Radicava® (Edaravone) (Intravenous)

Last Review Date: January 1, 2019  Number: MG.MM.PH.121

Medical Guideline Disclaimer

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Definition

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- **Initial dose**: 60 billable units (mg) daily for 14 days, followed by 14 days off per 28-day cycle
- **Subsequent doses**: 60 billable units (mg) daily for 10 days out of 14 days, followed by 14 days off per 28-day cycle

Guideline

I. **INITIAL APPROVAL CRITERIA**

*Radicava may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:*

**Amyotrophic Lateral Sclerosis †**

- Patient must have a diagnosis of ALS (disease duration for two years or less)
- Patient must be at least 18 years of age; **AND**
- The medication is being prescribed by a neurologist that specializes in ALS and/or neuromuscular disorders
- The patient has had an inadequate response, intolerance, or contraindication to riluzole (Rilutek)
- The patient has a Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
- Normal respiratory function %FVC ≥ 80%
- NO severe renal impairment (CrCl less than 30 mL/min) or end stage renal disease
- NO moderate to severe hepatic impairment (Child-Pugh Class C)

† FDA-labeled indication(s)

Limitations/Exclusions
If the above criteria are met, authorization may be granted for a 14 day period, followed by a 14 day drug-free period for initial treatment cycle.

II. RENEWAL CRITERIA
- Patient continues to meet the Initial Approval Criteria; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hypersensitivity reactions, sulfite allergic reactions, etc.; AND
- Patient has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy); AND
- Patient does not have a cumulative score on the ALSFRS-R of ≤ 3

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>ALS</td>
<td>60 mg (two consecutive 30 mg infusion bags) administered as an intravenous infusion over 60 minutes</td>
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<tr>
<td></td>
<td>- Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period</td>
</tr>
<tr>
<td></td>
<td>- Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods</td>
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</tbody>
</table>

Applicable Procedure Codes

| J1301 | Injection, edaravone, 1 mg |

Applicable NDCs

| 70510-2171-XX | Radicava 30 mg/100ml single dose bag |

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>G12.21</td>
<td>Amyotrophic lateral sclerosis</td>
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References

