Original Effective Date: 04/01/2011
Current Effective Date: 07/17/2025
Last P&T Approval/Version: 04/30/2025
Next Review Due By: 04/2026
Policy Number: C6480-A

Ampyra (dalfampridine)

PRODUCTS AFFECTED

Ampyra (dalfampridine), dalfampridine

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Multiple Sclerosis (MS)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. MULTIPLE SCLEROSIS:
1. Documented diagnosis of multiple sclerosis (MS)
   AND
2. Documentation that member is ambulatory

AND

3. Documentation of baseline timed 25-foot walk test (T25FW) or another objective measure of gait that provides evidence of significant walking impairment related to multiple sclerosis within the past 60 days [DOCUMENTATION REQUIRED]
   NOTE: Mobility testing is required for continued coverage. The same test should be performed before and after therapy and show improvement.
   AND
4. Documentation member is receiving concurrent therapy with a disease modifying agent for MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, glatiramer, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Plegridy, Ponvory, Ocrevus, Rebif, Tecfidera, Tysabri, Vumerity, or Zeposia)
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Ampyra (dalfampridine) include: History of seizures or a seizure disorder; History of hypersensitivity to dalfampridine, 4-aminopyridine, or other aminopyridine hypersensitivity, including a history of angioedema to the drug; concomitant use of dalfampridine with other forms of 4- aminopyridine (4-AP, fampridine), moderate or severe renal impairment (CrCl less than or equal to 50 mL/min).]
   AND
6. IF REQUEST IS FOR BRAND PRODUCT WITH GENERIC PREFERRED/FORMULARY (unless otherwise specified per applicable state regulations): Documentation the member has failed a trial of the respective generic product and/or the member cannot take the respective generic product due to a formulation difference in the active ingredient or due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives between the brand and the generic product which would result in a significant allergy or serious adverse reaction per the prescribing physician] [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. MULTIPLE SCLEROSIS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documentation of improvement in timed walking speed as documented by the T25FW (timed 25-foot walk) or another objective measure of gait from pre-treatment baseline [DOCUMENTATION REQUIRED]
   AND
3. Documentation member continues to receive concurrent therapy with a disease modifying agent for MS (e.g., Aubagio, Avonex, Bafiertam, Betaseron, Briumvi, glatiramer, Extavia, Gilenya, Glatopa, Kesimpta, Lemtrada, Mavenclad, Mayzent, Plegridy, Ponvory, Ocrevus, Rebif, Tecfidera, Tysabri, Vumerity, or Zeposia)
   AND
4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a neurologist or multiple sclerosis specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

QUANTITY:
Maximum daily dose 20mg

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Multiple Sclerosis Agents- Potassium Channel Blockers

FDA-APPROVED USES:
Indicated to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.
This drug is not indicated to decrease relapse rate or prevent the accumulation of disability.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Appendix 1:
Objective measure of gait:
The timed 25-foot walk (**T25FW**) is a rating scale that assesses mobility based on time and degree of assistance required when walking 25 feet as quickly as possible but safely.

The Expanded Disability Status Scale (EDSS) is a standard neurological examination that rates the seven functional systems plus "other". These ratings are then used with observations and information on gait and use of assistive devices to rate the EDSS. The EDSS score ranges from 0 (normal neurological examination) to 10 (death) in half-point increments.
Kurtzke Expanded Disability Status Scale (EDSS)
0.0 – Normal neurological exam (all grade 0 in all Functional System (FS) scores*).
1.0 – No disability, minimal signs in one FS* (i.e., grade 1).
1.5 – No disability, minimal signs in more than one FS* (more than 1 FS grade 1).
2.0 – Minimal disability in one FS (one FS grade 2, others 0 or 1).
2.5 – Minimal disability in two FS (two FS grade 2, others 0 or 1).
3.0 – Moderate disability in one FS (one FS grade 3, others 0 or 1) or mild disability in three or four FS (three or four FS grade 2, others 0 or 1) though fully ambulatory.
3.5 – Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3 (others 0 or 1) or five grade 2 (others 0 or 1).
4.0 – Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combination of lesser grades exceeding

limits of previous steps; able to walk without aid or rest some 500 meters.
4.5 – Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability usually consisting of one FS grade 4 (others or 1) or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 300 meters.
5.0 – Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work a full day without special provisions); (Usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades usually exceeding specifications for step 4.0).
5.5 – Ambulatory without aid for about 100 meters; disability severe enough to preclude full daily activities; (Usual FS equivalents are one grade 5 alone, others 0 or 1; or combination of lesser grades usually exceeding those for step 4.0).
6.0 – Intermittent or unilateral constant assistance (cane, crutch, brace) required to walk about 100 meters with or without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).
6.5 – Constant bilateral assistance (canes, crutches, braces) required to walk about 20 meters without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).
7.0 – Unable to walk beyond approximately 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day; (Usual FS equivalents are combinations with more than one FS grade 4+; very rarely pyramidal grade 5 alone).
7.5 – Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; May require motorized wheelchair; (Usual FS equivalents are combinations with more than one FS grade 4+).
8.0 – Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms; (Usual FS equivalents are combinations, generally grade 4+ in several systems).
8.5 – Essentially restricted to bed much of day; has some effective use of arm(s); retains some self-care functions; (Usual FS equivalents are combinations, generally 4+ in several systems).
9.0 – Helpless bed patient; can communicate and eat; (Usual FS equivalents are combinations, mostly grade 4+).
9.5 – Totally helpless bed patient; unable to communicate effectively or eat/swallow; (Usual FS equivalents are combinations, almost all grade 4+).
10.0 – Death due to MS.
*Excludes cerebral function grade 1.
Note 1: EDSS steps 1.0 to 4.5 refer to patients who are fully ambulatory and the precise step number is defined by the Functional System score(s). EDSS steps 5.0 to 9.5 are defined by the impairment to ambulation and usual equivalents in Functional Systems scores are provided.
Note 2: EDSS should not change by 1.0 step unless there is a change in the same direction of at least one step in at least one FS.

Other spatiotemporal and kinetic measures of gait:
Speed, knee flexion during swing phase, ankle dorsiflexion during contact and swing period, stride length, pelvic tilt, hip extension, stance period, step time, step width

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Ampyra (dalfampridine) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Ampyra (dalfampridine) include: History of seizures or a seizure disorder; History of hypersensitivity to dalfampridine, 4-aminopyridine, or other aminopyridine hypersensitivity, including a history of angioedema to the drug; concomitant use of dalfampridine with other forms of 4-aminopyridine (4-AP, fampridine), moderate or severe renal impairment (CrCl less than or equal to 50 mL/min).

Exclusions/Discontinuation:
Do not prescribe or use dalfampridine with Firdapse (amifampridine phosphate) due to duplicative effects and an increased risk for serious side effects, such as seizures, since both drugs are aminopyridine class potassium channel blockers.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Ampyra TB12 10MG
Dalfampridine ER TB12 10MG

REFERENCES

1. Ampyra (dalfampridine) **extended-release tablets, for oral use** [prescribing information]. Ardsley, NY: Acorda Therapeutics, Inc; June 2022.
2. Brown TR, Simnad VI. A Randomized Crossover Trial of Dalfampridine Extended Release for Effect on Ambulatory Activity in People with Multiple Sclerosis. Int J MS Care. 2016 Jul- Aug;18(4):170-6.
3. Guo A, Grabner M, Palli SR et al. Treatment patterns and health care resource utilization associated with dalfampridine extended release in multiple sclerosis: a retrospective claims database analysis. Clinicoecon Outcomes Res. 2016 May 12;8:177- 86
4. National Multiple Sclerosis Society. 2022. Functional Systems Scores (FSS) and Expanded Disability Status Scale (EDSS). [online] Available at: <https://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-MS-Researchers/Research-Tools/Clinical-Study-Measures/Functional-Systems-Scores-(FSS)-and-Expanded-Disab> [Accessed 1 April 2022].
5. Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). Neurology. 1983 Nov;33(11):1444-52.
6. Haber A, LaRocca NG. eds. Minimal Record of Disability for multiple sclerosis. New York: National Multiple Sclerosis Society; 1985.

7. Motl, R. W., Cohen, J. A., Benedict, R., Phillips, G., LaRocca, N., Hudson, L. D., & Rudick, R. (2017). Validity of the timed 25-foot walk as an ambulatory performance outcome measure for multiple sclerosis. Multiple Sclerosis Journal, 23(5), 704–710. https://doi.org/10.1177/1352458517690823
8. Coca-Tapia, M., Cuesta-Gómez, A., Molina-Rueda, F., & Carratalá-Tejada, M. (2021). Gait Pattern in People with Multiple Sclerosis: A Systematic Review. Diagnostics, 11(4), 584. https://doi.org/10.3390/diagnostics11040584

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Appendix Contraindications/Exclusions/Discontinuation References	Q2 2025
REVISION- Notable revisions: Require Medical Information Continuation of Therapy Duration of Approval Quantity Appendix References	Q2 2024
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Quantity Contraindications/Exclusions/ Discontinuation References	Q2 2023
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Appendix Contraindications Available Dosage Forms References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file