Medimpact

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	SABRIL,	07377		GPI-10	
	VIGABATRIN,			(7217008500)	
	VIGADRONE				

GUIDELINES FOR USE

- 1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or in consultation with a neurologist
 - The requested medication will be used as adjunctive therapy
 - The potential benefits outweigh the risk of vision loss
 - The patient had a trial of or contraindication to THREE antiepileptic medications, at least two of which must be generic (e.g., carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.** If no, continue to #2.

- 2. Does the patient have a diagnosis of infantile spasms and meet ALL of the following criteria?
 - The patient is 1 month to 2 years of age
 - Therapy is prescribed by or in consultation with a neurologist
 - The requested medication will be used as monotherapy
 - The potential benefits outweigh the risk of vision loss

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VIGABATRIN (Sabril, Vigadrone)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Refractory complex partial seizures (a type of seizure)
 - 2. Infantile spasms (a type of seizure disorder in infancy and childhood)

(Denial text continued on the next page)

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VIGABATRIN

GUIDELINES FOR USE (CONTINUED)

B. If you have refractory complex partial seizures, approval also requires:

- 1. You are 2 years of age or older
- 2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
- 3. The requested medication will be used as adjunctive (add-on) therapy
- 4. The potential benefits outweigh the risk of vision loss
- 5. You had a trial of or contraindication (harmful for) to THREE antiepileptic medications, at least two of which must be generic (seizure drugs such as carbamazepine, divalproex/valproic acid, oxcarbazepine, levetiracetam immediate-release/extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

C. If you have infantile spasms, approval also requires:

- 1. You are 1 month to 2 years of age
- 2. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
- 3. The requested medication will be used as monotherapy (one drug for treatment)
- 4. The potential benefits outweigh the risk of vision loss

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sabril.

REFERENCES

• Sabril [Prescribing Information]. Deerfield, IL: Lundbeck, October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Commercial Effective: 05/22/23 Created: 05/22 Client Approval: 05/23

P&T Approval: 04/22