Pharmacy Drug Policy & Procedure

Policy Name:	Sabril (vigabatrin)	Policy #:	2376P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Sabril or vigabatrin.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Sabril or vigabatrin under the specialty pharmacy benefit when the following criteria have been met.

Other formulations of vigabatrin (such as Vigpoder or Vigadrone) are excluded from coverage because they have not been shown to offer any additional clinical value compared to the generic formulation.

Criteria

1. Criteria for Coverage for Infantile Spasms

1.1 Documented diagnosis of Infantile Spasms
1.2 Used as monotherapy in pediatric patients for whom the potential benefits outweigh the potential risk of vision loss
1.3 Age 1 month to 2 years
1.4 Coverage of branded products require documented allergic reaction to generic vigabatrin
1.5 Approval Time
- 12 months or 2 years of age (whichever comes first)

2. Criteria for Coverage of Complex Partial Seizures

2.1 Documented diagnosis of Complex Partial Seizures
2.2 Member is 16 years of age
2.3 Used as adjunctive therapy and CPS is refractory to other antiepileptic agents, such as levetiracetam, carbamazepine, zonisamide, or phenytoin
2.4 Inadequate response to at least 2 alternative treatments for CPS, such as divalproex or valproic acid
2.5 Coverage of branded products require documented allergic reaction to generic vigabatrin
2.6 Approval Time
- Initial Approval: 12 months
- Re-approval Time: 12 months, if substantial clinical benefit from treatment

CPT Codes

HCPCS Codes

References

1. Sabril (vigabatrin) [prescribing information]. Cincinnati, OH: Patheon; January 2024.

2. Glauser T, Ben-Menachem E, Bourgeois B, et al. Updated ILAE evidence review of antiepileptic drug efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes. Epilepsia 2013; 54:551.
3. 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.

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