

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

Annual review by staff

Updated references



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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



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Clinical Criteria Logic

Initial Request:

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

Renewal Request:

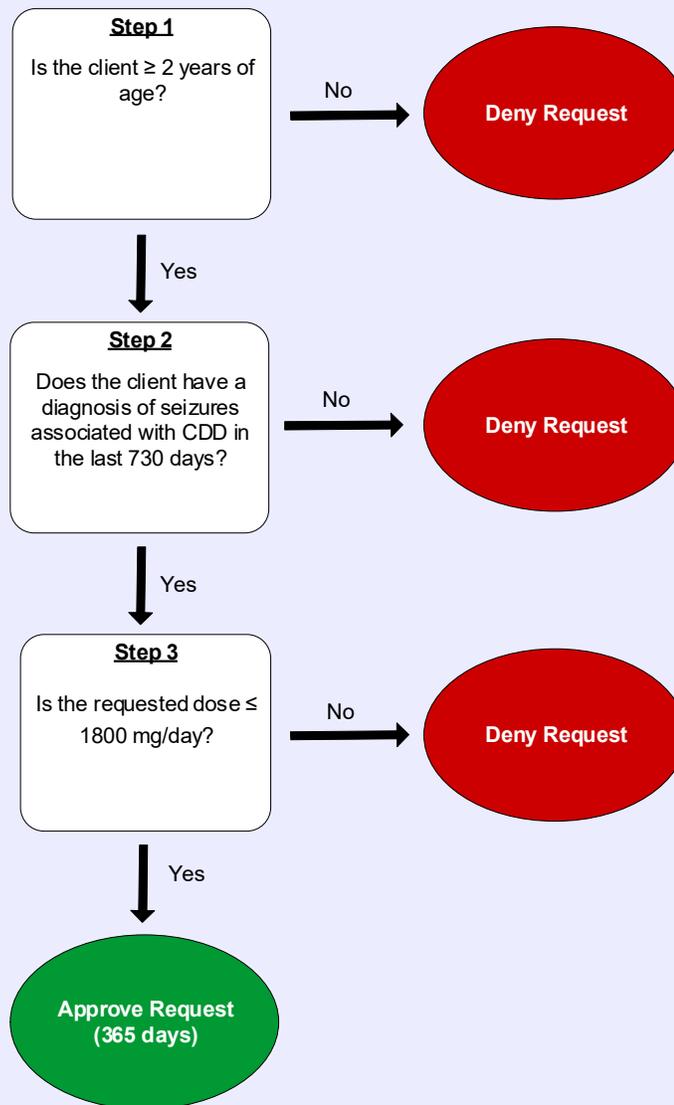
1. Has the client had therapy with Ztalmy for at least 90 days in the last 120 days?
 Yes – Approve (365 days)
 No – Deny



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Clinical Criteria Logic Diagram

Initial Request:

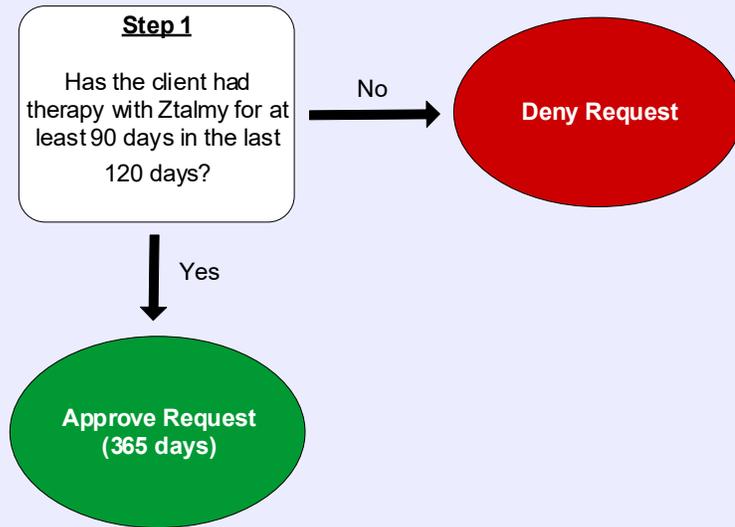




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Clinical Criteria Logic Diagram

Renewal Request:





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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



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Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2024. Available at www.clinicalpharmacology.com. Accessed on January 30, 2024.
2. Drug Facts and Comparisons. eFacts [online]. 2024. Available from Wolters Kluwer Health, Inc. Accessed on January 30, 2024.
3. Ztalmy Prescribing Information. Radnor, PA. Marinus Pharmaceuticals, Inc. June 2023.



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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
02/23/2024	Annual review by staff Updated references