

## Policies Repository



# AmeriHealth.

**Policy Title** Vigabatrin (Sabril®)

**Policy Number** FS.CLIN.95

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

<b>Policy</b>	<p><b>Vigabatrin (Sabril®)</b> is an anticonvulsant indicated for the following:</p> <ul style="list-style-type: none"> <li>As monotherapy for infants and children with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss</li> <li>As adjunctive therapy for adults 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</li> </ul>
<b>Policy description</b>	<p><b>Vigabatrin's (Sabril®)</b> precise mechanism of anti-seizure effect is unknown. It is thought to be the result of its action as an irreversible inhibitor of <math>\gamma</math>-aminobutyric acid transaminase (GABA-T), the enzyme responsible for the metabolism of the inhibitory neurotransmitter GABA. This action results in enhanced levels of GABA in the central nervous system. No direct correlation between plasma concentration and efficacy has been established. Duration of drug effect is presumed to be dependent on the rate of enzyme re-synthesis rather than on the rate of elimination of the drug from the systemic circulation.</p>
<b>Policy guideline inclusion</b>	<p><b>Vigabatrin (Sabril®)</b> is approved when <b>one</b> of the following inclusion criteria is met:</p> <ul style="list-style-type: none"> <li>Documented diagnosis of Infantile Spasms (IS) in infants 1 month to 2 years of age</li> <li>Documented diagnosis of refractory complex partial seizures in patients 16 years and older</li> <li>Documentation of continuous therapy with Vigabatrin (Sabril)</li> </ul>
<b>Policy guideline exclusion</b>	<p><b>Vigabatrin (Sabril®)</b> is denied when <b>all</b> of the following exclusion criteria are found:</p> <ul style="list-style-type: none"> <li>No documented diagnosis of Infantile Spasms (IS) in infants 1 month to 2 years of age</li> <li>No documented diagnosis of refractory complex partial seizures in patients 16 years and older</li> <li>No documentation of continuous therapy with Vigabatrin (Sabril)</li> </ul>

**Policy List of**

Brand Name	Generic Name
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<b>Applicable Drugs</b>	Sabril   vigabatrin
<b>Dosing and Administration</b>	Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.
<b>Policy references</b>	<p>Sabril® (vigabatrin). In: Facts and Comparisons [<a href="http://online.factsandcomparisons.com">http://online.factsandcomparisons.com</a>]. Indy, IN: Walter Kluwer Health Inc. Accessed May 18, 2011.</p> <p>Sabril® (vigabatrin): Drugdex [<a href="http://www.micromedex.com">http://www.micromedex.com</a>]. Greenwood Village, CO: Thomson Micromedex. Accessed May 18, 2011.</p> <p>Sabril [package insert]. Deerfield, IL: Lundbeck Inc.; February 2010.</p>
<b>Policy Link to Related Policies</b>	
<b>Version effective date</b>	07/01/2011

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