Updated: 09/2019
DMMA Approved: 09/2019

Request for Prior Authorization for Spinraza (nusinersen)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Spinraza (nusinersen) Prior Authorization Criteria:

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:

- Confirmed diagnosis of spinal muscular atrophy (SMA) confirmed by genetic testing including ALL of the following:
  - Documentation of genetic testing confirming either two or three copies of SMN2 gene.
  - Confirmation of ONE of the following:
    - Homozygous deletions of SMN1 gene (e.g., absence of the SMN1 gene);
    - Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7);
    - Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7(allele 1) and mutation of SMN1 (allele 2)
- 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
- 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
- **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 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):
- **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.

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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 Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 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:
Health Options 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:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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

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