

PHARMACY POLICY STATEMENT North Carolina 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

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 all the above requirements are met, 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
- Medication must be prescribed by a pediatric neurologist or an epileptologist; AND

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



