Mass General Brigham
Health Plan

Ztalmy (ganaxolone)
Effective 11/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Ztalmy (ganaxolone) is a neuroactive steroid gamma-aminobuytric acid (GABA) A receptor positive modulator 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.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member has a diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
2. Member is 2 years of age or older
3. Requested medication is prescribed by or in consultation with a neurologist.

Continuation of Therapy
Requests for reauthorization will be approved when all of the following criteria are met:

1. Documentation member has had a positive response to therapy (e.g., decrease in number or frequency of seizures member is experiencing)

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

References

1. Ztalmy (ganaxolone) [prescribing information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; April 2024.

Review History

2/14/2023 - Created and Reviewed at Feb P&T, Effective 3/1/2024.
08/11/2025 – Reviewed and updated at August P&T. Updated language for members who are new to the Plan. Updated initial criteria to include minimum age of 2 years or older and removed genetic testing requirement. Updated verbiage for specialist prescriber. Updated reauthorization criteria to require documentation that member has had a positive response to therapy. Effective 11/01/2025.