Effective Date: 09/12/2018

Nevada Health Solutions LLC

NHS MEDICAL POLICY

Radicava (edaravone)
Medicine 2018-001

A. Radicava (edaravone) may be indicated for the INITIAL treatment of amyotrophic lateral sclerosis (ALS) when ALL the following are present:

1	The member has been diagnosed with amyotrophic lateral sclerosis (ALS) by a neurologist and documentation of that diagnosis has been submitted.
2	Treatment with Radicava (edaravone) is prescribed and supervised by a neurologist.
3	An ALS Functional Rating Scale-Revised (ALSFRS-R) has been submitted and the member scores 2 or more in all items of the ALSFRS-R criteria before or at the start of treatment.
4	Pulmonary function testing has been submitted and the member has a forced vital capacity of 80% or more before or at the start of treatment.
5	The member does not have a documented allergy to sulfite.
6	With items #1 – 5 met, initial authorization may be for up to 6 cycles (64 doses over 168 days).

B. CONTINUATION of treatment with Radicava (edaravone), may be indicated when ALL the following are present:

1	The member previously met all criteria when the treatment was initiated.
2	Treatment with Radicava (edaravone) is prescribed and supervised by a neurologist.
3	The provider documented that the member is tolerating Radicava (edaravone) with ongoing benefit and no adverse effects.
4	The member does not have a tracheostomy and is not dependent on mechanical ventilation.
5	With items #1 – 3 met, continued authorization may be for up to 6 cycles (60 doses over 168 days).

SOURCES

1. UpToDate.com was accessed Jun 20, 2018:
    - Diagnosis of amyotrophic lateral sclerosis and other forms of motor neuron disease
    - Edaravone: Drug information
2. FDA.gov was accessed Jun 20, 2018: Edaravone
3. Abe K, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener 2014; 15(7–8):610–7.
4. Castrillo-Viguera C, et al. Clinical significance in the change of decline in ALSFRS-R. Amyotroph Lateral Scler. 2010;11(1-2):178-80.
5. Cedarbaum JM, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999; 169(1): 13–21.
6. Geevasinga N, et al. Diagnostic critera in amyotrophic lateral sclerosis: A multicenter prospective study. Neurology. 2016 Aug 16; 87(7): 684-90.
7. Nagase M, et al. Increased oxidative stress in patients with amyotrophic lateral sclerosis and the effect of edaravone administration. Redox Rep. 2016 May;21(3):104-12.
8. Writing Group on Behalf of the Edaravone (MCI-186) ALS 17 Study Group. Exploratory double-blind, parallel-group, placebo-controlled extension study of edaravone (MCI-186) in amyotrophic lateral sclerosis. Amyotroph Lateral Scler Frontotemporal Degener. 2017 Oct;18(sup1):20-31.
9. Writing Group on Behalf of the Edaravone (MCI-186) ALS 17 Study Group. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2017 Jul;16(7):505-512.

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

J3490, S9379, 99601, 99602

Appendix A: Radicava (edaravone) Recommended Dosing
Initial cycle: 60 mg once daily for 14 days, followed by a 14-day drug-free period.
Subsequent cycles: 60 mg once daily for 10 days within a 14-day period, followed by a 14-day drug-free period.

Appendix B: ALS Functional Rating Scale (revised) (ALSFRS-R)

Speech	4 – Normal 3 – Detectable speech disturbance 2 – Intelligible with repeating 1 – Speech combined with non-vocal communication 0 – Loss of useful speech
Salivation	4 – Normal 3 – Slight, definite excess of saliva in mouth, may have nighttime drooling 2 – Moderately excessive saliva, may have minimal drooling

	1 – Marked excess of saliva with some drooling 0 – Marked drooling, requires constant tissue or handkerchief
Swallowing	4 – Normal 3 – Early eating problems, occasional choking 2 – Dietary consistency changes 1 – Needs supplemental tube feeding 0 – NPO
Handwriting	4 – Normal 3 – Slow or sloppy, all words are legible 2 – Not all words are legible 1 – Able to grip pen, not able to write 0 – Unable to grip pen
Cutting food and handling utensils in patients WITHOUT gastrostomy	4 – Normal 3 – Somewhat slow and clumsy, no help needed 2 – Slow and clumsy, some help needed, can cut most foods 1 – Food must be cut by someone but can still feed slowly 0 – Needs to be fed
Cutting food and handling utensils in patients WITH gastrostomy	4 – Normal 3 – Clumsy but can perform all manipulations independently 2 – Some help needed with closures and fasteners 1 – Provides minimal assistance to caregiver 0 – Unable to perform any aspect of task
Dressing and hygiene	4 – Normal 3 – Independent and complete self-care with effort or decreased efficiency 2 – Intermittent assistance or substitute methods 1 – Needs attendant for care 0 – Total dependence
Turning in bed and adjusting bed clothes	4 – Normal 3 – Slow and clumsy, no help needed 2 – Can turn alone or adjust sheets, but with great difficulty 1 – Can initiate, but not turn or adjust sheets alone 0 – Helpless
Walking	4 – Normal 3 – Early ambulation difficulties 2 – Walks with assistance 1 – Non-ambulatory functional movement 0 – No purposeful leg movement
Climbing stairs	4 – Normal 3 – Slow 2 – Mild unsteadiness or fatigue 1 – Needs assistance 0 – Unable
Dyspnea (new)	4 – None 3 – Occurs when walking 2 – Occurs with eating, bathing and/or dressing 1 – Occurs at rest, difficulty breathing while sitting or lying 0 – Significant difficulty, mechanical support under consideration
Orthopnea	4 – None

(new)	3 – Some difficulty breathing at night, does not routinely use more than two pillows 2 – Needs more than pillows to sleep 1 – Can only sleep sitting up 0 – Unable to sleep
Respiratory insufficiency (new)	4 – None 3 – Intermittent use of BIPAP 2 – Continuous use of BIPAP overnight 1 – Continuous use of BIPAP during day and night 0 – Invasive mechanical ventilation (intubation or tracheostomy)

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
09/12/2019	Annual review and approval by UM Committee
09/12/2020	Annual review and approval by UM Committee
09/12/2021	Annual review and approval by UM Committee
09/19/2022	Annual review and approval by UM Committee
08/23/2023	Annual review and approval by UM/QM Committee
08/23/2024	Annual review and approval by UM/QM Committee
06/27/2025	Annual review and approval by UM/QM Committee
06/25/2026	Annual review and approval by UM/QM Committee