

**Pharmacy Policy**

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**Diacomit**

**Policy Number:** 9.201

**Version Number:** 1.0

**Version Effective Date:** 6/1/2021

Product Applicability <input type="checkbox"/> <b>All Plan<sup>+</sup> Products</b>	
<b>Well Sense Health Plan</b>	<b>Boston Medical Center HealthNet Plan</b>
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" 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**

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**Products Affected:**

- **Diacomit (stiripentol)**

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

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

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	2. Member will use clobazam concurrently; <b>AND</b> 3. An inadequate response or intolerance to a trial 2 anticonvulsant agents
<b>Age Restriction</b>	2 years of age or older
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Initial: 6 months Reauthorization: 12 months
<b>Other criteria</b>	Reauthorization: 1. Adherence with therapy; <b>AND</b> 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
2/11/2021	6/1/2021	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

2/11/2021	New policy created	6/1/2021	P&T Committee
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### Next Review Date:

February 2022

### Other Applicable Policies

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### Reference to Applicable Laws and Regulations, If Any

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### 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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