AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: (select drug below)

❑ **Sabril®** (vigabatrin) **tablets**	❑ **Sabril®** (vigabatrin) **packets**
❑ **vigabatrin packets**	❑ **vigabatrin tablets**
❑ **Vigadrone®** (vigabatrin) **packets**	❑ **Vigpoder®** (vigabatrin) **packets**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (must be measured within the last 30 days): _____**kg** **Date:** _____

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Recommended Dosage:

Indication	Dose
Infantile spasms	• Infants and Children 1 month to 2 years of age: Oral: Powder for oral solution: Initial: 50 mg/kg/day divided twice daily; may titrate upwards by 25 to 50 mg/kg/day increments every 3 days based on response and tolerability; maximum daily dose: 150 mg/kg/day divided twice daily; **Note:** To taper, decrease dose by 25 to 50 mg/kg/day every 3 to 4 days. • Withdraw therapy in 2 to 4 weeks if a substantial clinical benefit is not observed or discontinue treatment if evidence of treatment failure becomes obvious earlier than 2 to 4 weeks.
Refractory complex partial seizures, adjunctive treatment	• Dose dependent upon weight and/or age. • Withdraw therapy if a substantial clinical benefit is not observed within 3 months of treatment initiation; discontinue therapy if evidence of treatment failure becomes obvious earlier than 3 months.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

DIAGNOSIS: (Please check one of the applicable diagnoses below)

❑ Infantile Spasms

- ❑ Prescribing physician is a neurologist or has consulted with a neurologist
- ❑ Member is between the ages of 1 month and 2 years of age with a diagnosis of infantile spasms
- ❑ Member must meet **ONE** of the following:
  - ❑ Member's baseline vision has been assessed by an ophthalmologist or the member's vision will be assessed within 4 weeks of initiating Sabril therapy and at least every 3 months while on therapy. Vision testing is also recommended 3 to 6 months after discontinuation of Sabril therapy
  - ❑ Member is blind or has been formally exempt from vision assessment in the Vigabatrin REMS Program
- ❑ Requested dose does **NOT** exceed FDA approved maximum dose for indication

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❑ Refractory Complex Partial Seizures (CPS)

- ❑ Prescribing physician is a neurologist or has consulted with a neurologist
- ❑ Member is 2 years of age or older with refractory complex partial seizures who has responded inadequately to alternative treatments
- ❑ Member has tried and failed at least 3 antiepileptic medications for complex partial seizures such as carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproic acid, divalproex sodium, or zonisamide
- ❑ Vigabatrin will be used in combination with at least one other antiepileptic medication
- ❑ Member must meet **ONE** of the following:
  - ❑ Member's baseline vision has been assessed by an ophthalmologist or the member's vision will be assessed within 4 weeks of initiating Sabril therapy and at least every 3 months while on therapy. Vision testing is also recommended 3 to 6 months after discontinuation of Sabril therapy
  - ❑ Member is blind or has been formally exempt from vision assessment in the Vigabatrin REMS Program
- ❑ Requested dose does **NOT** exceed FDA approved maximum dose for indication

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ For Both Infantile Spasms and Refractory Complex Partial Seizures (CPS)

- ❑ Member continues to meet all of the initial criteria listed above for the applicable diagnosis
- ❑ Provider must submit current progress notes documenting efficacy demonstrating that member is stable from baseline or has a positive response to vigabatrin therapy
- ❑ Requested dose does not exceed FDA approved maximum dose for indication

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 4/16/2020
REVISED/UPDATED: ~~6/12/2020~~; ~~10/11/2021~~**; 1/22/20274**