



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Antiseizure Medications – Xcopri Drug Quantity Management Policy – Per Rx
- Xcopri® (cenobamate tablets – SK Life Science)

REVIEW DATE: 05/08/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Xcopri is indicated for the treatment of **partial-onset seizures** in adults.¹

Dosing

Xcopri is administered orally once daily.¹ The recommended dosage and titration schedule and maximum daily dose are provided in Table 1. Xcopri tablets can be taken whole or may be crushed and mixed with water either to administer via mouth as an oral suspension or via nasogastric tube. If Xcopri is to be discontinued the dose should be gradually reduced over a 2-week period, unless safety concerns require abrupt withdrawal. In patients with mild to moderate hepatic impairment, the maximum recommended dose of Xcopri is 200 mg once daily (QD). Use of Xcopri in patients with severe hepatic impairment is not recommended.

Table 1. Recommended Dosing for Partial-Onset Seizures in Adults.¹

Initial Dosage	
Week 1 and 2	12.5 mg QD
Titration Regimen	
Weeks 3 and 4	25 mg QD
Weeks 5 and 6	50 mg QD

Weeks 7 and 8	100 mg QD
Weeks 9 and 10	150 mg QD
Maintenance Dosage	
Week 11 and thereafter	200 mg QD
Maximum Dosage	
If needed based on clinical response and tolerability, dose may be increased above 200 mg by increments of 50 mg once daily every 2 weeks up to 400 mg.	400 mg QD

QD – Once daily.

Availability

Xcopri is supplied in bottles containing 30 tablets in the following strengths: 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg.¹ Titration blister packs (28-days) are available in the following strengths: 12.5 mg/25 mg (12.5 mg for 14 days and 25 mg for 14 days), 50 mg/100 mg (50 mg for 14 days and 100 mg for 14 days), and 150 mg/200 mg (150 mg for 14 days and 200 mg for 14 days). An additional 14-day blister pack (14 x 12.5 mg tablets) is also FDA-approved, but not available at this time. Maintenance blister packs (28-days) are available in the following strengths: 250 mg/day (28 x 100-mg tablets and 28 x 150-mg tablets) and 350 mg/day (28 x 150-mg tablets and 28 x 200-mg tablets).

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote dose consolidation, to prevent stockpiling and waste, and to address potential order entry error of Xcopri. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx	
Xcopri® (cenobamate tablets)	25 mg tablets	30 tablets	90 tablets	
	50 mg tablets	30 tablets	90 tablets	
	100 mg tablets	30 tablets	90 tablets	
	150 mg tablets	30 tablets	90 tablets	
	200 mg tablets	30 tablets	90 tablets	
	Titration Blister Packs			
	12.5 mg/25 mg (contains 14 tablets of each strength, 12.5 mg and 25 mg)	28 tablets	28 tablets	
	50 mg/100 mg (contains 14 tablets of each strength, 50 mg and 100 mg)	28 tablets	28 tablets	
	150 mg/200 mg (contains 14 tablets of each strength, 150 mg and 200 mg)	28 tablets	28 tablets	
	Maintenance Blister Packs			

	250 mg/day (contains 28 x 100-mg tablets and 28 x 150-mg tablets)	56 tablets	168 tablets
	350 mg/day (contains 28 x 150-mg tablets and 28 x 200-mg tablets)	56 tablets	168 tablets

Antiseizure Medications – Xcopri Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Xcopri 25 mg tablets

No overrides recommended.

Xcopri 50 mg tablets

No overrides recommended.

Xcopri 100 mg tablets

No overrides recommended.

Xcopri 150 mg tablets

- 1. If the patient is taking a daily dose of 300 mg, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

Xcopri 200 mg tablets

- 1. If the patient is taking a daily dose of 400 mg, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.

Xcopri Titration Blister Packs (12.5 mg/25 mg tablets, 50 mg/100 mg tablets, 150 mg/200 mg tablets)

No overrides recommended.

Xcopri Maintenance Blister Packs (250 mg/day and 350 mg/day)

No overrides recommended.

REFERENCES

- 1. Xcopri® tablets [prescribing information]. Paramus, NJ: SK Life Science; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
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Annual Revision	Policy was updated to reflect the existing quantity limits when product is obtained via home delivery. No criteria changes.	04/24/2023
Annual Revision	Xcopri 25 mg tablets: A new quantity limit of 30 tablets per dispensing at retail and 90 tablets per dispensing at home delivery was added to the policy. No clinical overrides apply.	05/08/2024

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