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IN BRIEF

Dupilumab *(Dupixent)* for Chronic Spontaneous Urticaria

The subcutaneously injected interleukin (IL)-4 receptor alpha antagonist dupilumab (*Dupixent* – Sanofi/Regeneron) has been approved by the FDA for treatment of chronic spontaneous urticaria in patients ≥12 years old who remain symptomatic despite H_1-antihistamine treatment. Dupilumab was approved earlier for treatment of asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, and chronic obstructive pulmonary disease with an eosinophilic phenotype.[1-3]

STANDARD TREATMENT — H_1-antihistamines are used for initial treatment of chronic spontaneous urticaria. Patients who do not have an adequate response to FDA-approved doses of H_1-antihistamines may respond to higher doses. The recombinant anti-IgE monoclonal antibody omalizumab (*Xolair*, and biosimilar), like dupilumab, is approved for use in patients who have symptoms despite treatment with H_1-antihistamines. Cyclosporine has been used off label in patients who had an inadequate response to omalizumab.[4]

CLINICAL STUDIES — FDA approval of dupilumab for the new indication was based on the results of two double-blind trials (CUPID A and C) in patients with chronic spontaneous urticaria who remained symptomatic despite H_1-antihistamine treatment (given at or above FDA-approved dosages) and had not previously been treated with omalizumab. Patients were randomized to receive dupilumab or placebo in addition to their background H_1-antihistamine for 24 weeks. Improvements from baseline in the urticaria activity score (UAS7) and the itch severity score (ISS7) were statistically significantly greater with dupilumab than with placebo in both trials.[5]

In a third trial (CUPID Study B) in patients who had an inadequate response to or were unable to tolerate omalizumab, improvements in the ISS7 score at week 24 were not statistically significantly greater with dupilumab than with placebo.[5]

No head-to-head trials comparing dupilumab with omalizumab or other drugs used for treatment of chronic spontaneous urticaria are available.

ADVERSE EFFECTS — Injection-site reactions, upper respiratory tract infections, herpes infections, nasopharyngitis, conjunctivitis, arthralgia, myalgia, dizziness, and diarrhea have been reported with dupilumab. Hypersensitivity reactions, including anaphylaxis and serum sickness, have occurred. Eosinophilic pneumonia and vasculitis consistent with eosinophilic granulomatosis with polyangiitis have been reported, but a causal relationship has not been established. The omalizumab label contains a boxed warning about the risk of anaphylaxis; there is no such warning in the label of dupilumab.

DRUG INTERACTIONS — Use of live vaccines should be avoided in patients receiving dupilumab.

DOSAGE, ADMINISTRATION, AND COST — The recommended dosage of dupilumab for treatment of chronic spontaneous urticaria in adults and those 12-17 years old who weigh ≥60 kg is 600 mg (two 300-mg injections) once, followed by 300 mg once every 2 weeks. In patients 12-17 years old who weigh 30-<60 kg, the initial dose is 400 mg (two 200-mg injections), followed by 200 mg once every 2 weeks. Dupilumab should be injected subcutaneously into the thigh, abdomen, or upper arm; patients or caregivers can be trained to administer the drug at home. A single 300-mg dose of *Dupixent* costs about $2000.[6]

CONCLUSION — The injectable interleukin (IL)-4 receptor alpha antagonist dupilumab *(Dupixent)* was more effective than placebo in patients with chronic spontaneous urticaria who remained symptomatic despite treatment with H_1-antihistamines and who had not been treated with omalizumab. Whether symptoms will recur when dupilumab is stopped is unclear. How dupilumab compares to omalizumab (*Xolair*, and biosimilar) or other drugs for this indication remains to be established. ■

1. Dupilumab (Dupixent) for asthma. Med Lett Drugs Ther 2019; 61:6.
2. Dupilumab (Dupixent) for eosinophilic esophagitis and prurigo nodularis. Med Lett Drugs Ther 2023; 65:18.

3. Dupilumab (Dupixent) for COPD. Med Lett Drugs Ther 2025; 67:11.
4. T Zuberbier et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy 2022; 77:734.
5. M Maurer et al. Dupilumab in patients with chronic spontaneous urticaria (LIBERTY-CSU CUPID): two randomized, double-blind, placebo-controlled, phase 3 trials. J Allergy Clin Immunol 2024; 154:184.
6. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. June 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.