Clinical Policy Title:	dalfampridine
Policy Number:	RxA.336
Drug(s) Applied:	Ampyra®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Dalfampridine (Ampyra®) is a potassium channel blocker. It is indicated to improve walking in patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
dalfampridine (Ampyra®)	Multiple Sclerosis	10 mg twice daily (approximately 12 hours apart)	20 mg/day

Dosage Forms

- Extended-release tablets: 10 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all)**:**

1. Diagnosis of MS;
2. Prescribed by or in consultation with a neurologist;
3. Age 18 years of age or older;
4. Member has sustained walking impairment but is able to walk with or without assistance;
5. Member had inadequate response to generic dalfampridine;
6. Dose does not exceed 20 mg (2 tablets) per day.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Multiple Sclerosis (must meet all)**:**

1. Member is currently receiving dalfampridine that has been authorized by RxAdvance or the member has

met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 mg (2 tablets) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CrCl: Creatinine Clearance
FDA: Food and Drug Administration
MS: Multiple Sclerosis
OCT2: Organic Cation Transporter 2

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of seizure;
  - Moderate or severe renal impairment (CrCl ≤ 50mL/min);
  - History of hypersensitivity to Ampyra® or 4-aminopyridine.

- Boxed Warning(s):
  - None reported.

Appendix D: General Information

- Use of doses above 10 mg twice daily may increase the risk of seizures.
- Patients with mild renal impairment (CrCl 51-80 mL/min) may exhibit Ampyra® levels that approach those attained at higher doses and that have been associated with a higher risk of seizures. Ampyra® should be used with caution in this patient population, and CrCl should be estimated or known prior to initiating Ampyra® therapy.
- CrCl can be estimated using the Cockcroft-Gault formula: CrCl = [(140-age) x (weight in kg) x (0.85 if female)] / (72 x Cr).
- Concurrent use with OCT2 inhibitors, such as cimetidine, may cause increased exposure to dalfampridine and potential risk of seizures.

References

1. Ampyra® Prescribing Information. Ardsley NY: Acorda Therapeutics, Inc; February 2021. Available at http://www.ampyra.com. Accessed May 28, 2021.
2. Samkoff LM, Goodman AD. Symptomatic management in multiple sclerosis. Neurol Clin. 2011; 29: 449-463.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed:	07/10/2020	09/14/2020

1) Policy title table was updated 2) Dosing information updated 3) Continued Therapy criteria II.A.1. was was rephrased to “Member is currently receiving dalfampridine that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy” 4) Length of duration for initial therapy and continued therapy approval was updated 5) References were updated		
Policy was reviewed: 1) Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2) Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 3) Initial approval criteria I.A.5 was updated to add,”Member had...dalfampridine.” 4) Appendix A was updated to include abbreviation OCT2. 5) Appendix D was updated to include “ Concurrent use with OCT2 inhibitors, such as cimetidine …” 6) References were reviewed and updated	5/28/2021	09/14/2021