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Federal Employee Program.

ZILBRYSQ (zilucoplan)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zilbrysq (zilucoplan) binds to complement protein C5 and inhibits cleavage into C5a and C5b. Blocking the formation of C5b inhibits the subsequent formation of terminal complex C5b-9. The precise mechanism by which Zilbrysq exerts its therapeutic effect in generalized myasthenia gravis is unknown but is presumed to involve reduction in C5b-9 deposition at the neuromuscular junction (1).

Regulatory Status

FDA-approved indication: Zilbrysq is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive (1).

The International Consensus Guidance for Management of Myasthenia Gravis recommends the use of chronic IVIG and immunosuppressants. There is a lack of data demonstrating the safety and efficacy of concomitant therapy of IVIG with Zilbrysq (2).

Zilbrysq includes a boxed warning citing the risk of life-threatening and fatal meningococcal infections. Additionally, all patients must be vaccinated with a meningococcal vaccine at least 2 weeks prior to receiving their first dose (1).

Zilbrysq is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Zilbrysq REMS, prescribers must enroll in the program (1).

In addition, Zilbrysq has warnings regarding pancreatitis and pancreatic cysts and using caution when administering Zilbrysq to patients with any other systemic infection (1).

The safety and effectiveness of Zilbrysq in pediatric patients less than 18 years of age have not been established (1).

Summary

Zilbrysq (zilucoplan) is a complement inhibitor indicated for the treatment of patients with



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generalized myasthenia gravis (gMG). Zilbrysq includes a boxed warning citing the risk of life-threatening and fatal meningococcal infections. Zilbrysq is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). In addition, Zilbrysq has warnings regarding pancreatitis and pancreatic cysts and using caution when administering Zilbrysq to patients with any other systemic infection. The safety and effectiveness of Zilbrysq in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Zilbrysq while maintaining optimal therapeutic outcomes.

References

1. Zilbrysq [package insert]. Smyrna, GA: UCB, Inc.; April 2024.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016; 87(4):419. Epub 2016 Jun 29.