Ztalmy (ganaxolone)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ztalmy (ganaxolone) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: Chart notes or medical record documentation of enzyme assay or genetic testing demonstrating pathogenic or likely pathogenic mutation in the CDKL5 gene
B. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy (e.g., decrease in seizures)

Prescriber Specialty

This medication must be prescribed by or in consultation with a neurologist.

Criteria for Initial Approval

Cyclin-Dependent Kinase-Like 5 (CDKL5) deficiency disorder (CDD)
Authorization of 6 months may be granted for treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) when the member has a confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.

Continuation of Therapy
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for CDKL5 deficiency disorder when the member achieves or maintains a positive clinical response to therapy (e.g., decrease in seizures).

Ztalmy (ganaxolone) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit	FDA-recommended dosing
Ztalmy (ganaxolone) 50 mg/mL oral suspension	10 bottles per 30 days	Patients weighing 28 kg or less: Days 1-7: 6 mg/kg three times daily Days 8-14: 11 mg/kg three times daily Days 15-21: 16 mg/kg three times daily Days 22 to ongoing: 21 mg/kg three times daily Patients weighing more than 28 kg: Days 1-7: 150 mg three times daily Days 8-14: 300 mg three times daily Days 15-21: 450 mg three times daily Days 22 to ongoing: 600 mg three times daily

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

1. Ztalmy [package insert]. Radnor, PA: Marinus Pharmaceuticals, Inc.; March 2022.

POLICY HISTORY

Policy #: 05.04.69
Original Effective Date: August 29, 2022
Reviewed: July 2022
Revised:
Current Effective Date: August 29, 2022