



# AmeriHealth.

**Policy Title** Dalfampridine (Ampyra™)

**Policy Number** FS.CLIN.98

**Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.**

**This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.**

**Members are advised to use participating pharmacies in order to receive the highest level of benefits.**

<b>Policy</b>	<p><b>Dalfampridine (Ampyra™)</b> is indicated for treatment to improve walking in patients with multiple sclerosis (MS).</p> <p>The use of Dalfampridine (Ampyra™) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).</p>
<b>Policy description</b>	<p><b>Dalfampridine's (Ampyra™)</b> formerly known as fampridine is a broad spectrum potassium channel blocker. This blocking ability may improve the conduction of nerve signals in nerve fibers whose insulating myelin coating has been damaged by Multiple Sclerosis.</p>
<b>Policy guideline inclusion</b>	<p><u>Initial Criteria (Approval for 6 months)</u> <b>Dalfampridine (Ampyra™)</b> is approved when <b>all</b> of the following inclusion criteria are met:</p> <ul style="list-style-type: none"><li>• Documentation of diagnosis of Multiple Sclerosis</li><li>• Documentation of contraindication or failure or concurrent therapy with at least <b>one</b> of the following medications:<ul style="list-style-type: none"><li>○ Avonex (interferon beta-1a)</li><li>○ Betaseron (interferon beta-1b)</li><li>○ Copaxone (glatiramer acetate)</li><li>○ Extavia (interferon beta-1b)</li><li>○ Novantrone (mitoxantrone)</li><li>○ Rebif (interferon beta-1a)</li><li>○ Tysabri (natalizumab)</li><li>○ Gilenia (fingolimod)</li></ul></li></ul> <p><u>Reauthorization Criteria (indefinite):</u> <b>Dalfampridine (Ampyra™)</b> is approved when the following inclusion criterion is found: Documentation of a 20% improvement in walking speed</p>

	<p><u>Quantity limit Criteria</u>  <b>Dalfampridine (Ampyra™)</b> is approved in quantities greater than 60 tablets per 30 days when the following inclusion criterion is met:  Documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the requested dose</p>				
<p><b>Policy guideline exclusion</b></p>	<p><u>Initial Criteria (Approval for 6 months)</u>  <b>Dalfampridine (Ampyra™)</b> is denied when <b>any</b> of the following exclusion criteria are found:</p> <ul style="list-style-type: none"> <li>• No documentation of diagnosis of Multiple Sclerosis</li> <li>• No documentation of contraindication or failure or concurrent therapy with at least <b>one</b> of the following medications: <ul style="list-style-type: none"> <li>○ Avonex (interferon beta-1a)</li> <li>○ Betaseron (interferon beta-1b)</li> <li>○ Copaxone (glatiramer acetate)</li> <li>○ Extavia (interferon beta-1b)</li> <li>○ Novantrone (mitoxantrone)</li> <li>○ Rebif (interferon beta-1a)</li> <li>○ Tysabri (natalizumab)</li> <li>○ Gilenia (fingolimod)</li> </ul> </li> </ul> <p><u>Reauthorization Criteria:</u></p> <p><b>Dalfampridine (Ampyra™)</b> is denied when the following exclusion criterion is found:  No documentation of a 20% improvement in walking speed</p> <p><u>Quantity limit Criteria</u>  <b>Dalfampridine (Ampyra™)</b> is denied in quantities greater than 60 tablets per 30 days when the following exclusion criterion is found:  No documentation of a randomized</p>				
<p><b>Policy List of Applicable Drugs</b></p>	<table border="1"> <thead> <tr> <th data-bbox="500 1157 734 1192">Brand Name</th> <th data-bbox="734 1157 1084 1192">Generic Name</th> </tr> </thead> <tbody> <tr> <td data-bbox="500 1192 734 1228">Ampyra</td> <td data-bbox="734 1192 1084 1228">Dalfampridine</td> </tr> </tbody> </table>	Brand Name	Generic Name	Ampyra	Dalfampridine
Brand Name	Generic Name				
Ampyra	Dalfampridine				
<p><b>Dosing and administration</b></p>	<p>Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.</p>				
<p><b>Policy references</b></p>	<p>Ampyra™ (Dalfampridine) [package insert]. Hawthorne, NY: Acorda Pharmaceuticals; January 2010.</p> <p>Dalfampridine (Ampyra™). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed September 10, 2010.</p> <p>Dalfampridine (Ampyra™). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed September 10, 2010.</p> <p>Goodman AD, Brown TR, et al: Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. Lancet. 2009 Feb 28; 373(9665):732-8.</p>				
<p><b>Policy link to related policies</b></p>					
<p><b>Version effective date</b></p>	<p>October 1, 2011</p>				

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