



Prior Authorization Approval Criteria

Sabril (vigabatrin)

Generic name:	vigabatrin
Brand name:	Sabril
Medication class:	antiepileptic drug
FDA-approved uses:	Infantile Spasms Refractory Complex Partial Seizures
Available dosage forms:	Powder for oral solution: 500mg 500mg tablet
Usual dose:	Infantile Spasms – 50mg/kg/day twice daily up to 150mg/kg/day. Refractory Complex Partial Seizures – 500mg twice daily up to 1.5 grams twice daily. Dose adjustment recommended in renally impaired patients.
Approximate monthly cost: (based on AWP 2009)	For adults for Refractory Complex Partial Seizures- \$1849.20-\$5,547.60/month
Duration of therapy:	to be determined by prescribing physician based on patient response

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.

Refractory Complex Partial Seizures

- Must be clinically diagnosed with refractory complex partial seizures.
- Must be prescribed by a neurologist.
- Must be 18 years of age or older.
- Patient must have tried and failed at least 2 other anticonvulsant agents.
- Must be used as adjunct therapy.
- Potential benefit must outweigh the potential risk of vision loss.
- Must have vision tested at baseline before beginning treatment and at least every 3 months.

Infantile Spasms

- Must be clinically diagnosed with infantile spasms.
- Must be prescribed by a neurologist
- Must be between the ages of 1 month to 2 years old.
- Potential benefit must outweigh the potential risk of vision loss.
- Must have vision tested to the extent possible depending on the age of the child at baseline before beginning treatment and at least every 3 months.

Criteria for continuation of therapy:

Refractory Complex Partial Seizures

- Must provide updates on eye exams upon renewal.
- Must show a substantial clinical benefit within 3 months of starting treatment in order to

continue therapy.

Infantile Spasms

- Must provide updates on eye exams upon renewal.
- Must show a substantial clinical benefit within 2-4 weeks of starting treatment in order to continue therapy.

Caution:

- Peripheral visual field defect, the risk increases with higher doses and longer duration.
- Should not be used with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefit outweighs the risk.

Monitoring:

Refractory Complex Partial Seizures and Infantile Spasms

- Vision must be tested at baseline and then every 3 months

Contraindication:

- None at this time according to the package insert.

Not approved if:

- Patient does not meet the above stated criteria.
- Patient has not had a baseline eye exam.

Special considerations:

- FDA mandated REMS associated with Sabril.
- The drug is shipped directly to the patient.
- Available only through a special restricted distribution program called SHARE, by calling 1-888-45-SHARE.
- Only prescribers and pharmacies registered with SHARE may prescribe and distribute Sabril.
- For infants the drug is usually taken for 6-9 months. Dosage is often reduced at this point to see if symptoms re-emerge. If so, the dosage is increased to previous levels.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/09/09