vigabatrin (Sabril®, Vigadrone®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO072

Description

Vigabatrin's (Sabril, Vigadrone) full mechanism of action is unknown at this time; however, it is an orally administered agent that has irreversible inhibition of gamma-aminobutyric acid transaminase (GABA-T).

Length of Authorization

- Initial: Three months for complex partial epileptic seizure, and one month for West Syndrome
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
vigabatrin (Sabril)	500mg tablets	Refractory complex partial epileptic seizure, adjunct therapy	180 tablets/30 days
vigabatrin (Sabril, Vigadrone)	500mg/packet powder for oral suspension		180 packets/30 days
		West Syndrome (infantile spasms)	120 packets/30 days
Vigafyde Soln 100mg/mL	100 mg/mL solution	infantile spasms in pediatric patients	750mL/30 days

Initial Evaluation

I. **Vigabatrin (Sabril, Vigadrone, Vigafyde)** may be considered medically necessary when the following criteria below are met:
   A. Medication is prescribed by, or in consultation with, a neurologist; **AND**
   B. The member has had an ophthalmologic examination prior to initiating vigabatrin (Sabril) or will be examined no later than four weeks after initiation of therapy; **AND**
      1. The member will have an ophthalmologic examination at least every three months during treatment; **OR**
   C. The member is blind prior to initiation of therapy; **AND**
   D. Generic vigabatrin OR vigabatrin (Vigadrone) is prescribed, or documentation is provided regarding clinical rationale as to why generic vigabatrin or vigabatrin (Vigadrone) is not appropriate or is contraindicated; **AND**
   E. A diagnosis of one of the following:
      1. **Complex partial epileptic seizure (focal onset impaired awareness seizure)**; **AND**
         i. Vigabatrin (Sabril, Vigadrone) will be used in combination with at least one other anti-epileptic medication (i.e., used as adjunct therapy) such as carbamazepine, phenytoin, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, divalproex sodium, zonisamide, tiagabine; **AND**

ii. A trial and failure of at least two anti-epileptic medications listed above; **AND**
iii. Member is two years of age or older; **OR**

2. **West Syndrome (Infantile Spasms)**; **AND**
   i. Member is between one month and two years of age; **AND**
   ii. The prescribed dose does not exceed 150 mg/kg/day

II. Vigabatrin (Sabril, Vigadrone) is considered investigational when used for all other conditions, including but not limited to:
   A. Seizures that are not considered complex partial epileptic or focal onset impaired awareness seizures
   B. Tourette's disorder
   C. Substance abuse (e.g., cocaine, methamphetamine, alcohol dependence)
   D. Autoimmune encephalitis

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Provider attestation that ophthalmologic examination has been completed every three months since initiation of therapy; **AND**
IV. Generic vigabatrin OR vigabatrin (Vigadrone) is prescribed, or documentation is provided, regarding clinical rationale as to why generic vigabatrin or vigabatrin (Vigadrone) is not appropriate or is contraindicated **AND**
V. A reduction in the severity or frequency of seizures or spasms; **AND**
   A. **Complex partial epileptic seizure (focal onset impaired awareness seizure)**; **AND**
      1. The medication continues to be used in combination with at least one other anti-epileptic medication (i.e., used as adjunct therapy) such as carbamazepine, phenytoin, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, divalproex sodium, zonisamide, tiagabine; **OR**
   B. **West Syndrome (Infantile Spasms)**; **AND**
      1. Clinical benefit has been assessed and documented within the first two to four weeks of treatment (please note: extensions will not be given if assessment has not taken place within four weeks of treatment initiation); **AND**
      2. The prescribed dose does not exceed 150 mg/kg/day

Supporting Evidence

I. Vigabatrin (Sabril, Vigadrone) has a black box warning for permanent vision loss, and those who take the medication are at risk for vision loss with any amount of medication. The risk increases with greater doses and duration of vigabatrin (Sabril, Vigadrone) administration. This medication is available through a Risk Evaluation Mitigation Strategy (REMS) Program, and a specialist will need to be involved in prescribing to ascertain if the benefits of vigabatrin (Sabril, Vigadrone) outweigh the risk of vision loss.
II. Recommended ophthalmologic monitoring should start at baseline or within four weeks of initiating therapy, every three months during therapy, and through three to six months post discontinuation.
III. Vigabatrin (Sabril, Vigadrone) is FDA-approved for complex partial epileptic seizures (focal onset impaired awareness seizure) for ages two years and older and West Syndrome (infantile spasms) for ages one month to two years. In complex partial epileptic seizure, the medication is FDA-approved in the refractory setting after failure of other therapies and should be used in addition to at least one other anti-epileptic (i.e., vigabatrin [Sabril, Vigadrone] is an adjunct therapy).
IV. Vigabatrin (Vigadrone) is an AA-rated authorized generic of Sabril and is fully substitutable for both Sabril and generic vigabatrin 500mg/packet for oral solution.
V. The max dose of vigabatrin (Sabril, Vigadrone) is 3000 mg/day for complex partial epileptic seizure and a maximum of 150 mg/kg/day for West Syndrome.
VI. For West Syndrome, significant clinical benefit should be realized within four weeks of therapy initiation, and the medication should be discontinued if not. Due to the risks associated with the medication, continuation of therapy will not be grated in absence of clinical benefit.

Investigational or Not Medically Necessary Uses

All indications listed below have not been sufficiently studied for safety and efficacy or have inconclusive evidence for use of vigabatrin (Sabril, Vigadrone).

I. Seizures that are not considered complex partial epileptic or focal onset impaired awareness seizures
II. Tourette's disorder
III. Substance abuse (e.g., cocaine, methamphetamine, alcohol dependence)
IV. Autoimmune encephalitis

References

1. Sabril [Prescribing Information]. Deerfield, IL: Lundbeck. January 2020.
2. Vigadrone [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC. February 2020.
3. Approved Risk Evaluation and Mitigation Strategies (REMS). Food and Drug Administration. October, 2017. https://www.accessdata.fda.gov/Scripts/Cder/Rems/index.cfm?event=RemsDetails.page&REMS=364. Accessed March 4, 2019.

4. Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. Vigabatrin REMS for Healthcare Professionals. https://www.vigabatrinrems.com/#Main. Accessed March 4, 2019.
5. Scheffer IE, Berkovic S, Capovilla G, et al. ILAE classification of the epilepsies: Position paper of the ILAE Commission for Classification and Terminology. *Epilepsia*. 2017;58(4):512-521.
6. 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.
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.
8. Köhler U, Forberg J. [Results of treatment of 718 endometrial cancers with reference to clinical and morphologic prognostic factors]. *Zentralbl Gynakol*. 1989;111(15):1033-41.

Policy Implementation/Update:

Action and Summary of Changes	Date
Added vigafyde soln to QL table	08/2024
Updated minimum age for use as adjunct therapy for refractory complex seizures to age two and older to align with FDA-label age-expansion; Added Vigadrone packets to policy	03/2021
Date created	03/2019