Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 29, 2024

Ztalmy® (ganaxolone)

LENGTH OF AUTHORIZATION: Initial Therapy - 6 months
Continuation of Therapy – 1 year

REVIEW CRITERIA:

- Patient must be ≥ 2 years of age.
- Patient must have a documented diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD).
  - Genetic testing results confirming the presence of a pathogenic or likely pathogenic mutation in the CDKL5 gene must be submitted.
- Patient has had an inadequate response or intolerance on at least 2 previous antiepileptic drug trials *(clinical documentation detailing the response to previous therapies must be submitted)*.
- Medication must be prescribed by or in consultation with a neurologist.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response from baseline (e.g., Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 50 mg/ml oral suspension. Each bottle contains 110 mL of suspension.