MONTANA HEALTHCARE PROGRAMS
March 7, 2018

Physician Administered Drug Prior Authorization Criteria for Spinraza®

Version , 3-7-18
Spinraza® Nusinersen

12mg/mL (2.4mg/mL) clear and colorless solution in a single-dose vial for intrathecal administration

Mechanism of Action:
"SPINRAZA® is an antisense oligonucleotide (ASO) designed to treat SMA caused by mutations in chromosome 5q that lead to SMN protein deficiency. Using in vitro assays and studies in transgenic animal models of SMA, SPINRAZA® was shown to increase exon 7 inclusion in SMN2 messenger ribonucleic acid (mRNA) transcripts and production of full-length SMN protein." [1]

Indication:

SPINRAZA® is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA).[1]

Dosage Form/Strength:

- Injection: 12mg/5mL (2.4mg/mL) as a clear and colorless solution in a single-dose vial.

Criteria for Approval:

1. Initial Authorization Request must include:
    - Monitoring plan
    - Previous therapies trialed and the nature of the failure
    - Complete medication regimen
2. The patient will be treated by a specialist. **AND, ALL OF THE FOLLOWING**
    a. Diagnosis was confirmed by genetic testing
    b. Type I, II, or III SMA
    c. Patient is 15 years old or younger at initiation of treatment
    d. Prescriber agrees to do a platelet count and coagulation test before each dose. Patient must have a platelet count of > 50,000 cells per microliter
    e. Prescriber agrees to do quantitative spot urine testing before each dose
    f. Obtain a baseline motor milestone score from **ONE** the following assessments:
        - HINE

- CHOP-INTEND
- Upper Limb Module (ULM)
- Hammersmith Functional Motor Scale (HFMS)

Criteria for Reauthorization Approval:

1. Age appropriate tests for follow-up with the Department and to be measured by the Hammersmith Infant Neurologic Exam (HINE), 6 Minute Walk Test (6MWT), or Upper Limb Module (UML) as shown below and shown to be a responder.

Per the Package Insert for the HINE for infant to early childhood:

2. "A treatment responder was defined as any patient with at least a 2-point increase (or maximal score of 4) in ability to kick (consistent with improvement by at least 2 milestones), or at least a 1-point increase in the motor milestones of head control, rolling, sitting, crawling, standing or walking (consistent with improvement by at least 1 milestone). To be classified as a responder, patients needed to exhibit improvement in more categories of motor milestones than worsening."
3. For Ambulatory patients: 6 Minute Walk Test (6MWT), or Physical Therapy evaluation of strength and weaknesses before treatment and while treatment is ongoing.
4. For Non-ambulatory patients: Upper Limit Module (UML)
5. The subsequent authorization of Spinraza® is to be discontinued for failure to show response and outcomes through the HINE, HFMS or other appropriate test.

Criteria for Denial:

1. Following loading doses and throughout treatment, missing doses will be cause for discontinuing treatment and loss of authorization.; **OR,**
2. Known hypersensitivity to Spinraza® or any of its excipients.

Length of Authorization:

1. Initial coverage may be approved for 3 months through the loading doses.
2. Subsequent re-authorizations may be approved for an additional 6 months.

Quantity Limit:

1. The dispensing limit is 1 vial per 120 days.
2. Quantity limit does not apply for loading doses which include 4 doses (4 vials), administering 1 vial every 14 days for 3 doses, then the 4th dose 30 days following the 3rd dose and a maintenance dose 4 months after 4th dose.

CAUTIONS:

- Spinraza® must be administered by a healthcare professional trained in lumbar puncture and intrathecal injection.
- Spinraza® must be prescribed at no more than 12mg per dose administration.
- Close monitoring and adequate follow-up is required in both circumstances for the safety of the patient.
- The member will be monitored at baseline and at each dose, with for the following laboratory tests: platelet count, coagulation testing, and quantitative spot urine protein testing. Member is monitored for bleeding complications.

References / Footnotes:

1. Spinraza® [package insert]. Cambridge, MA: Biogen Inc. December 2016.
2. Gold Standard, Inc. Spinraza. Clinical Pharmacology [database online].

Available at: http://www.clinicalpharmacology.com. Accessed July 20, 2017.