STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

SPINRAZA® (nusinersen)
Billed under: J2326

SPINRAZA is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Spinraza treats spinal muscular atrophy caused by mutations in chromosome 5q that lead to survival motor neuron (SMN) protein deficiency by binding to a specific sequence in the intron downstream of exon 7 of the SMN2 messenger ribonucleic acid (mRNA) transcript thereby increasing production of full-length SMN protein. SPINRAZA is administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

NOTE: Prior Authorization requests for Spinraza must be submitted as a medical claim

Initial authorization for the administration of Spinraza may be approved when all of the following criteria is met:

1. Prescriber must be a Neurologist experienced in the treatment of SMA, or by a physician in close consultation with such a neurologist; **AND**

2. Documentation must be submitted showing the patient has a diagnosis of Spinal Muscular Atrophy (SMA) confirmed by genetic testing; **AND**

3. Documentation must be submitted indicating that the patient has had the following laboratory tests at baseline and prior to each administration:
   a. platelet count
   b. prothrombin time
   c. activated partial thromboplastin time
   d. quantitative spot urine protein testing; **AND**

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4. Prescriber must submit documentation of a baseline motor exam using at least one of the following measures of motor function:
   a. Hammersmith Infant Neurologic Exam (HINE)
   b. Hammersmith Functional Motor Scale (HFMSE)
   c. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

Initial authorization will be for 6 months: initial SPINRAZA treatment with 4 loading doses. The first three loading doses should be administered at 14-day intervals. The 4th loading dose should be administered 30 days after the 3rd dose (4 doses x 6 months).

Criteria for Continuation Approval (Maintenance dosing given every 4 months):

1. Patient must continue to satisfy all criteria required for initial PA approval; **AND**
2. Documented evidence must be submitted showing clinically significant improvement in SMA associated symptoms, such as lack of progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease by submission of medical records with the most recent results (**≤ 6 months prior to request**) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by at least one of the following exams:
   a. HINE
   b. HFMSE
   c. CHOP-INTEND

NOTE: For older individuals (>24 months), alternative means of motor assessment (e.g. Medical Research Council [MRC] strength test, 6-minute walk, upper limb module testing, pulmonary function testing) are appropriate alternatives.

Continuation requests will be authorized for 12 months: maintenance dose of one dose every 4 months (3 doses x 12 months).

References:

Government Agency, Medical Society, and Other Authoritative Publications:

1. Spinraza [package insert]. Cambridge, MA: Biogen; 2024. https://www.spinraza.com/content/dam/commercial/spinraza/caregiver/en_us/pdf/spinraza-prescribing-information.pdf (Accessed 05/19/2023)
2. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534611.htm (Accessed 05/19/2023)
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209531lbl.pdf (Accessed 05/19/2023)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member according to BMS coverage and policy guidelines.