	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Medical Management Drug Policies</b>	<i>Policy Number</i>	MMDP083
		<i>Effective Date</i>	05/01/2023
		<i>Review Date</i>	04/19/2023
	<i>Subject</i> <b>Radicava IV</b>	<i>Revision Date</i>	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords:** Radicava intravenous

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## **I. POLICY**

- A. Radicava intravenous (edaravone) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

## **II. POLICY CRITERIA**

- A. **Radicava IV** may be approved for patients meeting the following:
- Documentation has been submitted showing the following:
    - Patient has a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS)
    - Patient has scores of at least 2 points on all 12 areas of the revised ALS Functional Rating Scale (ALSFRS-R)
    - Patient does not require continuous use of noninvasive or invasive ventilatory support during the day and night
  - Prescriber is, or has consulted with, a neurologist, neuromuscular specialist, or physician specializing in the treatment of ALS

## **III. AUTHORIZATION PERIOD/LIMITATIONS**


- Initial approval will be limited to 12 months of therapy
- Approval for continuation of therapy may be extended in 12-month intervals with documentation showing the patient has had a positive clinical response to Radicava therapy, and invasive ventilation is not required

## **IV. EXCLUSIONS**

- A. Radicava IV will not be approved for the following:
- Any indications or uses that are not FDA-approved or guidelines-supported

## **V. RECOMMENDED DOSE**

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

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## VI. CODES

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**Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.**

Medication	HCPCS/CPT Code
Injection, edaravone, 1 mg	J1301

## VII. REFERENCES

1. Radicava and Radicava ORS [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2022.
2. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. Eur J Neurol. 2012;19(3):360-75.
3. Writing Group, Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. Lancet Neurol. 2017; 16:505-512.

## VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/19/2023	Policy Creation

Review Dates: 04/19/2023

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