

## Specialty Pharmacy Program

### Sabril® (vigabatrin)

#### DESCRIPTION

Sabril is an antiepileptic drug indicated for the treatment of infantile spasms in children and for the treatment of complex partial seizures in adults. Sabril acts by increasing gamma-aminobutyric acid (GABA) levels in the central nervous system. Sabril should only be used in patients for whom the potential benefit outweighs the risk of vision loss.

#### APPROVAL DURATION

##### Initial therapy

Infantile spasms: 4 weeks

Complex partial seizures: 3 months

##### Maintenance therapy

Infantile spasms: 6 months

Complex partial seizures: 1 year

#### APPROVAL CRITERIA

- I. Patient must meet the following criteria:
  - A. Visual assessment by an ophthalmologist at baseline or no longer than 4 weeks after starting Sabril therapy AND
  - B. Visual assessment by an ophthalmologist every 3 months while on Sabril therapy AND
  - C. Patient does not have or is not at high risk for other types of irreversible vision loss AND
  - D. Patient is not using other medications associated with serious ophthalmologic effects such as retinopathy or glaucoma AND
  - E. Patient shows substantial clinical benefit from Sabril therapy.
- AND
- II. Diagnosis is complex partial seizures AND
  - A. Patient is 16 years of age or older AND
  - B. Sabril is used as adjunctive therapy AND
  - C. Patient has complex partial seizures refractory to an adequate regimen of carbamazepine (CBZ) or phenytoin (PHT) OR
  - D. Patient cannot tolerate CBZ or PHT OR
  - E. Patient has a contraindication to CBZ or PHT.
- OR
- III. Diagnosis is infantile spasms AND
  - A. Patient is 1 month to 2 years of age AND
  - B. Sabril is used as monotherapy.