Washington State Health Care Authority

Agents for ALS – edaravone (Radicava)

Medical policy no. 74.50.90 Effective Date: October 1st, 2021

Note: New-to-market drugs in this class are non-preferred and subject to this prior authorization (PA) policy. Non-preferred agents in this class, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed.

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Edaravone is indicated for the treatment of amyotrophic lateral sclerosis (ALS). ALS is a rare progressive neurogenerative disorder which causes muscle weakness, eventually leading to paralysis and death. Edaravone was found to provide no clinical benefit in a wide population of patients with ALS. A 24-week study which evaluated edaravone in a smaller population of patients, in earlier stages of ALS, demonstrated a slower functional decline when compared to placebo.

Medical necessity

Drug	*Medical Necessity*
edaravone (Radicava)	**Edaravone (Radicava)** may be considered medically necessary when used for the treatment of: • Amyotrophic lateral sclerosis

Clinical policy:

Clinical Criteria	
Amyotrophic Lateral Sclerosis (ALS) edaravone (Radicava)	Edaravone (Radicava) may be authorized when **ALL** of the following are met: 1. Client is 18 years of age or older; **AND** 2. Diagnosis of definite or probable ALS based on **ONE** of the following: a. El Escorial World Federation of Neurology criteria (Airlie House criteria); **OR** b. Awaji-Shima criteria; **OR** c. Gold Coast Criteria; **AND** 3. Prescribed by or in consultation with a neurologist; **AND** 4. Clinical documentation is submitted which include **ALL** of the following: a. If known, date of disease onset; **AND** b. If known, date of initial diagnosis; **AND** c. Forced vital capacity (if not available, provide explanation and plan to assess respiratory function using consistent metrics); **AND**

	d. Most recent revised ALS functional rating (ALSFRS-R) score; **AND** 5. Patient is receiving riluzole **OR** is not a candidate to receive riluzole due to intolerance or contraindication (e.g. hepatitis, elevated transaminase levels, ANC less than 500/mm^3, interstitial lung disease) If all of the above criteria are met, the request will be **approved for 6 months** If all criteria are not met, but there are documented medically necessary circumstances based on judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Criteria (Reauthorization) Edaravone (Radicava) may be reauthorized when **ALL** of the following are met: 1. Prescribed by or in consultation with a neurologist; **AND** 2. Documentation supporting disease stability or mild progression indicated by a slowing of decline (patient not experiencing rapid disease progression while on therapy) on the ALSFRS-R; **AND** 3. Clinical documentation is submitted which include **ALL** of the following: a. Forced vital capacity (if not available, provide explanation and plan to assess respiratory function using consistent metrics); **AND** b. Most recent revised ALS functional rating (ALSFRS-R) score; If all of the above criteria are met, the request may be **reauthorized for 6 months** If all criteria are not met, but there are documented medically necessary circumstances based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits

Indication	Dose and Quantity Limits
ALS – Initial cycle	• 60 mg IV once daily for 14 days, followed by a 14-day drug-free period
ALS – Subsequent cycle	• 60 mg IV once daily for 10 days within a 14-day period, followed by a 14-day drug-free period

Coding:

HCPCS Code	*Description*
J1301	Injection, edaravone, 1 mg

Definitions

Term	Description
ALS functional rating scale (revised) (ALSFRS-R)	A commonly used functional rating system for persons with ALS (Cedarbaum, 1999).
Awaji-Shima criteria	Diagnostic criteria used for ALS (Douglass, 2010; Hardiman, 2011)
El Escorial/revised Airlie House criteria (El Escorial is also known as Airlie House)	Diagnostic criteria for ALS (Brooks, 2000; Douglass, 2010). Designed for research purposes to ensure appropriate inclusion of subjects into clinical trials.
Gold Coast Criteria	Diagnostic criteria used for ALS (Shefner 2020)

References

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History

Date	Action and Summary of Changes
04/21/2021	Approved by DUR Board
02/17/2021	Updated clinical criteria to incorporate DUR Board feedback.
11/17/2020	Specialist reviewed policy and provided feedback. Policy updated to incorporate new feedback. Added language in clinical policy section for cases which do not meet policy criteria
06/17/2020	Reviewed at DUR Board meeting - Recommendations: Revisit reauthorization criteria, consult with ALS specialist, re-review in December
4/8/2020	No changes
2/3/2020	Update existing draft policy
8/2/2018	New policy