

## Pharmacy Policy

# Epidiolex

**Policy Number:** 9.222

**Version Number:** 2.0

**Version Effective Date:** 6/01/2021

### Product Applicability All Plan+ Products

#### Well Sense Health Plan

New Hampshire Medicaid

#### Boston Medical Center HealthNet Plan

MassHealth ACO

MassHealth MCO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

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

## Prior Authorization Policy

### Products Affected:

- Epidiolex (cannabidiol)

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

<b>Required Medical Information</b>	<p>One of the following diagnoses:</p> <ol style="list-style-type: none"> <li>1. Member has a diagnosis of Lennox-Gastaut Syndrome; AND             <ol style="list-style-type: none"> <li>a. Member is 1 year of age or older; AND</li> <li>b. Prescribed by a neurologist; AND</li> <li>c. The Member has had an inadequate response or intolerance to at least two of the following anticonvulsant medications:                 <ol style="list-style-type: none"> <li>i. Valproic acid derivatives</li> <li>ii. Topiramate</li> </ol> </li> </ol> </li> </ol>
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	<ul style="list-style-type: none"> <li>iii. Lamotrigine</li> <li>iv. Felbamate</li> <li>v. Banzel (rufinamide)</li> </ul> <p>2. Member has a diagnosis of Dravet Syndrome; AND</p> <ul style="list-style-type: none"> <li>a. Member is 1 year of age or older; AND</li> <li>b. Prescribed by a neurologist; AND</li> <li>c. The Member has had an inadequate response or intolerance to at least two of the following anticonvulsant medications: <ul style="list-style-type: none"> <li>i. Valproic acid derivatives</li> <li>ii. Topiramate</li> <li>iii. Clobazam</li> <li>iv. Diacomit in combination with valproic acid and clobazam</li> </ul> </li> </ul> <p>3. Member has a diagnosis of seizures associated with Tuberous Sclerosis Complex (TSC); AND</p> <ul style="list-style-type: none"> <li>a. Member is 1 year of age or older; AND</li> <li>b. Prescribed by a neurologist; AND</li> <li>c. The member has had an inadequate response or intolerance to at least two of the following anticonvulsant medication: <ul style="list-style-type: none"> <li>i. Vigabatrin (Sabril)</li> <li>ii. Topiramate</li> <li>iii. Lamotrigine</li> <li>iv. Oxcarbazepine</li> <li>v. Levetiracetam</li> </ul> </li> </ul>
<b>Coverage Duration</b>	12 months

## Clinical Background Information and References

1. Devinsky O, Cross JH, Laux L, et al. Trial of cannabidiol for drug-resistant seizures in the Dravet syndrome. *N Engl J Med.* 2017; 376:2011-20.
2. Devinsky O, Patel AD, Cross JH, et al. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. *N Engl J Med.* 2018; 378:1888-97.
3. Dravet Syndrome. (2020, June 05). Retrieved November 06, 2020, from <https://rarediseases.org/rare-diseases/dravet-syndrome>
4. Epidiolex prescribing information. Carlsbad, CA: Greenwich Biosciences, Inc.; 2020 July. Accessed December 2020.

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5. Lennox-Gastaut Syndrome. (2020, June 05). Retrieved November 06, 2020, from <https://rarediseases.org/rare-diseases/lennox-gastaut-syndrome/>

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
2/11/2021	P&T annual review. No criteria changes recommended.	6/01/2021	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;

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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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