Pharmacy Medical Necessity Guidelines: Vigabatrin

Effective: July 20, 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

FDA-APPROVED INDICATIONS

Vigabatrin (Sabril®) is an antiepileptic drug (AED) indicated for:

- Refractory Complex Partial Seizures in patients ≥2 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.

Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision, which can result in disability. Vision assessment is recommended at baseline (no later than 4 weeks after starting vigabatrin), 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 vigabatrin discontinuation.

Due to the risk of vision loss, vigabatrin 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 vigabatrin for Members when **ALL** of the following criteria are met and limitations do not:

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 vigabatrin 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 2 years of age or older with a diagnosis of refractory complex partial seizures

AND

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

AND

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

AND

5. One of the following:
   a. The Member's baseline vision has been assessed by an ophthalmologist or the Member's vision will be assessed within 4 weeks of initiating vigabatrin 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.
4. Requests for vigabatrin in which the Pediatric Behavioral Health Medication Initiative (PBHMI) polypharmacy limits are exceeded will also be also be reviewed against the PBHMI Polypharmacy criteria.
5. 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. FDA NEWS RELEASE. Sabril Approved by FDA to Treat Spasms in Infants and Epileptic Seizures. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm179855.htm [Accessed March 2011]
2. Sabril (vigabatrin) [prescribing information]. Cincinnati, OH: Patheon; January 2020.
3. French JA, et al. A double-blind, placebo-controlled study of vigabatrin three g/day in patients with uncontrolled complex partial seizures. Vigabatrin Protocol 024 Investigative Cohort. Neurology 1996 Jan;46(1):54-61.
4. Dean C, et al. Dose-Response Study of Vigabatrin as add-on therapy in patients with uncontrolled complex partial seizures. Epliepsia 1999 Jan;40(1):74-82
5. Elterman RD, et al. Randomized trial of vigabatrin in patients with infantile spasms. Neurology 201 Oct;57(8):1416-1421.
6. Jason TL, et al. Clinical profile of vigabatrin as monotherapy for treatment of infantile spasms. Neuropsychiatr Dis Treat 2010; 6: 731–740
7. Waterhouse EJ, et al. Treatment of refractory complex partial seizures: role of vigabatrin. Neuropsychiatr Dis Treat. 2009; 5: 505–515
8. Appleton, Re, et al. Randomised, placebo-controlled study of vigabatrin as first-line treatment of infantile spasms. Epilepsia. 1999; 40.11: 1627-1633.
9. Lux, Andrew. Et al. The united kingdom infantile spasms study comparing vigabatrin with prednisolone or tetracosactide at 14 days: a multicentre, randomised controlled trial. The Lancet. 2004; 364, 1773-1778.
10. Sergott, Andrew, et al. Evidence-based review of recommendations for visual function testing in patients treated with vigabatrin. Neuro-Ophthalmology. 2010, 34(1), 20-35.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. November 4, 2014: No changes.
2. November 10, 2015: No changes.
3. January 1, 2016: Administrative change to rebranded template.
4. 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.
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
6. 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.
7. October 16, 2018: Administrative update to template.
8. November 13, 2018: Effective 11/19/18, removed the PBHMI age limit criteria.
9. October 15, 2019: Administrative update; added to the limitations section that requests for members who exceed the PBHMI polypharmacy limits will be reviewed against the PBHMI polypharmacy criteria.
10. July 14, 2020: Changed title from "Sabril" to "Vigabatrin" to reflect that product is available generically. Updated criteria for diagnosis of refractory complex partial seizures to allow approval for members two years of age and older. Added language regarding samples to the limitations section of the MNG.

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