

Omalizumab (Xolair) Criteria for Use in Chronic Spontaneous Urticaria (CSU) Criteria for Use January 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

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.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERNet](#) or [PBM INTRANet](#) site for further information.

Exclusion Criteria

If any of the following is selected, the patient will NOT meet criteria for omalizumab

- Prior severe hypersensitivity reaction to omalizumab or any of its ingredients

Inclusion Criteria

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

- Provider is a VA or VA Community Care allergy specialist, dermatologist or designated expert in the management of allergic conditions.
- Diagnosis of severe chronic spontaneous urticaria (e.g., UAS7 \geq 28 and/or UCT <12) ^{^1}
- Unacceptable symptoms despite a therapeutic trial ^{^2} of 1 non-sedating H₁ antihistamine titrated up to 4 times the usual daily dose.
- Has an epinephrine rescue device (e.g., pen, etc.) available at the time of injection and for at least 24 hours after the injection.
- Omalizumab therapy is initiated in a healthcare setting.

^{^1} UAS7=urticaria activity score over the prior 7 days. representing urticaria activity. Scores range from 0-42 and include assessment of both itch and hives severity. Scores \geq 28 represent more severe symptoms. UCT is the urticaria control test. Scores range from 0-16 with scores \geq 12 representing well-controlled disease.

^{^2} Therapeutic trial=at least 2 weeks at usual doses and then titrated up to 4 times the maximum daily dose and followed for 1 to 4 weeks after doses are maximized for improvement in symptoms, as tolerated.

Additional Information:

The dose of omalizumab in CSU is not dependent upon free or total serum IgE levels or body weight.

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 are taught to recognize signs and symptoms of anaphylaxis and able to treat anaphylaxis appropriately

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Contact: Catherine Kelley, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services-
Formulary Management (12PBM)