



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

# 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 medication and can be found in Medical Policy #[621](#).

## 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. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>. Patients must have pharmacy benefits under their subscriber certificates.

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

| Drug    | Formulary Information |
|---------|-----------------------|
|         | Standard              |
|         | Formulary Status      |
| Ampyra™ | PA Required           |

We cover Ampyra™ (dalfampridine) when **ALL** of the following criteria are met:

Initial:

- Documented diagnosis of Multiple Sclerosis
- Documentation of significant limitations of instrumental activities of daily living (i.e. meal preparation, household chores) attributable to slow ambulation
- The patient has no history of seizure disorder
- The patient does not have moderate or severe renal impairment (defined as creatinine clearance ( $\text{Cl}_{\text{cr}}$ )  $\leq 50\text{ml/min}$ )
- Must meet one of the following:
  - 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
- Medication prescribed by neurologist

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

Continuation:

- 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  
Clinical Pharmacy Department  
One Enterprise Drive  
Quincy, MA 02171  
Tel: 1-800-366-7778  
Fax: 1-800-583-6289

## Managed Care Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.  
Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtch which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

## PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.  
Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtch which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

## Policy History

| Date           | Action   |
|----------------|--|
| 1/2014         | Updated ExpressPAtch language and remove Blue Value.   |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates.<br>No changes to policy statements. |
| 1/2012         | Reviewed - Medical Policy Group - Neurology and Neurosurgery.<br>No changes to policy statements.              |
| 1/2011         | Reviewed - Medical Policy Group - Neurology and Neurosurgery.<br>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

**Request for Outpatient Retail Pharmacy Prior Authorization****Fax to: Clinical Pharmacy Program (800) 583-6289****Phone Authorization (800)366-7778 or Web: <https://provider.express-path.com>**

We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

| <b>Patient Information (REQUIRED)</b>   |       |    |
|---|-------|----|
| Name  |       |    |
| BCBSMA ID Number  |       |    |
| Is the patient a BCBSMA employee?<br>If yes, please fax request to: (617) 246-4013  | Yes   | No |
| Date of Birth   |       |    |
| Patient's Diagnosis or ICD-9-CM code  |       |    |
| <b>Physician Information (REQUIRED)</b>   |       |    |
| Name  |       |    |
| Medical Specialty   |       |    |
| BCBSMA Provider number/NPI number   |       |    |
| Telephone Number  |       |    |
| Fax Number  |       |    |
| Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No                                |       |    |
| Contact Name (if different from physician)  |       |    |
| Please select one of the three following sections to complete, depending on the nature of your request for the above-named patient. |       |    |
| Formulary Exception Request   |       |    |
| Name of non-covered drug you want to prescribe  |       |    |
| Reason for Individual Consideration Request (please check one):   |       |    |
| <input type="checkbox"/> Treatment failure with the following covered drugs in class  |       |    |
| <input type="checkbox"/> Documented adverse reaction to the following covered drugs   |       |    |
| <input type="checkbox"/> Other clinical reason (please specify) _____   |       |    |
| <b>Quality Care Dosing Override Request</b>   |       |    |
| Drug name, strength and quantity requested:   |       |    |
| Clinical reason for override (please specify)   |       |    |
| <b>Outpatient Retail Pharmacy Prior Authorization Request</b>   |       |    |
| Drug name:  |       |    |
| Start/End date (must be one year or less):  |       |    |
| Associated Co-morbid diagnosis:   |       |    |
| MD Signature:   | Date: |    |