Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Radicava (Edaravone)		
MNG #: 011	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☒Yes ☐No**	**Approval Date:** 5/2/2019;	**Effective Date:** 09/15/2019;
Last Revised Date: 3/26/2020; 5/19/2021; 07/01/2021	**Next Annual Review Date:** 05/02/2020, 3/26/2021; 5/19/2022; 07/01/2022	**Retire Date:**

OVERVIEW:

Radicava (edaravone) is an intravenous medication that is FDA-approved for the treatment of Amyotrophic Lateral Sclerosis (ALS). Radicava (edaravone) is designated as an orphan drug that prevents oxidative damage to cell membranes in the central nervous system. It has been found to slow the functional deterioration in some patients with ALS, however, the mechanism by which the drug inhibits this progression is unknown.

DEFINITIONS:

Amyotrophic Lateral Sclerosis (ALS): A refractory and progressive motor neuron disorder, also known as Lou Gehrig's Disease, that is characterized by muscle weakness, disability, and death. Upper motor neuron involvement results in hyperreflexia and spasticity from degeneration of the lateral corticospinal tracts in the spinal cord. Lower motor neuron involvement results in weakness, atrophy, fasciculations from muscle denervation.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance may cover the use of Radicava (edaravone) for **initial therapy** in the treatment of Amyotrophic Lateral Sclerosis (ALS), when all of the following criteria are met:

- Documented diagnosis of definite or probable amyotrophic lateral sclerosis based on EI Escorial revised criteria for a duration of ≤ 2 at the start of treatment,
- Prescribing physician is a neurologist or has consulted with a neurologist,
- Documentation of a recent ALS Functional Rating Scale-Revised (ALSFRS-R) score ≥ 2 on each individual item of the ALSFRS-R criteria at the start of treatment,
- Documentation that confirms the patient has a Percent Forced Vital Capacity (%FVC) ≥ 80% at the start of treatment, **AND**
- Member is currently stable on Rilutek (riluzole) **OR** has a documented contraindication, intolerance, or hypersensitivity to Rilutek (riluzole).

Commonwealth Care Alliance may cover the use of Radicava (edaravone) for **continuation of therapy** in the treatment

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of Amyotrophic Lateral Sclerosis (ALS), when all of the following criteria are met:

- Documented diagnosis of definite or probable amyotrophic lateral sclerosis based on EI Escorial revised criteria,
- The prescribing physician is a neurologist or has consulted with a neurologist,
- Member is not dependent on invasive ventilatory support or tracheostomy,
- Member is currently stable on Rilutek (riluzole) **OR** has a documented contraindication, intolerance, or hypersensitivity to Rilutek (riluzole), **AND**
- Documented benefit from therapy with Radicava (edaravone)
    - This is demonstrated by stabilization or slowing in the decline of functional abilities (ALSFRS-R score preferred) or decrease in symptom severity or frequency

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will not cover the use of Radicava (edaravone), under the following conditions, including but not limited to:

- If Radicava (edaravone) is used for treatment for all other diagnoses not related to ALS,
- If the member requires continuous non-invasive ventilatory support or invasive ventilation

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws (including the Plan's applicable government program contracts) that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations.

AUTHORIZATION:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

HCPCS Code	Description
J1301	Injection, Edaravone, 1 mg [Radicava]

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are

medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

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REVISION LOG:

REVISION DATE	DESCRIPTION
05/11/2021	Added more information on Radicava in the overview (e.g. pharmacological class and mechanism of action), definition of amyotrophic lateral sclerosis, and that Radicava is not indicated for individuals who require invasive ventilation or continuous non-invasive ventilatory support. Removed clinical trial information for consistency. Wording in decision guideline section changed: changed diagnosis of ALS to include definite and probable, prescribing physician may be the neurologist or have consulted a neurologist, sign for the scores for the values (ALSFRS-R and percent forced vital capacity), added intolerance and hypersensitivity to Rilutek, and in documented benefits to include reduction in symptom severity or frequency.
05/02/2019	Reviewed and approved by CCA's Medical Policy Committee
3/26/2020	KH reviewed and update document.

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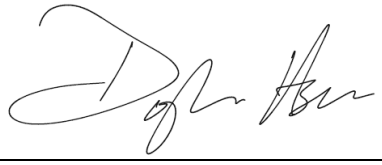
APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
	5/2/2019
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Click here to enter text.	
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	5/2/2019
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