

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Vigabatrin (generic for Sabril), Vigadrone
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Vigabatrin is a gamma-aminobutyric acid-transaminase (GABA-T) inhibitor initially approved by the FDA in 2009. It is indicated for the treatment of refractory complex partial seizures as adjunctive therapy in patients 2 years of age and older who have responded inadequately to several alternative treatments. Vigabatrin is also indicated for monotherapy for infantile spasms in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. Vigadrone is the oral solution formulation of Vigabatrin.

Vigabatrin (generic for Sabril) and Vigadrone will be considered for coverage when the following criteria are met:

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

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 within 90 days of starting therapy or no later than 4 weeks after starting treatment).
7. **Dosage allowed/Quantity limit:** 180 tablets/packets per 30 days
 - 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 all the above requirements are met, the medication will be approved for 3 months.

For reauthorization:

