CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Vigabatrin (Sabril, Vigadrone, Vigafyde, Vigpoder)
BENEFIT TYPE	Pharmacy
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.

Vigabatrin (Sabril, Vigadrone, Vigafyde, Vigpoder) 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 vision assessment no later than 4 weeks after starting treatment).
6. **Dosage allowed/Quantity limit:** 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 all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 6 months.

Refractory Complex Partial Seizures – Sabril, Vigpoder and Vigadrone Only

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** 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:** 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**:
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 all the above requirements are met, the medication will be approved for an additional 6 months.

CareSource considers Vigabatrin (Sabril, Vigadrone, Vigafyde, Vigpoder) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/08/2018	New policy for Sabril created. Policy placed in the new format.
01/29/2021	Changed title name to Vigabatrin (generic for Sabril), added Vigadrone. Infantile Spasms: 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 reauthorization to 6 months; added member's age must be younger than 2 in reauthorization; specified clinical benefit requirements for reauthorization. Complex Partial Seizure: 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 reauthorization to 6 months; specified clinical benefit requirements for reauthorization.
06/30/2022	Updated references, Transferred to new format. Added quantity limits.
10/11/2024	Added Vigafyde and Vigpoder to the policy and changed name to Vigabatrin (Sabril, Vigadrone, Vigafyde, Vigpoder). Removed quantity limit from infantile spasms.

References:

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2. Vigadrone Tablets [package insert]. Upsher-Smith Laboratories, LLC; 2023.

3. Vigadrone Powder for Solution [package insert]. Upsher-Smith Laboratories, LLC; 2024.
4. Vigafyde [package insert]. Pyros Pharmaceuticals, Inc.; 2024.
5. Vigpoder [package insert]. Pyros Pharmaceuticals, Inc.; 2023.
6. Kanner AM et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(24):1117.
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