

Writing Letters of Appeal for OMLYCLO[®]

Your medical opinion matters

When health insurers deny coverage or a 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 OMLYCLO 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 OMLYCLO. 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

1-877-812-6662

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 April 10, 2026.
<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 OMLYCLO[®]

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/Claim number
- ✓ Condensed medical history of the patient
 - Including diagnosis, ICD-10 codes, lab results, 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 OMLYCLO is the most appropriate treatment option
- **Offer clinical rationale** to support OMLYCLO 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 OMLYCLO (eg, Section 12 [Clinical Pharmacology] and Section 14 [Clinical Studies] in the full Prescribing Information for OMLYCLO)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. OMLYCLO [prescribing information]. Jersey City, NJ. Celltrion Inc; 2025. 2. Internal appeals. Healthcare.gov. Accessed April 10, 2026. <https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/> 3. External review. Healthcare.gov. Accessed April 10, 2026. <https://www.healthcare.gov/appeal-insurance-company-decision/external-review/>

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Template for Letters of Appeal for OMYCLO[®]

Helping you organize your response

Pictured below is a sample template for writing your Letters of Appeal for OMYCLO. It includes helpful prompts and can be altered as needed to streamline the appeal process.

To create your letter, click the link beneath the letter images to download the template and begin editing. Once edited, the template content can be copied and pasted onto your practice's letterhead then sent via print, fax, or electronic upload to your patient's insurance provider.

[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 OMYCLO[®] (omalizumab-igec) 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 OMYCLO (omalizumab-igec), 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 [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps, IgE-mediated food allergies], [ICD-10-code(s)], with OMYCLO, a product indicated for the treatment of [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps, IgE-mediated food allergies].

In brief, treating [Patient Name] with OMYCLO subcutaneous (SC) injections [list dosing regimen] is medically appropriate and necessary and should be covered and reimbursed. [Health Plan Name] determined OMYCLO 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 [age]-year-old [male/female] patient who has been diagnosed with [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps, IgE-mediated food allergies], [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 OMYCLO]
- [Supporting letters from other specialist(s) who currently treat or previously treated the patient]
- [Additional comorbid conditions, if applicable]

My rationale for prescribing OMYCLO 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, potentially reduced efficacy or safety for the covered product compared to OMYCLO based on published data, 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 March 7, 2025, the U.S. Food & Drug Administration (FDA) approved OMYCLO for the treatment of [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps, IgE-mediated food allergies]. I feel treatment with OMYCLO is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for OMYCLO. I have also attached relevant lab test analyses and medical records to support my decision.

Summary

Considering my patient's condition and medical history, as well as my experience treating patients with [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps, IgE-mediated food allergies], I feel treatment with OMYCLO is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for OMYCLO. 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 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 OMYCLO, 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, applicable Letter of Medical Necessity, Letter of Medical Exception, Letter of Appeal, and other supporting documentation such as clinical literature]
[Include full Prescribing Information, including Medication Guide for OMYCLO]

References

[Include other relevant references and publications regarding OMYCLO]
[Copy of patient denial letter]
[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)]



Click here to download and customize the Letter of Appeal template.

This template is for informational purposes only and provides an outline of the types of information that may be required 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 OMLYCLO® (omalizumab-igec)

INDICATIONS

OMLYCLO® (omalizumab-igec) injection, is an anti-IgE antibody indicated for:

- **Moderate to severe persistent asthma** in adults and pediatric patients ≥6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)** in adult patients ≥18 years of age with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- **IgE-mediated food allergy** in adult and pediatric patients ≥1 year of age for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- **Chronic spontaneous urticaria (CSU)** in adults and adolescents ≥12 years of age who remain symptomatic despite H1 antihistamine treatment

Limitations of Use: Not indicated for acute bronchospasm or status asthmaticus; emergency treatment of allergic reactions, including anaphylaxis; and other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of omalizumab products. Anaphylaxis has occurred as early as after the first dose of omalizumab products, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate OMLYCLO therapy in a healthcare setting and closely observe patients for an appropriate period of time after OMLYCLO administration. Healthcare providers administering OMLYCLO should be prepared to manage anaphylaxis, which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of OMLYCLO should be based on criteria to mitigate risk from anaphylaxis.

Contraindications: Severe hypersensitivity reaction to omalizumab products or any ingredient of OMLYCLO.

Anaphylaxis. Life-threatening anaphylaxis has occurred after use of omalizumab products, with signs/symptoms including bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue; it can occur as early as the first dose, beyond 1 year after starting, and has been reported up to 4 days after administration. Initiate OMLYCLO in a healthcare setting equipped to manage anaphylaxis and observe patients for an appropriate period after dosing; educate patients on signs/symptoms and the need for immediate medical care. Risk is increased in patients with a history of anaphylaxis to foods, medications, or other causes. After therapy is safely established, self-administration OMLYCLO prefilled syringe may be appropriate for selected patients/caregivers based on risk mitigation (including no prior history of anaphylaxis, at least 3 supervised doses without hypersensitivity, ability to recognize and appropriately treat anaphylaxis, and ability to perform SC injections correctly). Discontinue OMLYCLO in patients who experience a severe hypersensitivity reaction.

Malignancy. Malignant neoplasms have been observed in clinical studies; the impact of longer exposure and use in patients at higher baseline risk is not known, and limitations of longer-term observational data preclude definitively ruling out a malignancy risk with omalizumab products.

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Acute Asthma Symptoms and Deteriorating Disease. Omalizumab products have not been shown to relieve acute asthma exacerbations; do not use OMLYCLO to treat acute bronchospasm or status asthmaticus. Advise patients to seek medical care if asthma remains uncontrolled or worsens after starting OMLYCLO.

Corticosteroid Reduction. Do not abruptly discontinue systemic or inhaled corticosteroids when starting OMLYCLO for asthma or CRSwNP; taper gradually under physician supervision. In CSU patients, use of omalizumab products in combination with corticosteroids has not been evaluated.

Eosinophilic Conditions. In rare cases, patients with asthma on omalizumab products have developed serious systemic eosinophilia, sometimes with vasculitis consistent with Churg-Strauss syndrome, often in the setting of oral corticosteroid reduction. Be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy; a causal association has not been established.

Fever, Arthralgia, and Rash. In post-approval use, a serum sickness-like constellation (arthritis/arthralgia, rash, fever, lymphadenopathy) has occurred 1 to 5 days after injections and may recur with additional doses; stop OMLYCLO if this constellation develops.

Parasitic (Helminth) Infection. Monitor patients at high risk of geohelminth infection during OMLYCLO therapy; available data are insufficient to define the duration of monitoring needed after stopping treatment. A clinical trial in a high-risk setting observed more infections with omalizumab than placebo; response to appropriate anti-geohelminth treatment was not different between groups.

Laboratory Tests. Total serum IgE increases after dosing and may remain elevated for up to 1 year after discontinuation due to drug:IgE complexes; do not use total IgE levels obtained less than 1 year after discontinuation to reassess dosing regimen for asthma, CRSwNP, or IgE-mediated food allergy because these levels may not reflect steady-state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis. OMLYCLO should not be used for the emergency treatment of allergic reactions, including anaphylaxis. Instruct patients that OMLYCLO is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

Most Common Adverse Reactions

- **Asthma:** In patients ≥12 years, reported in ≥1%: arthralgia, general pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In pediatric patients (6 to <12 years), reported in ≥3%: nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- **CRSwNP:** In ≥3% of adult patients: headache, injection site reactions, arthralgia, upper abdominal pain, and dizziness.
- **IgE-Mediated Food Allergy:** In ≥3% of patients: injection site reactions and pyrexia.
- **CSU:** In ≥2% of patients: nausea, nasopharyngitis, sinusitis, upper respiratory tract infections (viral and non-viral), arthralgia, headache, and cough.

Please see the full Prescribing Information for complete details. To report suspected adverse reactions, contact CELLTRION USA INC. at 1-800-560-9414 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.com