Omalizumab (XOLAIR) for Asthma
Criteria for Use
August 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive omalizumab.

- ☐ Prior severe hypersensitivity reaction to omalizumab or any of its ingredients
- ☐ Do not use to treat acute exacerbation of asthma or status asthmaticus

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Care is provided by a VA/VA Community Care pulmonologist, immunologist, allergist, or designated expert in the management of asthma
- ☐ Diagnosis of moderate to severe persistent asthma
- ☐ Pre-treatment serum IgE is 30 to 700 IU/mL[1]
- ☐ Positive skin tests or *in vitro* reactivity to common aeroallergens (e.g., dust mites, pet dander, cockroach)
- ☐ Receiving medium to high dose inhaled corticosteroids and long-acting beta-agonist or other controller medication(s)
- ☐ Inadequate symptom control (e.g., short-acting beta-agonist use, nighttime awakening due to asthma more than once weekly, limitation with normal activity, Asthma Control Test less than 19) **OR** asthma exacerbation(s) requiring systemic corticosteroids in the last 12 months
- ☐ Adherent to asthma medications as evidenced by a review of prescription refill history during the last 12 months
- ☐ Should be nonsmoking or receiving smoking cessation treatment if smoking[2]
- ☐ Has an epinephrine pen available at time of injection and for at least 24 hours after injection
- ☐ Therapy to be initiated in a healthcare setting

[1] Data for use in patients with baseline IgE serum levels up to 1500 IU/mL are available (considered off-label in the US). Use of omalizumab in such patients should be adjudicated locally.

[2] There is limited information on the efficacy and safety of omalizumab in patients who smoke. The decision to use omalizumab in patients who have had unsuccessful attempts at smoking cessation should be made on a case-by-case basis.

Additional Inclusion Criteria for Self-Administration

- ☐ Provider has determined that self-administration with prefilled syringe by patient or caregiver is appropriate
- ☐ No previous history of anaphylaxis to omalizumab or other agents (e.g. food, drugs, biologics, etc.)
- ☐ At least 3 doses were administered in healthcare setting with no hypersensitivity reactions
- ☐ The patient and/or caregiver must be trained in and demonstrate the correct subcutaneous injection technique
- ☐ The patient and/or caregiver are taught to recognize signs and symptoms of anaphylaxis and is able to treat anaphylaxis appropriately

Other Justification

☐ Patient has confirmed Ig-E mediated food allergy and a need for treatment with omalizumab to reduce the risk of type 1 allergic reactions, including anaphylaxis, and prescribed by a specialist in Allergy and Immunology.

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