Medicare Advantage Medical Benefit Drug Policy

BlueCross BlueShield Nebraska

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Effective Date: 04/01/2023

Radicava® (edaravone)

HCPCS: J1301

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with a neurologist
   d. Start of treatment is within 2 years of diagnosis with amyotrophic lateral sclerosis (ALS)
      OR
      After 2 years of diagnosis, with a percent predicted vital capacity value of ≥ 80 %.
   e. Submission of a baseline metrics from the ALSFRS-R (Revised ALS Functional Rating Scale)
   f. Currently receiving treatment and will continue to receive treatment with riluzole, if tolerated
   g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in the BCBSNE MA Part B drugs prior authorization list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: 6 months
   c. Renewal Criteria: Continuation of coverage requires submission of patient assessments using the ALSFRS-R or other clinical documentation to determine if Radicava is slowing the progression of ALS

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Radicava and Radicava ORS are indicated for the treatment of ALS

- ALS is a neurodegeneration disease characterized by rapid loss of upper and lower motor neurons, resulting in death by paralysis and respiratory failure usually within 24-48 months. It has been suggested that pathogenesis of neuronal degeneration in ALS may be unique in different individuals, which is one reason ALS research and development has had minimal advancements. One primary suggestion is that oxidative stress to motor neurons is largely responsible for the pathogenesis of ALS onset and progression.

- It is proposed that by reducing free radicals that cause oxidative stress on motor neurons, radical damage may be minimized, thus preventing progression of ALS. One primary tool to measure progression of ALS is called Revised ALS Functional Rating Scale (ALSFRS-R), which has been used in many clinical trials to determine treatment efficacy.

- The American Academy of Neurology (AAN) and the European Federation of Neurological Sciences (EFNS) have provided guidelines for the management of ALS. Both guidelines recommend initiating riluzole as soon as possible after diagnosis along with non-pharmacotherapy. Non-pharmacotherapy goals are to maintain autonomy as long as possible through supportive care. The AAN guidelines were reaffirmed in January of 2020 and have not yet been updated to include Radicava.

- The AAN recommends a multidisciplinary care approach that includes a neurologist when treating/caring for patients with ALS.

- The first of two Phase III trials failed to show significant difference between the treatment group and placebo in relativity to the ALSFRS-R score. Researchers determined that inclusion criteria (duration of disease within 3 years and forced vital capacity (FVC) at least 70%) had to be more stringent to observe responders. [
- The second Phase III trial was conducted over 24 weeks and met a power of 80%. Based on the modified inclusion criteria (duration of disease within 2 years and FVC at least 80%), the trial concluded a significant difference in ALSFRS-R score between treatment group and placebo group.

- It is the Northeast Amyotrophic Lateral Sclerosis Consortum (NEALS) clinical investigators' opinion that a therapy that results in a change of 20-25% or greater in the slope of the ALSFRS-R would be considered clinically meaningful.

References:

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7. Anon. Package insert: Radicava (edaravone). Mitsubishi Tanabe Pharma. Revised: 2017 May.

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Policy History		
#	Date	Change Description
1.0	Effective Date: 04/01/2023	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*