Harvard Pilgrim Health Care | TUFTS Health Plan

# Pharmacy Medical Necessity Guidelines: **Antiseizure Medications**

*Effective: June 9, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

Lennox-Gastaut Syndrome (LGS) is a rare and severe form of epilepsy that is characterized by a triad of mixed seizure patterns, impaired intellectual development, and electroencephalography (EEG) abnormalities. It has been shown to occur in 5% of patients with epilepsy.

Dravet syndrome (DS) is a rare, catastrophic form of epilepsy that begins in the first year of life with frequent and/or prolonged seizures, previously known as Severe Myoclonic Epilepsy of Infancy (SMEI), which affects 1 in 15,700 infants born in the U.S.

**Epidiolex (cannabidiol)** is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

**Libervant (diazepam)** buccal film is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age.

**Nayzilam (midazolam)** nasal spray is a benzodiazepine indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

**Valtoco (diazepam)** nasal spray is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 years of age and older.

**Ztalmy (ganaxolone)** oral suspension is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in patients 2 years of age and older.

## Clinical Guideline Coverage Criteria
## Epidiolex (cannabidiol)

The plan may authorize coverage of **Epidiolex (cannabidiol)** when all the following criteria are met:

1. The patient has a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

**AND**

   a. Meets all of the following:
      i. The patient is 1 year of age or older

**AND**

      ii. Trial and failure with TWO anticonvulsants used for Lennox-Gastaut syndrome (e.g., clobazam [Onfi], lamotrigine, valproate, rufinamide [Banzel], felbamate [Felbatol], levetiracetam [Keppra])

**AND**

      iii. Prescribed by or in consultation with a neurologist

**OR**

2. The patient has a diagnosis of seizures associated with Dravet syndrome (DS)

**AND**

   a. Meets all of the following:
      i. The patient is 1 year of age or older

**AND**

      ii. Prescribed by or in consultation with a neurologist

**OR**

3. The patient has a diagnosis of seizures associated with tuberous sclerosis complex (TSC)

**AND**

   a. Meets all of the following:
      i. The patient is 1 year of age or older

**AND**

      ii. Prescribed by or in consultation with a neurologist

### Libervant (diazepam) buccal film

The plan may authorize coverage of **Libervant (diazepam)** buccal film when all the following criteria are met:

1. The patient is diagnosed with a seizure disorder and needs acute treatment on hand for seizures

**AND**

2. The patient is 2 to 5 years of age

### Nayzilam (midazolam) Nasal Spray

The plan may authorize coverage of **Nayzilam (midazolam**) nasal spray when all the following criteria are met:

1. The patient is diagnosed with a seizure disorder and needs acute treatment on hand for seizures

**AND**

2. The patient is 12 years of age or older

### Valtoco (diazepam) Nasal Spray

The plan may authorize coverage of **Valtoco (diazepam)** nasal spray when all of the following criteria are met:

1. The patient is diagnosed with a seizure disorder and needs acute treatment on hand for seizures

**AND**

2. The patient is 2 years of age or older

### Ztalmy (ganaxolone) oral suspension

The plan may authorize coverage of **Ztalmy (ganaxolone)** oral suspension when all the following criteria are met:

1. The patient has a diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)

**AND**

2. The patient is 2 years of age or older

**AND**

3. Prescribed by or in consultation with a neurologist

## Limitations

1. Approval for Libervant buccal film will be authorized for 12 months.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

## Codes

None

## References


1. Devinsky O, Cilio MR, Cross H, et al. Cannabidiol: pharmacology and potential therapeutic role in epilepsy and other neuropsychiatric disorders. Epilepsia. 2014;55(6):791-802.
2. Devinsky O, Cross JH, Laux L, et al; Cannabidiol in Dravet Syndrome Study Group. Trial of cannabidiol for drug-resistant seizures in the Dravet syndrome. N Engl J Med. 2017;376(21):2011-2020.3
3. Devinsky O, Patel AD, Cross JH, et al; GWPCARE3 Study Group. Effect of cannabidiol on drop seizures in the Lennox-

Gastaut syndrome. N Engl J Med. 2018;378(20):1888- 1897.
4. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences Inc; July 2025.
5. Nayzilam (midazolam) nasal spray [prescribing information]. Plymouth, MN: Proximagen, LLC; Jan 2023.
6. Randle S. Tuberous sclerosis complex: Management and prognosis. In: Dashe JF, ed.
7. Temple R. NDA approval letter: Epidiolex (cannabidiol) (NDA 210365). 2018 Food and Drug Administration website.
8. UpToDate [database online]. Waltham, MA: UpToDate, 2021. https://www.uptodate.com. Accessed June 8, 2021.
9. Valtoco (diazepam spray). [prescribing information]. San Diego, CA: Neurelis, Inc., June 2025.
10. Ztalmy (ganaxolone) oral suspension [prescribing information]. Marinus Pharmaceuticals, Inc: Radnor, PA; Nov 2025.
11. Libervant (diazepam) buccal film [prescribing information]. Warren, NJ: Aquestive Therapeutics; April 2024.

## Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: Administrative updates with limitation– removed Epidiolex and Ztamly age restriction (already addressed in criteria), and added for a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions.
- June 11, 2024: No changes.
- September 10, 2024: Added criteria for Libervant buccal film. Effective October 1, 2024.
- June 10, 2025: Updated age requirement for Valtoco criteria to 2 years of age or older based on expanded FDA labeling. Administrative update to overview with Valtoco's expanded age indication in patients with epilepsy 2 years of age and older. Effective July 1, 2025.
- June 9, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.