



MASSACHUSETTS

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Pharmacy Medical Policy **Ampyra™ (dalfampridine)**

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Policy Number: 246

BCBSA Reference Number: None

Related Policies

- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy [#621A](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Step Therapy <input type="checkbox"/> Quality Care Dosing		Pharmacy Operations: Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy last updated 7/1/2023
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	To request for coverage: Physicians may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.
Policy applies to Commercial Members: <ul style="list-style-type: none"> • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary 		Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043 Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

Please refer to the chart below for the formulary and PA status of the medications affected by this policy

Drug	Formulary Information
	Standard
	Formulary Status
Ampyra™ (dalfampridine)	PA Required
dalfampridine	PA Required

We may cover dalfampridine when **ALL** of the following criteria are met:

Initial:

- Documented diagnosis of Multiple Sclerosis, **AND**
- Documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores) attributable to slow ambulation, **AND**
- The patient has no history of seizure disorder, **AND**
- The patient does not have moderate or severe renal impairment (defined as creatinine clearance (Cl_{cr}) ≤ 50ml/min), **AND**
- Medication prescribed by neurologist, **AND**
- Must meet one of the following:
 - Before treatment patient must be able to walk 25 feet in 8-60 seconds with walking aids if needed (timed 25-Foot Walk (T25FW) test), **OR** Patient has an Expanded Disability Status Score (EDSS) of greater than or equal to 4.5 but less than 7

If approved, authorization length valid for **3 months of therapy**.

Continuation:

We may cover Ampyra™ (dalfampridine) when the above criteria is met and with previous use of dalfampridine.

- Documentation of at least 20% improvement in timed 25-Foot Walk test (timed 25-Foot Walk (T25FW) test) from baseline or improvement in EDSS scores.

If approved, authorization length valid **for additional 1 year**.

We do not cover the above drugs for other conditions not listed above.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Policy History

Date	Action
7/2023	Reformatted Policy.
11/2018	Updated to add dalfampridine to the policy.
6/2017	Updated address for Pharmacy Operations.
1/2014	Updated ExpressPAtH language and remove Blue Value.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/1/2011	New policy describing covered and non-covered indications. Effective 1/1/2011.

References

1. Ampyra™ [package insert]. Hawthorne, NY: Acorda Therapeutics, Inc.: 2010.
2. Goodman AD, Brown T, Krupp LB et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet* 2009; 373:732-8.
3. Goodman AD, Schwid S, Brown T et al. Sustained-release fampridine consistently improves walking speed and leg strength in multiple sclerosis: a phase 3 trial. *World Congress of Treatment and Research in Multiple Sclerosis, Montreal, 2008, Program, Poster session 3 – Late Breaking News, P909.*
4. Kragt JJ, van der Linden FA, Nielsen JM et al. Clinical impact of 20% worsening on timed 25-foot walk and 9-hole peg test in multiple sclerosis. *Mult Scler* 2006; 12:594-8.
5. Goodman AD, Brown TR, Cohen J, et al. Dose comparison trial of sustained-release fampridine in multiple sclerosis. *Neurology* 2008; 71:1134-41.

Endnotes

1. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meetings on 7/13/2010 and 9/14/2010

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>