CIMZIA® (certolizumab pegol)

Guide to Writing a Letter of Appeal*

Composing a Letter of Appeal

When a patient's health plan denies a prior authorization (PA) request for **CIMZIA® (certolizumab pegol)**, you can submit a letter of appeal in response to the official denial letter. In the letter of appeal, you can explain your clinical rationale for prescribing **CIMZIA**, provide supporting documentation that addresses the reason(s) for the denial, and request approval.

Preparing an effective Letter of Appeal

Follow plan-specific guidelines

- Some health plans may require you to use their specific appeal form (often on its website); if there are questions, do not hesitate to directly contact the plan

Confirm the health plan's time frame for submitting an appeal

- If appropriate, mark the appeal request "urgent" based on the patient's needs and the health plan's timelines
  - Expedited review may be required in the case of medical urgency. When requested, you can expect to receive a decision within 72 hours. For more information on this, visit healthcare.gov.

Understand the reason for denial and include why you believe the decision should be reconsidered

- If the denial was for inaccurate or incomplete information, correct or update the discrepancies
- If the denial was for a medical reason, include specific and relevant medical information that, in your independent clinical judgment, supports the use of CIMZIA for your patient in accordance with the health plan's criteria
- Directly address and provide supporting documents to refute any specific rationale cited in the denial

Provide documentation as applicable

- The letter of appeal on your letterhead or health plan's appeal form (if required)
  - Patient's full name, date of birth, and health plan policy/group number
  - Prescribing healthcare provider's name, National Provider Identifier (NPI) number, practice name, address, phone number, fax number, and email
  - Acknowledgment of the plan's policy and reasons for denial
  - Rationale for why treatment is medically necessary and why the decision should be reconsidered
  - Patient's medical history
  - Summary of recommendations
- Supporting documentation, provided at the same time and in the correct order indicated in the health plan's appeal instructions
  - Letter of Medical Necessity
  - A copy of the plan's denial letter
  - Relevant patient documentation, such as physician notes, laboratory results, and medical records

***This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Use of the information in this letter does not guarantee that the health plan will provide reimbursement or coverage for CIMZIA and is not intended to be a substitute for, or an influence on, your independent medical judgment.**

Selected 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.
Please click to access the full Prescribing Information, or visit CIMZIAhcp.com

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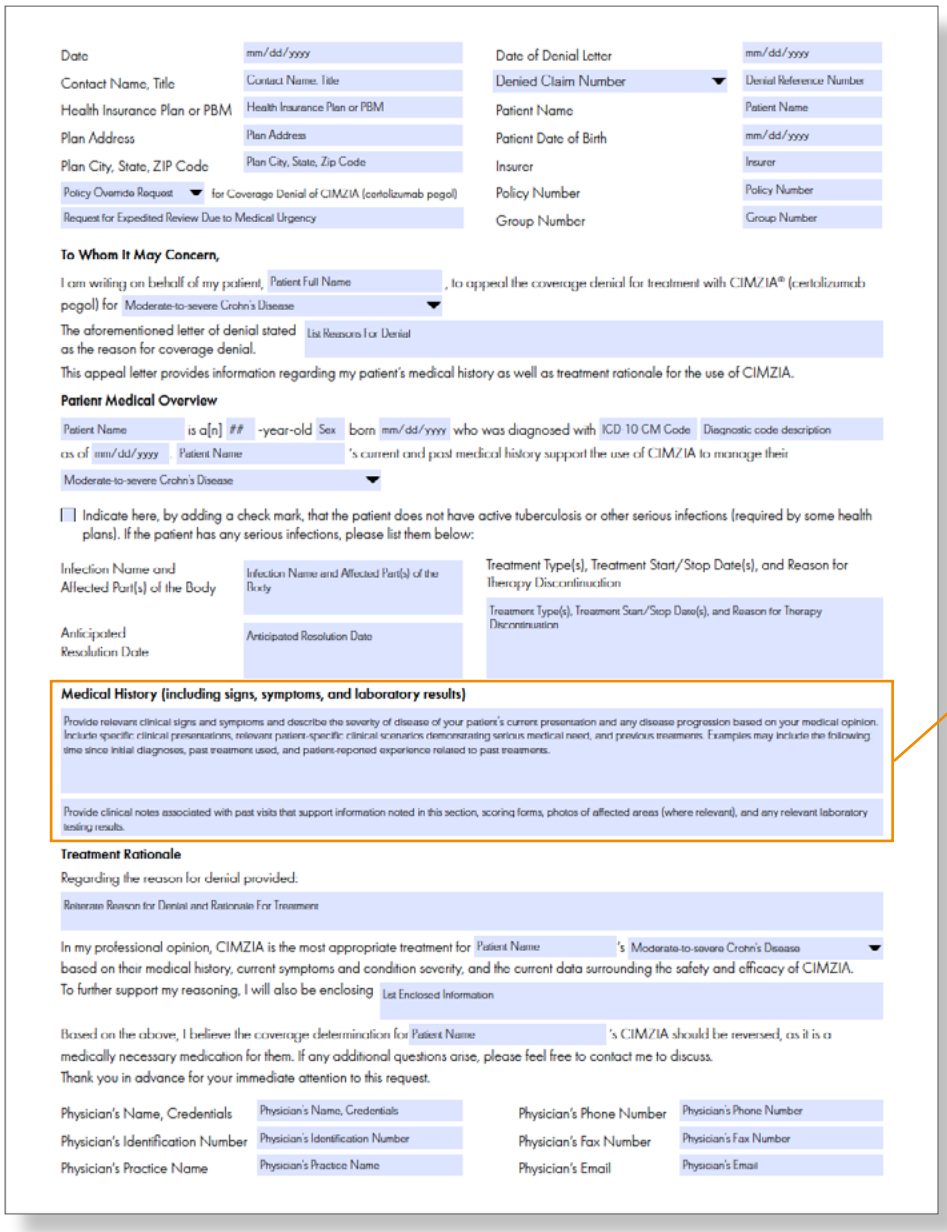
Letter of Appeal Guide*

Sample Letter of Appeal

The following is a sample appeal letter that can be followed and customized based on your patient's specific medical history and identifiable information by clicking **here**. This sample letter can serve as a starting point for your rationale as to why this patient requires **CIMZIA® (certolizumab pegol)**; however, medical judgment and discretion is advised when drafting this letter. Payers may also require specific forms be completed in addition to the appeal letter; therefore, knowledge of the process is critical to reversing a denial. This letter should be drafted on the physician's letterhead and be signed by the prescribing physician.



Date mm/dd/yyyy
Contact Name, Title Contact Name, Title
Health Insurance Plan or PBM Health Insurance Plan or PBM
Plan Address Plan Address
Plan City, State, ZIP Code Plan City, State, Zip Code
Policy Override Request for Coverage Denial of CIMZIA (certolizumab pegol)
Request for Expedited Review Due to Medical Urgency

Date of Denial Letter mm/dd/yyyy
Denied Claim Number Denial Reference Number
Patient Name Patient Name
Patient Date of Birth mm/dd/yyyy
Insurer Insurer
Policy Number Policy Number
Group Number Group Number

To Whom It May Concern,

I am writing on behalf of my patient, Patient Full Name, to appeal the coverage denial for treatment with CIMZIA® (certolizumab pegol) for Moderate-to-severe Crohn's Disease
The aforementioned letter of denial stated List Reasons For Denial as the reason for coverage denial.
This appeal letter provides information regarding my patient's medical history as well as treatment rationale for the use of CIMZIA.

Patient Medical Overview

Patient Name is a[n] ## -year-old Sex born mm/dd/yyyy who was diagnosed with ICD 10 CM Code Diagnostic code description as of mm/dd/yyyy. Patient Name 's current and past medical history support the use of CIMZIA to manage their Moderate-to-severe Crohn's Disease

☐ Indicate here, by adding a check mark, 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 the Body: Infection Name and Affected Part(s) of the Body
Anticipated Resolution Date: Anticipated Resolution Date
Treatment Type(s), Treatment Start/Stop Date(s), and Reason for Therapy Discontinuation: Treatment Type(s), Treatment Start/Stop Date(s), and Reason for Therapy Discontinuation

Medical History (including signs, symptoms, and laboratory results)

Provide relevant clinical signs and symptoms and describe the severity of disease of your patient's current presentation and any disease progression based on your medical opinion. Include specific clinical presentations, relevant patient-specific clinical scenarios demonstrating serious medical need, and previous treatments. Examples may include the following: time since initial diagnoses, past treatment used, and patient-reported experience related to past treatments.

Provide clinical notes associated with past visits that support information noted in this section, scoring forms, photos of affected areas (where relevant), and any relevant laboratory testing results.

Treatment Rationale

Regarding the reason for denial provided,
Reiterate Reason for Denial and Rationale For Treatment
In my professional opinion, CIMZIA is the most appropriate treatment for Patient Name 's Moderate-to-severe Crohn's Disease based on their medical history, current symptoms and condition severity, and the current data surrounding the safety and efficacy of CIMZIA.
To further support my reasoning, I will also be enclosing List Enclosed Information
Based on the above, I believe the coverage determination for Patient Name 's CIMZIA should be reversed, as it is a medically necessary medication for them. If any additional questions arise, please feel free to contact me to discuss.
Thank you in advance for your immediate attention to this request.

Physician's Name, Credentials: Physician's Name, Credentials
Physician's Identification Number: Physician's Identification Number
Physician's Practice Name: Physician's Practice Name
Physician's Phone Number: Physician's Phone Number
Physician's Fax Number: Physician's Fax Number
Physician's Email: Physician's Email

Click to access the full Prescribing Information

Directly address the reason for denial and include relevant medical information that, in your clinical judgment, supports your patient's appropriate use in accordance with the health plan's criteria. See next page for specific examples of patient medical history to consider including.

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Details to consider including with your CIMZIA® (certolizumab pegol) Letter of Appeal*

Examples of medical history for a Letter of Appeal

- **Documented diagnosis of CIMZIA indication, including:**
  - Reducing the signs and symptoms of Crohn's disease 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 or severely active rheumatoid arthritis.
  - Treatment of adult patients with active psoriatic arthritis.
  - Treatment of adults with active ankylosing spondylitis.
  - Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
  - Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- **Pertinent signs and symptoms, laboratory test results, and clinical classifications responsible for the patient's diagnosis.**
  - Include information on any complications due to diagnosed disease.
- **All treatments the patient has trialed, duration of the trial, dosing, and any impact (positive or negative) these treatments had on the patient and their condition, and the reason for discontinuation.**
- **Reasons the patient cannot/should not use any of the other treatment options listed in the utilization management criteria.**
  - Consider drug-drug interactions, drug-condition interactions, and significant patient medical history that may steer your decisions.
  - Patient populations (e.g., pregnancy status)

Note: This is not an all-inclusive list. Please use clinical judgment when deciding materials to include for review.

Common reasons for denial

Below is a list of some of the most common reasons a health plan my initially deny coverage of **CIMZIA** that can be addressed in a Letter of Appeal using the patient's medical history and your clinical judgment.

- **Unclear understanding of CIMZIA indication**
- **Lack of information regarding previous treatments, including those required for CIMZIA initiation**
- **Missing clinical information to support initiation of CIMZIA, including medical history, all pertinent laboratory results, and all previously trialed therapies, including reason for their discontinuation**

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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 adults 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 moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. CIMZIA is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

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%).

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Date	mm / dd / yyyy	Date of Denial Letter	mm / dd / yyyy
Contact Name, Title	Contact Name, Title	Denied Claim Number	Denial Reference Number
Health Insurance Plan or PBM	Health Insurance Plan or PBM	Patient Name	Patient Name
Plan Address	Plan Address	Patient Date of Birth	mm / dd / yyyy
Plan City, State, ZIP Code	Plan City, State, Zip Code	Insurer	Insurer
Policy Override Request for Coverage Denial of CIMZIA (certolizumab pegol)		Policy Number	Policy Number
Request for Expedited Review Due to Medical Urgency		Group Number	Group Number

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Physician's Name, Credentials	Physician's Name, Credentials	Physician's Phone Number	Physician's Phone Number
Physician's Identification Number	Physician's Identification Number	Physician's Fax Number	Physician's Fax Number
Physician's Practice Name	Physician's Practice Name	Physician's Email	Physician's Email