Pharmacy Policy

Spinraza

Policy Number: 9.315
Version Number: 1
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

Products Affected:

- **Spinraza (nusinersen)**

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

Covered Use	All medically excepted indications unless otherwise excluded
Exclusion Criteria	Receiving concomitant SMN modifying therapy
Required Medical Information	**Spinraza** Documentation of all of the following: 1. Diagnosis of spinal muscular atrophy type I, II, or III; ***AND*** 2. Medical records confirming either 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygous mutation; ***AND***

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	3. The member has more than two copies of SMN2; ***AND*** 4. 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*** 5. Documentation of baseline motor function test from one or more of the following: a. Hammersmith Infant Neurologic Exam (HINE) b. Hammersmith Functional Motor Scale Expanded (HFMSE) c. 6-minute walk test (6MWT) d. Upper limb module (ULM) e. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP _INTEND); **AND** 6. Provider attests that Spinraza will not be use concomitantly with Zolgensma
Age Restrictions	None
Prescriber Restriction	Prescribed by or in consultation with a neurologist, neuromuscular specialist or in consultation with a neurologist with expertise in the diagnosis of spinal muscular atrophy
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Quantity Limit	4 treatments for the first 2 months, then 1 treatment (12 mg/5mL) every 4 months thereafter
Other criteria	Reauthorization 1. Medical records documenting positive response to therapy as shown by improvement in motor function tests or stability of function

Clinical Background Information and References

1. Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen Inc.; December 2016.
2. Bodamer OA. Spinal muscular atrophy. UptoDate. Last updated Feb 11, 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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.075 Spinal Muscular Atrophy Policy retired, created a separate policy for Spinraza	1/1/2020	P&T Committee

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

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.