

# FDA adds Fasenra indication for severe asthma in children

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The U.S. Food and Drug Administration has approved an additional indication for AstraZeneca's Fasenra (benralizumab) as an add-on maintenance treatment for patients aged 6 to 11 years with severe asthma and an eosinophilic phenotype.

This indication was supported by evidence from the Phase III TATE trial, as well as [data](#) from additional well-controlled trials in adult and adolescent populations. Results among [children](#) aged 6 to 11 years old show that Fasentra met the primary end points, demonstrating pharmacokinetics and pharmacodynamics with severe eosinophilic asthma. The [safety](#) and tolerability results were also consistent with the known profile.

The recommended dose for Fasentra is 30 mg for patients ages 6 years and older who weigh  $\geq 35$  kg, while a new 10-mg dose will be available for patients aged 6 to 11 years who weigh

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