CLINICAL MEDICATION POLICY	
Policy Name:	Spinraza™ (nusinersen)
Policy Number:	MP-018-MC-ALL
Responsible Departments:	Medical Management; Clinical Pharmacy
Provider Notice Date:	06/19/2017
Original Effective Date:	07/19/2017
Annual Approval Date:	04/19/2018
Revision Date:	N/A
Products:	North Carolina Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 4

DISCLAIMER

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ provides coverage under the medical benefits of the Company's Medicare products for medically necessary intravenous administration of Spinraza.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

DEFINITIONS

Spinal Muscular Atrophy (SMA) – A genetic disorder that is characterized by degeneration of the anterior horn cells in the spinal cord and motor nuclei in the lower brainstem. These diseases are classified by Types I through IV, depending upon the age of onset and the clinical course. The incidence of spinal muscular atrophy affects from 1 in 6,000 to 1 in 10,000 people.

Hammersmith Functional Motor Scale Expanded – A validated functional motor scale devised for use in children with SMA Type II and Type III to give objective information on motor ability and clinical progression.

Hammersmith Infant Neurological Exam – A widely used method for assessing neuromotor development in infants between 2 and 24 months of age.

Non-5q-Spinal Muscular Atrophy Diseases – The forms of SMA caused by genes that are not located in the survival motor neuron (SMN) region of chromosome 5.

PROCEDURES

1. Spinraza is considered medically necessary as an intrathecal infusion for the treatment of Spinal Muscular Atrophy (SMA) when the member meets all the following criteria:
   A. Must be prescribed by, or in consultation with, a neurologist or pediatric neurologist; AND
   B. Presymptomatic or symptomatic pediatric or adult members with a confirmed diagnosis of SMA Types I, II, or III by submission of laboratory testing demonstrating mutations in chromosome 5q that lead to survival motor neuron (SMN) protein deficiency; AND
   C. The following laboratory tests will be performed at baseline and prior to each dose of Spinraza and as clinically needed:
      1) Platelet count
      2) Prothrombin time; activated partial thromboplastin time
      3) Quantitative spot urine protein testing; AND
   D. Dosing is within the following prescribing-supported parameters:
      1) Recommended dose is 12 mg (5 mL) per administration
      2) Spinraza should be initiated with four loading doses
         a. First three loading doses should be administered at 14-day intervals
         b. Fourth loading dose should be administered 30 days after the third dose
         c. A maintenance dose should be administered once every four months thereafter; AND
   E. Administration of Spinraza must be performed by a health care provider experienced in performing lumbar punctures.

2. Contraindications
   There are no known contraindications to Spinraza.

3. When services are not covered
   Spinraza is not covered for conditions other than those listed above because the scientific evidence has not been established.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis (es) for which it is prescribed. These requests will be reviewed on a case-by-case basis to determine medical necessity.

When non-formulary criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Spinraza is inpatient and/or outpatient centers.

6. Coverage Determination
   Gateway Health℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

   There is no specific NCD or North Carolina LCD for Spinraza. For additional information, please see:
   http://www.palmettogba.com/palmetto/providers.nsf/docscat/Providers~JM%20Part%20B~Medical%20Policies~LCDs%20Coverage%20Articles%20NCDs

GOVERNING BODIES APPROVAL

The FDA approved Spinraza on December 23, 2016 for the treatment SMA in pediatric and adult patients. Spinraza is the first survival motor neuron-2 (SMN2)-directed antisense oligonucleotide approved for the treatment of SMA.

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
J3490	Unclassified drugs
J3590	Unclassified biologics
96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring spinal puncture [when associated with administration of nusinersen]

Diagnosis Codes

ICD-10 Codes	Description
G12.0	Infantile Spinal Muscular Atrophy, Type I [Werdnig-Hoffmann]
G12.1	Other inherited Spinal Muscular Atrophy • Childhood form, Type II Spinal Muscular Atrophy • Juvenile form, Type III Spinal Muscular Atrophy [Kugelberg-Welander]

POLICY SOURCE(S)

Cuisset JM, Estournet B. Recommendations for the Diagnosis and Management of Typical Childhood Spinal Muscular Atrophy. Rev Neurol. 2012 Dec; 168(12):902-9.

Wang CH, Finkel RS, Bertini ES et al. Consensus Statement for Standard of Care in Spinal Muscular Atrophy. J Child Neurol. 2007 Aug; 22(8):1027-49.

SPINRAZA (nusinersen) [Product Information Label]. Cambridge, MA. Biogen Inc. December 2016. Accessed on March 6, 2017 and available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209531lbl.pdf .

United States Census Bureau: Accessed on March 7, 2017 and available at: http://www.census.gov/popclock.

Genetics Home Reference. Spinal muscular atrophy. U.S. National Library of Medicine. Accessed on March 7, 2017 and available at: https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy#synonyms.

Policy History

Date	Activity
04/07/2017	Initial policy developed
04/19/2017	QI/UM Committee approval
07/19/2017	Provider effective date