Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Radicava (Edaravone)

<table>
<thead>
<tr>
<th>MNG #: 011</th>
<th>☒ SCO ☒ One Care</th>
<th>Prior Authorization Needed?</th>
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<tbody>
<tr>
<td>Clinical: ☒</td>
<td>Operational: ☐</td>
<td>Informational: ☐</td>
</tr>
<tr>
<td>Medicare Benefit: ☒ Yes ☐ No</td>
<td>Approval Date: 5/2/2019;</td>
<td>Effective Date: 09/15/2019</td>
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<tr>
<td>Last Revised Date:</td>
<td>Next Annual Review Date: 05/02/2020;</td>
<td>Retire Date:</td>
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OVERVIEW:
Radicava (edaravone) is a medication used to treat Amyotrophic Lateral Sclerosis (ALS). It was approved for ALS in the US based on a small randomized controlled clinical trial with people who had early-stage ALS in Japan, who were administered the drug for 6 months; it had failed two earlier trials in people with all stages of ALS. I.V. edaravone was approved by the FDA in May 2017 to treat people with amyotrophic lateral sclerosis (ALS) in the United States. The cost of edaravone in the US is approximately $145,000 per year.

DECISION GUIDELINES:

Clinical Coverage Criteria:
For initial therapy, there must be a documented diagnosis of amyotrophic lateral sclerosis based on El Escorial revised criteria. In addition, ALL of the following criteria must be met:

- Prescribing physician is a neurologist.
- ALS Functional Rating Scale-Revised (ALS-FRS-R) score > 2 on each individual item of the score.
- %FVC (Forced Vital Capacity) > 80% of predicted.
- Disease duration of 2 years or less at beginning of treatment.
- Member is currently stable on Rilutek (riluzole), or has a contraindication to Rilutek (riluzole).

For continuation of therapy, ALL of the following criteria must be met:

- The prescribing physician is a neurologist.
- Documentation of one of the following:
  - Member is stable on Rilutek (riluzole)
  - Prescriber has indicated clinical inappropriateness of Rilutek (riluzole).
- Documentation of normal respiratory function, defined as percent-predicted forced vital capacity ≥ 80% of predicted
- Documentation of a benefit from therapy with Radicava (edaravone), as demonstrated by a slowing in the decline of functional abilities (ALSFRS-R score preferred).
LIMITATIONS/EXCLUSIONS:
- Requests for Radicava (edaravone) for members who do not meet the above criteria will be considered not medically necessary
- Requests for Radicava (edaravone) for members who do not have a diagnosis of ALS will be considered experimental.

AUTHORIZATION:

Prior Authorization is required.

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 service area 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.

RELATED REFERENCES:
Medical Necessity Guideline


8. The First ALS Drug In 22 Years Is Approved -- And It Costs 4 Times What It Does In Japan; Matthew Harper, Forbes magazine, May 5, 2017 accessed at: https://www.forbes.com/sites/matthewherper/2017/05/05/fda-approves-first-new-drug-to-treat-als-in-22-years/#20a2809d7fb3 on April 22, 2019

REVISION LOG:

<table>
<thead>
<tr>
<th>REVISION DATE</th>
<th>DESCRIPTION</th>
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<tr>
<td>05/02/2019</td>
<td>Reviewed and approved by CCA’s Medical Policy Commitee</td>
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APPROVALS:

Thomas A. Amoroso, MD                Medical Director, Utilization Management
CCA Senior Clinical Lead [Print]               Title [Print]

Signature

04/22/2019

Lori Tishler, MD                Senior Vice President, Medical Services
CCA CMO or Designee [Print]               Title [Print]

Signature

5/1/2019