

Specialty Guideline Management

vigabatrin products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sabril	vigabatrin
Vigadrone	vigabatrin
Vigafyde	vigabatrin
Vigpoder	vigabatrin

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Sabril, vigabatrin, Vigadrone, Vigpoder^{1-4,6}

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

Vigafyde⁵

Monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Infantile Spasms^{1-7,10}

Authorization of 4 weeks may be granted for treatment of infantile spasms (infantile epileptic spasms syndrome [IESS]) in members less than 2 years of age.

Complex Partial Seizures (Sabril, vigabatrin, Vigadrone, Vigpoder only)^{1-4,6,8-9}

Authorization of 3 months may be granted for treatment of refractory complex partial seizures when member has had an inadequate response to at least two alternative treatments for complex partial seizures.

Continuation of Therapy

Infantile Spasms

Authorization of 6 months may be granted for members requesting vigabatrin for continuation of therapy when member has shown substantial clinical benefit from vigabatrin therapy.

Complex Partial Seizures (Sabril, vigabatrin, Vigadrone, Vigpoder only)

Authorization of 12 months may be granted for members requesting vigabatrin for continuation of therapy when member has shown substantial clinical benefit from vigabatrin therapy.

References

1. Sabril [package insert]. Deerfield, IL: Lundbeck Inc.; October 2021.
2. Vigabatrin for oral solution [package insert]. Malvern, PA: Endo USA; August 2023.
3. Vigabatrin tablet [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; November 2022.

Reference number(s)
1770-A

4. Vigadrone [package insert]. Maple grove, MN: Upsher-Smith Laboratories, LLC; March 2023.
5. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals. Inc.; June 2024.
6. Vigpoder [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.
7. 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(24):1974-1980.
8. Faught E. Vigabatrin therapy for refractory complex partial seizures: review of clinical trial experience in the United States. *Acta Neurol Scand*. 2011;124(192):29-35.
9. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. *Neurology*. 2018;91:82-90.
10. Carmant L. Vigabatrin therapy for infantile spasms: review of major trials in Europe, Canada, and the United States; and recommendations for dosing. *Acta Neurol Scand*. 2011;124(192):36-47.