

Pharmacy Policy

Diacomit

Policy Number: 9.201

Version Number: 2.0

Version Effective Date: 6/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth - MCO
	<input checked="" type="checkbox"/> MassHealth - ACO
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Diacomit (stiripentol)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	Documentation of the following: 1. Diagnosis of seizures in Dravet Syndrome; AND

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	2. Member will use clobazam concurrently; AND 3. An inadequate response or intolerance to a trial 2 anticonvulsant agents
Age Restriction	2 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. Adherence with therapy; AND 2. Clinical condition has improved or stabilized

Applicable Coding:

None

Clinical Background Information and References

1. Diacomit (stiripentol) [prescribing information]. 60000 BEAUVAIS – France: Biocodex; August 2018. (Accessed January 2020)
2. Diacomit drug information. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed January 2020).
3. Nascimento, F. et al. Dravet syndrome: Management and prognosis. Last updated: February 1, 2019. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on April 2, 2019).

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
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Policy Revisions History			
12/1/2020	9.025 Diacomit Policy retired, new policy created	1/1/2021	Pharmacy & Therapeutics (P&T) Committee
2/11/2021	P&T annual review. No recommended criteria changes	6/1/2021	Pharmacy & Therapeutics (P&T) Committee

Next Review Date:

February 2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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