Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

Edaravone (Radicava IV or ORS)

Notes:

- Quantity Limits: Yes
- IV = intravenous
- ORS = oral suspension
- ALSFRS-R = Amyotrophic Lateral Sclerosis Function Rating Scale Revised

Non-formulary **edaravone** (**Radicava IV or ORS**) requires a clinical review before being ordered. Appropriateness will be based on the following criteria:

<u>Initiation (new start) criteria</u>: Non-formulary edaravone (Radicava IV or ORS) will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Prescribed by neurologist with expertise/interest in diagnosing/treating patients with amyotrophic lateral sclerosis (ALS)
- ALSFRS-R score of 2 points or better on all 12 items within 2 months prior to treatment
- ALSFRS-R score of 4 points for dyspnea, orthopnea, and respiratory insufficiency within 2 months prior to treatment
- Definite or probable ALS with duration of 2 years or less from symptom onset
- Forced vital capacity (FVC) of 80% or higher within 2 months prior to treatment
- Current riluzole use or intolerance/contraindication to use
- For IV use only: Patient willing/able to have a tunneled catheter long-term

<u>Criteria for new members entering Kaiser Permanente already taking the</u> <u>medication who have not been reviewed previously</u>: Non-formulary edaravone (Radicava IV or ORS) will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- FVC greater than 50%
- If using BiPAP for breathing support, using 12 hours per day or less
- Patient does NOT have a tracheotomy

<u>Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication</u>: Non-formulary edaravone (Radicava IV or ORS) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

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- Prescribed by neurologist with expertise/interest in diagnosing/treating patients with ALS
- FVC greater than 50%
- If using BiPAP for breathing support, using 12 hours per day or less
- Patient does not have a tracheotomy
- Patient is not currently enrolled in hospice care

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