Mass General Brigham
Health Plan

Dalfampridine ER (Ampyra)
Effective 08/01/2020

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	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 the plan directly.

<u>Continuation of Therapy</u>
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

Appendix

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

References

1. Ampyra (dalfampridine) [prescribing information]. Ardsley, NY: Acorda Therapeutics Inc; December 2019
2. Lugaresi 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.
07/21/2021- Reviewed July P&T; no clinical changes.