Pharmacy Policy

Anticonvulsants – Unified Formulary

Policy Number: 9.230
Version Number: 1
Version Effective Date: 7/1/2021

Product Applicability

☐ **All Plan+ Products**

Well Sense Health Plan

☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan

☒ MassHealth ACO

☒ MassHealth MCO

☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct

☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:§

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

* Available as an A-rated generic, both brand and A-rated generic require a PA
† Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent
§ Use of anticonvulsants in members less than 18 years of age is discussed in the **MassHealth Pediatric Behavioral Health Medication Initiative guideline**.

Procedure:
The **MassHealth Pediatric Behavioral Health Medication Initiative** may apply to MassHealth members <18 years of age due to polypharmacy, age, and/or drug restrictions. As indicated within this guideline, please refer to the **Pediatric Behavioral Health Initiative** guideline to assess appropriateness of therapy.

Approval Diagnosis:	See Individual Approval Criteria for Diagnosis *All other indications not addressed in the guideline or appendix will be reviewed*

	on a case by case basis.

Approval Criteria:
 	
Sabril® (vigabatrin)*
 	
Infantile Spasms, Epilepsy/seizure disorder
 	
*Available as an A-rated generic, both brand and A-rated generic require PA.
 	
† Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent
	Prescriber provides documentation of **ALL** of the following:
	1. 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:
	    1. Member is ≥2 years of age
	    2. Member will be using the requested agent as adjunctive therapy*
	    3. Inadequate response or adverse reaction to any 2 anticonvulsants *(history of claims is sufficient for failed trials)*†
	
	Notes:
	• **For requests that do not clearly document use as adjunct therapy, clinical judgement may be used to consider approval based on current medication regimen and/or claims (e.g., recent paid claims for multiple antiepileptics, medical records suggesting medications will be continued). Please consider outreach to the prescriber's office prior to denial if all other criteria is met and there is a question regarding use as adjunctive therapy.*
	• *†Trials with benzodiazepines other than clobazam (e.g., clonazepam, diazepam, lorazepam) or other non-anticonvulsant agents which may be used for seizures (e.g., phenobarbital, quinidine, Afinitor® [everolimus]) may be accepted as a trial if the indication is seizures. Agents being used PRN only should not be accepted as a trial.*
	• *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*

Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	• Prior authorization may be issued for **1 year** for all anticonvulsants • If the member is <18 years of age, review using the criteria and approval duration in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline, if applicable. • Provisional prior authorization may be issued for 1 month for members who do not meet the **Pediatric Behavioral Health Medication Initiative** guideline approval criteria to avoid risk of destabilization only if the member was stabilized on the medication [e.g., medication was covered by a previous insurer or third party liability (TPL) claims]. Provisional approvals do not apply to new starts for medications that require prior authorization (e.g., drug, quantity limits, brand name). Prescriber outreach via telephone will be attempted on all provisional approvals.
Recertification Criteria:	• Requests can be recertified for **1 year** for all anticonvulsants.

Appendix:

Stability

.

Stability on a medication which requires a prior authorization for members with seizure AND/OR psychiatric diagnoses is generally sufficient to bypass approval criteria within the anticonvulsant guideline [please note additional requirements for specific agents below]. Stability on the requested medication can be determined by claims for 90 out of 120 days or as noted on the prior authorization request.

For members <18 years of age, all requests will be reviewed using the MassHealth Pediatric Behavioral Health Medication Initiative guideline, regardless of stability.

Grandfathering

Information is not applicable.

Additional Information

MassHealth Pediatric Behavioral Health Initiative

The Pediatric Behavioral Health Medication Initiative requires prior authorization for members <18 years of age for behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population. The aspects of the **MassHealth Pediatric Behavioral Health Medication Initiative** that may apply to the Anticonvulsant guideline include the following:

- Behavioral health medication polypharmacy (pharmacy claims for 4 or more behavioral health medications [i.e., $alpha_2$ agonists, antidepressants, antipsychotics, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, hypnotic agents, and mood stabilizers] filled within a 45 day period)
- Mood stabilizer polypharmacy (overlapping pharmacy claims for 3 or more mood stabilizers for ≥60 days within a 90 day period)
- Mood stabilizer pharmacy claim for pediatric members less than 6 years old (agents considered to be used only for seizure diagnoses are not included)

Anticonvulsants Approved for Seizure Indications Only (excluded from PBHMI age restrictions)
Sabril® (**vigabatrin**)

Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative guideline** to assess appropriateness of therapy when reviewing prior authorization requests for pediatric members <18 years of age.

Compelling cases - Clinical and/or Supervisor Review

If clinical review/supervisor is not available and compliance is an issue, please approve or deny based on your professional clinical judgment and forward to clinical review for follow-up. If necessary, attempt to contact the pharmacy for a 3 day emergency override.

Use of Anticonvulsants in Pregnancy

- Breastfeeding is NOT recommended on the following anticonvulsants → vigabatrin

Point of Sale (POS) Criteria

.

Criteria:

1. Claims for vigabatrin (017869, 017870) will usually process and pay at the pharmacy without a prior authorization if the member has ALL of the following: 1) diagnosis code for epilepsy/seizures, 2) paid claims in POPS for ≥90 days of therapy in the last 120 days of the requested agent.
2. Claims for vigabatrin (017869, 017870) will usually process and pay at the pharmacy without a prior authorization if the member has ALL of the following: 1) a diagnosis code for infantile spasms, 2) is < 2 years of age, 3) the prescriber is a neurologist.

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/13/2021	Created policy for MH Unified Formulary, policy date 4/8/21	7/1/2021	P&T Committee
4/22/2021	Updated policy to reflect changes from MH, age requirement for Sabril changed from 10 years to 2 years for diagnoses of epilepsy or seizure	7/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

References

.

Reference to Applicable Laws and Regulations, if Any