PRIOR AUTHORIZATION POLICY

POLICY: Multiple Sclerosis – Dalfampridine Prior Authorization Policy
- Ampyra® (dalfampridine extended-release tablets – Acorda, generic)

REVIEW DATE: 11/08/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Dalfampridine, a potassium channel blocker, is indicated to improve walking in adults with **multiple sclerosis**.[1] This was demonstrated by an increase in walking speed.

Safety

Dalfampridine is contraindicated in patients with a history of seizures; moderate or severe renal impairment (estimated creatinine clearance ≤ 50 mL/min); and in those with a history of hypersensitivity to dalfampridine or 4-aminopyridine.[1]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of dalfampridine. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with dalfampridine as well as the monitoring required for adverse events and long-term efficacy, approval requires dalfampridine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Ampyra® (dalfampridine extended-release tablets (Acorda, generic) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

1. **Multiple Sclerosis (MS).** Approve for the duration noted below if the patient meets one of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 4 months if the patient meets all of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient is ambulatory; AND
     - **iii.** Dalfampridine is being used to improve or maintain mobility; AND
     - **iv.** Patient has impaired ambulation as evaluated by an objective measure; AND
       Note: Examples of objective measures of ambulation include the Timed 25-Foot Walk and Multiple Sclerosis Walking Scale-12.
     - **v.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; OR
   - **B)** Patient Currently Receiving Dalfampridine. Approve for 1 year of the patient meets all of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient is ambulatory; AND
     - **iii.** Dalfampridine is being used to improve or maintain mobility; AND
     - **iv.** Medication is prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis; AND
     - **v.** According to the prescriber the patient has experienced an improvement or maintenance in walking speed or other objective measures related to ambulation.
       Note: Examples of objective measures of ambulation include the Timed 25-Foot Walk and Multiple Sclerosis Walking Scale-12.

CONDITIONS NOT COVERED

Ampyra® (dalfampridine extended-release tablets (Acorda, generic) is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ampyra® extended-release tablets [prescribing information]. Pearl River, NY: Acorda; June 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	10/26/2022
Annual Revision	No criteria change.	11/08/2023