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Coverage Policy Number **IP0049**

Vigabatrin

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for vigabatrin (Sabril®, Vigadrone®).

Coverage for vigabatrin (Sabril, Vigadrone) varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Vigabatrin (Sabril, Vigadrone) is considered medically necessary for the treatment of Infantile Spasms when the individual meets ALL of the following criteria:

1. 2 years of age or younger
2. Vigabatrin (Sabril, Vigadrone) is being used as monotherapy
3. The medication is prescribed by, or in consultation with, a neurologist

4. Non-Covered Product Criteria is met, refer to below table

Vigabatrin (Sabril, Vigadrone) is considered medically necessary for Treatment-Refractory Complex Partial Seizures when the individual meets ALL of the following criteria:

1. 2 years of age or older
2. Documentation of failure to at least **THREE** other antiepileptic drugs, unless contraindicated or intolerant
3. The medication is prescribed by, or in consultation with, a neurologist
4. Non-Covered Product Criteria is met, refer to below table

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Sabril (vigabatrin)	Documented trial of **vigabatrin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Vigadrone (vigabatrin)	Documented trial of **vigabatrin 500 mg tablets** (generic for Sabril) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Sabril (vigabatrin)	Domented trial of **vigabatrin** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Continuation of vigabatrin (Sabril, Vigadrone) is considered medically necessary for Infantile Spasms or Treatment-Refractory Complex Partial Seizures when initial criteria are met AND beneficial response is demonstrated (for example, reduced seizure severity, frequency, and/or duration).

Authorization Duration

Initial approval duration:

- **Infantile Spasms**: up to 6 months
- **Treatment-Refractory Complex Partial Seizures**: up to 6 months

Reauthorization approval duration:

- **Infantile Spasms**: up to 12 months
- **Treatment-Refractory Complex Partial Seizures**: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
Vigabatrin is indicated for the following:[1]

- **Monotherapy for infantile spasms** in patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. Vigabatrin is not indicated as a first line agent for complex partial seizures.
- **Adjunctive therapy for refractory complex partial seizures** in patients ≥ 2 years of age who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss.

According to the vigabatrin prescribing information, use the lowest dosage and shortest exposure to vigabatrin consistent with clinical objectives.[1] In patients with infantile spasms, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 2 to 4 weeks. In patients with refractory complex partial seizures, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 3 months of initiating treatment.

Safety
Vigabatrin has a Boxed Warning with regard to permanent vision loss.[1] In some cases, vigabatrin also can damage the central retina and may decrease visual acuity. The onset of vision loss from vigabatrin is unpredictable, and can occur within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years. The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of risk of vision loss. 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 the discontinuation of therapy. Once detected, vision loss due to vigabatrin is not reversible. Because of the risk of vision loss, vigabatrin should be withdrawn from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation and within 2 to 4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure becomes obvious. Because of the risk of permanent vision loss, vigabatrin is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Vigabatrin REMS Program.

Guidelines/Recommendations
In 2012 the American Academy of Neurology (AAN) and the Child Neurology Society updated the evidence-based guideline for the medical treatment of infantile spasms.[2] The guidelines note that low-dose adrenocorticotropic hormone (ACTH) is a first-line agent for the short-term treatment of infantile spasms. ACTH or vigabatrin may be useful for short-term treatment of infantile spasms, with ACTH considered preferentially over vigabatrin. Hormonal therapy (ACTH or prednisolone) may be considered for use in preference to vigabatrin in infants with cryptogenic infantile spasms, to possibly improve developmental outcome. A shorter lag time to treatment of infantile spasms with either hormonal therapy or vigabatrin possibly improves long-term developmental outcomes. The Infantile Spasms Working Group (ISWG) published a US consensus report on infantile spasms in 2010.[3] Data regarding ACTH use and vigabatrin use in infantile spasms were detailed.[3] ACTH is an effective first-line therapy for infantile spasms. Vigabatrin is considered a drug of first choice for infantile spasms comorbid with tuberous sclerosis complex, and it is the drug of second or third choice for children with other symptomatic or cryptogenic infantile spasms.

The American Academy of Neurology (AAN) and the American Epilepsy Society published a guideline update for treatment-resistant epilspsy (2018) that clobazam is probably effective as add-on therapy for LGS and is possibly effective as add-on therapy for treatment-resistant adult focal epilepsy.[4] Vigabatrin is effective as add-on therapy in treatment-resistant adult focal epilepsy based on two Class I studies, but it should not be used as a first-line treatment. The benefits of vigabatrin should be weighed against the risks, particularly the risk of irreversible retinopathy.

References

1. Sabril® tablets and oral solution [prescribing information]. Deerfield, IL: Lundbeck; October 2021. Vigadrone® powder packets [prescribing information]. Maple Grove, MN: Upsher-Smith; February 2020.
2. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: medical treatment of infantile spasms: Report of the guideline development subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2012;78:1974-1980.
3. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a US consensus report. *Epilepsia*. 2010;51(10):2175-2189.
4. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91:82-90.
5. Treiman DM. Management of refractory complex partial seizures: current state of the art. *Neuropsychiatr Dis Treat*. 2010;6:297-308.