MEDICATION POLICY:

Sabril®

Generic Name: Vigabatrin

Therapeutic Class or Brand Name: Sabril

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 7217008500

Preferred: Vigabatrin packets for solution (generic)

Non-preferred: Sabril packets for solution, Sabril tablets

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/25/2019

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

- 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. Kanner AM, et. al., Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018 Jul 10;91(2):74-81. doi: 10.1212/WNL.0000000000005755. Epub 2018 Jun 13.
2. Medi-Span®
3. Sabril® [Package insert] Deerfield, IL: Lundbeck; February 2019. Available at: http://www.lundbeck.com/upload/us/files/pdf/Products/Sabril_PI_US_EN.pdf

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
7/25/2019	1. Policy reviewed: no changes made
10/31/2018	1. Policy reviewed: no changes made
12/13/2017	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	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_Critieria.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	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_creteria_pdf/Sabril.pdf" **to** "http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/drug_criteria_pdf/Sabril_Critieria.pdf" **under References**.
12/27/2013	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.