MEDICAL MUTUAL®

Drug Policy

Policy:	Xcopri (cenobamate)	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

Xcopri is indicated for the treatment of partial-onset seizures in adult patients. While the precise mechanism by which Xcopri exerts its therapeutic effect is unknown, Xcopri is believed 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. Additional clinical trials are investigating Xcopri in other seizure types.

POLICY STATEMENT

This policy involves the use of Xcopri. Prior authorization is recommended for pharmacy benefit coverage of Xcopri. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xcopri as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Xcopri be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

AUTOMATION: When available, 1) ICD-10 code G40.0* confirming diagnosis of partial onset seizures AND 2) patient age of 18 years or older AND 3) history of at least one other anti-epileptic drug (including carbamazepine, divalproex, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, topiramate, valproic acid, and zonisamide) within the previous 730 days.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xcopri is recommended in those who meet the following criteria:

1. Partial Onset Seizures

Criteria. *Patient must meet the following criteria (A, B, and C):*

A. The patient is an adult 18 years of age or older; AND
B. The patient does NOT have Familial Short QT syndrome; AND
C. The patient's seizures have been inadequately controlled with prior use of at least one anti-epileptic drug (AED);

Note: Examples of anti-epileptic drugs include carbamazepine, divalproex, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, topiramate, valproic acid, zonisamide.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 Years
B) *Extended Approval:* 2 Years

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xcopri has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xcopri [prescribing information]. Paramus, NJ: SK Life Sciences, Inc.; June 2022.
2. Cenobamate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 12 December 2019. Accessed on 16 December 2019.