If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization:

1. Member has documentation of disease stability or clinical benefit from therapy, such as improved ALS functional rating scale score or no rapid disease progression while on therapy; AND
2. Member does not require invasive ventilation.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Appendix:

Diagnostic Criteria for ALS.

Diagnosis	El Escorial Revised Airlie House Criteria
Definite ALS	UMN (clinical exam) and LMN (clinical, electrophysiological or neuropathological exam) signs: • Bulbar region and > two spinal regions OR • Three spinal regions
Probable ALS	UMN and LMN signs in > two regions and UMN signs rostral to LMN signs
Probable ALS – laboratory-supported	• UMN + LMN signs in one region OR • UMN signs alone in one region and LMN signs via electrophysiological criteria of LMN loss > two regions
Possible ALS	• UMN and LMN signs in one region OR • UMN signs alone in > two regions OR • LMN rostral to UMN and unable to prove clinically probably ALS

UMN – Upper motor neuron; LMN – Lower motor neuron.

CareSource considers Radicava (edaravone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/16/2017	New policy for Radicava created.
09/15/2017	Disease duration and percent-predicted forced vital capacity (%FVC) requirements were removed. ALSFRS-R score requirement was modified.
08/23/2022	Annual Review. Transferred to new format. Added J code Added new oral formulation dosing. Clarified reauthorization criteria. Added neurology specialty prescriber. Added age requirement. Reduced initial authorization duration to 6 months. Removed exclusion criteria. Removed daily function requirement and clarified ALSFRS-R criteria. Updated references.

References:

1. Radicava [package insert]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
2. Cedarbaum JM, Stambler N, Malta E, at el. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. Journal of the Neurological Sciences, 169 (1999) 13 –21.
3. ALS Association. El Escorial World Federation of Neurology criteria for the diagnosis of ALS. www.alsa.org/assets/pdfs/fyi/criteria_for_diagnosis-1.pdf.
4. ALS Functional Rating Scale. Available at: http://www.outcomes-umassmed.org/als/alsscale.aspx.
5. Abe, K., Aoki, M., et al. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomised, double- blind, placebo-controlled trial. The Lancet Neurology. 2017; 16(7), 505-512.
6. Witzel S, Maier A, Steinbach R, et al. Safety and Effectiveness of Long-term Intravenous Administration of Edaravone for Treatment of Patients with Amyotrophic Lateral Sclerosis. *JAMA Neurol.* 2022;79(2):121–130.
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