

ZTALMY (ganaxolone oral suspension)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 2 years of age and older

Diagnosis

Patient must have the following:

Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

AND ALL of the following:

- 1. Molecular confirmation of a pathogenic or likely pathogenic mutation in the CDKL5 gene
- 2. Inadequate response, intolerance, or contraindication to at least **TWO** antiepileptic drugs (e.g., valproate, levetiracetam, clobazam, vigabatrin, etc.)
- 3. Prescriber agrees to monitor for the emergence or worsening of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior
- 4. Prescriber agrees to decrease Ztalmy dose gradually when discontinuing treatment

Prior - Approval Limits

Quantity 30 bottles (3300 mL) per 90 days

Duration 12 months

Prior – Approval Renewal Requirements

Age 2 years of age and older

Diagnosis

Patient must have the following:

Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)



ZTALMY (ganaxolone oral suspension)

AND ALL of the following:

- 1. Decrease in the number of seizures from baseline
- 2. Prescriber agrees to monitor for the emergence or worsening of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior
- 3. Prescriber agrees to decrease Ztalmy dose gradually when discontinuing treatment

Prior - Approval Renewal Limits

Same as above