



## News Articles, FDA Update, Pharmacology

### First drug to treat relapsing MS in pediatric patients approved

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The Food and Drug Administration (FDA) recently approved Gilenya (fingolimod), a sphingosine 1-phosphate receptor modulator, as the first treatment for relapsing forms of multiple sclerosis (MS) in pediatric patients 10 years of age and older.

Gilenya, an oral capsule given once daily, originally was approved for adults in 2010.

MS is a chronic illness in which the body's immune system is directed against the central nervous system. Relapsing MS is the most common form of the disease and is characterized by relapses followed by periods of partial or complete recovery.

The approval of Gilenya in pediatric patients was supported by a randomized, controlled clinical trial of 214 patients ages 10 to 17 years comparing Gilenya administered once daily and interferon (INF) beta-1a administered once weekly. The primary endpoint, the annualized relapse rate (ARR), was significantly lower in patients treated with Gilenya (0.122) than in patients who received INF beta-1a (0.675), and the relative reduction in ARR was 81.9%.

The safety profile of Gilenya in pediatric patients is similar to that seen in adult patients. Due to the risk of infections, the drug label recommends that pediatric patients complete all immunizations prior to initiating Gilenya therapy.

#### Resource

- [Gilenya labeling](#)