

SPECIALTY GUIDELINE MANAGEMENT

SABRIL (vigabatrin) tablets and powder for oral solution VIGADRONE (vigabatrin) powder for oral solution vigabatrin tablets and powder for oral solution

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. Infantile spasms: Monotherapy for pediatric patients with infantile spasms one month to two years of age for whom the potential benefits outweigh the potential risk of vision loss.
- B. 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.

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

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

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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Reference number
1770-A

2. Vigabatrin for oral solution [package insert]. Chestnut Ridge, NY: Par Pharmaceutical; October 2021.
3. Vigadrone [package insert]. Maple grove, MN: Upsher-Smith Laboratories, LLC; February 2020.
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5. Luna D, Dulac O, Pajot N, et al: Vigabatrin in the treatment of childhood epilepsies: a single-blind placebo-controlled study. *Epilepsia*. 1989; 30:430-437.
6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010;51:2175-2189.
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; 78:1974-1980.
8. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev*. 2013;6:CD001770.
9. Riikonen R. Recent advances in the pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
10. Pavone P, Striano P, Falsaperla R, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development*. 2014; 739-751.
11. Willmore LJ, Abelson MB, Ben-Menachem E, Pellock JM, Shields WD. Vigabatrin: 2008 Update. *Epilepsia*. 2009; 50(2):163-173.
12. Faught E. Vigabatrin therapy for refractory complex partial seizures: review of clinical trial experience in the United States. *Acta Neurol Scand*. 2011; 124(Suppl.192):29-35.