CIMZIA® (certolizumab pegol)

Composing a Letter of Medical Necessity

The following is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Healthcare providers (HCPs) are encouraged to contact third-party payers for specific information on their current coverage policies. For other questions, please call **CIMplicity®** at **1-866-4CIMZIA (1-866-424-6942)**.

The purpose of a Letter of Medical Necessity (LMN) is to explain the prescribing HCP's rationale and clinical decision-making when choosing a treatment.* LMNs are often required by plans when submitting a request for an Appeal, Formulary Exception, and/or Tiering Exception.

This resource provides information on the process of drafting a LMN. Included below is a checklist that can be followed when creating a LMN. In addition, attached to this document is a sample letter that includes information health plans often require. Note that some plans have specific coverage authorization forms that must be utilized to document a LMN.

Follow the patient's plan requirements when requesting CIMZIA (certolizumab pegol); otherwise, treatment may be delayed.

Use of the information in this letter does not guarantee that the health plan will provide reimbursement for CIMZIA and is not intended to be a substitute for, or an influence on, your independent medical judgment.

LMN Considerations

- Include the patient's full name, plan identification number, gender, date of birth, and the case identification number if a decision has already been rendered
- Provide a copy of the patient's records with the following details:
  - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code, and present-day condition and symptoms
  - The patient's recent history of infection(s), along with any allergies and existing comorbidities
- Note the severity of the patient's condition using the plan's preferred scoring system. Common scoring systems used depend on the patient's diagnosis
- Document prior treatments and the duration of each, including start/stop dates and reason(s) for discontinuation
  - Document any other patient characteristics and/or clinical considerations relevant to CIMZIA therapy
- Attach clinical documentation that supports your recommendation; this information may be found in the CIMZIA Prescribing Information and/or clinical peer-reviewed literature

*For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

Please see Important Safety Information on pages 4-6.
Please click to access the full Prescribing Information, or visit CIMZIAhcp.com.

Sample Letter of Medical Necessity

The purpose of a LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing CIMZIA® (certolizumab pegol) for a patient. LMNs are often required by plans when submitting a request for a Formulary/Medical Exception, Tiering Exception, or Appeals.

To use this template to assist in completing your request, please click here. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

[Date]
[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]
[Case identification]

To whom it may concern:

I am writing to provide additional information to support my claim for [patient's name] treatment of [indication] with CIMZIA® (certolizumab pegol). In brief, treatment with CIMZIA [dose, frequency] is medically appropriate and necessary for this patient. This letter outlines the patient's medical history and previous treatments that support my recommendation for treatment with CIMZIA.

- [Patient's gender and age]
- [Patient's relevant history, findings, and diagnosis; previous treatment of rheumatoid arthritis/psoriatic arthritis/ankylosing spondylitis/Crohn's disease/non-radiographic axial spondyloarthritis]
- [Past treatment start/stop date & patient's response to these therapies]
- [Brief description of the patient's recent symptoms, conditions, and any other patient characteristics or relevant clinical considerations]

____ Indicate here, by adding a checkmark, that the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient has any serious infections, please list them below:

Infection name and affected part(s) of body	Treatment type(s)	Treatment start/stop dates	Anticipated resolution date

Summary of your professional opinion:

[Insert rationale for prescribing CIMZIA here, including your professional opinion of the patient's likely prognosis or disease progression without CIMZIA treatment.]

Provide supporting references for your recommendation:

[Provide clinical rationale for treatment; this information may be found in the CIMZIA Prescribing Information and/or clinical peer-reviewed literature.]

Physician contact information:

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #]. Please send a copy of the coverage determination decision to [patient's name, street address, city, state, ZIP]. Please feel free to contact me, [HCP name], at [office phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]

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Include patient's medical records and supporting documentation:

- Clinical evaluation
- Scoring forms
- Photos of affected areas, where relevant
- Identify drug name and strength, dosage form, and therapeutic outcome

cimzia® (certolizumab pegol)

CIMPLICITY®* – COMPREHENSIVE SUPPORT FOR YOUR PATIENTS

cimplicity®
Confidence in care.

Our case managers can help eligible* patients get started on CIMZIA!

Call 1-866-4CIMZIA or go to CIMplicitycares.com

Get support for patients every step of the way

- Quickly confirm coverage when starting your patients on CIMZIA
- Simplify the prior authorization process from submission to follow-up and confirmation
- Intuitive digital platform supports your patient's treatment journey
- Live chat with experienced case managers
- Dedicated nurses provide personalized support to reinforce the education you provide

The CIMplicity program is designed to simplify and support the CIMZIA treatment experience for prescribers, office support staff and, most importantly, patients seeking therapy.

Connect your patients with a dedicated CIMplicity nurse in 3 steps:

1. Patient texts "CONNECT" to 87522
2. Patient receives a welcome text
3. Patient adds 844-UCB-NURSE to his/her contacts in preparation for nurse to call in the next 2 business days

Start your patients on CIMplicity today.

1. First, call 1-866-4CIMZIA to get your office on the new platform
2. Then log in to CIMplicitycares.com, click the Add a Patient button in the top right and fill out the patient information

   OR

   Fax a completed CIMplicity enrollment form to 866-949-2469

*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. Some program and eligibility restrictions may apply.

INDICATIONS

CIMZIA is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), and active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. CIMZIA is also indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PSO) who are candidates for systemic therapy or phototherapy, and for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adults with moderately to severely active disease who have had an inadequate response to conventional therapy.

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.

Important Safety Information continues on next page.

IMPORTANT SAFETY INFORMATION (cont)

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.

Important Safety Information continues on next page.

IMPORTANT SAFETY INFORMATION (cont)

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%).

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[Prior authorization department]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]
[Case identification]

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Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]