SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Drug Requested: Spinraza™ (nusinersen) **(J2326)**

Medication being provided by the physician's office

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:** _____

Dosing Limit: **(see below)**

Max Units (per dose and over time): **Loading:** 12mg on D1, D15, D29, and D59
Maintenance: 12mg every 112 days

- **Coverage is provided for six (6) months and may be renewed**

☐ 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.

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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 Criteria – 6 months

Concomitant use of Zolgensma® (onasemnogene abeparvovec-xioi) with Spinraza® is considered investigational and not covered.

❑ **Has member tried Zolgensma®?** ❑ Yes ❑ No

Spinraza® will only be approved after Zolgensma® use if there is documentation of clinical failure of Zolgensma® and the member qualifies for Spinraza® based on our criteria.

- Spinraza™ (nusinersen) is considered medically necessary for the treatment of spinal muscular atrophy (SMA) in individuals who meet **ALL** of the following criteria:

❑ Diagnosis of SMA defined by individuals who meet **BOTH** criteria A and B:

A. Documentation of confirmatory diagnosis by either:

1. SMA diagnosis test results confirming 0 copies of SMN1; **OR**
2. Molecular genetic testing of 5q SMA for any of the following:
   a. homozygous gene deletion; **OR**
   b. homozygous conversion mutation; **OR**
   c. compound heterozygote

B. Documentation of either:

1. Genetic testing confirming no more than 2 copies of SMN2; **OR**
2. SMA-associated symptoms before 6 months of age;

AND

❑ Nusinersen is prescribed by a provider with expertise in treating SMA

AND

❑ Medical records have been submitted documenting a baseline motor exam by a physician **{Neurologist or Physical Medicine and Rehabilitation (PMR) or physical therapist specializing in SMA motor exam evaluations and supervised by a Neurologist or PMR physician}** experienced in treating SMA and utilizing at least **one** of the following exam instruments, to establish this baseline motor ability:

- Hammersmith Infant Neurological Exam **(HINE)**

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- Upper Limb Module Test (non-ambulatory) **(ULM)**
- Hammersmith Functional Motor Scale Expanded **(HFMSE)**
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders **(CHOP INTEND)**

AND

- ❑ Initial approval will be for 4 doses to be given in accordance with the current FDA label instructions. **Protocol**: loading dose at day 0 (dose 1), day 14 (dose 2), day 28 (dose 3), 30 days post day 28 (dose 4).

AND

- ❑ The request is for the FDA-approved dosage only – nusinersen is a 12 mg suspension to be administered intrathecally.

Continuation Therapy – 6 months. 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.

- ❑ Continuation of treatment with nusinersen **beyond six (6) months** after initiation of therapy **and every six (6) months thereafter** is considered medically necessary for the treatment of SMA when individuals meet the following criteria:

- When initial therapy was determined to meet the above criteria

AND

- Member must be re-evaluated utilizing the same motor exam test done to establish baseline motor ability unless it is determined that original exam is no longer age appropriate.

AND

- The same criteria used for examiners as in the baseline exam are met.

AND

- Nusinersen will only be authorized for continuation of therapy if a patient is determined to be a responder by demonstrating an improved motor ability in repeat motor testing at 6 months from the first dose.

- To be classified as a responder, test scores from the indicated repeat motor test used must show **(submit ACTUAL assessment)**:

  - **HINE:** a 2-point increase (or maximal score of 4) in ability to kick; **OR** a 1-point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, standing, or walking). The patient showed improvement in more categories of motor milestones than worsening.

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- **ULM:** improvement of at least a 2-point increase in score from pretreatment baseline;
- **HFSME:** improvement of at least a 3-point increase in score from pretreatment baseline.
- **CHOP INTEND:** improvement of at least a 4 point increase in score from pretreatment baseline

AND

- Renewal authorization will follow the current FDA nusinersen labelling for maintenance dosing protocol of every 4 months.

AND

- Repeat motor testing must be done at each 6 month interval and must show additional motor improvement or maintenance of the previously demonstrated motor improvement.

AND

- If a member who is not previously dependent on a mechanical ventilator becomes dependent (defined as requiring mechanical ventilation for >21 days) while on nusinersen, DMAS will no longer authorize payment of nusinersen for that patient.

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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:** 2/19/2017;
REVISED/UPDATED: ~~6/8/2017~~; ~~7/3/2017~~; ~~8/25/2017~~; ~~12/13/2017~~; ~~1/3/2018~~; ~~7/6/2018~~; ~~8/30/2018~~; ~~10/8/2018~~; ~~(REFORMATTED)~~ ~~2/5/2019~~; ~~5/20/2019~~; ~~9/29/2019~~; ~~10/17/2019~~; ~~10/27/2019~~**(Reformatted) 10/16/2020**