



CIMZIA[®] (certolizumab pegol) In-Office Injection Co-Pay Savings Program



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 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.

Please see additional important safety information on back cover and full Prescribing information provided by the UCB representative, and visit www.CIMZIAhcp.com.



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

The CIMZIA \$0 Co-Pay Savings Program for In-Office Injection helps eligible, commercially insured patients save on their out-of-pocket costs for CIMZIA*

- Simplified patient enrollment process
- No income requirements
- No dollar limit per use
- Up to \$15,000 annual savings that can be applied toward CIMZIA In-Office Injection co-pay, co-insurance, deductibles, and/or out-of-pocket maximums

CIMZIA Co-Pay Savings Program information

Program website:

ioa.cimziasavingsprogram.com

Co-Pay Support Phone Line:

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

Contact your Field Reimbursement Manager for more information.

Please contact

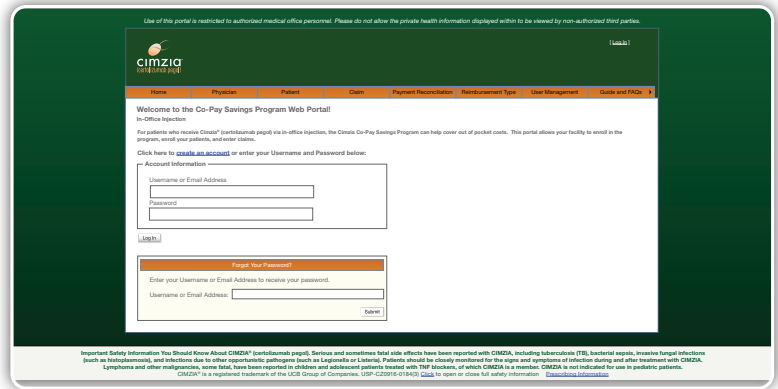
your **UCB Field Reimbursement Manager** if you need additional information or alternative approaches to manage the Co-pay Savings Program.

*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 (ie, 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.

The CIMZIA Co-Pay Savings Program Is Managed Through an Online Portal

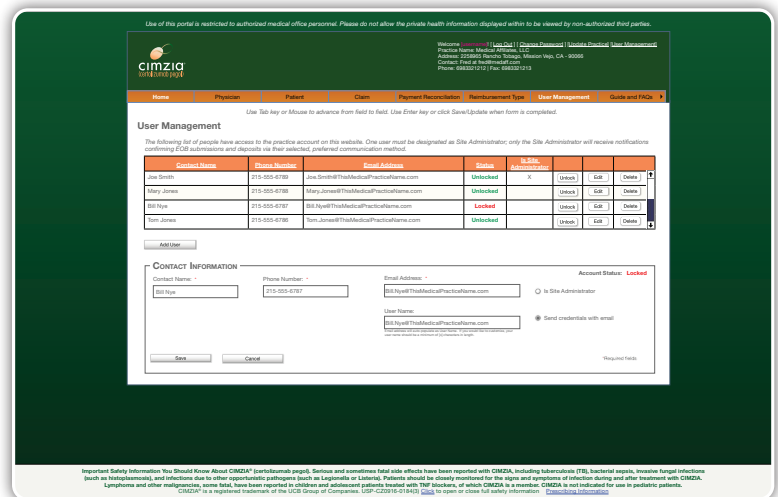
The online portal enables claims submission and payment via Electronic Funds Transfer (EFT).

- Enrollment for new offices via online portal at ioa.cimziasavingsprogram.com
- Patient enrollment and claim submission through portal
- 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
- Log-in with username or email and ability to retrieve forgotten passwords



The online portal now allows for:

- Site administrators to add secondary users to perform certain functions
- Account administrators to update their own banking information as needed
- Improved sorting and tracking on reconciliation screens, including claim ID
- Ability to add associated practices for accounts with referring practices/physicians



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FREQUENTLY ASKED QUESTIONS

- 1. 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 program if you wish; however, if you do switch to EFT, you can no longer use the Visa debit card program.
- 2. 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.
- 3. 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.
- 4. After my registration is complete, how long will it take from claim submission to payment?** When sending a claim, there is a clean claim * 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.
- 5. Can eligible patients use the CIMZIA Co-Pay Savings Program to meet their insurance deductible?** Yes. The CIMZIA Co-Pay Savings Program can be used for out-of-pocket expenses for CIMZIA® (certolizumab pegol), including co-payments, co-insurance, and deductibles. This program cannot be used for ancillary medical costs such as doctor visits or administration expenses.
- 6. Can the patient receive reimbursements through the CIMZIA Co-Pay Savings Program while he/she is simultaneously participating in another CIMZIA co-pay support program?** No. CIMZIA patients may participate in only one CIMZIA Co-Pay Savings Program at any given time. If the patient stops receiving CIMZIA via in-office administration and switches to self- or home-administered treatment, a different co-pay program would be needed to provide co-pay support for pharmacy-filled prescriptions.
- 7. Is there a maximum amount the CIMZIA Co-Pay Savings Program will cover per injection?** There is currently no limit per injection.[†] There is a \$0 co-pay per injection with a \$15,000 limit per calendar year for each patient.
- 8. 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.
- 9. How long after a date of service can I submit a claim for reimbursement?** 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.

- 10. Is there a patient assistance program (PAP) for patients who cannot afford this medication?** Yes. There is a PAP program for CIMZIA. Please call CIMplicity® at 1-866-4-CIMZIA (1-866-424-6942). Select option 2, and a case manager will be happy to assist you.
- 11. 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.
- 12. Who is eligible for the CIMZIA Co-Pay Savings Program?** The CIMZIA Co-Pay 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 CIMZIA Co-Pay Savings Program.** The CIMplicity program may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.†

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

† Subject to change.

‡ 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 (ie, 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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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%).

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