



**Dalfampridine ER (Ampyra)**  
Effective 08/01/20

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

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 who are currently receiving treatment with dalfampridine ER, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

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 ONE of 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:

Dalfampridine ER 10mg	60 tablets per 30 day
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### Appendix

Recommended Dosing	
Adult Dose	Pediatric Dose
<p><b>Walking improvement in MS:</b>            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; December 2019
2. Lugaesi A. Pharmacology and clinical efficacy of dalfampridine for treating multiple sclerosis. Expert Opin Drug Metab Toxicol 2015; 11:295
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

- 04/25/2011 – Reviewed
- 06/06/2011 – Effective
- 04/23/2012 – Reviewed
- 04/22/2013 – Reviewed
- 04/28/2014 – Reviewed
- 04/27/2015 – Reviewed
- 04/25/2016 – Reviewed
- 04/24/2017 – Reviewed



04/17/2019 – Reviewed in P&T Meeting

05/20/2020 – Reviewed May P&T Mtg; updated references, added started/stabilized statement; QL added to 'Limitations'. Effective 8/1/20.

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