Updated: 09/2019
PARP Approved: 10/2019

Prior Authorization Criteria

Spinraza (nusinersen)

All requests for Spinraza (nusinersen) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Spinraza (nusinersen) all of the following criteria must be met:

Coverage may be provided with a diagnosis of Spinal Muscular Atrophy and the following criteria is met:

- Member (pediatric or adult) must be presymptomatic or symptomatic with a confirmed diagnosis of SMA Types I, II, or III by submission of laboratory testing demonstrating corresponding mutations or deletions in chromosome 5q13 that lead to survival motor neuron (SMN) protein deficiency
- Medication must be prescribed by or in consultation with a neurologist or pediatric neurologist.
- The provider attests that the following laboratory tests will be performed at baseline, prior to each dose of Spinraza, and as clinically needed:
    - Platelet Count
    - Prothrombin time; activated partial thromboplastin time
    - Quantitative spot urine protein testing
- Member has documentation of a baseline evaluation, including a standardized assessment of moor function such as
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurologic Exam (HINE)
    - Upper limb module (ULM) score
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
    - Six-minute walk test
- **Initial Duration of Approval:** 4 months
- **Reauthorization Criteria**
    - Baseline assessment motor milestone score from ONE of the following assessments:
        - Hammersmith Functional Motor Scale Expanded (HFMSE)
        - Hammersmith Infant Neurologic Exam (HINE)
        - Upper limb module (ULM) score
        - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
        - Six-minute walk test
    - Documentation that the patient is responding to the medication based on the prescriber's assessment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or

peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

Updated: 09/2019
PARP Approved: 10/2019

Spinraza (nusinersen)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Does the member have a confirmed diagnosis of spinal muscular atrophy (SMA)?

☐ Yes ☐ No

Is there documentation of genetic testing confirming either two or three copies of SMN2 gene?
☐ Yes ☐ No

Is there confirmation of ONE of the following:

- Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);
  ☐ Yes ☐ No
- Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);
  ☐ Yes ☐ No
- Will the medication be prescribed by or in consultation with a neurologist or pediatric neurologist?
  ☐ Yes ☐ No

Does the provider attests that the following laboratory tests will be performed at baseline, prior to each dose of Spinraza, and as clinically needed?

- Platelet Count
- Prothrombin time; activated partial thromboplastin time
- Quantitative spot urine protein testing

☐ Yes ☐ No

Please attach baseline assessment motor milestone score from ONE of the following assessments:

- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Hammersmith Infant Neurologic Exam (HINE)
- Upper limb module (ULM) score
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Six-minute walk test

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Please attach baseline assessment motor milestone score from ONE of the following assessments:

- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Hammersmith Infant Neurologic Exam (HINE)
- Upper limb module (ULM) score
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Six-minute walk test

Is there documentation that the patient is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment (progression, stabilization, or decreased decline in motor function):

☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date