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

Explanation of color-coding

The attached sample letter is color-coded to help you compose a letter of medical necessity for each indication of XOLAIR. Please select the appropriate text based on the patient's indication.

RED = Patient-/practice-specific information
ORANGE = Moderate to severe persistent asthma
PURPLE = Chronic spontaneous urticaria
GREEN = Chronic rhinosinusitis with nasal polyps

 M-US-00020898(v1.0) 08/23

[Date]

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

Subject: **Letter of Medical Necessity for XOLAIR® (omalizumab) for subcutaneous use**

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 [moderate to severe persistent asthma/chronic spontaneous urticaria/chronic rhinosinusitis with nasal polyps].

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, prior treatments, the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (eg, underlying health issues, age) that have affected your treatment selection.]

Treatment Plan
[In 2003 the FDA approved XOLAIR for the treatment of moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.]
Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm, status asthmaticus, or for treatment of other allergic conditions.
[In 2014 the FDA approved XOLAIR for the treatment of chronic spontaneous urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.]
Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

[In 2020 the FDA approved XOLAIR for the treatment of chronic rhinosinusitis with nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.]

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
  - Response to all prior therapies (eg, name of therapy, dose, start date/stop date, length of treatment, and clinical response)
  - 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]