



MEDICATION POLICY

Generic Name: Vigabatrin

Therapeutic Class or Brand Name: Sabril®

Applicable Drugs (if Therapeutic Class):

Preferred: Vigabatrin packets for solution (generic)

Non-Preferred: Sabril® packets for solution, Sabril® tablets

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 12/13/17

GPI Code: 7217008500

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Refractory Complex Partial Seizures and criteria 1 through 2 are met:
 1. Documented failure of several alternative treatments.
 2. Minimum age requirement: 10 years old.
 - B. Infantile Spasms and criterion 1 is met:
 1. Age is between one month and two years old.
- II. Prescriber is a neurologist and must be enrolled in the Vigabatrin REMS Program.
- III. Non-preferred products (i.e. Sabril® packets for solution, Sabril® tablets) require a documented clinical reason containing details as to why generic vigabatrin is not appropriate or is contraindicated.

Exclusion Criteria:

- N/A

Other Criteria:

- Sabril® should be discontinued if a significant clinical response is not achieved within 3 months of initiation (for treatment of Refractory Complex Partial Seizures) or 2 to 4 weeks (for treatment of Infantile Spasms) or if clinical failure is obvious earlier.

Quantity/Days Supply Restrictions:

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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- Quantities of up to 180 tablets or packets per 30 days.

Approval Length:

- **Authorization:** 3 months.
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing a significant clinical response has been achieved and documentation that vision is being monitored periodically (or that patient is formally exempted from periodic ophthalmologic assessment).

Appendix:

N/A

References:

1. http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril_Criteria.pdf.
2. Medi-Span.
3. http://www.lundbeck.com/upload/us/files/pdf/Products/Sabril_PI_US_EN.pdf.

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Historical Tracking Of Changes Made To Policy	
12/13/2017	<ol style="list-style-type: none"> 1. Changed “N/A” to “Preferred: Vigabatrin packets for solution (generic); Non-Preferred: Sabril® packets for solution, Sabril® tablets” under Applicable Drugs. 2. Changed “II. Prescriber is a neurologist and must be enrolled in the Sabril® REMS Program” to “II. Prescriber is a neurologist and must be enrolled in the Vigabatrin REMS Program” under Prior Authorization Criteria. 3. Added “III. Non-preferred products (i.e. Sabril® packets for solution, Sabril® tablets) require a documented clinical reason containing details as to why generic vigabatrin is not appropriate or is contraindicated” under Prior Authorization Criteria.
10/6/2016	<ol style="list-style-type: none"> 1. Changed “II. Prescriber is a neurologist and must be enrolled in the SHARE Program” to “II. Prescriber is a neurologist and must be enrolled in the Sabril® REMS Program” under Prior Authorization Criteria. 2. Updated “http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril_Criteria.pdf” to “http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril_Criteria.pdf” and “http://www.lundbeck.com/upload/us/files/pdf/Products/Sabril_PI-CPS_US_EN.pdf” to “http://www.lundbeck.com/upload/us/files/pdf/Products/Sabril_PI_US_EN.pdf” under References.
4/23/2015	<ol style="list-style-type: none"> 1. Changed “Age between one month and two years old” to “Age is between one month and two years old” under Infantile Spasms diagnosis under Prior Authorization Criteria. 2. Changed “II. Documented enrollment of both prescriber and patient in the SHARE program - must provide copy of Treatment Initiation Form and a copy of the Patient-Physician Agreement Form; III. The prescribing provider must be a specialist in the neurology field of study” to “II. Prescriber is a neurologist and must be enrolled in the SHARE Program.” under Prior Authorization Criteria. 3. Changed Authorization from “3 months. Initial prior authorization will be approved for three months to assess safety and efficacy in the individual patient” to “3 months” under Approval Length. 4. Changed Re-Authorization from “1 year. Subsequent prior authorizations will be given in one year increments, upon submission of a letter of medical necessity showing a significant clinical response has been achieved. Must also submit a copy of a completed and signed Treatment Maintenance Form and a copy of a completed Ophthalmologic Assessment Form” to “1 year. An updated letter of medical necessity or progress notes showing a significant clinical response has been achieved and documentation that vision is being monitored periodically (or that patient is formally exempted from periodic ophthalmologic assessment)” under Approval Length. 5. Removed “http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Sabril.pdf” from References (link no longer valid). 6. Updated “http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril.pdf” to “http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril_Criteria.pdf” under References.
12/27/2013	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI code. 3. Changed the minimum age requirement for Refractory Complex Partial Seizures from 16 years old to 10 years old under Prior Authorization Criteria. 4. Removed “Negative pregnancy test for women of childbearing age” requirement under Prior Authorization Criteria. 5. Changed Quantities/Days Supplies Restrictions from “180 tablets or packets per 30 days” to “Quantities of up to 180 tablets or packets per 30 days”. 6. Updated references to include Medi-Span.

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