



Ampyra® (dalfampridine ER)
Effective April 17, 2019

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Ampyra® (dalfampridine ER) is a potassium channel blocker indicated to improve walking in adult patients with multiple sclerosis (MS).

Coverage Guidelines

Authorization may be granted for members with multiple sclerosis (MS) when ALL the following criteria are met, and documentation is provided:

1. Member is ≥18 years of age.
2. The prescribing physician is a neurologist or MS specialist.
3. Member has a baseline Timed 25-foot Walk test (T25ftWT) with a time range of 8 to 45 seconds.
 - a. Note: walking aids are acceptable; however, non-ambulatory patients will not be eligible for approval.

All other indications will be evaluated on a case-by case basis, including requests for members < 18 years of age. In addition, new members to the plan lacking the above parameters will be reviewed on a case-by-case basis by AllWays Health Partners directly.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member’s condition with the following parameters:

1. Stable walking speed without worsening of ambulation
2. At least a 20% improvement in the T25ftWT from baseline

Limitations

1. Initial approvals will be for 3 months.

2. Reauthorizations will be for 12 months.
3. The following quantity limits apply:
 - a. A quantity limit of 60 tablets per 30 days
 - b. A maximum of 30-day supply per fill

Appendix

Recommended Dosing	
Adult Dose	Pediatric Dose
<p>Walking improvement in MS: Extended-release oral tablet: 10 mg BID, taken approximately 12 hours apart, with or without food.</p> <p>Note: 10 mg BID is the maximum recommended dose.</p> <p>No additional benefit has been demonstrated at higher doses; however adverse events are increased at higher doses.</p>	<p>Safety and efficacy in patients under the age of 18 have not been established.</p>

References

1. Ampyra (dalfampridine) [prescribing information]. Ardsley, NY: Acorda Therapeutics Inc; September 2017
2. Acorda therapeutics announces availability of Ampyra™ (dalfampridine) [press release on the Internet]. Hawthorne (NY): Acorda Therapeutics; 2010 Mar 1. Available from: <http://phoenix.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-newsArticle&ID=1396678&highlight=>
3. Acorda therapeutics announces FDA approval of Ampyra™ (dalfampridine) to improve walking in people with multiple sclerosis – demonstrated by increases in walking speed) [press release on the Internet]. Hawthorne (NY): Acorda Therapeutics; 2010 Jan 22. Available from: <http://phoenix.corporate-ir.net/phoenix.zhtml?c=194451&p=irol-newsArticle&ID=1378105&highlight=>
4. Goodin DS, Frohman EM, Garmany GP, Halper J, Likosky WH, Lublin FD, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American academy of neurology and the MS council for clinical practice guidelines. *Neurology* 2002;58:169-178.
5. Oh J, O'Connor PW. Safety, tolerability and efficacy of oral therapies for relapsing-remitting multiple sclerosis. *CNS Drugs*. 2013;27:591-609.
6. Hobart J, Blight AR, Goodman A, Lynn F, Putzki N. Timed 25-foot walk: direct evidence that improving 20% or greater is clinically meaningful in MS. *Neurology*. 2013;80(16):1509-17.
7. Birnbaum G, Iverson J. Dalfampridine may activate latent trigeminal neuralgia in patients with multiple sclerosis. *Neurology*. 2014;83(18):1610-2.
8. Ruck T, Bittner S, Simon OJ, Gobel K, Wiendl H, Schilling M, et al. Long-term effects of dalfampridine in patients with multiple sclerosis. *Journal of the Neurological Sciences*. 2014;337(1-2):18-24.

Review History

04/25/11 – Reviewed
 06/06/11 – Effective
 04/23/12 – Reviewed
 04/22/13 – Reviewed
 04/28/14 – Reviewed



04/27/15 – Reviewed

04/25/16 – Reviewed

04/24/17 – Reviewed

04/17/19 – Reviewed in P&T Meeting

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.