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

Instructions for Use

This letter provides an example of the types of information that may be provided when a patient's insurance company denies coverage or prior authorization (PA) for 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 appeal 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

[Date]

[Payer name]

Attention: [Contact title/Medical Director]

[Address]

Subject: IgE-Mediated Food Allergy Letter of Appeal

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 am writing to request reconsideration of the denial of coverage for XOLAIR® (omalizumab) for subcutaneous use, which I have prescribed for my patient, [Patient First and Last Name].

As noted in the denial letter, coverage for XOLAIR was not approved due to [list reason(s) for the denial]. Listed below are the patient's medical history, diagnosis and treatment plan, which confirm the medical necessity and appropriate treatment with XOLAIR.

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-ourservices/reimbursement.html].

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

This patient has allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods.

[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. XOLAIR is 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.

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:

- Appeal form recommended by 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]