Pharmacy Medical Necessity Guidelines: Sabril (vigabatrin)

Effective: September 18, 2017

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<th>Prior Authorization Required</th>
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Pharmacy (RX) or Medical (MED) Benefit

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<th>RXUM</th>
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This Pharmacy Medical Necessity Guidelines applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**Fax Numbers:**

RXUM: 617.673.0988

**OVERVIEW**

**FDA-APPROVED INDICATIONS**

Sabril is an antiepileptic drug (AED) indicated for:
- Refractory Complex Partial Seizures in patients ≥10 years of age. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.
- Infantile Spasms as monotherapy in infants 1 month to 2 years of age.

Sabril can cause permanent bilateral concentric visual field constriction, including tunnel vision, that can result in disability. Sabril can also damage the central retina and may decrease visual acuity. The onset of vision loss can occur any time after starting Sabril (within weeks, to months or years). Vision assessment is recommended at baseline (no later than 4 weeks after starting Sabril), at least every 3 months during therapy, and about 3 to 6 months after therapy discontinuation. It is possible that vision loss can worsen despite Sabril discontinuation.

Sabril should be withdrawn from patients with refractory complex partial seizures who fail to show clinical benefit within 3 months and within 2-4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure is obvious.

Due to the risk of vision loss, Sabril is only available through a Risk Evaluation and Mitigation Strategy (REMS) program, called the Vigabatrin REMS Program.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Sabril (vigabatrin) for Members when ALL of the following medication-specific criteria are met and limitations do not apply:

**For the diagnosis of Infantile Spasm,**

1. The Member has been evaluated by a neurologist

   **AND**

2. The Member is between the ages of 1 month and 2 years of age with a diagnosis of Infantile Spasms

   **AND**

3. One of the following:
   - a. The Member’s baseline vision been assessed by an ophthalmologist or the Member’s vision will be assessed within 4 weeks of initiating Sabril therapy

   **OR**

   - b. The Member is blind or has been formally exempt from vision assessment in the Vigabatrin REMS Program.

**For the diagnosis of Refractory Complex Partial Seizures,**

1. The Member has been evaluated by a neurologist

   **AND**

2. The Member is 10 years of age or older with a diagnosis of refractory complex partial seizures
3. The Member has tried and failed at least 2 antiepileptic medications for complex partial seizures such as carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproic acid, divalproex sodium, zonisamide or tiagabine

4. Sabril will be used in combination with at least one other antiepileptic medication

5. One of the following:
   a. The Member’s baseline vision been assessed by an ophthalmologist or the Member’s vision will be assessed within 4 weeks of initiating Sabril therapy
   OR
   b. The Member is blind or has been formally exempt from vision assessment in the Vigabatrin REMS Program.

LIMITATIONS
1. Initial authorization for infantile spasm will be limited to 8 weeks up to 150 mg/kg/day. Subsequent authorization may be given to extend until the Member is 2 years of age, not to exceed 2 grams per day, based on submission of current progress notes from the physician documenting efficacy.

2. Initial authorization for the treatment of refractory complex partial seizures will be limited to 4 months up to 3 grams per day or up to 6 grams per day if the Member is new to the plan and has been stable on doses greater than 3 grams per day prior to enrollment or the provider indicates that a lower dose is now associated with decreased efficacy. Subsequent authorizations may be given in 12-months intervals, up to 6 grams per day, based on submission of current progress notes from the physician documenting efficacy.

3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES
None

REFERENCES

APPROVAL HISTORY
April 12, 2012: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 4, 2014: No changes.
- November 10, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Added approval criteria for Members less than six years of age. Updated criteria to reflect new names of Sabril REMS program. Updated minimum age for refractory complex partial seizures from 17 years of age to 10 years of age.
- September 12, 2017: Administrative update, updated the name of the REMS program from Sabril REMS program to Vigabatrin REMS program. Added to the limitations section that requests for brand-name products with AB-rated generics will be reviewed according to Brand Name criteria.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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