ALASKA MEDICAID
Prior Authorization Criteria

Ztalmy™ (ganaxolone)

FDA INDICATIONS AND USAGE[1]

Ztalmy™ is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator 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.

APPROVAL CRITERIA[1,2]

1. Patient is 2 years of age or older **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of CDKL5 deficiency disorder (CDD) **AND**;
4. Patient has a genetically confirmed mutation in the CDKL5 gene which is pathogenic or likely pathogenic **AND**
5. Patient has tried and failed or is currently taking at least two previous antiepileptic drugs.

DENIAL CRITERIA [1,2]

1. Failure to meet approval criteria

CAUTIONS[1]

- Controlled substance: Ztalmy contains ganaxolone, a schedule V controlled substance.
- Monitor patients for suicidal behavior and ideation.
- If discontinued, Ztalmy should be withdrawn gradually to minimize the risk of increased seizure frequency or status epilepticus.
- Ztalmy may cause fetal harm.

DURATION OF APPROVAL[1,2]

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months with confirmation of a sustained reduction in monthly seizure frequency from pre-treatment baseline
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QUANTITY LIMIT[1]

- 1800mg (36ml) daily

REFERENCES / FOOTNOTES:

1. Ztalmy™ (ganaxolone) [prescribing information]. Radnor, PA: Marinus; November 2022
2. Knight EMP, Amin S, Bahi-Buisson N, et al. Safety and efficacy of ganaxolone in patients with CDKL5 deficiency disorder: results from the double-blind phase of a randomised, placebo-controlled, phase 3 trial. Lancet Neurol. 2022;21:417-427