

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 is 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: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

- 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.

Dosing Limits:

A. Loading dose:

- 120 billable units (12mg) on day 1, day 15, day 29, and day 59

B. Maintenance dose:

- 120 billable units (12mg) every 112 days

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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 – 12 months

- Member must **NOT** have previously received treatment with SMA gene therapy (e.g., onasemnogene abeparvovec-xioi, etc.)
- Member will **NOT** use in combination with other agents for SMA (e.g., onasemnogene abeparvovec-xioi, risdiplam, etc.)
- Member must have the following laboratory tests at baseline and prior to each administration: platelet count, prothrombin time, activated partial thromboplastin time, and quantitative spot urine protein testing
- Member must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the SMN1 gene or dysfunctional mutation of the SMN1 gene
- Member must have a diagnosis of SMA phenotype I, II, or III
 - Member has ≤ 3 copies of the SMN2 gene (Note: Patients with >3 copies of the SMN2 gene will be reviewed on a case-by-case basis)
 - Member has symptomatic disease (i.e., impaired motor function and/or delayed motor milestones)
- Baseline documentation of one or more of the following:
 - Motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSSE), Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Bayley Scales of Infant and Toddler development Third Ed. (BSID-III), 6-minute walk test (6MWT), Upper Limb Module (ULM), Motor Function Measure 32 (MFM32), Revised Upper Limb Module (RULM), etc.
 - Respiratory function tests [e.g., forced vital capacity (FVC), etc.]
 - Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/timeframe
 - Member weight (for patients without a gastrostomy tube)

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Reauthorization Approval: 12 months. 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.

- Member continues to meet the relevant criteria identified in the initial criteria
- Member has an absence of unacceptable toxicity form the drug
- Member is being continuously monitored for a beneficial response to therapy

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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.****