



## Pharmacy Policy

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# Spinal Muscular Atrophy

**Policy Number:** 9.315

**Revision Number:** R0

**Version Effective Date:** 1/1/2021

Product Applicability  All Plan+ Products

**Well Sense Health Plan**

New Hampshire Medicaid

**Boston Medical Center HealthNet Plan**

MassHealth- MCO

MassHealth- ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

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**Products Affected:**

- Spinraza (nusinersen)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All medically excepted indications unless otherwise excluded
<b>Exclusion Criteria</b>	Receiving concomitant SMN modifying therapy
<b>Required Medical Information</b>	<ol style="list-style-type: none"> <li>1. Diagnosis of spinal muscular atrophy type I, II, or III; <b>AND</b></li> <li>2. Medical records confirming either 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygous mutation; <b>AND</b></li> <li>3. The member has more than two copies of SMN2; <b>AND</b></li> <li>4. Patient must have the following laboratory tests at baseline and prior to each administration: platelet count, prothrombin time; activated partial thromboplastin</li> </ol>

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	<p>time, and quantitative spot urine protein testing; <b>AND</b></p> <p>5. Documentation of baseline motor function test from one or more of the following:</p> <ol style="list-style-type: none"> <li>Hammersmith Infant Neurologic Exam (HINE)</li> <li>Hammersmith Functional Motor Scale Expanded (HFMSE)</li> <li>6-minute walk test (6MWT)</li> <li>Upper limb module (ULM)</li> <li>Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)</li> </ol> <p>6. Provider attests that Spinraza will not be use concomitantly with Zolgensma</p>
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a neurologist or in consultation with a neurologist with expertise in the diagnosis of spinal muscular atrophy
<b>Coverage Duration</b>	Initial: 6 months Reauthorization: 12 months
<b>Other criteria</b>	<p>Reauthorization: Documentation of the following:</p> <ol style="list-style-type: none"> <li>Medical records documenting positive response to therapy as shown by improvement in motor function tests or stability of function</li> </ol>

### Clinical Background Information and References

- Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen Inc.; December 2016.
- Bodamer OA. Spinal muscular atrophy. UptoDate. Last updated Feb 11, 2019.
- Zolgensma (onasemnogene abeparvovec-xioi) [prescribing information]. Bannockburn, IL: AveXis, Inc.; May 2019.

### Applicable Coding:

J -Code	Medication
J2326	Inj, nusinersen, 0.1mg

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

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## Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.075 Spinal Muscular Atrophy Policy retired, new policy created;	1/1/2021	P&T Committee, NH DHHS

### Next Review Date

2021

### Other Applicable Policies

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### Reference to Applicable Laws and Regulations, If Any

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### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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