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AAP News

Asthma

FDA approves drug for severe asthma

by Melissa Jenco, News Content Editor

The Food and Drug Administration (FDA) has approved a new drug for patients 12 years and older with severe asthma.

Nucala (mepolizumab), manufactured by GlaxoSmithKline, is a maintenance treatment for use with other asthma medications.

"This approval offers patients with severe asthma an additional therapy when current treatments cannot maintain adequate control of their asthma," Badrul Chowdhury, M.D., Ph.D., director of the Division of Pulmonary, Allergy, and Rheumatology Products in the FDA's Center for Drug Evaluation and Research, said in a news release.

The drug reduces levels of blood eosinophils and is administered every four weeks by an injection into the upper arm, thigh or abdomen.

Nucala was tested in three double-blind, randomized, placebo-controlled trials. Those taking the drug required fewer hospitalizations for asthma attacks and experienced a reduction in their daily oral corticosteroid dose, according to the FDA. However, they did not experience significant improvement in lung function measured by volume of air exhaled in one second.

Common side effects include headache, injection site reactions, back pain and weakness. Swelling of the face, mouth and tongue; dizziness; hives; breathing problems; rash and herpes zoster infections also can occur.

The FDA's approval comes despite its Pulmonary-Allergy Drugs Advisory Committee's decision in June to recommend the drug only for adults, saying there was not enough efficacy and safety data relating to children 12-17 years old.

Resources

- FDA briefing document on Nucala
- FDA Pulmonary-Allergy Drugs Advisory Committee meeting minutes regarding Nucala
- Information for parents about asthma symptoms
- Information for parents about asthma medications
- Centers for Disease Control and Prevention asthma resources