OPTIMA HEALTH PLAN

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 1-844-202-5034. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.***

Drug Requested: **Spinraza™** (nusinersen) **(J2326)** ***(Commercial)*** ***(Medical)***
(NDC: 64406-0058-01)

(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 Name/Form: _____ **Strength/Quantity:** _____

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

Diagnosis: _____ **ICD Code:** _____

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***

Medication being provided by the physician's office

CLINICAL CRITERIA: ***All boxes that apply must be checked to qualify. All documentation of labs MUST be submitted or request will be denied. Authorization process could be delayed if incomplete.***

Initial Approval Criteria: ***Approval would be for six (6) months***
(Please note: "YES" would be considered EXCLUDED for Spinraza™)

❑ 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 the majority of feeds are given by this route? ❑ 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

❑ Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by one of the following ***(Documentation of labs must be submitted or request will be denied)***:

- ❑ Homozygous deletion of the SMN1 gene **OR**
- ❑ Dysfunctional mutation of the SMN1 gene **OR**
- ❑ Compound conversion mutation

AND

(continued on next page)

- ***Documentation of both of the following*:**
  - Documentation of genetic testing confirming no more than 2 copies of SMN2 and Type 1 ***(Documentation of labs must be submitted or request will be denied)***

    AND
  - SMA-associated symptoms ***before*** 6 months of age

    AND
- Both baseline assessments with documentation of the following ***(Documentation of labs must be submitted or request will be denied)***:
  - Motor function/milestone: _____/32 **AND**
  - Hammersmith Infant Neurologic Exam (HINE): _____/68

    OR
  - Hammersmith Functional Motor Scale for SMA (HFMS)

***Continuation Therapy*:**
(All lab documentation MUST be submitted or request will 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 ***two (2) criteria*** ***(Documentation of labs must be submitted or request will be denied)***:
  - For continuation of therapy, the following ***two (2) assessments*** have increased (improved) or not changed from baseline score. ***(A decline from the baseline (6 months) over a 12-month evaluation would be considered not medically necessary.)***
    - Motor function/milestone: _____/32 **AND**
    - Hammersmith Infant Neurologic Exam (HINE): _____/68

      OR
    - Hammersmith Functional Motor Scale for SMA (HFMS)
  - 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.

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: _____

Phone Number: _____ Fax Number: _____

DEA/NPI #: _____

***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~~; **12/16/2017**;