

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Vigabatrin (generic for Sabril), Vigadrone
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see Dosage Allowed below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Vigabatrin (generic for Sabril) and Vigadrone are **non-preferred** products 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 is 1 month to 2 years of age; AND
2. Medication must be prescribed by a pediatric neurologist or an epileptologist; AND
3. Member has documented diagnosis of infantile spasms; AND
4. Medication must be used as monotherapy; AND
5. Member has documentation of vision assessment at baseline (test result required or plan to have vision assessment no later than 4 weeks after starting treatment).
6. **Dosage allowed:** Initiate therapy at 50 mg/kg/day given in 2 divided doses; subsequent doses can be titrated every 3 days per package insert, up to a maximum of 150 mg/kg/day given in 2 divided doses.

If member meets all the requirements listed above, the medication will be approved for 4 weeks.

For **reauthorization**:

1. Member is 2 years of age or younger; AND
2. Chart notes demonstrate clinical benefits from the initial use of medication (e.g., reduction of spasms), which outweigh the risks of vision loss.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

REFRACTORY COMPLEX PARTIAL SEIZURES

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication must be prescribed by a pediatric neurologist or an epileptologist; AND
3. Member has a documented diagnosis of refractory complex partial seizures (also known as focal seizures); AND
4. Medication must be used as adjunctive therapy with other antiepileptic drugs (e.g., carbamazepine, levetiracetam, lamotrigine, etc.); AND
5. Member has documentation of trial and failure with two other antiepileptic drugs; AND

6. Member has documentation of vision assessment at baseline (test result required or plan to have vision assessment no later than 4 weeks after starting treatment).
7. **Dosage allowed:**
 - a) Pediatric (2 to 16 years of age): administered in two divided doses, titrated to maintenance dose.
 - i) 10 kg to 15 kg: total daily starting dose 350 mg/day; maintenance dose 1050 mg/day;
 - ii) > 15 kg to 20 kg: total daily starting dose 450 mg/day; maintenance dose 1300 mg/day;
 - iii) > 20 kg to 25 kg: total daily starting dose 500 mg/day; maintenance dose 1500 mg/day;
 - iv) > 25 kg to 60 kg: total daily starting dose 500 mg/day; maintenance dose 2000 mg/day.
 - b) Pediatric weighing more than 60 kg and adults: initial dose 1000 mg/day (500 mg twice daily), titrated up to 3000 mg/day (1500 mg twice daily).

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes demonstrate clinical benefits from the initial use of medication (e.g., reduced seizure frequency or severity), which outweigh the risks of vision loss.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers vigabatrin (generic for Sabril) and Vigadrone 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.
01/29/2021	<p>Changed title name to vigabatrin (generic for Sabril), added Vigadrone.</p> <p><u>Infantile Spasms</u>: specified vision testing requirement at baseline to be either before or no more than 4 weeks after treatment started; removed documentation of vision testing during maintenance; reduced initial auth to 4 weeks and reauth to 6 months; added member's age must be younger than 2 in reauth; specified clinical benefit requirements for reauth.</p> <p><u>Complex Partial Seizure</u>: age expanded to 2 years old (previously 10); specified vision testing requirement at baseline to be either before or no more than 4 weeks after treatment started; removed documentation of vision testing during maintenance; updated dosing; reduced initial auth to 3 months and reauth to 6 months; specified clinical benefit requirements for reauth.</p>

References:

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4. Nelson GR. Management of infantile spasms. *Transl Pediatr*. 2015;4(4):260-270. doi:10.3978/j.issn.2224-4336.2015.09.01.
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8. 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.
9. Waterhouse EJ, Mims KN, Gowda SN. Treatment of refractory complex partial seizures: role of vigabatrin. *Neuropsychiatr Dis Treat*. 2009;5:505-515.
10. Treiman DM. Management of refractory complex partial seizures: current state of the art. *Neuropsychiatr Dis Treat*. 2010;6:297-308. Published 2010 Jun 24.
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Effective date: 07/01/2021

Revised date: 01/29/2021