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FDA approves first treatment for chronic rhinosinusitis with nasal polyps

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The U.S. Food and Drug Administration has approved Dupixent (dupilumab) to treat adults with nasal polyps (growths on the inner lining of the sinuses) accompanied by chronic rhinosinusitis (prolonged inflammation of the sinuses and nasal cavity). This is the first treatment approved for inadequately controlled chronic rhinosinusis with nasal polyps.

Dupixent is given by injection. The efficacy and safety of Dupixent were established in two studies with 724 patients, 18 years and older with chronic rhinosinusitis with nasal polyps who were symptomatic despite taking intranasal corticosteroids. Patients who received Dupixent had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group. Patients taking Dupixent also reported an increased ability to smell and required less nasal polyp surgery and oral steroids.

Dupixent was originally approved in 2017 for patients 12 and older with eczema that is not controlled adequately by topical therapies or when those therapies are not advisable. In 2018, Dupixent was approved as an add-on maintenance treatment for patients 12 years and older with moderate-to-severe eosinophilic asthma or with oral corticosteroid-dependent asthma.

The FDA granted this application Priority Review. The approval of Dupixent was granted to Regeneron Pharmaceuticals.