Sabril® (vigabatrin)

Policy Number: 5.01.532  Last Review: 03/2014
Origination: 02/2009  Next Review: 03/2015

Policy
BCBSKC will provide coverage for Sabril® when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered
The patient is a child between the ages of 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the risk of vision loss.

The patient is an adult with refractory complex partial seizures (CPS) who has 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 CPS.

When Policy Topic is not covered
The use of vigabatrin is considered investigational for other indications.

Considerations
Sabril requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service
Sabril is an oral gamma aminobutyric acid transaminase inhibitor¹. It is the first drug in the United States to receive FDA approval for the treatment of infantile spasms as monotherapy in infants where the benefits of treatment outweigh the risk of vision loss.⁴

Sabril tablets have been approved for adult use in combination with other medications to treat complex partial seizures that have not responded adequately to previous drug therapies.

Damage to vision is an important safety concern with the use of Sabril. The drug has a boxed warning to alert health care professionals to this risk of a progressive loss of peripheral vision with potential decrease in visual acuity. The risk of vision damage may increase based on the dosage and duration of use, but even the lowest doses of Sabril can cause vision damage. Periodic vision testing is required for those taking Sabril. Because of the risk of permanent vision damage, the drug is available only through a restricted distribution program.

Sabril was designated as an orphan drug by the FDA for use in treating infantile spasms. A drug is eligible for orphan drug designation if it is intended to treat a disease or condition that affects less than
Infantile spasms is a type of seizure seen in an epilepsy syndrome of infancy and early childhood known as West Syndrome. The onset is predominantly in the first year of life. The typical pattern of infantile spasms is a sudden bending forward and stiffening of the body, arms, and legs. Spasms tend to begin soon after arousal from sleep with individual spasms typically lasting for 1 to 5 seconds. These tend to occur in clusters, ranging from 2 to 100 spasms at a time. Infantile spasms usually stop by age 5, but are often replaced by other seizure types. West syndrome is characterized by infantile spasms, hypsarrhythmia, and mental retardation.³

Sabril was approved for infantile spasms on August 21, 2009⁴ based on two multicenter, randomized controlled trials.¹ Due to the risk of permanent vision loss, the FDA is requiring a Risk Evaluation and Mitigation Strategy (REMS) program for this product. This program, called the SHARE program, includes periodic vision testing and a restricted distribution program.⁵ The American Academy of Neurology (AAN) guidelines on infantile spasms suggest Sabril is possibly effective for the short-term treatment of infantile spasms, and in the short-term treatment of infantile spasms in the majority of children with tuberous sclerosis (Level C, Class III and IV evidence)⁶; however, these guidelines were published in 2004, years before the FDA approval of Sabril.

Complex Partial Seizures

Partial (focal) seizures begin in one hemisphere of the brain and, generally result in an asymmetric clinical manifestation. Patients experiencing complex partial seizures may have automatisms, memory loss, or an aberration of behavior. Patients are typically amnestic to these events. These seizures are difficult to diagnose and may be mistaken for a psychotic episode.⁷ Sabril was FDA approved on August 21st, 2009⁴ as adjunctive therapy for adult patients with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the potential risk of vision loss.² Clinical trials included patients who had a history of failure on an adequate regimen of carbamazepine or phenytoin.² According to the AAN practice guidelines for the treatment of refractory epilepsy, other treatments used as add-on therapies for refractory partial seizures include gabapentin, lamotrigine, tiagabine, topiramate, oxcarbazepine, levetiracetam, and zonisamide.⁸

Safety Concerns of Sabril

In addition to vision loss, other safety concerns for Sabril include the following: magnetic resonance imaging (MRI) abnormalities, neurotoxicity, suicidal behavior and ideation, withdrawal of antiepileptic drugs, anemia, somnolence and fatigue, peripheral neuropathy, weight gain, and edema.¹²

References


**Billing Coding/Physician Documentation Information**

N/A Sabril is considered a pharmacy benefit.

**Additional Policy Key Words**

N/A

**Related Topics**

N/A

**Policy Implementation/Update Information**

02/2010 New policy titled Sabril
02/2011 Reviewed – no changes recommended
02/2012 Reviewed – no changes recommended
03/2013 Reviewed – no changes recommended
03/2014 Reviewed – no changes recommended

This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.