Pharmacy Medical Necessity Guidelines: Vigabatrin

Effective: September 15, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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 medication-specific criteria are met and limitations do not apply:

Infantile Spasm

1. The Member has documented diagnosis of infantile spasms

AND

2. The Member is between the ages of 1 month to 2 years of age

AND

3. The Member has been evaluated by a neurologist

Refractory Complex Partial Seizures

1. The Member has a documented diagnosis of refractory complex partial seizures

AND

2. The Member is 2 years of age or older

and

3. The Member has been evaluated by a neurologist

AND

4. The Member has had an inadequate response, intolerance, or contraindication to at least 2 antiepileptic medications, such as carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproic acid, divalproex sodium, zonisamide or tiagabine

AND

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

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.
2. 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

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3. Elterman RD, et al. Randomized trial of vigabatrin in patients with infantile spasms. Neurology 201 Oct;57(8):1416-1421.
4. 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.
5. Jason TL, et al. Clinical profile of vigabatrin as monotherapy for treatment of infantile spasms. Neuropsychiatr Dis Treat 2010; 6: 731–740
6. 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.
7. Randle S. Tuberous sclerosis complex: management and prognosis. UpToDate. Available at: www.uptodate.com. Accessed 8 August 2023.
8. Sabril (vigabatrin) [prescribing information]. Cincinnati, OH: Patheon; October 2021.
9. 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.
10. Waterhouse EJ, et al. Treatment of refractory complex partial seizures: role of vigabatrin. Neuropsychiatr Dis Treat. 2009; 5: 505–515

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated previous trial to "inadequate response, intolerance, or contraindication to."
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. September 15, 2026: No changes.

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