INDICATIONS: All patients must have a detailed written or transcribed history and note on the chart prior to performing any procedure, detailing the need for SPINRAZATM (nusinersen).

I. Length of Authorization
Coverage will be provided annually and may be renewed.

II. Dosing Limits
A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   • Loading: 1 vial on: □ D1  □ D15  □ D29  and □ D59
   • Maintenance: 1 vial every 112 days
   B. Max Units (per dose and over time) [Medical Benefits]:
      • Loading 12 mg on D1, D15, D29 and D59
      • Maintenance: 12 mg vial every 112 days

III. Initial Approval Criteria
Coverage is provided in the following conditions:

Spinal Muscular Atrophy (SMA) †
☐ Patient must have the following laboratory tests at baseline and prior to each administration*: platelet count, prothrombin time: activated partial thromboplastin time, and quantitative spot urine protein testing; AND
☐ Patient retains meaningful voluntary motor function (e.g. manipulate objects using upper extremities, ambulate, etc.); AND
☐ Patient must have a diagnosis of 5q spinal muscular atrophy confirmed by either homozygous deletion of the SMN1 gene or dysfunctional mutation of the SMN1 gene; AND
☐ Patient must have one of the following SMA phenotypes; AND
   ☐ SMA
   ☐ SMA II with symptomatic disease (i.e. impaired motor function and/or delayed motor milestones)
   ☐ SMA III with symptomatic disease (i.e. impaired motor function and/or delayed motor milestones)
   • Baseline documentation of one or more of the following:
      ☐ Motor function/milestones including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), 6-minute walk test (6MWT), upper limb module (ULM), etc.
      ☐ Respiratory function tests [e.g., forced vital capacity (FVC), etc.]
      ☐ Exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the proceeding year/time frame
      ☐ Patient weight (for patients without a gastrostomy tube)
   † FDA - labeled indication(s)
* Laboratory tests should be obtained within several days prior to administration

IV. Renewal Criteria
☐ Patient continues to meet the criteria in Section III; AND
☐ Absence of unacceptable toxicity which would preclude safe administration of the drug. Examples of unacceptable toxicity include the following: significant renal toxicity, thrombocytopenia, coagulation abnormalities, etc.; AND
☐ Patient has responded to therapy compared to pretreatment baseline in one or more of the following:
   • Stability or improvement in net motor function/milestones, including but not limited to, the following validated scales: Hammersmith Infant Neurologic Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), 6-minute walk test (6MWT), upper limb module (ULM), etc
   • Stability or improvement in respiratory function tests [e.g., forced vital capacity (FVC), etc.]
   • Reduction in exacerbations necessitating hospitalization and/or antibiotic therapy for respiratory infection in the preceding year/time frame
   • Stable or increased patient weight (for patient without a gastrostomy tube)
   • Improvement/slowed rate of decline in the aforementioned measures

Physician’s Name (Print)  ____________________________  Signature  ____________________________ Date  ____________ Time  ____________
INDICATIONS: All patients must have a detailed written or transcribed history and note on the chart prior to performing any procedure, detailing the need for SPINRAZATM (nusinersen).

Patient education:
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Comments: __________________________________________________________________________________
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Source: Moda Health Plan, Inc. Medical Necessity Criteria
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