IgE-Mediated Food Allergy Sample Letter of Medical Necessity for XOLAIR® (omalizumab) for subcutaneous use

Instructions for Use

When submitting a prior authorization (PA) request to a patient's health insurance plan, including a letter of medical necessity can help explain the rationale and clinical decision-making behind the choice to prescribe XOLAIR.

Using the information in this sample letter does not guarantee that the health plan will provide reimbursement for XOLAIR. It is not intended to be a substitute for, or influence on, the independent medical judgment of the physician.

Some key reminders

- Letters of medical necessity should be signed by the physician only
- Include the appropriate International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code(s)
  - For a list of sample coding, visit **Genentech-Access.com/XOLAIR**
- Please refer to page 3 for the list of enclosures

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[Date]

[Payer name]
Attention: [Contact title/Medical Director]
[Address]

Subject: **Letter of Medical Necessity for Treatment of IgE-Mediated Food Allergy**

Patient: [Patient name]
Date of Birth: [MM/DD/YYYY]
Insurance ID number: [Insurance ID Number]
Insurance Group Number: [Insurance Group Number]
Case ID Number: [Case ID Number (if available)]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director],

I'm writing on behalf of my patient, [first and last name], to request prior authorization for treatment with XOLAIR® (omalizumab) for subcutaneous use. This letter provides information about the patient's medical history and diagnosis, and a summary of the treatment plan.

Patient's Clinical History
[Patient's name] is [a/an] [age]-year-old [male/female/transgender/etc.] patient who, as of [date], has been diagnosed with [diagnosis] ([ICD-10-CM code]) [Sample ICD-10-CM codes can be found here: https://www.genentech-access.com/ hcp/brands/xolair/learn-about-our-services/reimbursement.html].

This patient has been under my care since [date], having been referred to me by [referring physician's name] for [reason].

[Brief summary of rationale for treatment with XOLAIR. This includes a brief description of the patient's diagnosis, including the ICD-10-CM code, the severity of the patient's condition, as well as other factors (eg, underlying health issues, age) that have affected your treatment selection.]

Treatment Plan
In 2024, the FDA approved XOLAIR for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. To be used in conjunction with food allergen avoidance.

Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

I'm prescribing XOLAIR [dose, schedule and duration of treatment]. [Include any guidelines that may support the use].

Summary
Based on the above facts, I believe XOLAIR is not only indicated, but also medically necessary for this patient. If you have any further questions, please contact me at [phone number] or [email address]. Thank you for your consideration.

Enclosures
Enclosed are [List enclosures, which may include the following:

- Prior authorization or appeal letter recommended by the health plan
- Current/recent chart notes:
  - Date of initial diagnosis
  - Severity of condition
  - Any relevant comorbidities
- History prior to your care, if applicable
- Supportive literature
- XOLAIR Prescribing Information
- Patient's narrative]

Sincerely,

[Physician signature]
[Physician typed name and credentials]