vigabatrin (Sabril®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO072

Description

Vigabatrin (Sabril) is an orally administered agent that has irreversible inhibition of gamma-aminobutyric acid transaminase (GABA-T) but the full mechanism of action is unknown at this time.

Length of Authorization

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

Quantity limits

vigabatrin (Sabril)	Indication	Quantity Limit	DDID
500 mg/packet oral powder for solution	Refractory complex partial epileptic seizure, adjunct therapy.	180 packets/30 days	053531, 106740
500 mg tablets		180 tablets/30 days	036476, 106728
500 mg/packet oral powder for solution	West Syndrome	120 packets/30 days	053531, 106740

Initial Evaluation

I. Vigabatrin (Sabril) 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 is prescribed, or documentation is provided regarding clinical rationale as to why generic vigabatrin 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) 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, tigabine; **AND**

ii. A trial and failure of at least two anti-epileptic medications listed above; **AND**

iii. Member is 10 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) 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. Medication is prescribed by or in consultation with a neurologist; **AND**
II. Ophthalmologic examination has been completed at baseline and every three months since initiation of therapy; **AND**
III. Generic vigabatrin is prescribed, or documentation is provided regarding clinical rationale as to why generic vigabatrin is not appropriate or is contraindicated **AND**
IV. A reduction in the severity or frequency of seizures or spams; **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, tigabine; **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) 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) administration. This medication is available

through a Risk Evaluation Mitigation Strategy (REMS) Program, and a specialist shall be involved in prescribing to ascertain if the benefits of vigabatrin (Sabril) outweight the risk of vision loss.

II. Recommended ophthalmologic monitoring shall start at baseline or within four weeks of initiating therapy, every three months during therapy through three to six months post discontinuation.

III. Vigabatrin (Sabril) is FDA-approved for complex partial epileptic seizures (focal onset impaired awareness seizure) for ages 10 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 shall be used in addition to at least one other anti-epileptic (i.e., vigabatrin [Sabril] is an adjunct therapy).

IV. The max dose of vigabatrin (Sabril) is 3000 mg/day for complex partial epileptic seizure and a maximum of 150 mg/kg/day for West Syndrome.

V. For West Syndrome, significant clinical benefit should be realized within four weeks of therapy initiation, and the medication shall be discontinued if not. Due to the risks associated with the medication, continuation of therapy shall 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 vigabaril (Sabril).

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. June 2016.
2. 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.
3. Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. Vigabatrin REMS for Healthcare Professionals. https://www.vigabatrinrems.com/#Main. Accessed March 4, 2019.
4. 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.
5. 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.
6. 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.

7. 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.

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Action and Summary of Changes	Date