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5.75.006

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	May 8, 2015
Subject:	Topiramate powder	**Page:**	1 of 4

Last Review Date: December 13, 2024

Topiramate powder

Description

Topiramate powder

Background
Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) Topiramate targets sodium channels to change the activity of the receptors of the central nervous neurotransmitter GABA. Topiramate is an oral prescription medicine used to treat certain types of seizures (partial onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years and older, along with other medicines to treat certain types of seizures (partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome) in adults and children 2 years and older, and to prevent migraine headaches in adults and adolescents 12 years and older. Topiramate is available commercially in oral tablets with strengths up to 200mg (1).

Regulatory Status
FDA-approved indications: Topiramate powder is indicated for:

1. Monotherapy epilepsy: Initial monotherapy in patients ≥ 2 years of age with partial onset or primary generalized tonic-clonic seizures
2. Adjunctive therapy epilepsy: Adjunctive therapy for adults and pediatric patients (2 to 16 years of age) with partial onset seizures or primary generalized tonic-clonic seizures, and in patients ≥ 2 years of age with seizures associated with Lennox-Gastaut syndrome (LGS)
3. Migraine: Treatment for adults and adolescents 12 years of age and older for prophylaxis of migraine headache (1).

Topiramate powder may cause acute myopia and angle closure glaucoma and result in temporary or permanent visual symptoms, including possible permanent vision loss. Oligohidrosis and hyperthermia may occur with use, particularly in pediatric patients. Similar to other anti-seizure medications, topiramate powder may also cause central nervous symptoms and increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1).

Related policies

Policy

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

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

Topiramate powder may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Epilepsy / epileptic seizures
    a. 2 years of age or older
2. Migraine headache
    a. 12 years of age or older
    b. Used for prophylaxis
    c. Inadequate response, intolerance, or contraindication to alternate treatments

AND ALL of the following:

1. The patient must have tried and failed and/or have an intolerance to an existing commercially available oral products
2. All of the active ingredients in the oral formulation are prescription (RX) only products and are FDA approved for epilepsy or migraine headache

3. The final product will not exceed the FDA approved limits of 200mg per dose

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Epilepsy / epileptic seizures
    a. 2 years of age or older
2. Migraine headache
    a. 12 years of age or older
    b. Used for prophylaxis

AND ALL of the following:

1. The patient must have tried and failed and/or have an intolerance to an existing commercially available oral products
2. All of the active ingredients in the oral formulation are prescription (RX) only products and are FDA approved for epilepsy or migraine headache
3. The final product will not exceed the FDA approved limits of 200mg per dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Topiramate powder is used orally in dose units up to 200mg in patients who have tried and failed and/or have an intolerance to an existing commercially available oral product to treat certain types of seizures in adults and children 2 years and older, and to prevent migraine headaches in adults and adolescents 12 years and older (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Topiramate powder while maintaining optimal therapeutic outcomes.

References

1. Topamax [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2023.

Policy History

Date	Action
May 2015	Addition to PA
June 2015	Annual editorial review and reference update
December 2016	Annual editorial review Addition of ages to renewal section Policy number change from 5.12.06 to 5.75.06
September 2017	Annual review
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual review and reference update
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.75.006
December 2023	Annual review and reference update
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.