

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Ztalmy (Ganaxolone)

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document

Ztalmy (Ganaxolone)

- **Drugs requiring clinical prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Clinical prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

- Initial publication



Ztalmy (Ganaxolone)

Drugs Requiring Clinical Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Label Name	GCN
ZTALMY 50 MG/ML SUSPENSION	52095



Ztalmy (Ganaxolone)

Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 2 years of age?
 Yes – Go to #2
 No – Deny

2. Does the client have a diagnosis of seizures associated with **cyclin-dependent kinase-like 5 deficiency disorder (CDD)** in the last 730 days?
 Yes – Go to #3
 No – Deny

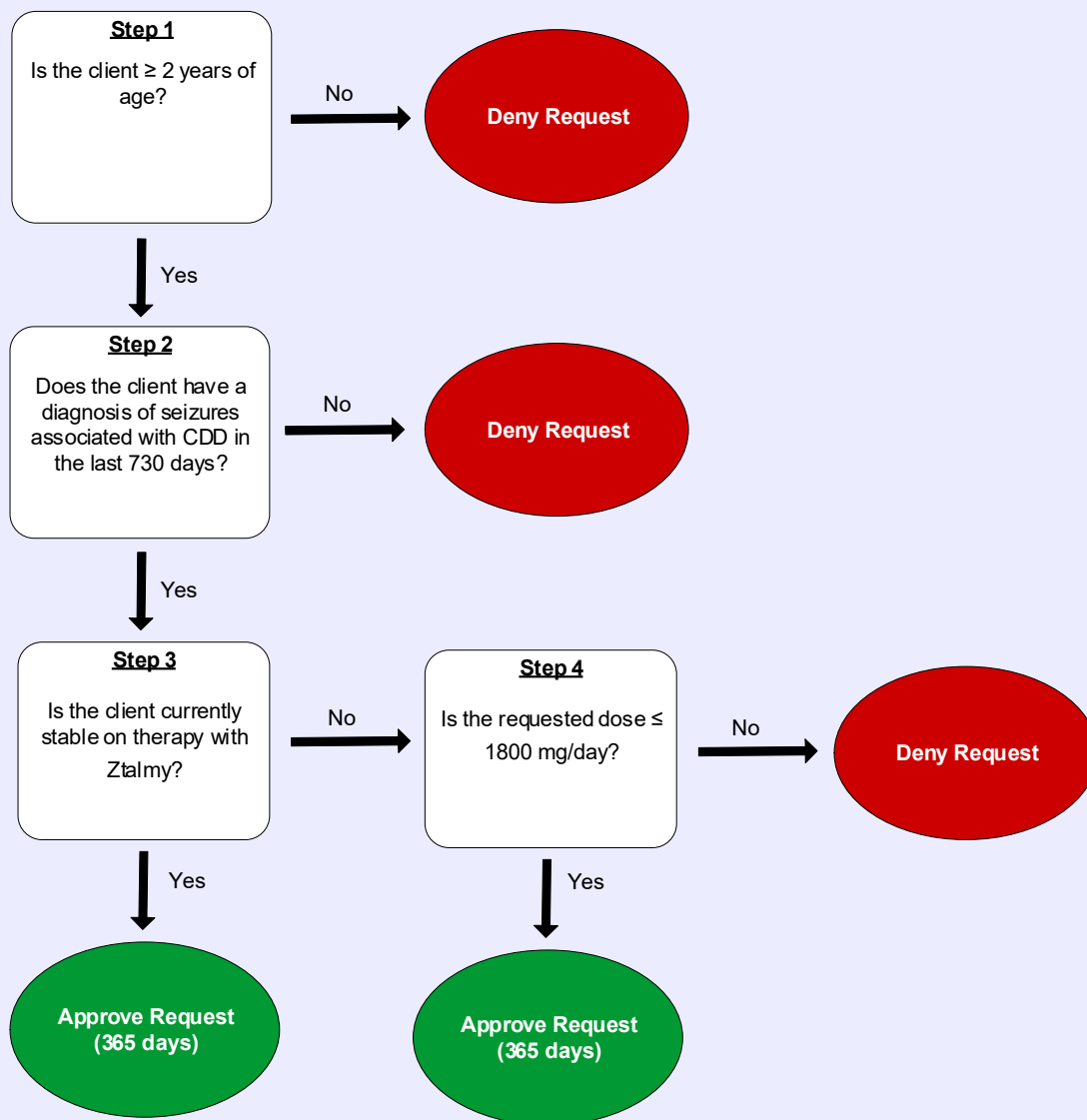
3. Is the client currently stable on therapy with Ztalmy?
 Yes – Approve (365 days)
 No – Go to #4

4. Is the requested dose less than or equal to (\leq) 1800 mg/day?
 Yes – Approve (365 days)
 No – Deny



Ztalmy (Ganaxolone)

Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

Step 2 (diagnosis of seizures associated with CDD)	
Required quantity: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
G4042	CYCLIN-DEPENDENT KINASE-LIKE 5 DEFICIENCY DISORDER



Ztalmy (Ganaxolone)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2023. Available at www.clinicalpharmacology.com. Accessed on January 20, 2023.
2. Drug Facts and Comparisons. eFacts [online]. 2023. Available from Wolters Kluwer Health, Inc. Accessed on January 20, 2023.
3. Ztalmy Prescribing Information. Radnor, PA. Marinus Pharmaceuticals, Inc. November 2022.



Ztalmy (Ganaxolone)

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/20/2023	Initial publication and presentation to the DUR Board