

XCOPRI (cenobamate)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xcopri (cenobamate) has been demonstrated to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the γ–aminobutyric acid (GABA_A) ion channel which could also contribute to its therapeutic effect in patients with seizures (1).

Regulatory Status

FDA-approved indication: Xcopri is indicated for the treatment of partial-onset seizures in adult patients (1).

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking Xcopri. DRESS has occurred when Xcopri was titrated rapidly (weekly or faster titration). No cases of DRESS were reported in an open-label safety study when Xcopri was titrated every 2 weeks. DRESS typically presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis sometimes resembling an acute viral infection. Eosinophilia is often present. If such signs or symptoms are present, the patient should be evaluated immediately. Xcopri should be discontinued immediately and not restarted if an alternative etiology for the signs or symptoms cannot be established (1).

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

Summary

Xcopri (cenobamate) has been demonstrated to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the γ–aminobutyric acid (GABA_A) ion channel which could also contribute to its therapeutic effect in patients with seizures. The safety and effectiveness of Xcopri 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



Federal Employee Program.

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Xcopri while maintaining optimal therapeutic outcomes.

References

1.	Xcopri [package	insert]. Paramus,	NJ: SK Life Science	, Inc.; April 2024.