Dupilumab (DUPIXENT) 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 Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If any of the following are selected, the patient will NOT meet criteria for dupilumab.

- ☐ Concurrent use of live or live attenuated vaccines (within the past 4 weeks)
- ☐ Untreated parasitic (helminth) infection (treat infection prior to initiating dupilumab)
- ☐ Concurrent use with therapeutic biologics unless potential benefit-risk favors use

Inclusion Criteria

All the following criteria must be selected 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 ≥28 and/or UCT <12) ^1
- ☐ Unacceptable symptoms despite a therapeutic trial ^2 of 1 non-sedating H_1 antihistamine titrated up to 4 times the usual daily dose.
- ☐ Inadequate response to a 3-month trial of omalizumab 300 mg every 4 weeks (minimum of 3 doses), unable to tolerate or not a candidate for omalizumab. ^3

^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 ≥28 represent more severe symptoms. UCT is the urticaria control test. Scores range from 0-16 with scores ≥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.

^3 Results from the CUPID Study B did not show a statistical difference in patients who were omalizumab intolerant or incomplete responders (after at least a 3-month trial or a minimum of 3 doses of omalizumab). However, authors comment that the study may have been underpowered to detect smaller differences in patients having an incomplete response to omalizumab. Small, single-center studies have shown benefit of dupilumab in these patients, but confirmatory studies are needed. Patients with type 2b autoimmune CSU (e.g., low total IgE levels and low eosinophil counts) may be more likely to benefit from a trial of dupilumab.

Additional Information:

Dupilumab may be preferred over omalizumab at sites where there is a lack of access to specialists in Allergy and Immunology.

Additional Inclusion Criteria

Select if applicable.

- ☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy. However, if pregnancy does occur, a pregnancy register exists, and enrollment is recommended.

Revised: N/A

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