Spinal Muscular Atrophy
Spinraza (nusinersen) J2326
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Documentation is provided that Patient has a confirmatory diagnosis by either:
- ☐ Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1; OR
- ☐ Molecular genetic testing of 5q SMA for any of the following:
- ☐ Homozygous gene deletion; or
- ☐ Homozygous conversion mutation; or
- ☐ compound heterozygote;

☐ Documentation is provided that Patient has either:
- ☐ Genetic testing confirming no more than 2 copies of SMN2; OR
- ☐ Onset of SMA-associated signs and symptoms before 21 months of age.

☐ Patient does not require use of invasive ventilatory support (tracheotomy with positive pressure) or use of non-invasive ventilator support (BiPAP) for more than 16 hours per day as a result of advanced SMA disease.

☐ Initial requests for Spinraza **following treatment with Zolgensma (onasemnogene abeparvovec-xioi)**

- ☐ When Spinraza therapy is determined to meet the above criteria; AND
- ☐ Documentation is provided that Patient has experienced a decline in clinical status (for example, loss of motor milestone) since receipt of gene therapy.

☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ When initial therapy was determined to meet the above criteria; AND
- ☐ Patient does not require use of invasive ventilatory support (tracheotomy with positive pressure) or use of non-invasive ventilator support (BiPAP) for more than 16 hours per day as a result of advanced SMA disease; AND
- ☐ Documentation is provided that Patient has clinically significant improvement in spinal muscular atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Spinal Muscular Atrophy Drug PA

Drug Name(s):
SPINRAZA NUSINERSEN

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Neurologist, Pediatric Neurologist or other related specialist

Coverage Duration:
Initial Approval will be for 6 months
Continuation will be for 12 months

FDA Indications:
Spinraza

- Spinal muscular atrophy

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/79E3C5/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/C73EF3/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932070&contentSetId=100&title=Nusinersen&servicesTitle=Nusinersen&brandName=Spinraza&UserMdxSearchTerm=Spinraza&=null#