

TOPIRAMATE POWDER

RATIONALE FOR INCLUSION IN PA PROGRAM

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:

- Monotherapy epilepsy: Initial monotherapy in patients ≥ 2 years of age with partial onset or primary generalized tonic-clonic seizures
- 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).

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



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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	e insert].	Titusville, I	NJ: Janssen	Pharmaceuticals	Inc.; May	/ 2023.
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