BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/15/11**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE: 11/16/17
	ARCHIVE DATE:

AMPYRA® (dalfampridine) extended release oral tablet
Dalfampridine ER oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Dalfampridine ER oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Ampyra and dalfampridine is considered ***medically necessary*** and will be approved with medical record documentation of **ALL** of the following:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of Multiple Sclerosis (MS) in a patient who is still ambulatory and has a baseline timed 25 foot walking speed of between 8-45 seconds **or** has significant limitations of instrumental activities of daily living attributable to slow ambulation

  3. Continues concurrent MS therapy
     - MS agents include:
       - Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Lemtrada, Novantrone, Ocrevus, Plegridy, Rebif, Tysabri, or Zinbryta as indicated

  4. Prescribed dosage will not be greater than 10mg twice daily

  5. The baseline Creatinine clearance (CrCl) is greater than 50 mL/min

  6. There are **NO** contraindications:
     - Contraindications include:
       - History of seizures or is at high risk for seizures
       - Moderate to severe renal impairment (CrCl ≤ to 50 mL/min)
       - Hypersensitivity to Ampyra or 4-aminopyrdine

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Ampyra and dalfampridine is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Improvement in walking speed of at least 20% over baseline
       - Remains ambulatory

  2. Individual has been adherent with the medication **and** the dose remains 10 mg every 12 hours

  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications include:
       - Seizure
       - Creatinine clearance ≤ 50 mL/min
       - Anaphylactic reaction

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4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Ampyra (dalfampridine) is indicated as a treatment to improve walking in patients with multiple sclerosis (MS). This is demonstrated by an increase in walking speed.

The mechanism by which Ampyra (dalfampridine) exerts its therapeutic effect in Multiple sclerosis (MS) has not been fully explained. Ampyra (dalfampridine) is a broad spectrum potassium channel blocker that blocks the exposed potassium channels and restores the action potential and improves neuronal conduction. In animal studies, Ampyra (dalfampridine) has been shown to increase conduction of action potentials in demyelinated axons through inhibition of potassium channels. Myelin destruction is considered a pathologic hallmark of multiple sclerosis. Demyelination exposes potassium channels, impairing the conduction and generation of action potential through the neuronal axons. As this is correlated with the appearance of clinically significant symptoms, restored conduction should enhance the quality of life for a MS patient. Ampyra does not alter the disease course and MS.

Multiple sclerosis is a chronic disease of the central nervous system (CNS) characterized by inflammation, demyelination, and axonal degeneration. Symptoms, severity, and course of MS in an individual vary and are unpredictable. Common symptoms include sensory disturbances in the limbs leading to gait and balance problems, optic nerve dysfunction and vision loss, dysphagia, bladder or bowel dysfunction, sexual dysfunction, fatigue, emotional lability, and cognitive impairment. It is estimated that 50% of untreated patients will require an assistive walking device within 15 years of disease onset.

Definitions:

Activities of daily living (ADL):

Instrumental ADL:
Prepare meals, shop for groceries or clothes, use the telephone, manage money, etc.

Self-care ADL:
Bathe, dress and undress, feed self, use the toilet, take medications, not bedridden

Resources:

Ampyra® (Dalfampridine) package insert issued January 2010 (0210427AW-1), reviewed on July 5, 2011.

Ampyra® (Dalfampridine) Managed Care Dossier February 3, 2010 (Version 1)

Ampyra® package insert revised by manufacturer 08-2012, reviewed on 11/12/2012

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Ampyra® package insert revised by manufacturer 01-2013, reviewed on 11/16/2013

Ampyra® package insert revised by manufacturer 01-2014, reviewed on 09/04/2014

Ampyra® package insert revised by manufacturer 12-2014, reviewed on 10/13/2015, 09/27/2016

Ampyra® Medication Guide

Ampyra® Risk Evaluation and Mitigation Strategy (REMS)

UpToDate: Symptom management of multiple sclerosis in adults. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/symptom-management-of-multiple-sclerosis-in-adults?source=search_result&search=multiple%20sclerosis%20symptoms&selectedTitle=2~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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