SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Radicava® (edaravone) IV (Codes J1301) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosing:

❑ **New starts:** 60mg (200mL) daily x 14 days followed by a 14 day drug free period, then 60mg (200mL) daily for 10 days out of the next 14 day period followed by a 14 day drug free period	Number of 28 day treatment cycles requested:
❑ **For renewals:** 60mg (200mL) daily for 10 days out of a 14 day period followed by a 14 day drug free period	

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Which of the following diagnosis does the patient have based on the El Escorial revised Criteria? **(Select One)**

- ❑ Clinically Defined ALS
- ❑ Clinically Probable ALS
- ❑ Clinically Probable-Laboratory ALS
- ❑ Clinically Possible ALS
- ❑ Clinically Suspected ALS

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval Length – 6 months (no more than 86 doses over 180 days)

❑ Prescriber is a neurologist

AND

❑ Member is ≥ 18 years of age

AND

❑ Member has diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) per the EL Escorial

AND

❑ Functionality retained on most activities of daily living **(defined as scores of 2 points or better on each individual item of the ALS Functional Rating Scale-Revised (ALSFRS-R) with the exception of dyspnea, orthopnea, and respiratory insufficiency which must be a score of 4) (must be submitted)**

ALSFRS-R Score For:	Score of 0	Score of 1	Score of 2	Score of 3	Score of 4
Speech Function	❑	❑	❑	❑	❑
Salivation Function	❑	❑	❑	❑	❑
Handwriting Function	❑	❑	❑	❑	❑
Cutting Food Function	❑	❑	❑	❑	❑
Dressing/Hygiene Function	❑	❑	❑	❑	❑
Turning in Bed Function	❑	❑	❑	❑	❑
Walking Function	❑	❑	❑	❑	❑
Climbing Stairs Function	❑	❑	❑	❑	❑
Dyspnea Function	❑	❑	❑	❑	❑
Orthopnea Function	❑	❑	❑	❑	❑
Respiratory Insufficiency Function	❑	❑	❑	❑	❑
Swallowing Function	❑	❑	❑	❑	❑

****Check the ALSFRS-R score that correlates to the patient for each of the following functions above****

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AND

- ❑ Member has normal respiratory function confirmed by a % forced vital capacity (%FVC) ≥ 80% at the start of treatment **(medical records must be attached; records attached must have been completed within the last SIX months)**

AND

- ❑ Disease duration of two (2) years or less **(progress notes must document date)**

AND

- ❑ No history of spinal surgery after onset of ALS

AND

- ❑ Medication will be used in combination with riluzole unless patient has an FDA labeled contraindication or intolerance to riluzole (explain the intolerance or contraindication if applicable): _____

_____

_____

Reauthorization Approval Length – 12 months (no more than 86 doses over 180 days).
All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Documentation the patient is benefiting from therapy (e.g. slowing in the decline of functional abilities, and change in ALSFRS-R score has not changed -7 points from last request) **Must submit recent ALSFRS form**

AND

- ❑ Member has normal respiratory function confirmed by a % forced vital capacity (%FVC) ≥ 70%

AND

- ❑ ALSFRS-R score for dyspnea, orthopnea, and respiratory insufficiency is 4 ❑ Yes ❑ No

AND

- ❑ Medication will be used in combination with riluzole unless patient has an FDA labeled contraindication or intolerance to riluzole (explain the intolerance or contraindication if applicable): _____

_____

_____

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Medication being provided by (check applicable box below):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 8/17/2017
REVISED/UPDATED: ~~9/28/2017~~; ~~12/30/2017~~; ~~5/24/2018; (Reformatted)~~ ~~3/19/2019; 7/8/2019; 9/20/2019;~~ **3/30/2020**