

New Hampshire Medicaid Fee-for-Service Program Spinraza® (nusinersen) Criteria

Approval Date: January 14, 2022

Criteria for Approval

1. Patient must have documentation of a confirmed diagnosis of spinal muscular atrophy (SMA); **AND**
2. Genetic testing is required to demonstrate SMN1 homozygous gene deletion or mutation; **AND**
3. Quantitative spot urine protein testing at baseline and prior to each dose; **AND**
4. Complete blood count at baseline and prior to each dose; **AND**
5. Nusinersen must be administered by a specialist with competency in intrathecal injection; **AND**
6. Patient has not received a previous treatment with Zolgensma®; **AND**
7. Patient is not currently receiving therapy with Evrysdi® (risdiplam); **AND**.
8. Provide baseline assessment using at least one of the following:
 - a. Hammersmith Functional Motor Scale Expanded (HFMSE)
 - b. Hammersmith Infant Neurologic Exam (HINE)
 - c. Six-minute walk test (6MWT)
 - d. Upper limb module (ULM) score

Criteria for Renewal

1. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include serious infections, life-threatening glomerulonephritis, thrombocytopenia, etc.; **AND**
2. Patient has demonstrated improvement or lack of progression in at least one of the following:
 - a. Hammersmith Functional Motor Scale Expanded (HFMSE)
 - b. Hammersmith Infant Neurologic Exam (HINE)
 - c. Six-minute walk test (6MWT)
 - d. Upper limb module (ULM) score

Quantity Limit:

- Initial: Four vials for the first 58 days
- Maintenance: One vial every 120 days

Length of Approval:

- Initial: Six months
- Renewal: One year

Criteria for Denial

Criteria for approval not met.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	10/24/2017
Commissioner	Approval	12/05/2017
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019
DUR Board	Revision	06/30/2020
Commissioner	Approval	08/07/2020
DUR Board	Revision	12/02/2021
Commissioner Designee	Approval	01/14/2022