Reference number(s)
5348-A

SPECIALTY GUIDELINE MANAGEMENT

ZTALMY (ganaxolone)

POLICY

I. 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 Indication
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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests: Chart notes or medical record documentation of enzyme assay or genetic testing demonstrating pathogenic or likely pathogenic mutation in the CDKL5 gene.
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy (e.g., decrease in seizures).

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Seizures associated with Cyclin-Dependent Kinase-Like 5 (CDKL5) deficiency disorder (CDD)
Authorization of 6 months may be granted for treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) when the member has a confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.

V. 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 seizures).

VI. REFERENCE

1. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; June 2023.