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5.75.032

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	June 5, 2020
Subject:	Xcopri	**Page:**	1 of 4

Last Review Date: June 13, 2024

Xcopri

Description

Xcopri (cenobamate)

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).

Related policies
Acthar gel, Sabril/Vigadrone

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xcopri may be considered **medically necessary** if the conditions indicated below are met.

Xcopri may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Partial-onset seizures

AND ALL of the following:

1. Prescriber agrees to monitor patient for signs and symptoms of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity
2. Prescriber agrees to titrate dose no faster than every 2 weeks

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Partial-onset seizures

AND the following:

1. Prescriber agrees to monitor patient for signs and symptoms of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 400 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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 Xcopri while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action

June 2020	Addition to PA. Annual review
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.75.032
December 2023	Annual review
June 2024	Annual editorial review and reference update. Changed quantity limit to MDDL dosing at 400 mg per day

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.