STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Spinraza® (nusinersen)
Prior Authorization Request Form

Effective 10/01/2017

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.

Initial Prior Authorization Criteria:

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

1. Spinraza must be prescribed by 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: platelet count, prothrombin time; activated partial thromboplastin time, and quantitative spot urine protein testing; **AND**

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.

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 month 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.

References

1.) Lexi-Comp drug monograph for Spinraza (Reviewed 6/30/2017)
2.) Spinraza Package Insert (updated 5/2017)
3.) UpToDate clinical monograph (reviewed 7/6/2017)