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Coverage Policy Number IP0031

Antiseizure Medications

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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. 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.

Overview

This policy supports medical necessity review for the following non-covered antiseizure medications:

- **Aptiom®** (eslicarbazepine tablets)
- **Briviact®** (brivaracetam tablets and oral solution)
- **Elepsia™ XR** (levetiracetam extended-release tablets)
- **Eprontia™** (topiramate oral solution)
- **Fycompa®** (perampanel tablets and oral suspension)
- **Lamictal® XR Starter Kit** (lamotrigine)
- **Motpoly XR** (lacosamide extended-release capsules)
- **Oxtellar® XR** (oxcarbazepine extended-release tablets)
- **Spritam®** (levetiracetam tablets for oral suspension)
- **Trokendi® XR (**topiramate extended-release capsules)
- **Xcopri®** (cenobamate tablets)
- **Zonisade™** (zonisamide oral suspension)

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria
Aptiom (eslicarbazepine tablets)	**Aptiom (eslicarbazepine)** is considered medically necessary for the treatment of seizure disorder.
Briviact (brivaracetam tablets and oral solution)	**Briviact (brivaracetam)** is considered medically necessary for the treatment of seizure disorder.
Elepsia XR (levetiracetam extended-release tablets)	**Elepsia XR (levetiracetam)** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Treatment of seizure disorder 2. Documented failure or intolerance to extended-release levetiracetam 500 mg or 750 mg tablet
Eprontia (topiramate oral solution)	**Eprontia (topiramate)** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Treatment of seizure disorder 2. Documented inability to use topiramate sprinkle capsule
Fycompa (perampanel tablets and oral suspension)	**Fycompa** (perampanel) is considered medically necessary for the treatment of seizure disorder.
Lamictal XR Starter Kit (lamotrigine)	**Lamictal XR Starter Kit (lamotrigine)** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Treatment of seizure disorder 2. Documented intolerance to lamotrigine
Motpoly XR (lacosamide extended-release capsule)	**Motpoly XR** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Treatment of seizure disorder 2. Failure, contraindication, or intolerance to lacosamide immediate-release tablets **OR** lacosamide oral solution
Oxtellar XR (oxcarbazepine extended-release tablets)	**Oxtellar XR (oxcarbazepine)** is considered medically necessary for the treatment of seizure disorder.
Spritam (levetiracetam tablets for oral suspension)	**Spritam (levetiracetam)** is considered medically necessary for the treatment of seizure disorder.

Non-Covered Product	Criteria
Trokendi XR (topiramate extended-release capsules)	**Trokendi XR (topiramate)** is considered medically necessary when there is documentation of **BOTH** of the following (1 and 2): 1. Treatment of ONE of the following (a or b): a. Seizure disorder b. Prophylaxis of migraine headache 2. Documented inability to use topiramate ER capsules
Xcopri (cenobamate tablets)	**Xcopri** (cenobamate) is considered medically necessary for the treatment of seizure disorder.
Zonisade (zonisamide oral suspension)	**Zonisade** (zonisamide) is considered medically necessary when there is documentation of **ALL** of the following: 1. 16 years of age or older 2. Treatment of seizure disorder 3. Used concomitantly with at least one other antiepileptic drug 4. Documented inability to swallow generic zonisamide capsules

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of antiseizure medications is considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Aptiom is indicated for the treatment of partial-onset seizures in patients years of age and older.[1]

Briviact is indicated for the treatment of partial-onset seizures in patients ≥ 1 month of age.[2]

Elepsia XR is indicated for the treatment of partial-onset seizures in patients ≥ 12 years of age.[3]

Eprontia is indicated for the following uses:[4]

- Initial monotherapy for the treatment of partial onset or primary generalized tonic-clonic seizures in patients ≥ 2 years of age.
- Adjunctive therapy for the treatment of partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut Syndrome in patients ≥ 2 years of age.

Fycompa is indicated for:[5]

- Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older.
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older.

Lamictal XR is indicated for the following:[6]
- Adjunctive therapy for primary generalized tonic-clonic seizures and partial onset seizures with or without secondary generalization in patients ≥ 13 years of age.
- Conversion to monotherapy in patients ≥ 13 years of age with partial seizures who are receiving treatment with a single ASM.

Motpoly XR is indicated for the treatment of partial-onset seizures in adults and in pediatric patients weighing ≥ 50 kg.[7]

Oxtellar XR is indicated for the treatment of partial seizures in patients ≥ 6 years of age.[8]

Spritam is indicated as adjunctive therapy in the treatment of:[9]
- Partial-onset seizures in patients ≥ 4 years of age and weighing > 20 kg with epilepsy.
- Myoclonic seizures, as adjunctive therapy in patients ≥ 12 years of age with juvenile myoclonic epilepsy.
- Primary generalized tonic-clonic seizures, as adjunctive therapy in patients ≥ 6 years of age with idiopathic generalized epilepsy.

Trokendi XR is indicated for the following uses:[10]
- Initial monotherapy for the treatment of partial onset or primary generalized tonic-clonic seizures in patients ≥ 6 years of age.
- Adjunctive therapy for the treatment of partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients ≥ 6 years of age.
- Prophylaxis of migraine headache in patients > 12 years of age.

Xcopri is indicated for the treatment of partial-onset seizures in adults.[12]

Zonisade is indicated as adjunctive therapy for the treatment of partial-onset seizures in adults and pediatric patients ≥ 16 years of age with epilepsy.[13]

References

1. Aptiom® tablets [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; March 2019.
2. Briviact® tablets, oral solution, and injection [prescribing information]. Smyrna, GA: UCB; May 2023.
3. Elepsia™ XR extended-release tablets [prescribing information]. Westfield, NJ: Tripoint; December 2020.
4. Eprontia™ oral solution [prescribing information]. Wilmington, MA: Azurity; October 2022.
5. Fycompa® tablets and oral suspension [prescribing information]. Woodcliff Lake, NJ: Eisai Inc.; February 2021.
6. Lamictal® XR [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.
7. Motpoly XR extended-release capsules [prescribing information]. Piscataway, NJ: Aucta; May 2023.
8. Oxtellar XR® extended-release tablets [prescribing information]. Rockville, MD: Supernus; December 2018.
9. Spritam® tablets for oral suspension [prescribing information]. Mason, OH: Prasco; January 2021.
10. Trokendi XR® extended-release capsules [prescribing information]. Rockville, MD: Supernus; October 2022.
11. Xcopri® tablets [prescribing information]. Paramus, NJ: SK Life Science; June 2022.
12. Zonisade™ oral suspension [prescribing information]. Wilmington, MA: Azurity; July 2022.