

OPTIMA HEALTH COMMUNITY CARE

PHARMACY 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 1-844-348-3720. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete information will delay authorization process.

Medication being provided by the physician's office

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

(The previously assigned C-code for Spinraza™ should no longer be used.)

DRUG INFORMATION: Complete all information below or authorization process will be delayed.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

CLINICAL CRITERIA: ALL boxes must be checked to qualify to ensure authorization will NOT be delayed.

Initial Approval Criteria – 6 months

- 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;
 - 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)
 - Upper Limb Module Test (non-ambulatory) (ULM)
 - Hammersmith Functional Motor Scale Expanded (HFMSSE)
 - 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.

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Continuation Therapy – 6 months

- 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
 - The patient 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:
 - **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.
 - **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 patient 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.

****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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

*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