AvMed

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 1-877-535-1391**. 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: Spinraza™ (nusinersen) **(J2326) (Medical)**
(NDC: 64406-0058-01)

Medication provided by the physician's office

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

Member Name: _____

Member AvMed #: _____ **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 reviews. 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: 6 months. Please note: "YES" responses would be considered EXCLUDED for Spinraza®.

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.

- ❑ Does member have?

  1. Respiratory insufficiency, defined by the medical necessity for invasive or non-invasive ventilation for greater than 6 hours during a 24-hour period, at screening? ❑ Yes ❑ No
  2. Medical necessity for a gastric feeding tube, where this route gives the majority of nutrients? ❑ Yes ❑ No
  3. Hypoxemia (O2 saturation awake less than 96%, without ventilation support)? ❑ Yes ❑ No
  4. Presence of an implanted shunt for the drainage of CSF or an implanted CNS catheter? ❑ Yes ❑ No
  5. Medical disability (e.g., wasting or cachexia, severe anemia, etc.) that would interfere with the assessment of safety? ❑ Yes ❑ No
  6. Severe contracture(s) or severe scoliosis on radiograph (Cobb angle >40 degrees) that will effect intrathecal infusion? ❑ Yes ❑ No
  7. Ability to walk independently (defined as the ability to walk unaided)? ❑ Yes ❑ No
  8. Ability to walk with assistance? ❑ Yes ❑ No
  9. HFMSE score >54? ❑ Yes ❑ No

- ❑ Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by **one** of the following **(ORIGINAL GENETIC labs included)**:

  - ❑ Homozygous deletion of the SMN1 gene,

    OR

  - ❑ Dysfunctional mutation of the SMN1 gene,

    OR

  - ❑ Compound conversion mutation

    AND

  - ❑ Documentation of genetic testing confirming no more than 4 copies of SMN2 and Type 1 -3;

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AND

- ❑ Documentation of baseline Movement assessments with **one** of the following:
  - ❑ Motor function/milestone: _____/32,

    OR
  - ❑ Hammersmith Infant Neurologic Exam (HINE): _____/68,

    OR
  - ❑ Hammersmith Functional Motor Scale for SMA (HFMS) _____/66 **(score >54 EXCLUDED)**

    AND
  - ❑ Baseline assessment of **one** of the following:
    - ❑ Number of hospitalization in the last 12 months _____

    OR
  - ❑ Baseline assessment of **one** of the following:
    - ❑ Number of hospitalization in the last 12 months _____

    OR
    - ❑ Number of antibiotic therapies for respiratory infection in the last 12 months _____

    OR
    - ❑ Current respiratory function test (e.g., forced vital capacity (FVC)): _____

Continuation Therapy. To qualify, check below all that apply. 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 spinal muscular atrophy (SMA) when individuals meet the following:

  - ❑ Member has shown an improvement or no decrease from baseline score **[a decline from the baseline (6 months) over a 12-month evaluation would be considered not medically necessary]**; all three (3) assessments below would be reviewed from previous baseline:
    - ❑ Number of **hospitalization** in the **last 6 months**: _____
    - ❑ Number of **antibiotics** therapy for respiratory infection in the **last 6 months**: _____
    - ❑ Current respiratory function test [e.g., forced vital capacity (FVC)]: _____

    AND

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- ❑ Documentation of Movement ASSESSMENT **within 30 days of request** must be provided or request may be denied:
  - ❑ Motor function/milestone: _____ /32;

    OR
  - ❑ Hammersmith Infant Neurologic Exam (HINE): _____ /68;

    OR
  - ❑ Hammersmith Functional Motor Scale for SMA (HFMS): _____ /66

    AND
- ❑ Permanent ventilation defined as tracheostomy or ≥ 16 hours ventilator support per day would be considered a failure of Spinraza™ and will not be approved for continuation. ❑ Yes ❑ No

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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: ~~4/14/2017~~; ~~4/25/2017~~; ~~4/28/2017~~; ~~5/3/2017~~; ~~5/17/2017~~; ~~5/29/2017~~; ~~7/3/2017~~; ~~7/5/2017~~; ~~8/1/2017~~; ~~9/17/2017~~; ~~12/31/2017~~; ~~10/16/2018~~; **(Reformatted)** ~~3/20/2019~~; ~~7/8/2019~~; **9/25/2019**;