

Amifampridine

Goal(s):

- Promote safe and effective use of amifampridine in the treatment of LEMS symptoms

Length of Authorization:

- Initial: 14 days
- Renewal: 1 to 3 months

Requires PA:

- Amifampridine

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/

Table 1: Maximum Recommended Dose

Formulation	Minimum age (years)	Weight (kg)	Single Dose Maximum	Cumulative Daily Maximum
Ruzurgi®	≥ 6	< 45	15 mg	50 mg
		≥ 45	30 mg	100 mg
Firdapse®	≥ 6	< 45	15 mg	40 mg
		≥ 45	20 mg	80 mg

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for continuation of therapy previously approved by the FFS program?	Yes: Go to Renewal Criteria	No: Go to #3
3. Is the diagnosis for Lambert-Eaton Myasthenic Syndrome (LEMS)?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Is the request for a non-preferred product and will the prescriber consider a change to a preferred product? Message: <ul style="list-style-type: none"> • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics Committee. 	Yes: Inform prescriber of preferred alternatives.	No: Go to #5

Approval Criteria		
5. Is the medication being prescribed by or in consultation with a neurologist?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Is there evidence based on chart notes or claims that the patient has a seizure disorder diagnosis or history of seizures?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #7
7. Is there evidence based on chart notes or claims that the patient has active brain metastases?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #8
8. Does the patient have a documented baseline ECG in the past 12 months demonstrating a QT interval < 450 milliseconds?	Yes: Go to #9	No: Pass to RPh. Deny; medical appropriateness
9. Is the amifampridine dose within the appropriate limits? (See Table 1 in criteria)	Yes: Go to #10	No: Pass to RPh. Deny; medical appropriateness
10. Has the patient been assessed with a baseline quantitative myasthenia gravis (QMG) exam (score>5), 3TUG walking test, or other validated measure of LEMS patient physical functioning?	Yes: Go to #11 Document baseline results.	No: Pass to RPh. Deny; medical appropriateness
11. Does the patient have follow-up appointments scheduled during weeks 1 and 2 after the proposed therapy initiation date?	Yes: Go to #12 Document appointment dates.	No: Pass to RPh. Deny; medical appropriateness
12. Will the patient and provider comply with all case management interventions and adherence monitoring requirements required by the Oregon Health Authority?	Yes: Approve for 2 weeks	No: Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the patient been taking amifampridine for ≥1 week AND has there been documented improvement from baseline in ambulation or physical functioning as assessed via the 3TUG, QMG score, or other validated LEMS assessment scale?	Yes: Document follow-up assessment scores Go to #2	No: Pass to RPh. Deny; medical appropriateness

Renewal Criteria

2. Is the amifampridine dose within appropriate limits? (See Table 1 in criteria)	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Has the patient experienced any new adverse effects since starting amifampridine therapy (e.g. seizures, arrhythmias)?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #4
4. Does the patient have documented evidence of >90% adherence to amifampridine for the previous approval period?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Has the patient been on >30 days of continuous amifampridine therapy?	Yes: Approve for 3 months	No: Approve for 30 days; Renewal consideration will require documentation of tolerance, clinical benefit, and adherence.

P&T/DUR Review: 11/19 (DE)
Implementation: 1/1/2019