

Ztalmy (ganaxolone) Oral Suspension

POLICY

I. INDICATION

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 Indications

1. Ztalmy (ganaxolone) 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 are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

An authorization may be granted for 6 months when all the following criteria are met:

1. The patient is 2 years of age or older; AND
2. Ztalmy (ganaxolone) is prescribed by, or in consultation with, a neurologist; AND
3. Dosing does not exceed (A OR B):
 - A. Weight \leq 28 kg: 63 mg/kg per day
 - B. Weight $>$ 28 kg: 1,800 mg per day; AND
4. Clinical documentation provided includes:
 - A. Enzyme assay or genetic testing in the form of chart notes or medical record documentation demonstrating pathogenic or likely pathogenic mutation in the CDKL5 gene; AND
 - B. Baseline monthly seizure frequency

III. CONTINUATION OF THERAPY

An authorization may be granted for 6 months when all the following criteria are met:

1. The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months; AND
2. As demonstrated in clinical documentation (e.g. chart notes/medical records):
 - A. The patient has demonstrated a positive clinical response to therapy (e.g. decrease in seizures); OR
 - B. Improvement in quality of life using a validated scale for the disease state

IV. QUANTITY LIMITS

Ztalmy (ganaxolone) oral suspension 50 mg/mL: 10 (110 mL) bottles per 30 days (36.667 mL/day)

V. REFERENCES

1. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; April 2024.
2. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed December 7, 2022.