 <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC Pharmacy Public Pharmacy Management Drug Policies	<i>Policy Number</i>	MEDS060	
		<i>Effective Date</i>	10/01/2010	
		<i>Review Date</i>	04/19/2023	
	<i>Subject</i>	Ampyra	<i>Revision Date</i>	02/22/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: ampyra

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I. POLICY

- A. Ampyra (dalfampridine) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
 2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA


- A. Ampyra may be approved for patients meeting the following:
1. Patient is 18 years of age or older
 2. Documented diagnosis of multiple sclerosis
 3. Documentation has been submitted showing the following:
 - a. Patient is currently ambulatory, with minimal walking impairment or use of a cane, crutch, or brace
 - b. Patient has had a timed 25-foot walk test
 - c. Patient has a CrCL greater than 50 mL/min
 - d. There is no past medical history of seizures

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be restricted to 3 months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing that the patient has had an improvement in functionality, activities of daily living, and other relevant clinical measures

IV. EXCLUSIONS

- A. Ampyra will not be approved for the following:
1. Use in members currently receiving Ampyra therapy that have not demonstrated greater than or equal to a 20% improvement from baseline in timed walking speed (timed 25 foot walk);
 2. Use in members with a past medical history of seizures or seizure disorder;
 3. Use in members with moderate to severe renal impairment (CrCl < 50 mL/min);
 4. Use in members who are currently unambulatory.

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5. Any indications or uses that are not FDA-approved, or guideline-supported
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Ampyra [prescribing information]. Hawthorne, NY: Acorda Therapeutics, Inc.; November 2021.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information/dosing and sources, removed process of initiation of request
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
01/19/2022	Updated clinical criteria to reflect Ampyra's FDA approval in adults
02/22/2023	Updated authorization guidance

Review/Revision Dates: 10/1/2010, 3/1/2014, 04/20/2016, 07/27/2017, 07/01/2018, 01/19/2022, 02/22/2023