

SPECIALTY GUIDELINE MANAGEMENT

SABRIL (vigabatrin) VIGADRONE (vigabatrin) VIGAFYDE (vigabatrin) VIGPODER (vigabatrin) vigabatrin

POLICY

I. 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

- A. Sabril, vigabatrin, Vigadrone, Vigpoder
 1. **Infantile spasms:** Monotherapy in pediatric patients one month to two years of age for whom the potential benefits outweigh the potential risk of vision loss.
 2. **Refractory Complex Partial Seizures:** Adjunctive therapy in patients two years of age and older who have responded inadequately to several alternative treatments. Vigabatrin products are not indicated as a first line agent for complex partial seizures.
- B. Vigafyde

Infantile spasms: Monotherapy in pediatric patients one month to two 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.

II. CRITERIA FOR INITIAL APPROVAL

- A. **Infantile Spasms**

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.
- B. **Complex Partial Seizures (Sabril, vigabatrin, Vigadrone, Vigpoder only)**

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.

III. CONTINUATION OF THERAPY

- A. **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.

B. 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.

IV. 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. Vigadrone [package insert]. Maple grove, MN: Upsher-Smith Laboratories, LLC; February 2020.
4. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc.; June 2024.
5. Vigpoder [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.
6. 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.
7. Willmore LJ, Abelson MB, Ben-Menachem E, et al. Vigabatrin: 2008 Update. *Epilepsia*. 2009; 50(2):163-173.
8. Xu Z, Gong P, Jiao X, et al. Efficacy of vigabatrin in the treatment of infantile epileptic spasms syndrome: A systemic review and meta-analysis. *Epilepsia Open*. 2023;8(2):268-277.
9. ILAE classification and definition of epilepsy syndromes with onset in neonates and infants: Position statement by the ILAE Task Force on Nosology and Definitions. *Epilepsia*. 2022;63(6):1349-1397.
10. Faught E. Vigabatrin therapy for refractory complex partial seizures: review of clinical trial experience in the United States. *Acta Neurol Scand Suppl*. 2011;(192):29-35.
11. Gatson TN, Freemont OA, Coleman RL, et al. Vigabatrin (Sabril) for the treatment of refractory complex focal seizures in adults: Pharmacology and clinical considerations. *Cureus*. 2023;15(10):e46414.