## Field Reimbursement Executive

CIMplicity<sup>®</sup> Savings Program and CIMplicity<sup>®</sup> Administration Savings Program for CIMZIA<sup>®</sup> (certolizumab pegol) Lyophilized Powder for In-Office Injection



### Indications

CIMZIA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). CIMZIA is indicated for the treatment of adult patients with active psoriatic arthritis (PsA). CIMZIA is indicated for the treatment of adult patients with active ankylosing spondylitis (AS). CIMZIA is indicated for 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. CIMZIA is indicated for the treatment of adults with active psoriasis (PSO) or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. CIMZIA is indicated for the treatment of adults 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.





# Helping Eligible Patients Save on Out-of-Pocket Costs for CIMZIA® (certolizumab pegol) Lyophilized Powder for In-Office Injection

## The CIMplicity Savings Program helps eligible, commercially insured patients save on their out-of-pocket costs for CIMZIA Lyophilized Powder for In-Office Injection\*

- Provides CIMZIA to eligible patients for as little as \$0 per dose
- The CIMplicity Savings Program for CIMZIA Lyophilized Powder for In-Office Injection is managed through an online portal
- Requires a valid prescription for CIMZIA Lyophilized Powder consistent with FDA-approved product labeling



With the CIMplicity Administration Savings Program, eligible patients with commercial insurance can now save out-of-pocket expenses incurred for in-office administration of CIMZIA Lyophilized Powder.\*

\*See page 3 for full eligibility requirements

Contact your Field Re	imbursement Executive for n	nore information.
FRE NAME		Program website: cimziasavingsprogram.com Fax: 908-809-6248
PHONE		
EMAIL		CIMplicity Savings Support Phone Line For questions, please call
		1-877-705-4119 toll-free, Monday through Friday, 8 AM to 8 PM ET





## The CIMplicity Savings Program<sup>\*</sup> and CIMplicity Administration Savings Program for CIMZIA Lyophilized Powder<sup>†</sup> Are Managed Through an Online Portal



## The online portal enables patient enrollment, claims submission, and payment via Electronic Funds Transfer (EFT).

- Enrollment for new offices via online portal at ioa.cimziasavingsprogram.com
- Patient enrollment and claim submission through portal
- Copay claims paid via EFT to appropriate office bank account
- Bank reconciliation number and amount is listed by date, patient, and claims for all transactions
- Log-in with username or email and ability to retrieve forgotten passwords

The online	portal	offers:
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- Site administrators to add secondary users to perform certain functions
- Account administrators to update office banking information as needed
- Sorting and tracking on reconciliation screens, including claim ID
- Ability to add associated practices for accounts with referring practices/physicians

### \*CIMplicity<sup>®</sup> Savings Program

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

### <sup>†</sup>CIMplicity<sup>®</sup> Administration Savings Program for CIMZIA Lyophilized Powder

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







- Select the **"create an account"** link on the CIMplicity Savings Program portal **(ioa.cimziasavingsprogram.com)**.
- 2 Complete all fields. Under Reimbursement Type, select "EFT."
- 3 Enter all banking information and check the box indicating you agree to all terms. Click submit.
- 4 Select **Physician** tab and enter physicians.

## At this point, you have successfully enrolled.

Allow 5 to 7 business days for completion of EFT setup. You will receive an email stating EFT-Verified when the EFT registration process is complete. The notification will also be shown on the top right information bar of the portal stating EFT-Verified.

## Debit and manual payment options are also available. Call your FRE to discuss alternate options

## AFTER SUCCESSFULLY ENROLLING IN EFT:

• Your account will state **EFT-Pending** for 5 to 7 business days.

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- You will receive a notification stating EFT-Verified when the EFT registration process is complete.
   The notification will also be shown on the top right information bar of the portal stating EFT-Verified
- The identifier on your office's bank statement will be "copaysavingsprogram"
- Contact FRE if you require switching from Debit card to EFT.

## Enrolling Patients

On the CIMplicity Savings Program portal homepage, navigate to the **"Patient"** tab or select the **"Enroll a Patient"** hyperlink.

- 2 Select "Add New Patient" and enter all required fields.
- Confirm patient consent for enrollment
- The system will automatically assign a member ID.





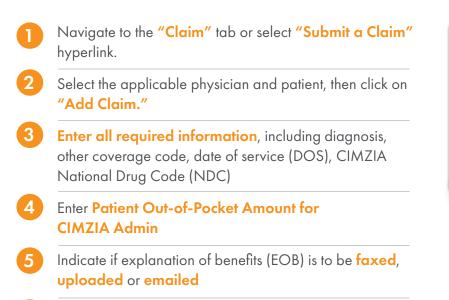


- Navigate to the **"Claim"** tab or select **"Submit a Claim"** hyperlink.
- 2 Select the applicable physician and patient, then click on "Add Claim."
- **Enter all required information**, including diagnosis, other coverage code, date of service (DOS), CIMZIA National Drug Code (NDC)
- 4 Enter Patient out-of-pocket amount for CIMZIA Drug
- 5 Indicate if explanation of benefits (EOB) is to be **faxed**, **uploaded** or **emailed** 
  - **Fax, upload or email** EOB.

Select "Save" to finish submitting the claim.

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## Submitting a Claim for the CIMplicity Administration Savings Program



Fax, upload or email EOB.

Select **"Save"** to finish submitting the claim.

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## Checking Status of a Claim



- Navigate to the "Claim" tab.
- Select the applicable physician, patient, and patient ID. The patient claim history will be shown.
- Each patient claim entered will initially state **PENDING**.
- When the claim processor starts reviewing the claim against the EOB and program business rules, the claim status will state QC.

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- When the review is complete, the patient claim information will state **APPROVED** or **DENIED**.
- If claim is denied, contact support line (1-877-705-4119) or your FRE
- When approved and processed, you will see the date that funds are deposited and the bank tracking number.
- A letter or email will be sent to the office and patient to verify the amount approved or the reason for claim denial.

After the patient EOB is submitted, the processing and payment of a claim will take up to 5 days.

## Payment Reconciliation

1	Navigate to the "Payment Reconciliation" to	ab.
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- Select the **Date of Service** or **Date of Deposit**.
- Select the Physician(s), Patient(s), and Associated Practice(s).
- Select the **Reconciliation Payment Option** (debit, EFT, or both).
- You have the option to export as either a PDF or **Excel**<sup>®</sup> document, and also the option to print a reconciliation document.

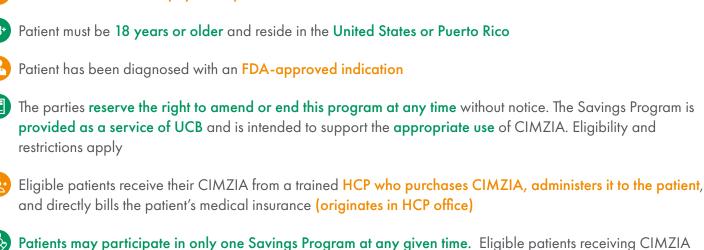
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## Helping Your Patients Save on Out-of-Pocket Costs for CIMZIA® In-Office Injection

## CIMplicity<sup>®</sup> Savings Program and CIMplicity Administration 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

Patients may participate in only one 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 Savings Program for In-Office Injection. Prior to the Specialty Pharmacy fulfilling their CIMZIA prescription, these patients must enroll themselves in the Savings Program for Patients Administering at Home by calling 1-866-4-CIMZIA (1-866-424-6942) or by visiting CIMZIA.com/signup

If a patient transfers from the Savings Program for Patients Administering at Home to the Savings Program for In-Office Injection OR from the Savings Program for In-Office Injection to the Savings Program for Patients Administering at Home, the annual cap continues to apply to the patient's annual maximum benefit

The CIMplicity Savings Program for CIMZIA In-Office Injection provides eligible patients with copay, coinsurance, or deducible associated with CIMZIA (HCPCS JO717). The CIMplicity Adminstration Savings Progam provides eligible patients with reimbursement for in-office administration-related costs (subject to an annual cap) for CIMZIA In-Office Injection. Both programs are subject to an annual cap

All reimbursement requests must be submitted within 180 days of the date of service. Reimbursement requests for CIMZIA out-of-pocket expenses not received within the 180-day limit may be rejected





## CIMplicity Savings Program Frequently Asked Questions

Is my office required to enroll in EFT? Your office is not required to enroll in EFT. You can stay in the Visa debit card 1 program if you wish; however, if you do switch to EFT, you can no longer use the Visa debit card program. Are other options available if my office doesn't have EFT? Other payment options are available, such as debit and manual. For more information, reach out to your FRE. How many administrators under the same account can be on the portal? Only one email address can be submitted for each account. One person from the practice must be designated as site administrator; however, multiple users under the same account can have access to the portal. How long will it take for my EFT registration to be processed? Once an account registers, there is a 5 to 7 day response time from the bank. Once the portal says EFT-Verified, it is ready to process. After my registration is complete, how long will it take from claim submission to payment? When sending a claim, there is a clean claim<sup>\*</sup> processing time of approximately 24 to 48 hours. Payment from the bank would be 2 days thereafter. Normal claim transactions will take up to 5 days. Can eligible patients use the CIMplicity Savings Program to meet their insurance deductible? Yes. The CIMplicity Savings Program can be used for out-of-pocket expenses for CIMZIA® (certolizumab pegol), including copayments, co-insurance, and deductibles. Can the patient receive reimbursements through the CIMplicity Savings Program while he/she is simultaneously participating in another CIMZIA support program? No. CIMZIA patients may participate in only one CIMZIA Savings Program for reimbursement of out-of-pocket expenses at any given time. If the patient stops receiving CIMZIA via in-office administration and switches to self- or home-administered treatment, a different program would provide copay support for pharmacy-filled prescriptions.

B) How do patients receive reimbursement for CIMZIA and its administration? The office submits an evidence of benefit (EOB) form by uploading it on the Copay Savings Program Portal @ www.cimziasavingsprogram.com. The office also has the option of faxing it to (908) 809-6248. The office will receive reimbursement on behalf of the patient the same way they do for the IOA Copay Savings Program today (EFT or Debit).

9) Is there a maximum amount the CIMplicity Savings Program will cover per injection? There is currently no limit per injection.<sup>†</sup> The patients pays as little as \$0 per dose.

**10** Does the program stipulate a minimum number of days between injections? No. The program does not have a frequency restriction; however, insurance providers may have separate limitations that could affect frequency.

11) How long after a date of service can I submit a claim for reimbursement? All reimbursement requests must be submitted within 180 days of the date of service. Reimbursement requests for CIMZIA In-Office Injection out-ofpocket expenses not received within the 180-day limit may be rejected.





12 Is there a patient assistance program (PAP) for eligible patients who cannot afford this medication? Yes. There is a PAP program for eligible patients who have been prescribed CIMZIA. Please call CIMplicity<sup>®</sup> at 1-866-4-CIMZIA (1-866-424-6942). Select option 2, and a case manager will be happy to assist you.

What do I do if a patient has experienced an adverse event or has a product complaint? For adverse events, medical information, or product complaints, call 1-866-4-CIMZIA (1-866-424-6942) and select option 4.

Who is eligible for the CIMplicity Savings Program and CIMplicity Administration Savings Program? The CIMplicity Savings Program is provided as a service of UCB for commercially insured patients and is intended to support the appropriate use of CIMZIA. Cash-paying and public-payer-funded patients are not eligible for the CIMplicity Savings Program. The CIMplicity program may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.<sup>‡</sup>

## CIMplicity Administration Savings for CIMZIA Lyophilized Powder Frequently Asked Questions

What is the CIMplicity Administration Savings Program? With the CIMplicity Administration Savings Program, eligible patients with commercial insurance can save out-of-pocket expenses incurred for in-office administration of CIMZIA.

- 2 Will the maximum amount allowed for administration be in addition to the maximum amount allowed under the CIMplicity Savings Program? Yes, the maximum amount available to support administration of In Office Injection patient out of-pocket costs will be in addition to the maximum amount to support copay, coinsurance, or deductible associated with CIMZIA (HCPCS J0717).
- Who is eligible for administration support? Patients who meet full eligibility requirements for the CIMplicity Savings Program, are prescribed CIMZIA In Office Injection and receive it through in office administration are eligible for the CIMplicity Administration Savings Program. Please see page 7 for full requirements.
  NOTE\* All reimbursement requests must be submitted within 180 days (6 months) of the date of service

4 How do patients enroll in the program? A member of office staff enrolls a patient through the savings program portal.

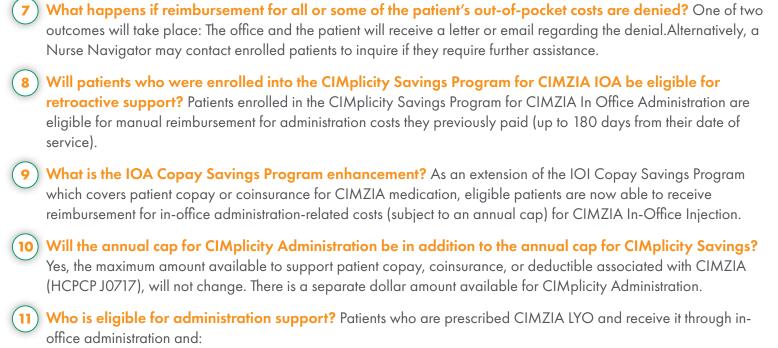
How do patients receive reimbursement for CIMZIA and its administration? The office submits an explanation of benefit (EOB) form by uploading it on the Copay Savings Program Portal at www.cimziasavingsprogram.com. The office also has the option of faxing it to (908) 809-6248. The office will receive reimbursement on behalf of the patient the same way they do for the CIMplicity IOA Savings Program for CIMZIA IOA today (EFT or Debit).

**How long does it take to be reimbursed once the EOB is submitted?** The processing and payment for the patient's out-of-pocket portions will take up to 5 business days.





# CIMplicity Administration Savings Frequently Asked Questions (continued)



- Have commercial insurance coverage for CIMZIA.
- Have proof insurance paid some portion of the cost of CIMZIA and the cost of the in-office administration.
- Are 18 years or older and reside in the US or Puerto Rico.
- Have a diagnosis consistent with a CIMZIA FDA-approved indication.

NOTE\* All reimbursement requests must be submitted within 180 days (6 months) of the date of service.

\*Clean claim: all information was provided accurately with no questions on submission items.

<sup>†</sup> Subject to change.

<sup>‡</sup> Eligibility: 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, Medigap, TRICARE, VA, and DoD) for reimbursement. The parties reserve the right to amend or end this program at any time without notice.

## CIMplicity Savings Program information

## **CIMplicity Savings Support Phone Line:**

For questions, please call 1-877-705-4119 toll-free, Monday through Friday, 8 AM to 8 PM ET

Contact your Field Reimbursement Executive for more information.



Program website: cimziasavingsprogram.com

Please see Important Safety Information on page 11 and refer to the full Prescribing Information provided by the sales representative, and visit CIMZIAhcp.com





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## **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.

## immunosuppression and malignancies not usually seen in this patient population.

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

- 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 (≥8%) were upper respiratory infections (18%), rash (9%), and urinary tract infections (8%).



