Reference number
1770-A

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. **Complex Partial Seizures:** Adjunctive therapy for adults and pediatric 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.

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 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 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

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2. Vigabatrin for oral solution [package insert]. Malvern, PA: Endo USA; August 2023.
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4. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals. Inc.; June 2024.
5. Vigpoder [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.
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8. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010:51:2175-2189.
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13. Willmore LJ, Abelson MB, Ben-Menachem E, et al. Vigabatrin: 2008 Update. *Epilepsia.* 2009; 50(2):163-173.
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