Pharmacy Medical Necessity Guidelines: Anticonvulsant Medications

Effective: September 21, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

Sympazan™ (clobazam) oral film is indicated for adjunctive treatment of seizures associated with LGS in patients two years of age and older.

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

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

Fintepla (fenfluramine) is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

Nazyzilam (midazolam) nasal spray is 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.

COVERAGE GUIDELINES

The plan may authorize coverage of **Sympazan** when the following criteria are met:

1. The member has a documented diagnosis of Lennox-Gastaut Syndrome, epilepsy, or seizure disorder

AND

2. The prescribing physician is a neurologist

AND

3. The Member has had an insufficient response or intolerance to at least one of the following medications:
   - Valproic acid derivative (e.g., Depakene®, Depakote®)
   - Topamax® (topiramate)
   - Lamictal® (lamotrigine)
   - Felbatol® (felbamate)
   - Banzel™ (rufinamide)

The plan may authorize coverage of **Epidiolex** for Members for the treatment of Lennox-Gastaut Syndrome when all of the following criteria are met:

1. The member has a documented diagnosis of Lennox-Gastaut Syndrome

AND

2. The prescribing physician is a neurologist

AND

3. The Member has had an insufficient response or intolerance to at least one of the following medications:
   - Valproic acid derivative (e.g., Depakene®, Depakote®)
   - Topamax® (topiramate)
   - Lamictal® (lamotrigine)
   - Felbatol® (felbamate)
   - Banzel™ (rufinamide)

The plan may authorize coverage of **Epidiolex** for Members for the treatment of Dravet Syndrome when all of the following criteria are met:

1. The member has a documented diagnosis of Dravet Syndrome

AND

2. The prescribing physician is a neurologist

AND

3. The Member has had an insufficient response or intolerance to at least one of the following medications or combinations:
   - Valproic acid derivative (e.g., Depakene®, Depakote®)
   - Topamax® (topiramate)
   - Clobazam (Onfi)
   - Diacomit in combination with valproic acid and clobazam

The plan may authorize coverage of **Epidiolex** for Members for the treatment of seizures associated with Tuberous Sclerosis Complex (TSC) when all of the following criteria are met:

1. The member has a documented diagnosis of Tuberous Sclerosis Complex (TSC)

AND

2. The prescribing physician is a neurologist

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

1. The member has diagnosis of Dravet syndrome

AND

2. The member is 2 years of age or older

AND

3. The prescribing physician is a neurologist

AND

4. The member is taking concomitant clobazam therapy

AND

5. The member is taking concomitant valproic acid, or there is documentation of contraindication or intolerance to valproic acid

The plan may authorize coverage of **Fintepla** for Members for the treatment of Dravet Syndrome when all of the following criteria are met:

1. The member has a documented diagnosis of Dravet Syndrome

AND

2. The member is at least 2 years of age

AND

3. The prescribing physician is a neurologist

AND

4. The Member has had an insufficient response or intolerance to at least one of the following medications or combinations:
   - Valproic acid derivative (e.g., Depakene®, Depakote®)

- Topamax® (topiramate)
- Clobazam (Onfi)
- Diacomit in combination with valproic acid and clobazam

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

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

AND

2. The Member is 12 years of age or older

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

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

AND

2. The member is 6 ears of age or older

LIMITATIONS

1. Coverage of Nayzilam (midazolam) nasal spray is limited to 1 box (2 nasal spray units) per fill
2. Coverage of Valtoco (diazepam) nasal spray is limited to 1 blister pack per fill
3. Diacomit, and Fintepla will only be covered for members who are two years of age and older.
4. Epidiolex will only be covered for members who are one year of age and older.
5. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

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APPROVAL HISTORY

March 13, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- March 12, 2013: Added criteria #2; The Member has had an insufficient response or intolerance to at least one of the following medications: Valproic acid derivative (e.g., Depakene®, Depakote®), Topamax® (topiramate), Lamictal® (lamotrigine), Felbatol® (felbamate), Banzel™ (rufinamide)
- February 11, 2014: No changes
- February 10, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: No changes
- February 14, 2017: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- February 13, 2018: No changes
- November 13, 2018: For effective date January 8, 2019: Move Onfi tablets and suspension to not covered for the MA/RI EHB Formularies.

- January 8, 2019: Updated name of MNG to Onfi® (clobazam) and Sympazan™ (clobazam) and added Sympazan to PA criteria.
- February 12, 2019: Updated name of MNG to "Anticonvulsant Medications", added coverage criteria for Epidiolex for LGS and Dravet syndrome.
- July 9, 2019: Added criteria for Diacomit to the MNG.
- September 10, 2019: Updated the criteria for Onfi and Sympazan to require a diagnosis of Lennox-Gastaut Syndrome, epilepsy, or seizure disorder.
- October 15, 2019: Added Nayzilam (midazolam) nasal spray to the Medical Necessity Guidelines.
- March 10, 2020: Added Valtoco (diazepam) nasal spray to the Medical Necessity Guidelines.
- April 14, 2020: Administrative update to remove clobazam (Onfi) tablets from the MNG as PA is no longer required as of March 30, 2020. Onfi tablets and suspension are non-covered for Tufts Health Plan Small Group and Individual Plans. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives and submit a formulary exception request to the plan as indicated.
- June 9, 2020: Added criteria for Xcopri to the MNG. Added limitation language about use of samples.
- September 15, 2020: Added coverage criteria for Fintepla and added clobazam and Diacomit in combination with valproic acid and clobazam as an alternative prerequisite for Epidiolex for Dravet Syndrome. Added criteria for expanded indication of Epidiolex for seizures associated with Tuberous Sclerosis Complex (TSC) and expanded coverage for members age one and older for all indications. September Update: Removed Xcopri criteria, as PA was removed effective August 31, 2020.

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.

Provider Services