

## PHARMACY POLICY STATEMENT

### Indiana Medicaid

DRUG NAME	Sabril (vigabatrin)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home, Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see <b>Dosage Allowed</b> below
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Sabril (vigabatrin) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### INFANTILE SPASMS (West syndrome, X-linked infantile spasms syndrome)

For **initial** authorization:

1. Member has documented diagnosis of infantile spasms; AND
2. Member is an infant or a child between 1 months and 2 years of age; AND
3. Medication must be prescribed by a pediatric neurologist or an epilepsy physician specialist; AND
4. Sabril must be used as monotherapy; AND
5. Member has documentation of vision testing at baseline and every 3 months, up to 6 months following discontinuation of therapy.
6. **Dosage allowed:** Initiate therapy at 50 mg/kg/day given in 2 divided doses increasing total daily dose per package insert to a maximum of 150 mg/kg/day given in 2 divided doses.

*Note:* Only use Sabril if potential benefits outweigh the potential risk of vision loss.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

#### REFRACTORY COMPLEX PARTIAL SEIZURES

For **initial** authorization:

1. Member has a documented diagnosis of refractory complex partial seizures; AND
2. Member is 10 years of age or older; AND
3. Medication must be prescribed by a pediatric neurologist or an epilepsy physician specialist; AND
4. Sabril must be used as adjunctive therapy; AND
5. Member has documentation of failure of two alternative treatments for control of the complex partial seizures; AND

6. Member has documentation of vision testing at baseline and every 3 months, up to 6 months following discontinuation of therapy.
7. **Dosage allowed:** Adults >16 years of age: Initiate therapy at 500 mg twice daily, increasing total daily dose in 500 mg increments at weekly intervals depending on response. The recommended dose is 1500 mg twice daily. Pediatrics 10 to 16 years of age: Treatment is based on body weight. Initiate therapy at 250 mg twice daily, increasing total daily dose per package insert. The recommended maintenance dose is 1000 mg twice daily. Patients weighing more than 60 kg should be dosed according to adult recommendations.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Sabril (vigabatrin) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
10/08/2018	New policy for Sabril created. Policy placed in the new format.

References:

1. Sabril [package insert]. Deerfield, IL: Lundbeck Inc.; October 2013.
2. AAN/CNS evidence-based guideline update on medical treatment of infantile spasms. Neurology 2012; 78 (24): 1974 – 80. doi: 10.1212/WNL.0b013e318259e2cf.
3. Management and prognosis of infantile spasms. Daniel G Glaze. UpToDate [online database]. Available from: <http://www.uptodate.com>
4. Go CY, Mackay MT, Weiss SK, Stephens D, Adams-Webber T, Ashwal S, Snead, III OC. 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.
5. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Database Syst Rev. 2013.
6. French JA, Mosier M, Walker S, et al. A double-blind, placebo-controlled study of vigabatrin (3 g/day) in patients with uncontrolled complex partial seizures. Vigabatrin Protocol 024 Investigative Cohort. Neurology 1996;46(1):54-61.
7. Dean C, Mosier M, Penry K. Dose-response study of vigabatrin as add-on therapy in patients with uncontrolled complex partial seizures. Epilepsia. 1999;40(1):74-82.

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