



CIMZIA®

(certolizumab pegol)



Lyophilized Powder for In-Office Injection



Prefilled Syringe for At-Home Administration



CIMZIA® Electronic 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 **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.

Getting Started With CIMZIA® (certolizumab pegol)

Get Started

Once a clinical decision by a healthcare provider has been made to prescribe CIMZIA, use this resource to get your patient's treatment journey started.

CIMZIA Offers Two Formulations

In-Office Injection

CIMZIA Lyophilized Powder for Reconstitution (LYO)

May be appropriate for patients whom the physician determines:

- Are unable to self-inject
- Do not have access to a trained caregiver

Comes in a package that contains everything required for reconstitution and injection by an HCP



LYO
2 x 200 mg vials
NDC Number 50474-0700-62

Covered under Medical Benefit and Medicare Part B

At-Home Administration

CIMZIA Prefilled Syringe (PFS)

May be appropriate for patients whom the physician determines:

- Are able to self-inject and are appropriately trained
- Have access to a trained caregiver









PFS Starter Kit
6 x 200 mg/mL
prefilled syringes
NDC Number 50474-0710-81



PFS Kit
2 x 200 mg/mL
prefilled syringes
NDC Number 50474-0710-79

Covered under Pharmacy Benefit and Medicare Part D

CIMZIA Indications

CD	RA	PsA	AS	NR axSpA	PSO
					
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

Reference: 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 additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



CIMZIA® (certolizumab pegol) Recommended Dosing and Administration*



NDC Number
50474-0700-62

Dosing shown below 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 (NDC Number: 50474-0700-62).

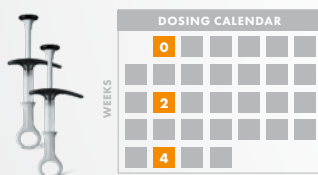
MONTH 1 ALL INDICATIONS



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



CD

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

NDC Number:
50474-0710-79

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

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.

Prefilled syringe designed for comfort and control in partnership with **OXO** **GOODGRIPS®**

OXO, Good Grips® and the associated logos are registered trademarks of Helen of Troy Limited and are used under license.

*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.

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.

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CIMZIA® (certolizumab pegol)

IN-OFFICE INJECTION

YOUR STEP-BY-STEP GUIDE

Keep this guide on hand for easy reference



Preparing to Use CIMZIA®

In-Office Injection for the First Time

- ✓ Contact a Group Purchasing Organization (GPO) to obtain contracted pricing for CIMZIA. You will need to join a GPO to access the CIMZIA GPO Contract Price.
NDC: 50474-0700-62¹
- ✓ Purchase CIMZIA directly from a Wholesaler or Specialty Distributor. Provide your **GPO** contract number to the **Wholesaler or Specialty Distributor** when purchasing CIMZIA.
- ✓ Check the CIMZIA reimbursement 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 Executive (FRE)
for additional information or assistance**

FRE 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.

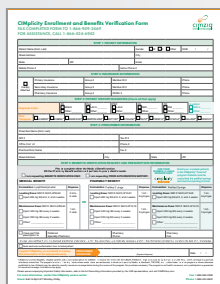
The information contained in this guide is for educational purposes only. It is intended to assist healthcare professionals in understanding the reimbursement process for CIMZIA when appropriately prescribed or administered. Any determination regarding if and how to seek reimbursement should be made 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 health care.

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 January 2022.

Please see additional Important Safety Information on page 32 and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



CIMZIA® In-Office Injection: Steps to Treatment



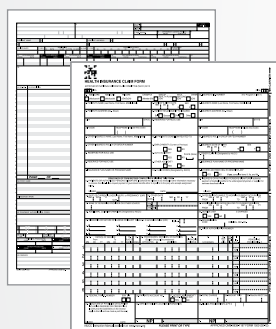
Step 1: Determining a Patient's Coverage

- Complete benefits investigation through CIMplicity®*
 - Have patient sign CIMplicity form
- Review benefits to confirm coverage
- 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
- **Copay assistance is available for eligible, commercially insured patients, please see eligibility criteria on page 25**



Contact your FRE if you have questions or need assistance.

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

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STEP 1 | DETERMINING A PATIENT'S COVERAGE

CIMZIA® 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 availability at https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeesched/pfs-federal-regulation-notice/cms-1751-f	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 additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, 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 using the CIMplicity Enrollment and Benefits Verification form to investigate benefits.

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

CIMplicity Enrollment and Benefits Verification Form
FAX COMPLETED FORM TO 1-866-949-2469
FOR ASSISTANCE, CALL 1-866-424-6942

STEP 1: PATIENT INFORMATION

Patient Name (First, Last) _____ Gender ☐ M ☐ F ☐ Other _____ DOB / / _____
 Street Address _____ City _____
 State _____ ZIP _____ Email _____
 Mobile Phone # _____ Home Phone # _____

STEP 2: INSURANCE INFORMATION

☐ Card(s) Attached

Primary Insurance	Group #	Member ID #	Phone
Secondary Insurance	Group #	Member ID #	Phone
Pharmacy Insurance	Group #	RX Bin #	Phone

STEP 3: PATIENT HISTORY/DIAGNOSIS (Check all that apply)

Diagnosis Code: RA ☐ MD0.9 ☐ PsA ☐ L40.5 ☐ PSO ☐ L40.0 ☐ AS ☐ M45 ☐ CD ☐ K50 ☐ nr-axSpA ☐ M45-A ☐ Other: _____
 Prior Therapies: ☐ HUMIRA® ☐ ENBREL® ☐ REMICADE® ☐ SIMPONI ARIA® ☐ ENTYVIO® ☐ STELARA® ☐ TALZ® ☐ TREMFYA® ☐ OTEZLA® ☐ XELJANZ® ☐ RINVOQ®

STEP 4: PRESCRIBER INFORMATION

STEP 5: BENEFITS VERIFICATION REQUEST AND PRESCRIPTION INFORMATION

Please complete either the Medical Benefit section OR the Pharmacy Benefit section as it pertains to your patient's needs.
☐ I am requesting BENEFITS VERIFICATION ONLY. ☐ I am requesting PRIOR AUTHORIZATION SUPPORT.

MEDICAL BENEFIT		PHARMACY BENEFIT	
Formulation: Lyophilized powder	Dispense	Formulation: Prefilled Syringe	Dispense
Loading Dose: NDC #: 50474-0700-62 <input type="checkbox"/> Inject 400 mg SQ at 0, 2, and 4 weeks.	3 kits - 6 vials	Loading Dose: NDC #: 50474-0710-81 <input type="checkbox"/> Inject 400 mg SQ at 0, 2, and 4 weeks.	1 kit - 6 syringes
Maintenance Dose: NDC #: 50474-0700-62 <input type="checkbox"/> Inject 400 mg SQ every 4 weeks. <input type="checkbox"/> Inject 200 mg SQ every 2 weeks. <input type="checkbox"/> Other: _____	1 kit - 2 vials	Maintenance Dose: NDC #: 50474-0710-79 <input type="checkbox"/> Inject 400 mg SQ every 4 weeks. <input type="checkbox"/> Inject 200 mg SQ every 2 weeks. <input type="checkbox"/> Other: _____	1 kit - 2 syringes

OR

FOR YOUR ELIGIBLE nr-axSpA PATIENTS ONLY	
Formulation: Prefilled Syringe	Dispense
Loading Dose: NDC #: 50474-0710-81 <input type="checkbox"/> Inject 400 mg SQ at 0, 2, and 4 weeks.	1 kit - 6 syringes
Maintenance Dose: NDC #: 50474-0710-79 <input type="checkbox"/> Inject 400 mg SQ every 4 weeks. <input type="checkbox"/> Inject 200 mg SQ every 2 weeks. <input type="checkbox"/> Other: _____	1 kit - 2 syringes

☐ I have sent this prescription to Preferred Specialty Pharmacy: _____ Pharmacy Phone: _____ Pharmacy Fax: _____
 My signature certifies that I am a licensed practitioner under state law, that the above therapy is medically necessary, and that the information provided is accurate to the best of my knowledge.
☐ Send electronic authorization form to listed patient

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

*CIMplicity Covered Eligibility: Eligible patients with a valid prescription for CIMZIA can receive treatment with the CIMZIA Prefilled Syringe at no cost for up to 2 years or until the patient's coverage is approved, whichever comes first. The program is not available to patients whose medications are reimbursed, in whole or in part, by Medicare, Medicaid, TRICARE, or any other federal or state program or where otherwise prohibited by law. Patients may be asked to verify insurance coverage status during the course of the program. No purchase necessary. The program is not health insurance, nor is participation a guarantee of insurance coverage. Limitations may apply.
Please see accompanying Important Safety Information, refer to the full Prescribing Information provided by the UCB representative, and visit CIMZIAhcp.com.
For more information, contact the CIMplicity service center:
 Hours: 8am to 8pm ET, Monday-Friday

**Fax: 1-866-949-2469
 Phone: 1-866-424-6942**



Complete patient enrollment online at simplicitycares.com

OR



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



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

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, 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®.



*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:	Payer Name:	Site of Care:
New/Reverification:	Payer Phone:	Payer Suggested Coding:
Patient:	Plan Name:	Payer Call Reference #:
DOB:	Plan Type:	Payer Contact:
MRN:	Policy Number:	BV Completed:
Diagnosis Code:		
Physician:		
Office Contact:		
Office Phone:		
Prior Biologics/History:		

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:	Plan Type:	Payer Contact:
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:		

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:				
Step Edit:				
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.				
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:	Preferred SP:	SP Phone:	SP Fax:	
Fam. Deductible:				
Benefit Cap:				
Step Edit:				
Additional Information:				

****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 payor (i.e., Medicare, 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 CIMZIAhcp.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: 1-866-4-CIMZIA (1-866-424-6942) Website: www.cimzia.com

USP-C220-10-0120

Preparing Patients for their Financial Responsibility



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

- Explain copay/co-insurance requirements for the medication and the office visit, and annual deductible, if applicable
- Discuss collection of out-of-pocket costs

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				
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:				
F 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?
G Pharmacy Benefit for Lyophilized Powder	Preferred SP:	SP Phone:	SP Fax:	
	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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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 2 | PURCHASING AND ADMINISTRATION**CIMZIA® 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**

- Case ID
- New/Reverification
- Patient
- DOB
- MRN
- Diagnosis Code
- Physician
- Office Contact
- Office Phone

C Plan Information

- Payer Name
- Payer Phone
- Plan Name
- Plan Type
- Policy Number
- Group
- Policy Effective Date
- Policy Expiration Date
- Policy Renewal Date

D Payer Contact Information

- Site of Care
- Payer Suggested Coding
- Payer Call Reference #
- Payer Contact
- BV Completed
- PBM
- PBM Phone
- Savings Card Eligible

E Medical Benefits

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

STEP 2 | PURCHASING AND ADMINISTRATION**To Obtain Pricing for CIMZIA®: 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	Contact Number
Cardinal VitalSource™	877.453.3972
Cornerstone Rheumatology™ GPO	800.768.2002
CuraScript® Matrix	877.599.7748
GastroGPO, LLC	440.250.3568
Gastrologix	610.727.0015
IPN (International Physician Group through Besse Medical)	877.728.3476
MHA™	800.642.3020
McKesson Specialty Health, OnMark	855.477.9800
MosaicGPO™ Solutions	800.768.2002
Unity	833.726.8766

*This list is subject to change without notice.

STEP 2 | PURCHASING AND ADMINISTRATION**To Purchase CIMZIA®: Purchase from either a Specialty Distributor or a Wholesaler**

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

Wholesaler or Specialty Distributor	Contact Number
Besse® Medical	800.543.2111
Cardinal Health™ Specialty Pharmaceutical Distribution	866.677.4844
CuraScript SD	877.599.7748
Henry Schein Inc.	800.772.4346
McKesson Specialty	855.477.9800
Metro Medical™ Distribution	800.768.2002
Oncology® Supply	800.633.7555

**Purchasing Checklist**

- ☒ Contact the GPO to become a member
- ☒ Provide the Specialty Distributor or Wholesaler with your GPO contract number when ordering CIMZIA
- ☒ Ask to receive the CIMZIA contract price
- ☒ 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® In-Office Injection Kit**

Every 400 mg CIMZIA 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****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 LYO vials stored at room temperature are immediately ready to be reconstituted**

AND/OR

**Refrigerated**

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

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

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.


cimzia®
(certolizumab pegol)

STEP 2 | PURCHASING AND ADMINISTRATION

Preparation and Administration Process

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® LYO 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° and 8°C (36° and 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° and 8°C (36° and 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 cimziaainoffice.com



Get step-by-step instructions on how to reconstitute, withdraw, and inject CIMZIA in your practice.

*Up to a maximum of 25°C (77°F).

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

Please see additional Important Safety Information on [page 32](#) and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



cimzia[®]
(certolizumab pegol)

STEP 3 | CODING AND BILLING

ICD-10-CM Codes for CIMZIA® In-Office Injection

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

ICD-10-CM CODE*†	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
M45.A#‡	Non-radiographic axial spondyloarthritis, descriptors vary
M46.8#	Other specified inflammatory spondylopathies, descriptors vary
L40.0	Psoriasis vulgaris, descriptors vary
L40.5#	Arthropathic 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.

‡A new ICD-10 sub-category for non-radiographic axial spondyloarthritis (nr-axSpA) was created and is available for use as of October 1, 2021. Beginning October 1, 2021, the subcategory of M45.A should be used to support patients with nr-axSpA. Please check with payers to ensure their systems have included this update. The ICD-10 diagnostic code of M46.8 will continue to support other specified inflammatory spondylopathies.

Reference: American Medical Association. *HCPCS Level II 2021 Professional*. United States; American Medical Association; 2021.

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



STEP 3 | CODING AND BILLING**Coding Information for CIMZIA® In-Office Injection
Claims Submissions**

Please contact your UCB FRE, 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, and confirm with patient specific insurance.

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 – injected

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 health care.

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 additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



STEP 3 | CODING AND BILLING

CIMZIA® 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 and its administration.

Physician Offices

Complete
the CMS-1500
Claim Form

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

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

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.

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

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare) 2. MEDICAID (Medicaid) 3. TRICARE (TRICARE) 4. CHAMPVA (CHAMPVA) 5. GROUP HEALTH PLAN (Group Health Plan) 6. FECA (FECA) 7. OTHER (Other)

1a. INSURED'S ID. NUMBER (For Program in Item 1) 2. PATIENT'S NAME (Last Name, First Name, Middle Initial) 3. PATIENT'S BIRTH DATE (MM/DD/YY) 4. INSURED'S NAME (Last Name, First Name, Middle Initial) 5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other) 7. INSURED'S ADDRESS (No., Street) 8. RESERVED FOR NUCC USE 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10. IS PATIENT'S CONDITION RELATED TO: 11. INSURED'S POLICY GROUP OR FECA NUMBER 12. RESERVED FOR NUCC USE 13. INSURED'S DATE OF BIRTH (MM/DD/YY) 14. AUTO ACCIDENT? 15. OTHER CLAIM ID (Designated by NUCC) 16. INSURED'S SEX (M, F) 17. RESERVED FOR NUCC USE 18. OTHER ACCIDENT? 19. CLAIM CODES (Designated by NUCC) 20. IS THERE ANOTHER HEALTH BENEFIT PLAN? 21. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 22. INSURED'S SIGNATURE (Print Name, Date) 23. PRIOR AUTHORIZATION NUMBER 24. DATE(S) OF SERVICE (From, To) 25. PLACE OF SERVICE (EMG, Other) 26. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS, Modifier) 27. DIAGNOSIS (ICD-10) 28. CHARGES (Gross, Net, Payor) 29. RESUBMISSION CODE 30. ORIGINAL REF. NO. 31. SIGNATURE OF PHYSICIAN OR SUPPLIER (Including Degrees or Credentials) 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # 34. SIGNATURE OF BILLING PROVIDER 35. DATE

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

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

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 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.

50474-0700-62 Certolizumab pegol lyo SC

J0717 96###

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® 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 46: 1 or 2 units, depending on number of injections.

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 LYO 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.

STEP 4 | SUPPORTING PATIENTS

Helping Your Patients Save on Out-of-Pocket Costs for CIMZIA® 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.*

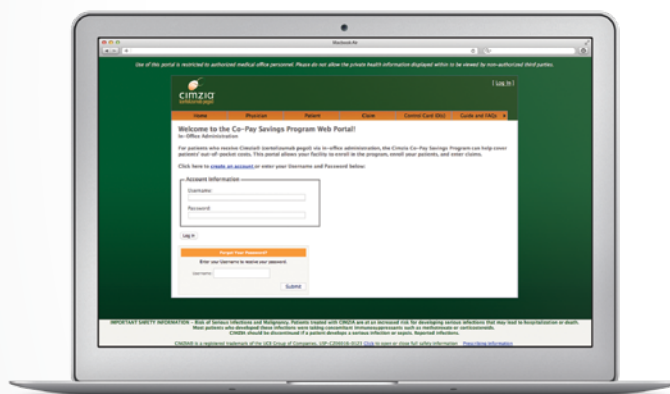
Note: If CIMZIA is shipped from the Specialty Pharmacy to the HCP office for HCP administration, the patient should be enrolled into the pharmacy co-pay program.

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 for medical benefits claims.

Advantages include:

- Enrollment for new offices via online portal at 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



cimziasavingsprogram.com

*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



**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 21 for In-office Injection Co-Pay Savings Program eligibility requirements. ►










Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



STEP 4 | SUPPORTING PATIENTS

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

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 parties **reserve the right to amend or end this program at any time** without notice. The Co-Pay Savings Program is **provided as a service of UCB** and is intended to support the **appropriate use** of CIMZIA. Eligibility and restrictions apply
-  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

CIMZIA® (certolizumab pegol)

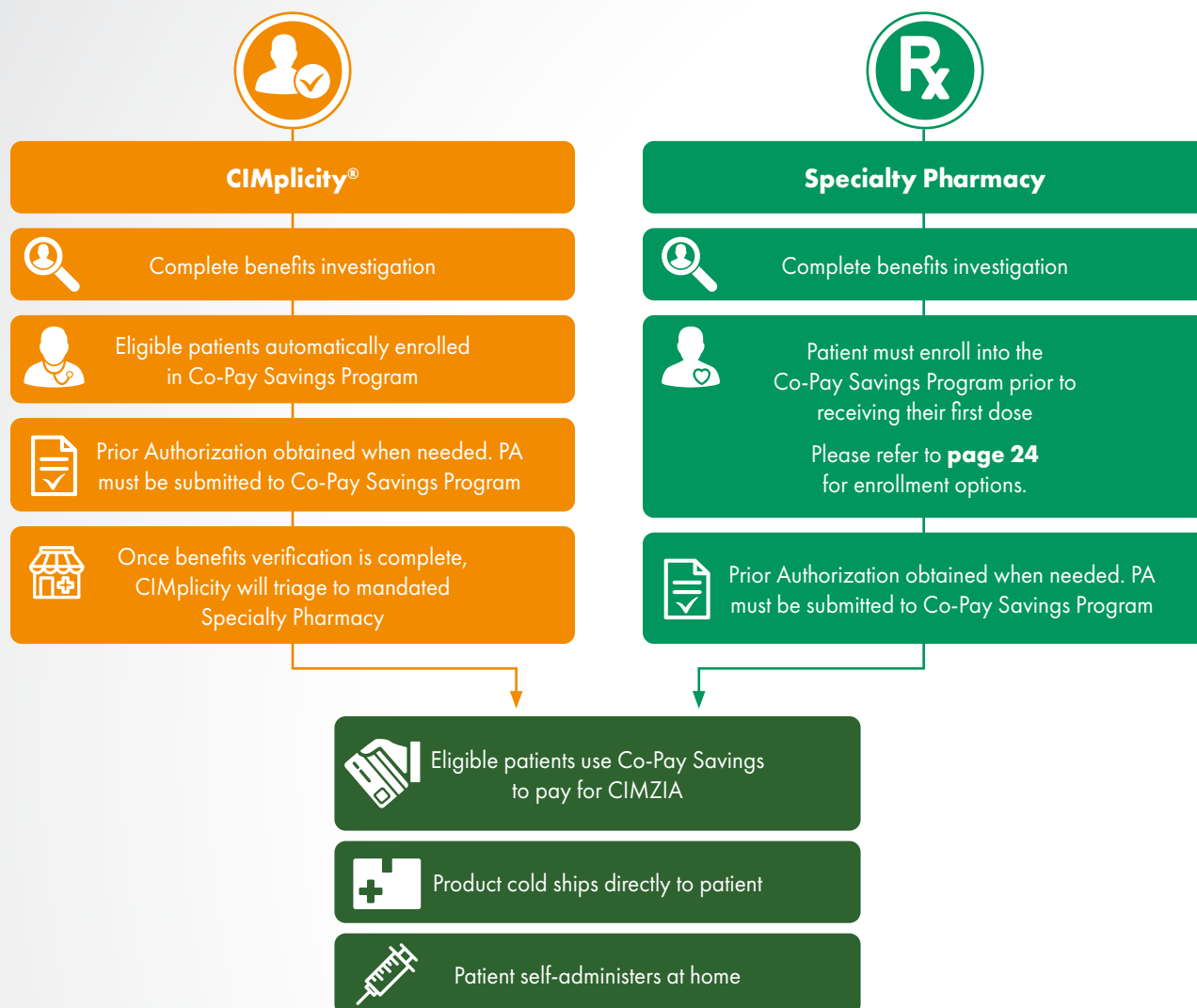
PHARMACY BENEFITS AND PROCESS

Keep this guide on hand for easy reference



At Home Patient Journey (post clinical decision)

HCP to Send CIMZIA PFS Prescription to CIMPlicity® HUB or Specialty Pharmacy of Choice



CIMZIA® is broadly available via open distribution. UCB has contracted with an enhanced network of specialty pharmacies to provide product specific support, see **page 27** for more details.



The CIMPlicity® Covered™ program[†] is available for certain indications within dermatology (PSO, PsA) and rheumatology (nr-axSpA). With CIMPlicity Covered, eligible patients with commercial insurance can receive treatment with CIMZIA PFS at no cost while coverage is being determined. For more details on CIMPlicity Covered for nr-axSpA, see **page 26**.

*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.

[†]CIMPlicity Covered eligibility: Eligible patients with a valid prescription for CIMZIA can receive treatment with the CIMZIA Prefilled Syringe at no cost for up to two years or until the patient's coverage is approved, whichever comes first. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program or where otherwise prohibited by law. Patients may be asked to reverify insurance coverage status during the course of the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Limitations may apply. For initial enrollment into the program, the patient must be experiencing a delay in, or have been denied, coverage for CIMZIA by their commercial insurance plan. To maintain eligibility in the program, the following are required: (1) a prior authorization request has been submitted and/or coverage remains unavailable for the patient; and (2) if the prior authorization is denied by the payer, the prescriber must submit an appeal within the first sixty (60) days of the prior authorization denial and a prior authorization must be submitted every six (6) months thereafter or documentation as may otherwise be required by the payer. UCB reserves the right to rescind, revoke, or amend this Program without notice.

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



CIMplicity® Savings Program for Patients Administering at Home



Eligible Patients* May Receive CIMZIA for a \$0 copay through the CIMplicity Savings Program

- Eligible patients can save on the cost of CIMZIA® throughout treatment
- **NOTE: Patients must be enrolled in the Co-Pay Savings Program prior to shipment of CIMZIA in order to be eligible for the savings**

Multiple Enrollment Options:



CIMplicity Auto-Enroll

OPTION 1: If the healthcare provider (HCP) sends prescription **directly to CIMplicity**, eligible patients will be **automatically enrolled**



Patient Self-Enroll

OPTION 2: Patients can enroll by calling **1-866-4-CIMZIA (1-866-424-6942)** or by visiting **CIMZIA.com/join-cimplicity**



Enrollment via Specialty Pharmacy

OPTION 3: Specialty pharmacies can enroll eligible patients by visiting **UCBSavings.com**



Enrollment via CIMplicity Nurse Navigators†

OPTION 4: Our dedicated nurses can enroll patients over the phone. To talk to a nurse, patient can sign up at **CIMZIA.com/join-CIMplicity** or call **1-844-822-6877**

Goal: Ensure all eligible patients have access to the CIMZIA Co-Pay Savings Program

*Certain restrictions apply. Please see full Eligibility Criteria and Terms on **page 25**. This offer is not available for patients eligible for Medicare, Medicaid or any other form of government insurance coverage.

†The program does not replace the care and medical advice of your patients' doctor. CIMplicity Nurse Navigators do not give medical advice and will direct your patients to share their treatment-related questions with their doctor.

Co-pay Savings Program Eligibility Requirements

-  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**
-  **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** (ie, Medicare, Medicaid, Medigap, TRICARE, VA, and DoD) for reimbursement
-  The parties **reserve the right to amend or end this program at any time** without notice. The Co-Pay Savings Program is **provided as a service of UCB** and is intended to support the **appropriate use** of CIMZIA. Eligibility and restrictions apply
-  Eligible patients either receive their CIMZIA directly from a **retail or specialty pharmacy** OR their CIMZIA is shipped to the healthcare professional (HCP) office via specialty pharmacy for the HCP to administer (**originates in pharmacy**)
-  The Co-Pay Savings program **cannot be applied to treatment administered in the office** unless CIMZIA is shipped from the Specialty Pharmacy to the HCP to administer. Patients **may participate in only one CIMZIA Co-Pay Savings Program at any given time**. If patient switches from self- or home-based treatment administration to in-office administration, and the office is directly billing the patient's medical insurance, the **patient would need to switch** to the program for in-office treatment and the office staff would enroll the patient
-  **Patient must be enrolled in the Savings Program prior to shipment of CIMZIA in order to be eligible for the savings.** Only CIMZIA out-of-pocket expenses incurred after the patient enrolls in the Co-Pay Savings Program are eligible for reimbursement

Eligible nr-axSpA Patients on CIMZIA® Can Receive Customized Support With the CIMplicity® Covered™ Program*

For eligible, commercially insured patients with nr-axSpA who can self-administer CIMZIA, the CIMplicity Covered program is specifically designed to help secure coverage. If coverage is delayed, UCB will provide your eligible patients with CIMZIA prefilled syringes for up to 2 years or until coverage is approved.

Coverage assistance
and support for
eligible patients with
non-radiographic axial
spondyloarthritis
(nr-axSpA)

Start your CIMZIA Patients on the CIMplicity Covered Program

1. **Complete and fax the Patient Enrollment form provided by your sales representative or utilize the CIMplicity Cares Portal that will automatically populate your CIMplicity Covered form for you to print, sign, and fax**
Prescriber must sign the form before it can be submitted
2. **Review returned verification of benefits, then complete the prior authorization (PA) and fax the completed form to 866-949-2469. See below for PA initiation options**
3. **Eligible patients* will be enrolled in the CIMplicity Covered program while coverage is determined**
4. **If PA is denied, to maintain eligibility of Cimplicity Covered, an appeal is required within 60 days**
5. **A prior authorization must be submitted every six (6) months thereafter or documentation as may otherwise be required by the payer**

The CIMplicity Covered program strives for no delay or interruption in treatment once the decision to prescribe CIMZIA has been made.

*Eligibility: Eligible patients with a valid prescription for CIMZIA can receive treatment with the CIMZIA Prefilled Syringe at no cost for up to two years or until the patient's coverage is approved, whichever comes first. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program or where otherwise prohibited by law. Patients may be asked to reverify insurance coverage status during the course of the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Limitations may apply. For initial enrollment into the program, the patient must be experiencing a delay in, or have been denied, coverage for CIMZIA by their commercial insurance plan. To maintain eligibility in the program, the following are required: (1) a prior authorization request has been submitted and/or coverage remains unavailable for the patient; and (2) if the prior authorization is denied by the payer, the prescriber must submit an appeal within the first sixty (60) days of the prior authorization denial and a prior authorization must be submitted every six (6) months thereafter or documentation as may otherwise be required by the payer. UCB reserves the right to rescind, revoke, or amend this Program without notice.

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



cimzia[®]
(certolizumab pegol)



CIMZIA® is broadly available via open distribution. Prescriptions may be sent to the specialty pharmacy of the patient's choosing

UCB has contracted with the specialty pharmacies listed below to provide product specific support*

Specialty Pharmacy Contact Details

Specialty Pharmacy	Phone Number	Fax Number
AcariaHealth	1-800-511-5144	1-877-541-1503
Accredo	1-844-516-3319	1-888-302-1028
AllianceRx Walgreens Prime	1-855-244-2555	1-844-343-3504
Amber Specialty Pharmacy	1-888-370-1724	1-877-645-7514
Amber (Hy-Vee Pharmacy Solutions)	1-877-794-9833	1-855-861-4941
Ardon Health	1-855-425-4085	1-855-425-4096
BioPlus Specialty Pharmacy	1-407-830-8820	1-800-269-5493
CVS Specialty Pharmacy	1-800-237-2767	1-800-323-2445
Humana Specialty Pharmacy	1-800-486-2668	1-877-405-7940
Kroger	1-888-355-4191	1-888-315-3270
Lumicera	1-855-847-3553	1-855-847-3558
Meijer Specialty Pharmacy	1-855-263-4537	1-877-222-5036
Optum Specialty Pharmacy	1-855-427-4682	1-877-342-4596
SenderraRx	1-855-460-7928	1-888-777-5645

*Additional specialty pharmacies may be added soon.

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



CIMplicity® is here to support your patients

Every Step of the Way

Full Suite of Services:



CIMplicity Savings Program

Eligible patients may receive their CIMZIA treatment for a \$0 copay.

- For In-Office Injection criteria and eligibility requirements, see [page 21](#)
- For At-Home Administration criteria and eligibility requirements, see [page 25](#)



Personalized Nurse Support*

CIMplicity nurses can help your patients with nutrition and wellness training, injection training and support, and help get them set up with a treatment journal, free sharps container, and medication reminders.



Benefit Verification and Prior Authorization Support

A step-by-step guide to help you get your CIMZIA patients through the approval process.

- For benefits verification and pay support, see [page 29](#)



Complimentary Sharps Containers

Free prefilled syringe disposal containers made to fit used CIMZIA syringes and needles.



Medication Reminders

Helpful medication reminders on the day and time your patients choose via phone, email, or text.

For your nr-axSpA patients, CIMplicity offers:



CIMplicity® Covered™

Eligible, commercially insured nr-axSpA patients whose insurance coverage is delayed or denied may receive free treatment for up to 2 years or until insurance coverage approval, whichever comes first.

Refer to [page 26](#) for additional program details. ►

*The program does not replace the care and medical advice of your patients' doctor. CIMplicity Nurse Navigators do not give medical advice and will direct your patients to share their treatment-related questions with their doctor.

Please see additional Important Safety Information on [page 32](#) and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.



CIMplicity® Prior Authorization Support Update

As part of CIMplicity Prior Authorization Support, CIMplicity Case Managers can now provide **additional support**, including **initiating CIMZIA Prior Authorizations on behalf of your practice** with most insurance carriers.



What CIMplicity can provide when requesting a Prior Authorization

- ✓ Patient demographics
- ✓ Provider information
- ✓ Patient ID number
- ✓ HCPCS code(s)
- ✓ CPT code(s)
- ✓ ICD-10 code
- ✓ Directions (per Patient Enrollment form)
- ✓ Quantity/length of therapy
- ✓ Tried and failed therapies

Please note that your CIMplicity Case Manager is only permitted to provide the plan with the information listed above.



After initiating your Prior Authorization, your Case Manager will

- Fax the required enrollment package (eg, medical records, chart notes, Prior Authorization form, Patient Enrollment form) to the payer on behalf of the office
- Provide the office with the pending Prior Authorization number
- Continue follow-up with insurance carrier on Prior Authorization determination

Once a Prior Authorization is approved, your Case Manager will document the information and send the office a reminder prior to the Prior Authorization expiration date.

How to Opt In for Prior Authorization Initiation Support

If you wish to opt in for Prior Authorization initiation support on an **individual patient-by-patient basis**, please **check “PA Support”** on the Patient Enrollment form or within the CIMplicity Cares portal.

If you wish to utilize this service for **all of your patients**, please **notify your CIMplicity Case Manager** and the process will be initiated on **all Prior Authorization cases for your practice**.

Your CIMplicity Case Manager is

Case Manager Name

Email (CIMplicity)

Phone Number

Fax Number

Simplifying the Process for CIMplicity® Support

Enabling Digital Options for Patients in a Virtual Environment

Patient HIPAA consent can now be captured electronically

A simplified electronic **HIPAA consent (eConsent)** process is now in place within the CIMplicityCares portal to help streamline patient access to CIMplicity Support for those patients who have not been able to sign the HIPAA consent form on the CIMplicity Patient Enrollment Form (PEF). Once HIPAA consent is signed by the patient, the patient will have access to additional services through CIMplicity:



UCB's Field Reimbursement Executive (FRE) team can provide the practice with patient-specific information related to product access for patients prescribed CIMZIA



Patients will obtain access to additional support offerings such as CIMplicity Nurse Navigators* and more

Verification of Benefits will continue while awaiting eConsent from patient

How to access eConsent for your patients



Step 1:

Access the CIMplicityCares portal by visiting CIMplicitycares.com

- Returning users: Log in with your user ID and password
- New to CIMplicitycares.com? Contact your **UCB Field Reimbursement Executive** to set up your account or to receive training on the portal



Step 2:

When creating a new "Patient Case," the office administrator should select "Yes" to the "Obtain Digital Patient Authorization?" question when completing the patient registration if the patient has provided their authorization.



Step 3:

Upon confirming with the patient, the office administrator should enter either the patient's email address OR mobile phone number, and check the box confirming patient consent to receive electronic messages from UCB.

*The program does not replace the care and medical advice of your patients' doctor. CIMplicity Nurse Navigators do not give medical advice and will direct your patients to share their treatment-related questions with their doctor.

Please see additional Important Safety Information on [page 32](#) and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.


cimzia
(certolizumab pegol)

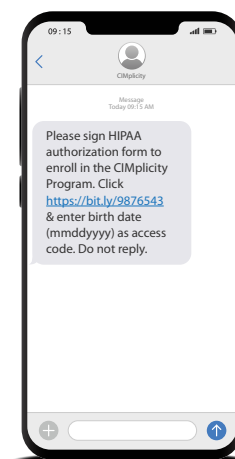
Simplifying the Process for CIMplicity® Support



Step 4:

Patient receives a link via email and/or text message to complete the HIPAA eConsent.

- Patient's access code will be their date of birth (mmddyyyy)

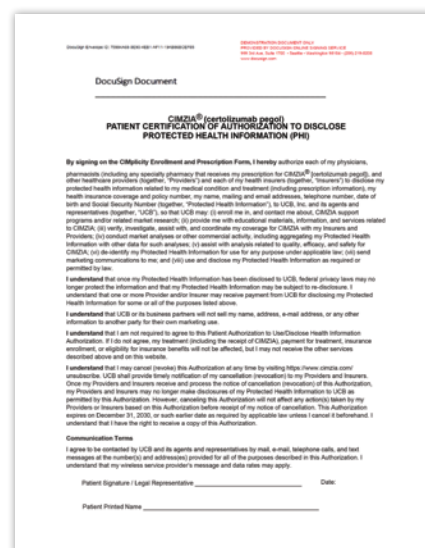


Step 5:

The link directs the patient to DocuSign, where they can complete and submit the HIPAA eConsent.

- Patient does not need to have a DocuSign account to access
- Patient will not need any additional log-in credentials with exception of their birth date
- Patient can sign and submit the eConsent from their computer or smart phone

Note: If the patient would like a copy of their signed form, they will need to print the form from DocuSign within 5 days. After 5 days, the link will expire. If the link is no longer valid, the patient may call their CIMplicity Nurse at 1-844-822-6877 and ask to receive a copy of their signed document OR they can have the office request the signed document be sent to the office from CIMplicity.



Once authorized, CIMplicity Case Managers, Field Reimbursement Executives, and CIMplicity Nurse Navigators* will be able to quickly access the information needed to improve patient support.

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.

*The program does not replace the care and medical advice of your patients' doctor. CIMplicity Nurse Navigators do not give medical advice and will direct your patients to share their treatment-related questions with their doctor.

Please see additional Important Safety Information on **page 32** and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com.

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



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