

FDA approves Zilbrysq for generalized myasthenia gravis

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The U.S. Food and Drug Administration has approved UCB's Zilbrysq (zilucoplan) for the treatment of adults with generalized myasthenia gravis.

Zilbrysq is a targeted peptide inhibitor of complement component 5 (C5) and is approved as a once-daily, self-administered, targeted therapy in

[patients](#) with anti-acetylcholine receptor (AChR)-antibody-positive generalized myasthenia gravis.

The approval of Zilbrysq is based on results from the Phase III RAISE study, in which patients were randomly assigned (1:1) to receive daily subcutaneous injections of 0.3 mg/kg Zilbrysq or placebo for 12 weeks.

Significant benefits were seen for the primary end point of improvements in symptoms and functional activities as measured by the Myasthenia Gravis-Activities of Daily Living at week 12. The most common adverse reactions in patients receiving Zilbrysq ($\geq 10\%$) were injection site reactions, upper respiratory tract infection, and diarrhea.

"Until now, people living with generalized myasthenia gravis have only had access to C5 [therapy](#) intravenously, which can be inconvenient and time consuming," Iris Loew-Friedrich, chief medical officer at UCB, said in a statement. "Now ... we hope a broad population of mild-to-severe adult patients with AChR-antibody-positive generalized [myasthenia gravis](#) will be able to have greater independence."

More information: [More Information](#)

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