

## 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)**

Reference number
1770-A

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.