Commercial/Healthcare Exchange PA Criteria

Effective: August 11th, 2022

Prior Authorization: Ztalmy

Products Affected: Ztalmy (ganaxolone) oral suspension

Medication Description: Ganaxolone's efficacy as an anticonvulsant is thought to result from positive allosteric modulation of the gamma-aminobutyric acid type A receptor in the CNS, although its precise mechanism is unknown

Covered Uses: Treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

Exclusion Criteria: None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Medication is prescribed by, or in consultation with, a neurologist

Age Restriction: Patient is 2 years of age or older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Seizures associated with Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)**
   A. Patient must be 2 years of age or older; **AND**
   B. Ztalmy is prescribed by, or in consultation with, a neurologist; **AND**
   C. Patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene

Renewal Criteria

1. Seizures associated with Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) **AND**
2. Confirmation of a sustained reduction in monthly seizure frequency compared to baseline

References:

1. Product Information: ZTALMY(R) oral suspension, ganaxolone oral suspension. Marinus Pharmaceuticals Inc (per FDA), Radnor, PA, 2022

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/11/2022

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