Edaravone (Radicava™)

Goal(s):

- To encourage use of riluzole which has demonstrated mortality benefits.
- To ensure appropriate use of edaravone in populations with clinically definite or probable amytrophic lateral sclerosis
- To monitor for clinical response for appropriate continuation of therapy

Length of Authorization:

Up to 12 months

Requires PA:

- Edavarone (pharmacy and physician administered claims)

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. Is the request for continuation of therapy of previously approved FFS criteria (after which patient has completed 6-month trial)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is this a treatment for amyotrophic lateral sclerosis (ALS)?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the diagnosis funded by OHP?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; not funded by the OHP.
5. Is the patient currently on riluzole therapy, OR have a documented contraindication or intolerance to riluzole?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the medication being prescribed by or in consultation with a neurologist?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. Go to #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Is there a baseline documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with ≥2 points in each of the 12 items?	**Yes:** Record baseline score. (0 [worst] to 48 [best]) Approve for 6 months based on FDA-approved dosing.*	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the medication being prescribed by or in consultation with a neurologist?	**Yes**: Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Has the prescriber provided documentation that the use of Radicava (edarvone) has slowed in the decline of functional abilities as assessed by a Revised ALS Functional Rating Scale (ALSFRS-R) with no decline more than expected given the natural disease progression (5 points from baseline over 6 months)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness Use clinical judgment to approve for 1 month to allow time for appeal. MESSAGE: "Although the request has been denied for long-term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal."
3. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is there a documentation of the revised ALS Functional Rating Scale (ALSFRS-R) score with ≥2 points in each of the 12 items?	**Yes:** Record score. (0 [worst] to 48 [best]) Approve for 12 months.	**No:** Pass to RPh. Deny; medical appropriateness

* = see below for summary of FDA-approved dosage and administration. Consult FDA website for prescribing information details at www.fda.gov

***Dosage and Administration:**

60 mg (two consecutive 30 mg infusion bags) IV infusion over 60 minutes

- Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period
- Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free period