at the vial wall rather than directly on CIMZIA
2. **Gently swirl** each vial of CIMZIA for about one minute without shaking, assuring that all of the powder comes in contact with the Sterile Water for Injection. The swirling should be as gentle as possible in order to avoid creating a foaming effect
3. Continue swirling every 5 minutes as long as non-dissolved particles are observed. Full reconstitution may take as long as 30 minutes

The final reconstituted solution contains 200 mg/mL and should be a clear-to-opalescent, colorless-to-pale yellow liquid essentially free from particles

- Once reconstituted, CIMZIA can be stored in the vials for up to 24 hours between 2° to 8°C (36° to 46°F) prior to injection. Do not freeze

Administration

- Prior to injecting, reconstituted CIMZIA should be at room temperature
- Do not leave reconstituted CIMZIA at room temperature for more than 2 hours prior to administration
- Withdraw the reconstituted solution into a separate syringe for each vial using a new 20-gauge needle for each vial so that each syringe contains 1 mL of CIMZIA (200 mg of certolizumab pegol)
- Replace the 20-gauge needle(s) on the syringes with a 23-gauge(s) for administration
- Inject the full contents of the syringe(s) subcutaneously, by pinching the skin of the abdomen or thigh

Where a 400-mg dose is required, 2 injections are required; therefore, separate sites should be used for each 200-mg injection.



For more information and resources visit cimziainoffice.com

*Up to a maximum of 25°C (77°F).

Reference: 1. CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 3 | CODING AND BILLING

ICD-10-CM Codes for CIMZIA® (certolizumab pegol) In-Office Injection

The following list provides ICD-10-CM Codes that may relate to the use of CIMZIA In-Office Injection for its approved indications.

ICD-10-CM CODE ^{1*†}	ICD-10-CM CODE DESCRIPTION
K50.##	Crohn's disease, descriptors vary
K50.10	Crohn's disease of large intestine without complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.90	Crohn's disease, unspecified, without complications
M05.0##	Felty's syndrome, descriptors vary
M05.4##	Rheumatoid myopathy with rheumatoid arthritis, descriptors vary
M05.6##	Rheumatoid arthritis, descriptors vary
M05.7##	Rheumatoid arthritis, RF(+), descriptors vary
M05.8##	Other rheumatoid arthritis, RF(+), descriptors vary
M06.0##	Rheumatoid arthritis, RF(-), descriptors vary
M06.8##	Other specified rheumatoid arthritis, descriptors vary
M06.9	Rheumatoid arthritis, unspecified
M45.#	Ankylosing spondylitis, descriptors vary
M46.8# [‡]	Non-radiographic axial spondyloarthritis, descriptors vary Other specified inflammatory spondylopathies, descriptors vary
L40.0#	Psoriasis vulgaris, descriptors vary
L40.5#	Arthropathic psoriasis, descriptors vary
L40.8#	Other psoriasis, descriptors vary
L40.9	Psoriasis, unspecified

Special notes: While we have provided a sample of potential ICD-10-CM codes for billing as they pertain to the approved indications for CIMZIA treatment, the ultimate responsibility for correct coding lies with the service provider. The codes included in this chart are not intended to encourage or suggest use of any drug that is inconsistent with US Food and Drug Administration (FDA)-approved indications and usage. The codes provided are not intended to be exhaustive and are subject to change. Please consult your ICD-10 code book for a detailed list of codes and additional information, including dosing information, which may vary by indication and patient demographic. Also, please contact your payers individually for specific guidance regarding their implementation of the new code set and any coding requirements (procedure codes, payer's use of modifiers, etc) that might pertain uniquely to their organization.

RF, rheumatoid factor.

*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 and 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.

‡Starting October 1, 2020, the diagnostic codes for non-radiographic axial spondyloarthritis (nr-axSpA) will be indexed to the existing ICD-10 subcategory of M46.8. ICD-10 diagnostic code of M46.8 will continue to support other specified inflammatory spondylopathies, in addition to nr-axSpA. Please check with payers to ensure their systems have included this update.

Reference: 1. American Medical Association. *HCPCS Level II 2018 Professional*. United States; American Medical Association; 2018.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 3 | CODING AND BILLING

Coding Information for CIMZIA® (certolizumab pegol) In-Office Injection Claims Submissions

Please contact your UCB Field Reimbursement Manager, CIMplicity® or the Payer for additional CIMZIA Coding Information.

Drug/Biologic Codes

CODE TYPE	CODE	DEFINITION
HCPCS (J Code) ¹	J0717	Certolizumab pegol, 1 mg
NDC 1500 Form ²	50474-0700-62	CIMZIA Kit: 2 x 200 mg lyophilized powder vials
NDC 5010 Electronic Transition Codes	N4 50474-0700-62 UN1	CIMZIA Kit: 2 x 200 mg lyophilized powder vials

CPT®/Drug Administration Codes

Current Procedural Terminology codes which may be appropriate when CIMZIA is administered by a healthcare professional.

CPT® ³	96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular
	96401*	Chemotherapy administration, subcutaneous or intramuscular

*Some Medicare jurisdictions only reimburse CPT Code 96372, so please check with your local MAC for any coverage limitations.

Revenue Codes (CMS-1450/UB-04—for use in hospital outpatient department)⁴

Revenue	0636	Drugs requiring detailed coding
	0330	Radiology—therapeutic
	0331	Radiology—therapeutic; chemotherapy—inject

References: **1.** American Medical Association. *HCPCS Level II 2018 Professional*. United States; American Medical Association; 2018. **2** CIMZIA [prescribing information]. Smyrna, GA: UCB, Inc. **3.** American Medical Association. *CPT® 2018 Professional*. United States; American Medical Association; 2018. **4.** Understanding hospital revenue codes. Value Healthcare Services website. <http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/>. Accessed August 3, 2020.

Disclaimer: The information contained in this guide is for educational purposes only. It is intended to assist healthcare professionals in understanding the reimbursement process for CIMZIA when appropriately prescribed or administered. Any determination regarding if and how to seek reimbursement should be made by the appropriate members of the physician office and in consideration of the specific patient. Although payers generally reimburse for CIMZIA, it is the plan details that dictate coverage of the individual patient's healthcare.

The information contained in this guide represents no statement, promise, or guarantee by UCB concerning reimbursement of CIMZIA and injection services and UCB does not recommend or endorse the use of any particular diagnosis or procedure code. Importantly, payer coverage, reimbursement codes, and payment are subject to continual change; information contained in this guide is current as of August 2020.

Current Procedural Terminology (CPT) Codes and descriptors are ©2020 by American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



STEP 3 | CODING AND BILLING

CIMZIA® (certolizumab pegol) In-Office Injection Sample Claim Forms

Sample CMS-1500 and CMS-1450/UB-04 forms are provided below as general examples of the application of various codes. Remember, if claim forms are not accurately completed, there is a risk of denial or delay in payment for CIMZIA In-Office Injection and its administration.

Physician Offices

Complete
the CMS-1500
Claim Form

HEALTH INSURANCE CLAIM FORM																		CARRIER →
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12																		
PICA <input type="checkbox"/>																PICA <input type="checkbox"/>		
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BEN LUNG <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S ID NUMBER (For Program in Item 1)																PATIENT AND INSURED INFORMATION ↑
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE MM DD YY		SEX M <input type="checkbox"/> F <input type="checkbox"/>		4. INSURED'S NAME (Last Name, First Name, Middle Initial)												
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No., Street)														
CITY		STATE		CITY												STATE		
ZIP CODE		TELEPHONE (Include Area Code)		ZIP CODE												TELEPHONE (Include Area Code)		
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:																
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>																
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)																
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>																
		d. CLAIM CODES (Designated by NUCC)																
11. INSURED'S POLICY GROUP OR FECA NUMBER																		PATIENT AND INSURED INFORMATION ↓
12. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>																		
13. INSURED'S OTHER CLAIM ID (Designated by NUCC)																		
14. INSURED'S PLAN NAME OR PROGRAM NAME																		
15. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.																		
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)																		OR SUPPLIER ↓
20. OUTSIDE L... YES <input type="checkbox"/>																		
21. PRIOR AUTHORIZATION NUMBER																		
22. DISMISSION CODE ORIGINAL REF. NO.																		
23. BILLING PROVIDER INFO & PH #																		
25. FEDERAL TAX ID. NUM.																		
26. SERVICE FACILITY LOCATION INFORMATION																		
27. ACCEPT ASSIGNMENT YES <input type="checkbox"/> NO <input type="checkbox"/>																		
28. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS																		
29. BILLING PROVIDER INFO & PH #																		
30. SIGNATURE OF PHYSICIAN OR SUPPLIER																		
31. BILLING PROVIDER INFO & PH #																		
32. BILLING PROVIDER INFO & PH #																		
33. BILLING PROVIDER INFO & PH #																		

Item 19: Some payers may ask providers to specify CIMZIA dosage, NDC, and route of administration.*

* Some payers require inclusion of the NDC for all medical claims on Commercial and Medicare Advantage plans.

50474-0700-62 Certolizumab pegol lyo SC

Item 21: Include appropriate ICD-10 diagnosis code. Consult your ICD-10-CM coding manual for a complete list of specific codes.

Item 24D: Include appropriate CPT and HCPCS codes. CPT codes may vary by payer.

Item 24G: 1 or 2 units, depending on number of injections.

Item 24E: Refers to the diagnosis for this service (see box 21).

Item 24G: 200 mg or 400 mg units (J0717, certolizumab pegol).†

Note: For billing purposes, 1 mg = 1 unit of drug.

† Dosing may vary by indication and patient demographic.

J0717

96###

A

A

400

2

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

STEP 3 | CODING AND BILLING

CIMZIA® (certolizumab pegol) In-Office Injection Sample Claim Forms

Hospital Outpatient Department (HOPD)

Complete the
CMS-1450/UB-04
Claim Form

Item 42: Indicate revenue codes.
Example: 0636 attached to J0717
0330 or 0331 attached to CPT code 96372 or 96401

Item 44: Include appropriate CPT and HCPCS codes. CPT codes may vary by payer.

Item 43: Describe procedure.

Item 46: 200 mg or 400 mg units (J0717, certolizumab pegol).
Note: For billing purposes, 1 mg = 1 unit of drug.
* Dosing may vary by indication and patient demographic.

Item 66: Include appropriate ICD-10 diagnosis code. Consult your ICD-10-CM coding manual for a complete list of specific codes.

Item 74: Include appropriate ICD-10-PCS procedure code and date of administration

The CIMZIA In-Office Injection CMS-1500 and CMS-1450/UB-04 sample claim forms are intended solely as a resource tool to assist billing staff regarding reimbursement issues. Any determination about if and how to seek reimbursement should be made only by the appropriate members of the physician's office in consultation with the physician and in consideration of the procedure performed or therapy provided to a specific patient.

Payers may require physicians to report different codes when billing for CIMZIA In-Office Injection. We recommend verifying a health plan's coding policies. For more information on specific policies and other questions, contact the health plan.

Note: The coding information contained herein is gathered from various resources and is subject to change. Healthcare providers should select the most appropriate codes with the highest level of detail to describe the patient's condition and the services rendered to the patient. It is the healthcare provider's sole responsibility to determine and submit appropriate codes. Healthcare providers should contact insurers to verify coverage and correct coding procedures prior to submitting claims, as information on coverage and coding is subject to change without notice.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.

STEP 4 | SUPPORTING PATIENTS

Helping Your Patients Save on Out-of-Pocket Costs for CIMZIA® (certolizumab pegol) In-Office Injection

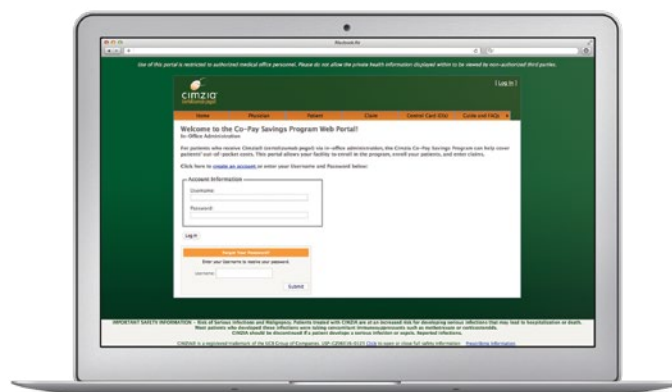
The **Co-pay Savings Program for in-office injection** helps eligible, commercially insured patients save on their out-of-pocket costs for CIMZIA In-Office Injection.* Each eligible patient can receive up to \$15,000 annual savings which can be applied toward CIMZIA In-Office Injection co-pay, co-insurance, deductibles, and/or out-of-pocket maximums.

Electronic Funds Transfer (EFT)

The Co-pay Savings Program is managed through a user-friendly online portal that enables office staff to submit co-pay savings program claims online via EFT.

Advantages include:

- Enrollment for new offices via online portal at ioa.cimziasavingsprogram.com
- Patient enrollment and claim submission through portal
- Co-pay claims paid via EFT to appropriate bank account
- Bank reconciliation number and amount is listed by date, patient, and claims for all transactions



ioa.cimziasavingsprogram.com



**Co-Pay Support
Phone Line**

For questions, please call 1-877-705-4119
toll-free, Monday through Friday from 8:00 AM – 8:00 PM ET

*Please see page 22 for common Co-Pay Savings Program eligibility requirements.

Please see Important Safety Information on the back cover.
Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.












cimzia®
(certolizumab pegol)


STEP 4 | SUPPORTING PATIENTS

Helping Your Patients Save on Out-of-Pocket Costs for CIMZIA® (certolizumab pegol) In-Office Injection

Co-Pay Savings Program Eligibility Requirements

Common Co-Pay Savings Program Eligibility Requirements for In-Office Injection

-  Available to individuals with **commercial insurance coverage** for CIMZIA
-  Patient's **insurance must pay some portion** of the cost of CIMZIA
-  Patient must be **18 years or older** and reside in the **United States or Puerto Rico**
-  Patient has been diagnosed with an **FDA-approved indication**
-  The maximum annual benefit amount is **\$15,000 per calendar year**
-  If a **patient transfers** from the CIMZIA Co-Pay Savings Program for Patients Administering at Home to the CIMZIA Co-Pay Savings Program for In-Office Injection OR from the CIMZIA Co-Pay Savings Program for In-Office Injection to the CIMZIA Co-Pay Savings Program for Patients Administering at Home, the \$15,000 annual cap continues to apply to **the patient's annual maximum benefit**
-  Eligible patients receive their CIMZIA from a trained **HCP, where the HCP is purchasing CIMZIA and administering it to the patient** and directly billing the patient's medical insurance (**originates in HCP office**)
-  **Patients may participate in only one CIMZIA Co-Pay Savings Program at any given time.** Eligible patients receiving CIMZIA shipped via Specialty Pharmacy either to the office (on behalf of the patient) or directly to the patient are not eligible for the CIMZIA Co-Pay Savings Program for In-Office Injection. **Prior to the Specialty Pharmacy fulfilling their CIMZIA prescription,** these patients must enroll themselves in the CIMZIA Co-Pay Savings Program for Patients Administering at Home by calling **1-866-4-CIMZIA** (1-866-424-6942) or by visiting **CIMZIA.com/signup**
-  The CIMZIA Co-Pay Savings Program can be used for out-of-pocket expenses for CIMZIA, including co-payments, co-insurance, and deductibles associated with CIMZIA (HCPCS J Code J0717). This program cannot be used for ancillary medical costs such as doctor visits or administration expenses
-  All reimbursement requests must be submitted within **180 days (6 months) of the date of service.** Reimbursement requests for CIMZIA administration not received within the 180-day limit will be rejected

Please contact  your **UCB Field Reimbursement Manager** if you need additional information or alternative approaches to manage the Co-pay Savings Program.

Please see Important Safety Information on the back cover.

Please ask your UCB representative for the full Prescribing Information and visit CIMZIAhcp.com.



cimzia®
(certolizumab pegol)

STEP 4 | SUPPORTING PATIENTS

Additional Patient Support Programs



CIMplicity Nurse Support Program*

The CIMplicity Nurse Support Program provides supplemental CIMZIA education including dosing and injection training, as well as related disease state information and support services to reinforce the education you have already provided to your patients who have been prescribed CIMZIA.[†]

To get started, patients can call

1-866-4CIMZIA (1-866-424-6942) or text "CONNECT" to **1-317-793-3098** or **87522**.

Foundation Assistance

Alternative sources of funding may be available to assist eligible patients in financial need.

CIMplicity can provide information on independent foundations that may have funding available to help minimize patient drug costs.



ucbCARES®

For answers to patient questions from specially trained ucbCARES associates, your patients can call: **1-844-599-CARE (2273)**, Monday-Thursday, 8:00AM – 8:00PM ET and Friday, 8:00AM – 5:00PM ET, with 24/7 after-hours call support.

ucbCARES is staffed by nurses, pharmacists, and experienced customer care specialists who can provide your patients with information on:

- UCB products and disease states
- Product safety and quality
- Financial assistance

Patient Assistance Program (PAP)

UCB, the maker of CIMZIA, is committed to helping patients get the treatment they need. The CIMZIA Patient Assistance Program helps eligible and qualified patients who are uninsured or underinsured and have no other access to medication. Patients must meet all eligibility requirements to qualify, including income verification and benefit investigation. Patients may apply online at <http://www.askucbcare.com/financial-assistance>.

Patients with any federal or state government insurance programs, such as Medicare, are not eligible for the CIMZIA Patient Assistance Program.

*CIMplicity Program is provided as a service of UCB and is intended to support the appropriate use of CIMZIA. The CIMplicity Program may be amended or canceled at any time without notice. Eligibility and restrictions apply.

[†]The program does not replace the care and medical advice of your patient's healthcare provider. CIMplicity Nurses do not give medical advice and will direct your patients to share their treatment-related questions with their healthcare provider.

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. CIMZIA is not indicated for use in pediatric patients.

- 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 which 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

- Patients on CIMZIA should not receive live or live-attenuated vaccines.

ADVERSE REACTIONS

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

Please see full prescribing information provided by the UCB representative and visit www.CIMZIAhcp.com.



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