Edaravone (Radicava® or Radicava ORS®)

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 amyotrophic lateral sclerosis
- To monitor for clinical response for appropriate continuation of therapy.

Length of Authorization:

- Up to 12 months

Requires PA:

- Edaravone (pharmacy and provider 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 the diagnosis a FDA approved indication?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the patient currently on riluzole therapy, OR have a documented contraindication or intolerance to riluzole?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness
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. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. _____ Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. 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 (**Table 1**)	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Has the prescriber provided documentation that the use of edaravone 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 #2	**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."
2. Does the patient have documented percent-predicted forced vital capacity (%FVC) ≥ 80%?	**Yes:** Record lab result. Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. 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

Table 1. FDA Approved Dosing. (Consult FDA website for prescribing information details at www.fda.gov)

Edaravone (RADICAVA) intravenous solution	Edaravone (RADICAVA ORS) oral suspension
60 mg (two consecutive 30 mg infusion bags) IV infusion over 60 minutes	105 mg (5mL) taking orally or via feeding tube in the morning after overnight fasting. Food should not be consumed for 1 hour after administration except water.
• 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	