Ampyra™ (dalfampridine) Prior Authorization with Quantity Limit

OBJECTIVE
The intent of the Ampyra (dalfampridine) Prior Authorization (PA) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies and according to dosing recommended in product labeling. The PA program will consider Ampyra appropriate for patients with multiple sclerosis who are treated by, or whose prescribers have consulted with a specialist in the area of the patients’ diagnoses, who have documented significant limitations attributable to slow ambulation, who are receiving a disease modifying agent if indicated, who are ambulatory, and who do not have any FDA labeled contraindications to therapy. The criteria will also allow for a patient who has any FDA approved diagnosis that is not already addressed in the criteria set and who has no contraindications to therapy. The dosing requested for initial therapy for all approvable indications must be at or below the program limit unless it is below the FDA labeled limit and cannot be dose optimized. Renewal criteria include documentation of stabilization or improvement of the baseline walking speed or baseline EDSS score. The renewal dose of Ampyra will have the same restrictions as initial criteria.

TARGET DRUGS AND PROGRAM QUANTITY LIMIT

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity Per Day Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampyra (dalfampridine)</td>
<td>62406030007420</td>
<td>M, N, O, or Y</td>
<td>2 tablets</td>
</tr>
</tbody>
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PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL
Ampyra will be approved when ALL of the following are met:

1. ONE of the following:
   a. ALL of the following
      i. The patient has a diagnosis of multiple sclerosis (MS) **AND**
      ii. If the patient has relapsing form of MS, ONE of the following:
         1. The patient is receiving concurrent therapy with a disease modifying agent [e.g. Aubagio, Avonex(IM), Betaseron, Copaxone, Extavia, Gilenya, Glatopa, Lemtrada (IV), Novantrone, Plegridy, Rebif, Tecfidera, or Tysabri (IV)] **OR**
         2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a disease modifying agent
iii. The prescriber is a specialist in the area of the patient’s diagnosis (e.g. neurologist) or has consulted with a specialist in the area of the patient’s diagnosis

iv. There is documentation of significant limitations attributable to slow ambulation

v. BOTH of the following:
   1. The patient is ambulatory
   2. The prescriber has documented the patient’s baseline timed 25 foot walk and EDSS score

OR
b. The patient has another FDA approved diagnosis

2. The patient does not have any FDA labeled contraindications to therapy with the requested agent

AND
3. One of the following:
   a. The requested quantity (dose) is less than or equal to the program quantity limit
   OR
   b. All of the following
      i. The requested quantity (dose) is above the set limit
      AND
      ii. The requested quantity (dose) requested is at or below the FDA labeled dose
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

Length of Approval: 6 months for MS and 12 months for another FDA approved diagnosis

Renewal Criteria
1. The patient has been previously approved for therapy through Prime Therapeutics Prior Authorization Review process

AND
2. If the patient has the diagnosis of multiple sclerosis, then the patient has demonstrated a stabilization or improvement from baseline in timed walking speed (timed 25 foot walk) or EDSS score

AND
3. The patient does not have any FDA labeled contraindications to therapy with the requested agent

AND
4. ONE of the following:
   a. The requested quantity (dose) is less than or equal to the program quantity limit
   OR
   b. All of the following
i. The requested quantity (dose) is above the set limit
   AND
ii. The requested quantity (dose) requested is at or below the FDA labeled dose
   AND
iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the limit

**Length of Approval:** 12 months

<table>
<thead>
<tr>
<th>Agent</th>
<th>Contraindication(s)</th>
</tr>
</thead>
</table>
| **Ampyra** (dalfampridine) | • History of seizures  
|                    | • Moderate to severe renal impairment (CrCl < 50 mL/min [not an eGFR with this value])  
|                    | • hypersensitivity to dalfampridine or 4-aminopyridine                     |