Anticonvulsants
Sabril (vigabatrin)
Vigadrone (vigagatrin)
Effective 3/1/23

Plan	☒ MassHealth ☐ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Sabril (vigabatrin) is FDA approved for the following indications:

- Monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss.
- Adjunctive therapy for adults and pediatric patients ≥2 years of age 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.

No PA	Drugs that require PA
	Sabril® (vigabatrin) * † § Vigadrone® (vigabatrin) §

* Available as an A-rated generic, both brand and A-rated generic require a PA

† Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent

§ Excluded from MassHealth Pediatric Behavioral Health Medication Initiative restrictions.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if prescriber provides documentation that the member meets **ALL** following criteria and documentation has been submitted:

1. The member has a diagnosis of infantile spasms, epilepsy, or a seizure disorder
2. Prescriber is a neurologist or consult notes from a neurology office are provided
3. For a diagnosis of infantile spasms: member is < 2 years of age
4. For a diagnosis of epilepsy or a seizure disorder: **ALL** of the following:
    a. Member is ≥ 2 years of age
    b. Member will be using the requested agent as adjunctive therapy
    c. Paid claims or physician documented inadequate response or adverse reaction to any 2 anticonvulsants indicated for seizures (e.g., clobazam, phenobarbital, quinidine, Afinitor® [everolimus])
5. If the request is for **vigabatrin** or **Vigadrone**, the prescriber must provide medical records documenting an inadequate response, allergic response or adverse reaction to Sabril or a clinical rationale for prescribing the non-preferred generic equivalent

Off-Label Indications

Non-preferred brand name anticonvulsants with A-rated generic (no substitution):

Prescriber provides documentation of **ALL** of the following:

1. Individual drug PA criteria must be met first where applicable
2. The prescriber provides documentation of **ONE** of the following:
    a. **BOTH** of the following:
        i. Diagnosis of epilepsy/seizure disorder
        ii. Member is stable on the requested formulation per claims history
    b. **Medical records** documenting **ONE** of the following:*
        i. An allergic response or adverse reaction to the generic product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product.
        ii. An inadequate response to the generic product.

Non-preferred generic anticonvulsants (where brand name is preferred):

Prescriber provides documentation of **ALL** of the following:

1. Individual drug PA criteria must be met first where applicable within established less costly alternative trials for the individual drug
2. The prescriber provides **medical records** documenting **ONE** of the following:*^
    a. An allergic response or adverse reaction to the Brand Name product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product.
    b. An inadequate response to the Brand Name product.

* Any request for Brand Name (for which an A-rated generic is available) or non-preferred generic (for which the brand formulation is preferred) in members requiring a ketogenic diet is approvable regardless of previous trials or medical records of those trials.

^ If a prescriber documents that a specific NDC for a non-preferred generic is utilized/required, trial with the brand preferred agent can be bypassed for epilepsy/seizure disorder.

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy

Limitations

Initial approvals and reauthorizations will be granted for 12 months

References

1. Sabril (vigabatrin) [prescribing information]. Deerfield, IL: Lundbeck; February 2020.

Review History

05/19/2021: Created and Reviewed at May P&T to be in compliance with MH UPPL for 7/1/21. Effective 07/01/2021.
03/16/2022 – Reviewed and Updated for March P&T; renamed criteria Anticonvulsants to match MH UPPL; updated to no longer apply PBHMI restrictions (polypharmacy or age) to anticonvulsants used for seizure-only indications. Brand preferred removed for Sabril; vigabatrin is available both brand and generically and both require PA.
05/18/2022 – Reviewed and Updated for May P&T; matched MH UPPL. Sabril will be added back to the brand preferred over generic list. Clarified that Vigadrone and vigabatrin require previous use of Sabril. Added Appendix for ketogenic diet. Effective 7/1/22.
01/11/23 – Reviewed and updated for Jan P&T. Removed Appendix and added into criteria. Added Off Label Indications section. Effective 3/1/23.

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