

Specialty Guideline Management

Ztalmy

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ztalmy	ganaxolone

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Ztalmy is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests

Chart notes or medical record documentation of genetic test demonstrating pathogenic or likely pathogenic variation in the CDKL5 gene.

Reference number(s)
5348-A

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response to therapy (e.g., decrease in seizure frequency).

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Seizures Associated with Cyclin-Dependent Kinase-Like 5 (CDKL5) Deficiency Disorder (CDD)¹⁻²

Authorization of 6 months may be granted for members 2 years of age or older for treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) when the member has confirmed pathogenic or likely pathogenic variant in the CDKL5 gene.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members (including new members) requesting reauthorization for seizures associated with CDKL5 deficiency disorder when the member has achieved or maintained a positive clinical response to therapy (e.g., decrease in seizure frequency).

References

1. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; August 2025.
2. Ganaxolone for treating seizures caused by CDKL5 deficiency disorder in people 2 years and over. London: National Institute for Health and Care Excellence (NICE). 2025 Feb 12. (National Institute for Health and Care Excellence: Technology Appraisals, No. TA1033.)