SPECIALTY GUIDELINE MANAGEMENT

SABRIL (vigabatrin) tablets and powder for oral solution
vigabatrin powder for oral solution

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Infantile spasms: Sabril is indicated as monotherapy for pediatric patients with infantile spasms one month to two years of age for whom the potential benefits outweigh the potential risk of vision loss.

2. Complex Partial Seizures: Sabril is indicated as adjunctive therapy for adults and pediatric patients ten years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Sabril is not indicated as a first line agent for complex partial seizures.

B. Compendial Use: Refractory complex partial seizures in children younger than ten years of age who have inadequately responded to at least two alternative treatments.

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

A. Infantile Spasms

Authorization of 4 weeks may be granted for the treatment of infantile spasms.

B. Complex Partial Seizures

Authorization of 3 months may be granted for the treatment of complex partial seizures when member has had an inadequate response to at least two alternative treatments for complex partial seizures.

III. CONTINUATION OF THERAPY

A. Infantile Spasms

Authorization of 6 months may be granted for members requesting Sabril for continuation of therapy when member has shown substantial clinical benefit from Sabril therapy.

B. Complex Partial Seizures

Authorization of 12 months may be granted for members requesting Sabril for continuation of therapy when member has shown substantial clinical benefit from Sabril therapy.
IV. REFERENCES
3. CVS Caremark Clinical Program Review. Focus on Seizure Disorders Programs; October 1, 2013.