



wellsense.org | 877-957-1300

## Pharmacy Policy

# Diacomit (stiripentol)

Policy Number: 9.201

Revision Number: R0

Version Effective Date: 1/1/2021

### Product Applicability All Plan+ Products

#### Well Sense Health Plan

New Hampshire Medicaid

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#### Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

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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:

<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: <ol style="list-style-type: none"> <li>1. Diagnosis of seizures in Dravet Syndrome; <b>AND</b></li> <li>2. Member will use clobazam concurrently; <b>AND</b></li> <li>3. Trial and failure of two preferred products from anticonvulsant – second generation class (See appendix A)</li> </ol>
<b>Age Restriction</b>	2 years of age or older

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<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

Appendix A

<b>ANTICONVULSANTS – SECOND GENERATION PREFERRED</b>
clobazam (generic for Onfi®)
gabapentin (generic for Neurontin®)
Gabitril®
lamotrigine/ODT/XR (generic for Lamictal®/ODT/XR)
levetiracetam/ER (generic for Keppra/XR®)
pregabalin (generic for Lyrica®) (requires additional clinical PA)
tiagabine (generic for Gabitril®)
topiramate (generic for Topamax®)
topiramate ER (generic for Qudexy XR®)
vigabatrin (generic for Sabril®)
zonisamide (generic for Zonegran®)

**Clinical Background Information and References**

1. Diacomit (stiripentol) [prescribing information]. 60000 BEAUVAIS – France: Biocodex; August 2018.
2. Diacomit drug information. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on April 2, 2019).
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).

<b>Original Approval Date</b>	<b>Original Effective Date</b>	<b>Policy Owner</b>	<b>Approved by</b>
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12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS
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Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	Discontinued Policy 9.025 and created a new policy for NH. Updated criteria requiring trial of 2 preferred agents to align with NH PDL requirements	1/1/2021	P&T Committee, NH DHHS

**Next Review Date:**

2021

**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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