

Dalfampridine

Goal(s):

- To ensure appropriate drug use and limit to patient populations in which the drug has been shown to be effective and safe.

Length of Authorization:

- Up to 12 months

Requires PA:

- Dalfampridine

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Does the patient have a diagnosis of Multiple Sclerosis?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the medication being prescribed by or in consultation with a neurologist?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Is the request for continuation of therapy previously approved by the FFS program (patient has completed 2-month trial)?	Yes: Go to Renewal Criteria	No: Go to #5
5. Does the patient have a history of seizures?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #6
6. Is a documented estimated glomerular filtration rate (eGFR) showing the product is not contraindicated? Note: Dalfampridine is contraindicated in patients with moderate or severe renal impairment (CrCl ≤ 50 mL/min)	Yes: Go to # 7	No: Pass to RPh. Deny; medical appropriateness
7. Is the patient ambulatory with a walking disability requiring use of a walking aid OR; have moderate ambulatory dysfunction and does not require a walking aid AND able to complete the baseline timed 25-foot walk test between 8 and 45 seconds?	Yes: Approve initial fill for 2-month trial.	No: Pass to RPh. Deny; medical appropriateness

Renewal Criteria

1. Has the patient been taking dalfampridine for ≥ 2 months with documented improvement in walking speed while on dalfampridine ($\geq 20\%$ improvement in timed 25-foot walk test)?

Yes: Approve for 12 months

No: Pass to RPh. Deny; medical appropriateness

Clinical Notes:

- Because fewer than 50% of MS patients respond to therapy and therapy has risks, a trial of therapy should be used prior to beginning ongoing therapy.
- The patient should be evaluated prior to therapy and then 4 weeks to determine whether objective improvements which justify continued therapy are present (i.e. at least a 20% improvement from baseline in timed walking speed).
- Dalfampridine is contraindicated in patients with moderate to severe renal impairment.
- Dalfampridine can increase the risk of seizures; caution should be exercised when using concomitant drug therapies known to lower the seizure threshold.

P&T Review: 10/22 (DM); 6/21 (DM); 8/20 (DM); 6/20; 11/17; 5/16; 3/12
Implementation: 1/1/23, 8/16, 9/1/13