

Nucala® (mepolizumab) – New indication

- On September 25, 2020, the [FDA announced](#) the approval of [GlaxoSmithKline's Nucala \(mepolizumab\)](#), for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.
- Nucala is also approved for:
 - The add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
 - Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- HES is a heterogeneous group of rare disorders associated with persistent eosinophilia with evidence of organ damage. Symptoms include skin rashes, itching, asthma, difficulty breathing, abdominal pain, vomiting, diarrhea, arthritis, muscle inflammation, congestive heart failure, deep venous thrombosis and anemia.
- The approval of Nucala for the new indication was based on a 32-week, randomized, double-blind, placebo-controlled study in 108 adult and adolescent patients aged 12 years and older with HES. Patients received Nucala or placebo once every 4 weeks while continuing their stable HES therapy. Efficacy was established based upon the proportion of patients who experienced a HES flare during the 32-week treatment period. A HES flare was defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.
 - The proportion of patients who experienced a HES flare or withdrew from the study in the Nucala and placebo treatment groups were 28% and 56%, respectively ($p = 0.002$).
 - The risk of first HES flare over the treatment period was 66% lower for patients treated with Nucala vs. placebo ($p = 0.002$).
- The recommended dose of Nucala for the treatment of HES is 300 mg administered once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections into the upper arm, thigh, or abdomen. Individual 100-mg injections should be administered at least 5 cm (approximately 2 inches) apart.
 - Refer to the Nucala drug label for dosing for asthma and EGPA.