

Writing Letters of Appeal for AVTOZMA[®]

Your medical opinion matters

When health insurers deny coverage or prior authorization, there are options. Patients, advocates, or healthcare providers can appeal these decisions.

Two types of appeals¹

✓ **Internal appeals** request an insurance company to conduct a full and fair review of its decision. *The insurance company must speed up its process for urgent cases.*

✓ **External review appeals** request a review by an independent third party. External review means the insurance company will not have the final say about paying the claim.

Learn how the process differs for each type of appeal at [healthcare.gov/appeal-insurance-company-decision](https://www.healthcare.gov/appeal-insurance-company-decision)



Tools to empower your appeals

The following pages offer advice for writing a Letter of Appeal for AVTOZMA and provide a letter template to help ensure your clinical input is taken into consideration.

NOTE: Utilizing the information provided here does not guarantee a plan will provide reimbursement for AVTOZMA. Additionally, this information is not intended to replace or influence your medical judgment.



Celltrion CONNECT[®] is here to help

Celltrion CONNECT and your dedicated FRM are available to assist with:

- Benefit verifications
- Access issues
- Prior authorizations
- Financial support

Call
1-877-81CONNC
(1-877-812-6662),
Monday–Friday
between 8 AM–8 PM ET, or visit
www.celltrionconnect.com
to learn more.

FRM, field reimbursement manager.

Reference: 1. How to appeal an insurance company decision. Healthcare.gov. Accessed January 15, 2025.
<https://www.healthcare.gov/appeal-insurance-company-decision/>

Please see Important Safety Information on page 4 and full [Prescribing Information](#), including Boxed Warning.

Advice for Writing Letters of Appeal for AVTOZMA[®]

Information you will need to complete your Letter of Appeal

- ✓ Full name and date of birth of the patient
- ✓ Insurance policy/ID number of the patient
- ✓ Letters showing treatment denial, including explanation of benefits documents
- ✓ Case ID number
- ✓ Condensed medical history of the patient
 - Including diagnosis, ICD-10 codes, comorbidities, and allergies
- ✓ List of current and previous treatments
 - Including dates for starting, stopping, and cause(s) for discontinuation
- ✓ Overview of the patient's condition and symptoms
- ✓ Clinical support for your recommendations

Additional guidance for writing your Letter of Appeal

- **It is important to review the insurance plan's Explanation of Benefits**, as this will help you explain how your patient meets benefits criteria or why it makes sense to exclude your patient from certain criteria
- **Be sure to clearly state** why AVTOZMA is the most appropriate treatment option
- **Offer clinical rationale** to support AVTOZMA as your treatment choice
 - Include clinical data, such as patient chart notes and laboratory results
- **List any additional patient attributes and/or clinical factors** relevant to your clinical opinion
 - Consider attaching any clinical evidence you feel will support your recommendation for AVTOZMA (eg, Section 12 [Clinical Pharmacology] and Section 14 [Clinical Studies] in the full Prescribing Information for AVTOZMA)¹

NOTE: Please exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

Keeping insurer timing and processes in mind

- **Review the procedure** for submitting your appeal letter to ensure you meet insurer and state requirements
 - This includes mode of submission (eg, fax, phone, email, insurer website)
- **Internal appeals** need to be submitted within 6 months (180 days) of receiving a claim denial notice²
- **External review appeals** need to be submitted within 4 months (120 days) of receiving a claim denial notice³
- **Keep track** of your appeal/request status and follow up with the insurer as needed

ICD-10, International Classification of Diseases, Tenth Revision.

References: 1. AVTOZMA [prescribing information]. Jersey City, NJ. Celltrion Inc; 2025. 2. Internal appeals. Healthcare.gov. Accessed January 15, 2025. <https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/> 3. External review. Healthcare.gov. Accessed January 15, 2025. <https://www.healthcare.gov/appeal-insurance-company-decision/external-review/>

Please see Important Safety Information on page 4 and full Prescribing Information, including Boxed Warning.

Template for Letters of Appeal for AVTOZMA[®]

Helping you organize your response

Pictured below is a template for writing your Letters of Appeal for AVTOZMA therapy. You will find this editable content on pages 5 to 6 of this guide. The template includes helpful prompts and can be altered as needed.

To create your letters, simply edit the “live” text directly within the template pages, print, and fax or mail as needed.

You can also copy and paste the template page text into your practice’s letterhead before making needed edits and then printing, faxing, or mailing as needed.

[Physician Name, address, phone number, and tax ID number]

[Date]

Patient Name: [Patient Name]
 Patient Date of Birth: [Patient Date of Birth]
 Insurance Plan: [Name of Insurance Plan]
 Member ID: [Member ID #]
 Group Number: [Group Number]
 Insurance Plan Address: [Address of Insurance Plan]
 Claim or Explanation of Benefit #: [Claim/Explanation of Benefit #]

Re: Action Required: Request for Reconsideration of AVTOZMA[®] (tocilizumab-anoh) Coverage for [Patient Name]

To whom it may concern:

My name is [Physician Name], and I am a [board-certified medical specialty] [NPI]. This letter serves as my [first/second] appeal for approval of AVTOZMA (tocilizumab-anoh), which was originally denied to [Patient Name] on [Date]. I am writing this letter to provide additional information to support my request to treat [Patient Name], who has been diagnosed with [condition], [ICD code(s)], with AVTOZMA, a product indicated for the treatment of [relevant condition].

In brief, treating [Patient Name] with AVTOZMA [intravenously] [list dosing regimen] is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name] determined AVTOZMA was not covered for [Patient Name] because [reason(s) for denial]. This letter provides my clinical rationale and relevant information about the patient’s medical history and treatment to support my appeal.

Patient’s Clinical History and Treatment Rationale

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition] [ICD-10 code(s)] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Elaborate on the patient’s clinical/medical history, condition, and symptoms]

[The following items are important:]

- [Previous treatments, including drug names, duration of treatment(s), and responses to those treatments and (utilizing and referring to the Past Treatment section on the next page can help condense your explanation)]
- [Relevant laboratory results at key points in the treatment journey]
- [Acute and chronic complications]
- [Why you believe it is medically necessary for the patient to receive AVTOZMA]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]

My rationale for prescribing AVTOZMA is based on [the patient’s disease course, including history of disease, laboratory results, symptoms, and previous treatments]. [Include medical reasoning for choosing to bypass any alternative medications covered by the health plan (eg, infectious diseases due to multiple infusions, potential for patient inability to comply with labeled dosing requirements of covered/preferred products over an extended period of time, and any applicable treatment guidelines)].

Continued

Past Treatment

- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]

Treatment Plan

On January 30, 2025, the U.S. Food & Drug Administration (FDA) approved AVTOZMA for the treatment of [relevant condition]. [Include the plan of treatment (dosage, length of treatment, number of doses for which an exception may be needed—if applicable) and clinical practice guidelines that support the use of AVTOZMA]. [Consider mentioning experts in the field who also support the treatment.]

Summary

Considering my patient’s condition and medical history, as well as my experience treating patients with [relevant condition], I feel treatment with AVTOZMA is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for AVTOZMA. I have also attached relevant lab test analyses and medical records to support my decision.

I am requesting an expedited review of this appeal, the enclosed documents, and the supporting evidence provided by my office and by a board-certified and specialty-matched physician who can render a decision based upon the information shared above. If you have any further questions about this matter, please contact me at [Healthcare Provider Phone Number], via email at [Healthcare Provider Email], or by fax at [Healthcare Provider Fax Number]. I look forward to receiving your timely response and approval of this claim.

Once my patient is approved for treatment with AVTOZMA, I will discontinue the treatment/prescription of [alternate BRAND (generic) name (if applicable)].

If you do not feel the information provided has established medical necessity, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an applicable medical specialty.

Sincerely,

[Physician Name]
[Physician Signature]

Enclosures

[List enclosures, which may include medical records/clinical notes for AVTOZMA, AVTOZMA Prescribing Information, Letter of Medical Necessity (if applicable), and other supporting documentation]
[Include full Prescribing Information]

References

[Include other relevant references and publications regarding AVTOZMA]
 [Copy of patient denial letter (if applicable)]
 [Clinical progress notes]
 [Patient’s lab results]
 [Documentation of hospitalization/emergency room visits and/or unscheduled office visits]
 [List of medications provided (including dosages, dates used, and if samples were given)]

This template is for informational purposes only and provides an outline of the types of information that may be required or helpful when responding to a patient’s insurer. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not a substitute for, nor should it be considered an influence on, the clinical decision of the prescribing healthcare professional. Celltrion makes no representations or warranties about the template or its fitness for any specific use. Celltrion is not responsible for any changes made to the template document. All billing and coding decisions are the responsibility of the relevant physician.

Indications and Important Safety Information for AVTOZMA® (tocilizumab-anoh)

INDICATIONS

AVTOZMA® (tocilizumab-anoh) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- **Rheumatoid Arthritis (RA):** Adult patients with moderately to severely active RA who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- **Giant Cell Arteritis (GCA):** Adult patients with GCA.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA):** Patients 2+ years-old with active PJIA.
- **Systemic Juvenile Idiopathic Arthritis (SJIA):** Patients 2+ years-old with active SJIA.
- **Cytokine Release Syndrome (CRS):** Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.
- **Coronavirus Disease 2019 (COVID-19):** Hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS INFECTIONS

Patients treated with tocilizumab products including AVTOZMA 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.

If a serious infection develops, interrupt AVTOZMA until the infection is controlled. Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease.** Patients, except those with COVID-19, should be tested for latent tuberculosis before AVTOZMA use and during therapy. Treatment for latent infection should be initiated prior to AVTOZMA use.
- **Invasive fungal infections, including candidiasis, aspergillosis, and pneumocystis.** Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
- **Bacterial, viral and other infections due to opportunistic pathogens.**

The risks and benefits of treatment with AVTOZMA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with AVTOZMA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Contraindications: Known hypersensitivity to tocilizumab products.

Serious Infections. Serious and sometimes fatal infections, including bacterial, mycobacterial, invasive fungal, viral, and opportunistic infections, have been reported with tocilizumab products, including AVTOZMA. Common serious infections include pneumonia, urinary tract infections, cellulitis, herpes zoster, and sepsis, while opportunistic infections such as tuberculosis and cryptococcus have also occurred. Patients with chronic or recurrent infections, tuberculosis exposure, or underlying conditions predisposing to infections should have the risks and benefits of AVTOZMA carefully evaluated. Monitor patients closely during and after treatment for signs of infection, and discontinue AVTOZMA if a serious infection develops, initiating appropriate antimicrobial therapy as needed.

Gastrointestinal (GI) Perforation. Gastrointestinal perforation events, primarily associated with diverticulitis, have been reported in clinical trials of tocilizumab. Use AVTOZMA cautiously in patients at increased risk for gastrointestinal perforation. Promptly evaluate any patient experiencing new abdominal symptoms to ensure early detection and management of this condition.

Hepatotoxicity. Serious hepatic injury, including cases of liver transplant and death, has occurred with tocilizumab products, with onset ranging from months to years. Some cases involved marked transaminase elevations ($>5\times$ ULN), while others presented with mild elevations and symptoms of liver dysfunction. Risk is higher with hepatotoxic drugs like methotrexate. Baseline and regular liver tests are required for RA, GCA, PJIA, and SJIA patients, with specific monitoring intervals based on the condition. Do not initiate AVTOZMA if ALT or AST $>1.5\times$ ULN (RA/GCA) or $>10\times$ ULN (COVID-19), and discontinue if ALT or AST $>5\times$ ULN. Evaluate symptoms of liver injury promptly, and only restart treatment if liver test abnormalities are resolved and attributed to another cause.

Changes in Laboratory Parameters. Treatment with tocilizumab products, including AVTOZMA, has been associated with neutropenia, thrombocytopenia, elevated liver enzymes, and lipid abnormalities. Infections are uncommon with treatment-related neutropenia, but AVTOZMA should not be initiated in RA or GCA patients with ANC $<2000/\text{mm}^3$ or platelet counts $<100,000/\text{mm}^3$, and treatment is not recommended if ANC drops below $500/\text{mm}^3$ or platelets below $50,000/\text{mm}^3$. For COVID-19 patients, AVTOZMA is not recommended with ANC $<1000/\text{mm}^3$ or platelets $<50,000/\text{mm}^3$. Monitor neutrophils, platelets, and liver enzymes 4–8 weeks after starting therapy and every 3 months thereafter, adjusting treatment as needed. Lipid levels, including cholesterol and triglycerides, may increase and should be assessed 4–8 weeks after initiation, with management per clinical guidelines. A similar pattern is observed in PJIA and SJIA, requiring specific monitoring intervals for these populations. Refer to Dosage and Administration for modifications based on test results.

Immunosuppression. The effect of tocilizumab products on malignancy development is unknown, though malignancies were observed in clinical studies. As an immunosuppressant, AVTOZMA may increase the risk of malignancies.

Hypersensitivity Reactions, Including Anaphylaxis. Hypersensitivity reactions, including anaphylaxis and fatal events, have been reported with tocilizumab products. Anaphylaxis requiring discontinuation occurred in 0.1% to 0.7% of trial patients, with postmarketing cases reported at various doses, with or without premedication, and as early as the first infusion. AVTOZMA intravenous infusions must be administered by healthcare professionals equipped to manage anaphylaxis. For subcutaneous use, patients must seek immediate medical attention if hypersensitivity symptoms occur. Discontinue AVTOZMA permanently if anaphylaxis or other hypersensitivity reaction occurs. Do not use in patients with known hypersensitivity to tocilizumab products.

Demyelinating Disorders. The impact of tocilizumab on demyelinating disorders is unknown, but rare cases like multiple sclerosis and polyneuropathy were reported in RA studies. Monitor for symptoms and use caution in patients with preexisting or recent demyelinating disorders.

Active Hepatic Disease and Hepatic Impairment. Treatment with AVTOZMA is not recommended.

Live Vaccines. Avoid concurrent use of live vaccines with AVTOZMA, as clinical safety and secondary transmission risk are unknown. Follow guidelines on timing between live vaccines and AVTOZMA.

Adverse Reactions reported in $\geq 5\%$ of tocilizumab-treated patients include upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, and injection site reactions.

For more information about AVTOZMA, please see full Prescribing Information, including Boxed Warning.

[Physician Name, address, phone number, and tax ID number]

[Date]

Patient Name: [Patient Name]

Patient Date of Birth: [Patient Date of Birth]

Insurance Plan: [Name of Insurance Plan]

Member ID: [Member ID #]

Group Number: [Group Number]

Insurance Plan Address: [Address of Insurance Plan]

Claim or Explanation of Benefit #: [Claim/Explanation of Benefit #]

Re: Action Required: [Letter of Medical Necessity] [Letter of Medical Exception]—Coverage Request for AVTOZMA® (tocilizumab-anoh) for [Patient Name]

To whom it may concern:

My name is [Physician Name], and I am a [board-certified medical specialty] [NPI]. I am writing on behalf of my patient [Patient Name] to document the [medical necessity] [medical need for formulary exception] for AVTOZMA (tocilizumab-anoh) for [intravenous] use [list dosing regimen] for my patient, a current member of [Health Plan Name]. This letter provides information about the patient's medical history and diagnosis and a statement summarizing my treatment rationale.

I have prescribed AVTOZMA, which is medically appropriate and necessary for this patient who has been diagnosed with [condition], [ICD code(s)]. Therefore, I am requesting that [Health Plan Name] remove any medical policy or guideline requirements in this case so that AVTOZMA can be made available to my patient as a covered medication.

Patient's Clinical History and Treatment Rationale

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition], [ICD-10-code(s)] as of [date of diagnosis]. [He/she] has been in my care since [date].

[Elaborate on the patient's clinical/medical history, condition, and symptoms]

[The following items are important:]

- [Previous treatments, including drug names, duration of treatment(s), and responses to those treatments (utilizing and referring to the Past Treatment section on the next page can help condense your explanation)]
- [Relevant laboratory results at key points in the treatment journey]
- [Acute and chronic complications]
- [Why you believe it is medically necessary for the patient to receive AVTOZMA and/or why a medical formulary exception should be made]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]

My rationale for prescribing AVTOZMA is based on [the patient's disease course, including history of disease, laboratory results, symptoms, and previous treatments]. *[Include medical reasoning for choosing to bypass any alternative medications covered by the health plan (eg, infectious diseases due to multiple infusions, potential for patient inability to comply with labeled dosing requirements of covered/preferred products over an extended period of time, and any applicable treatment guidelines)].*

Continued

Past Treatment

- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]
- [Drug name] [start date MM/YY] – [stop date MM/YY] [List the reasons for discontinuing]

Treatment Plan

On January 30, 2025, the U.S. Food & Drug Administration (FDA) approved AVTOZMA for the treatment of **[relevant condition]**. *[Include plan of treatment (dosage, length of treatment, number of doses for which an exception may be needed—if applicable) and clinical practice guidelines that support the use of AVTOZMA]. [Consider mentioning experts in the field who also support the treatment].*

Summary

Based on the patient's condition and medical history, as well as my experience treating patients with **[relevant condition]**, I have concluded that treatment with AVTOZMA is medically appropriate in this case. I further attest *[include physician expectations regarding clinical outcomes for the patient]*.

I am requesting an expedited review of this request by a board-certified and specialty-matched physician who can render a decision based upon the information included above and the supporting documentation I am enclosing. If you have any questions, please contact me at **[physician phone number]** for a peer-to-peer discussion. I would be pleased to speak to you in more detail about why **[AVTOZMA is medically necessary] [a formulary exception for AVTOZMA is needed]** for **[Patient Name]** for the treatment of **[relevant condition]**.

If you do not feel that the information provided has established **[medical necessity] [a medical reason for formulary exception]**, please provide me with your detailed rationale based upon the standards of care, the specialty of the physician who reviewed this case, and whether they are board certified in an appropriate medical specialty.

I look forward to receiving your timely response and approval of AVTOZMA.

Sincerely,

[Physician Name]

[Physician Signature]

Enclosures

[List enclosures, which may include medical records/clinical notes for AVTOZMA, AVTOZMA Prescribing Information, Letter of Medical Necessity (if applicable), and other supporting documentation]
[Include full Prescribing Information, including Medication Guide]

References

[Include other relevant references and publications regarding AVTOZMA]
[Copy of patient denial letter (if applicable)]
[Clinical progress notes]
[Patient's lab results]
[Documentation of hospitalization/emergency room visits and/or unscheduled office visits]
[List of medications provided (including dosages, dates used, and if samples were given)]



Please click here to download and customize the Letter of Appeal.