BlueCross BlueShield Federal Employee Program

ZTALMY
(ganaxolone oral suspension)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ztalmy (ganaxolone) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator. The precise mechanism by which Ztalmy exerts its therapeutic effects in the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) is unknown, but its anticonvulsant effects are thought to result from positive allosteric modulation of the gamma-aminobutyric acid type A ($GABA_A$) receptor in the central nervous system (1).

Regulatory Status

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 (1).

Ztalmy contains warnings for somnolence, sedation and suicidal behavior and ideation (1).

Ztalmy dose should be decreased gradually when discontinuing treatment. As with all antiepileptic drugs, abrupt discontinuation should be avoided, when possible, to minimize the risk of increased seizure frequency and status epilepticus (1).

The safety and effectiveness of Ztalmy in pediatric patients less than 2 years of age have not been established (1).

Summary

Ztalmy (ganaxolone) is a $GABA_A$ receptor positive modulator for the treatment of seizures associated with CDKL5 deficiency disorder (CDD). Patients should be monitored for suicidal behavior and thoughts and the dose should be gradually decreased upon discontinuation to reduce the risk of increased seizure frequency. The safety and effectiveness of Ztalmy in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Ztalmy while maintaining optimal therapeutic outcomes.

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References

1. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; April 2024.