Xolair® Omalizumab

FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg

NAVIGATING ACCESS TO XOLAIR FOR IgE-MEDIATED FOOD ALLERGY PATIENTS

A guide to securing coverage before payer policies are established

IgE=immunoglobulin E.

MODELS ARE FOR ILLUSTRATIVE PURPOSES ONLY.

INDICATION

XOLAIR® (omalizumab) is indicated 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.

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 XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR 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 XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Understanding Coverage for XOLAIR for IgE-Mediated Food Allergy

On February 16, 2024, XOLAIR was approved 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.

Immediately after the approval of XOLAIR for food allergy, **payers may not have finalized their policies/formularies** or established clear prior authorization criteria.[1]

Healthcare providers may use the payer's medical/formulary exception process to secure coverage for XOLAIR.[1]

The steps on the following page may help you as you seek to secure coverage for patients while payers finalize their policies/formularies.

MODEL IS FOR ILLUSTRATIVE PURPOSES ONLY.

The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Genentech and Novartis Pharmaceuticals Corporation make no representation or guarantee concerning coverage or reimbursement for any service or item.

IMPORTANT SAFETY INFORMATION (cont)

CONTRAINDICATIONS

XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Securing Coverage for XOLAIR

1 Perform a benefits investigation (BI) to determine XOLAIR coverage

- XOLAIR Access Solutions can conduct a BI on behalf of your patients so you can understand their coverage
- If the outcome of the BI indicates that XOLAIR is not covered, access may be available via the medical exception process

2 Establish medical necessity

☐ Complete the payer's medical/formulary exception form (if available)
- XOLAIR Access Solutions can help you identify these forms and offer resources as you request medical/formulary exception for your patient

☐ Compose a letter of medical necessity
- In the letter, be sure to include:
  - The date of diagnosis
  - Severity of the condition
  - Patient demographic information
  - Attestation about the patient's experience with food avoidance
  - Rationale as to why this patient should be taking XOLAIR
- A sample letter of medical necessity can be found at XOLAIRHCP.com

☐ Attach relevant documentation, including:
- Positive skin prick test
- A serum allergen-specific IgE level test
- History of severe allergic response, including anaphylaxis
- Supportive literature
- A copy of the US Prescribing Information
- A copy of the FDA approval letter, which can be found under the Forms and Documents section of Genentech-Access.com/XOLAIR and/or by scanning the QR code here

FDA=US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Anaphylaxis: Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials and in postmarketing spontaneous reports. In premarketing clinical trials in patients for a different indication, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

3 If denial persists, you may file an appeal.*

☐ Review the denial letter to help you understand the reason for the denial
- A sample appeal letter can be found on XOLAIRHCP.com

☐ Provide additional information and documentation as needed
- XOLAIR Access Solutions can provide resources as you prepare an appeal submission, per your patient's plan requirements

☐ Submit the appeal
- XOLAIR Access Solutions can follow up with a patient's health insurance plan about the status of the appeal

For help navigating the coverage process

Visit Genentech-Access.com/XOLAIR

Fax **(800) 704-6612**

Call **(800) 704-6610**

Contact your **Field Reimbursement Manager**

*Appeals cannot be completed or submitted by Genentech Access Solutions on your behalf.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

Important Safety Information (cont)

WARNINGS AND PRECAUTIONS (cont)

Anaphylaxis (cont): A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy: Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients for a different indication found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Fever, Arthralgia, and Rash: In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection: Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests: Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for IgE-mediated food allergy patients, because these levels may not reflect steady state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis
XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

IgE-Mediated Food Allergy: The most common adverse reactions (≥3% incidence in XOLAIR-treated patients) included: injection site reaction (15.5%) and pyrexia (6.4%). Safety data obtained from adults (n=3) in this trial was limited.

Injection Site Reactions: Injection site reactions occurred at a rate of 15.5% in XOLAIR-treated patients compared with 10.9% in placebo-treated patients. The types of injections included: urticaria, discomfort, erythema, pain, and rash. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.

Injection Site Reactions in Healthy Adults: In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

Cardiovascular and Cerebrovascular Events from Clinical Studies for a Different Indication: A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication to evaluate the long term safety of XOLAIR, including the risk of malignancy. Similar percentages of patients in both cohorts were current (5%) or former smokers (29%). Patients had a mean age of 45 years and were followed for a mean of 3.7 years. More XOLAIR-treated patients were diagnosed with a severe form of the condition studied (50%) compared to the non-XOLAIR-treated patients (23%). A higher incidence rate (per 1000 patient-years) of overall cardiovascular and cerebrovascular serious adverse events (SAEs) was observed in XOLAIR-treated patients (13.4) compared to non-XOLAIR-treated patients (8.1). Increases in rates were observed for transient ischemic attack (0.7 vs 0.1), myocardial infarction (2.1 vs 0.8), pulmonary hypertension (0.5 vs 0), pulmonary embolism/venous thrombosis (3.2 vs 1.5), and unstable angina (2.2 vs 1.4), while the rates observed for ischemic stroke and cardiovascular death were similar among both study cohorts. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy: Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Reference: 1. Patient Advocate Foundation. Filing a formulary exception. Accessed January 18, 2024. https://www.patientadvocate.org/explore-our-resources/insurance-denials-appeals/filing-a-formulary-exception/

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

For help navigating the coverage process

Visit Genentech-Access.com/XOLAIR

Call **(800) 704-6610**

Fax **(800) 704-6612**

Contact your **Field Reimbursement Manager**

Genentech
A Member of the Roche Group

NOVARTIS

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg