Sabril Vigadrone

Description

Sabril (vigabatrin), Vigadrone (vigabatrin)

Background
Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) Sabril/Vigadrone targets the enzyme GABA-transferase (GABA-T), which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures of the complex partial type that have been refractory to prior therapies. Sabril/Vigadrone also treats infantile spasms in children 2 years of age or under (1-2).

Regulatory Status
FDA-approved indications: Sabril/Vigadrone is an antiepileptic drug (AED) indicated for (1-2):

1. Refractory complex partial seizures - in patients 10 years of age or older. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.
2. Infantile Spasms - monotherapy in infants 1 month to 2 years of age.

Off-label Use:
Refractory complex partial seizures in patients 3 – 9 years of age. The majority of patients included in the original clinical trials that evaluated the use of vigabatrin for the treatment of refractory partial seizures were adults, and therefore efficacy and safety had not been established in this age group at that time. However, further studies conducted have
demonstrated that the use of vigabatrin is effective in decreasing seizure frequency in this population of pediatric patients compared with baseline (3-4).

Sabril/Vigadron may cause temporary or permanent vision symptoms, including double vision and blurring, and has boxed warnings for vision loss that may continue after ending therapy; including possible permanent loss. Patients, prescribers, and pharmacies must all be enrolled in SHARE REMS program. All patients should have a baseline vision check and be periodically monitored for both visual field and acuity. Similar to other AEDs, Sabril/Vigadron also increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1-2).

Related policies
Acthar gel

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sabril/Vigadron may be considered medically necessary for the treatment of infantile spasms or refractory complex partial seizures and if the conditions indicated below are met.

Sabril/Vigadron may be considered investigational for all other diagnoses.

**Prior-Approval Requirements**

**Diagnoses**

Patient must have ONE of the following:

1. Infantile spasms
   a. Used as monotherapy

2. Refractory complex partial seizures (CPS)
   a. Inadequate response, intolerance, or contraindication to alternate treatments

AND ALL of the following:

1. Patient and prescriber are enrolled in the SHARE REMS program
2. Baseline vision assessment and confirmation vision will be assessed every 3 months during therapy

Prior – Approval *Renewal* Requirements

**Diagnoses**

Patient must have **ONE** of the following:

1. Infantile spasms  
   a. Used as monotherapy

2. Refractory complex partial seizures (CPS)

**AND** the following:

1. Vision will be assessed every 3 months during therapy
2. Patient and prescriber are enrolled in the SHARE REMS program

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration** 12 months

**Prior – Approval *Renewal* Limits**

**Duration** 12 months

**Rationale**

**Summary**

Sabril/Vigadrone is an anti-epileptic drug that targets the enzyme, GABA-transferase (GABA-T) which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures; it also treats infantile spasms. Sabril/Vigadrone has boxed warnings for the risk of vision loss, possibly permanent, in some cases (1-2).
Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Sabril/Vigadrone while maintaining optimal therapeutic outcomes.

References

**Policy History**

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<tr>
<td>December 2014</td>
<td>Addition to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual review and reference update</td>
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<td>December 2016</td>
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<td>Addition of the 10 years of age and older to the renewal section for CPS</td>
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<td>September 2017</td>
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<td>March 2018</td>
<td>Removal of age requirements from initiation and renewal section for all</td>
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<td>June 2018</td>
<td>Annual review and reference update</td>
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<td>May 2019</td>
<td>Changed policy name to Sabril Vigadrone (vigabatrin)</td>
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.