

Policy Name:	Ztalmy (ganaxolone)	Policy #:	3141P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Ztalmy.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Ztalmy under the specialty pharmacy benefit when the following criteria have been met.

Procedures

1. Coverage Criteria

- 1.1 Diagnosis of seizures with confirmation of CDKL5 deficiency based on genetic testing
- 1.2 Prescribed by a neurologist (doctor of the nervous system)
- 1.3 Patient age 2 years or older
- 1.4 Documentation of monthly seizures at baseline
- 1.5 Documentation of trial and failure of at least two previous antiepileptic therapies
- 1.6 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Ztalmy by both a pharmacist and medical director

2. Approval Period

- 2.1 Initial Approval: 12 months
- 2.2 Subsequent Approvals: 12 months with documentation of beneficial therapy (reduction of monthly seizures compared to baseline)

References

1. Ztalmy (ganaxolone) [prescribing information]. Radnor, PA: Marinus Pharmaceuticals; June 2023.
2. Knight EMP, Amin S, Bahi-Buisson N, et al; Marigold Trial Group. 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(5):417-427.
3. Kanner AM, Ashman E, Gloss, D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology.* 2018 Jul 10;91(2):74-81.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract

language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.