cimplicity®

PRIOR AUTHORIZATION REQUEST & LETTER OF MEDICAL NECESSITY GUIDE

DRAFTING A PRIOR AUTHORIZATION REQUEST

The following information 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).

Most health plans require a Prior Authorization Request (PAR) and supporting documentation, such as a Letter of Medical Necessity (LMN), to process a claim for biologic treatments. A prior authorization allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

This resource provides a "how-to" when drafting a PAR and LMN. Included is a list of sample payer requirements and a checklist, outlining what to include for each request. Attached to this document is a sample letter that includes information many health plans require to process the PAR and/or LMN.

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

Use of the information in this sample 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.

PRIOR AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. Your CIMZIA Field Access Specialist (FAS) may be able to provide you with prior authorization requirements for specific plans and pharmacy benefit managers. CIMplicity® and/or specialty pharmacies can assist with identifying prior authorizations, form requirements, and step edit therapies.

2. All CIMZIA prior authorization forms should be completed and submitted to the specialty pharmacy/plan by your office.

3. If you expect that a plan-specified step edit therapy will not be well tolerated by the patient, or another therapy is more appropriate for the patient, a request may be submitted to the plan to bypass this requirement. **For more information, refer to Composing a Letter of Medical Necessity below.**

4. Plans will usually allow up to three levels of appeal for prior authorization denials. The third appeal may include a review by an external review board or hearing.

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 **Important Safety Information** on page 4 and full **Prescribing Information** enclosed, or visit **CIMZIAhcp.com.**

PRIOR AUTHORIZATION CONSIDERATIONS

- Verify and record that all of the prior authorization requirements for the plan have been met
- If applicable, provide evidence that all step edit therapy prerequisites have been met. For step edit therapy exception requests, include wording explaining why CIMZIA (certolizumab pegol)® is medically appropriate for the patient in place of a prerequisite/step edit therapy
- If required, use the health plan's Prior Authorization Request Form that can be found on the plan's website. Your CIMZIA FAS and/or CIMplicity® may also be able to assist you in locating the plan-specific form
- Include relevant dosing information: Length of treatment, prior medications and dosing, and dosing for the medication being requested
- Include relevant patient details: Joint involvement, body surface area (BSA), difficult-to-treat areas, mobility limitations (e.g. inability to use hands during a flare), photos, and ICD-10 codes

COMPOSING A LETTER OF MEDICAL NECESSITY

If your patient's plan requires an LMN to explain the prescribing HCP's rationale and clinical decision making when choosing CIMZIA, you will be required to submit a request for Formulary/Medical Exception, Tiering Exception, or Appeals.

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:

LMN CONSIDERATIONS

- Assess the patient's history, diagnosis with specific ICD-10 code, and present-day condition and symptoms
- Consider 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

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 **Important Safety Information** on page 4 and full **Prescribing Information** enclosed, or visit **CIMZIAhcp.com.**

SAMPLE PRIOR AUTHORIZATION REQUEST / LETTER OF MEDICAL NECESSITY

You may use the included template to assist in completing your request. **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]

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

[Provider Prefix] [First and Last Name]
[Address 1]
[Address 2]
[City], [State], [Zip]

To whom it may concern:

This letter serves as a prior authorization request for CIMZIA® (certolizumab pegol) for [Patient's name] [Plan identification, and group number], for the treatment of [diagnosis and ICD code].

[Provide relevant information including length of treatment, prior medication use, diagnosis, and dosing for medication being requested.]

[Provide patient information, including gender, age, relevant history, joint involvement, BSA (body surface area), difficult-to-treat areas, mobility limitations (e.g., inability to use hands during a flare) and a brief description of the patient's recent symptoms and conditions.]

____ Indicate here, by adding a checkmark, that the patient does not have active tuberculosis or other serious infections (required by some health plans).

____ Indicate here 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 Ex: (MM/DD/YY–MM/DD/YY)	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#, Fax#]

The prior authorization decision may be faxed to [Fax#]

Please send a copy of coverage determination decision to [patient's name, address, city, state, ZIP]

Sincerely,

[Physician's name and signature]
[Medical specialty]
[NPI #]
[Practice name]

[Patient's name and signature]

If you need to compose a Letter of Medical Necessity, consider including the patient information below:

- Patient's name
- Indication
- Willingness to provide more information
- Patient's dosage of CIMZIA

Consider including patient's medical records and supporting documentation:

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

If this prior authorization request letter is intended to appeal a plan's step edit requirement, consider adding these components:

- Required step edit therapies
- Call out that the step edit therapies were attempted prior to treatment with CIMZIA
- Request step edit therapy should be bypassed
- Provide a statement indicating why these step edit therapy requirements are inappropriate for this patient

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 **Important Safety Information** on page 4 and full **Prescribing Information** enclosed, or visit **CIMZIAhcp.com.**

IMPORTANT SAFETY INFORMATION

INDICATIONS

- CIMZIA is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- CIMZIA is indicated for the treatment of adults with active psoriatic arthritis.

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

Please see full **Prescribing Information** enclosed, or visit **CIMZIAhcp.com**.