SPECIALTY GUIDELINE MANAGEMENT

SABRIL (vigabatrin)

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 when Sabril is used as a single agent (monotherapy).

B. Complex Partial Seizures
Authorization of 3 months may be granted for the treatment of complex partial seizures when both of the following criteria are met:
1. Sabril will be used as adjunctive therapy
2. 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. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limit applies (for complex partial seizures only): 3,000 mg per day.

V. REFERENCES

1. Sabril [package insert]. Deerfield, IL: Lundbeck Inc.; September 2015.
2. Livingston JH, Beaumont D, Arzimanoglou A, et al: Vigabatrin in the treatment of epilepsy in children. *Br J Clin Pharmacol*. 1989; 27:109S-112S.
3. Luna D, Dulac O, Pajot N, et al: Vigabatrin in the treatment of childhood epilepsies: a single-blind placebo-controlled study. *Epilepsia.* 1989; 30:430-437.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at http://www.micromedexsolutions.com. Accessed May 23, 2016.
5. American Society of Health System Pharmacists. AHFS Drug Information. Bethesda, MD. Electronic Version 2015. http://www.online.lexi.com. Accessed May 23, 2016.
6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. *Epilepsia*. 2010:51:2175-2189.
7. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: Medical treatment of infantile spasms: Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology.* 2012; 78:1974-1980.
8. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. *Cochrane Database Syst Rev*. 2013;6:CD001770.
9. Riikonen R. Recent advances in the pharmacotherapy of infantile spasms. *CNS Drugs* 2014; 28:279-290.
10. Pavone P, Striano P, Falsaperla R, et al. Infantile spasms syndrome, West Syndrome and related phenotypes: what we know in 2013. *Brain & Development* 2014; 739-751.
11. Willmore LJ, Abelson MB, Ben-Menachem E, Pellock JM, Shields WD. Vigabatrin: 2008 Update. *Epilepsia.* 2009; 50(2):163-173.
12. Faught E. Vigabatrin therapy for refractory complex partial seizures: review of clinical trial experience in the United States. *Acta Neurol Scand* 2011; 124(Suppl.192):29-35.