Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Spinraza (nusinersen)
BILLING CODE	J2326 (1 unit = 0.1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 12 mg or 5 mL per administration
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Spinraza (nusinersen) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SPINAL MUSCULAR ATROPHY (SMA)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a neurologist with expertise in the treatment of SMA; AND
2. Member has documented diagnosis of SMA type I, II or III confirmed by BOTH of the following diagnostic test results (both a and b):
   a) The mutation or deletion of genes in chromosome 5q resulting in **one** of the following:
      i) homozygous gene deletion OR mutation (e.g., homozygous deletion of exon 7 at locus 5q13);
      ii) compound heterozygous mutation (e.g., deletion of SMN1 exon 7(allele 1) and mutation of SMN1 (allele 2));
   b) Genetic testing confirming 2 or 3 copies of SMN2; AND
3. Member has documented laboratory tests at baseline and prior to each dose of Spinraza as listed below:
   a) Platelet count; AND
   b) Prothrombin time; activated partial thromboplastin time; AND
   c) Quantitative spot urine protein testing; AND
4. Member has documentation of baseline of at least **one** of the following exams (based on patient age and motor ability):
   a) Hammersmith Infant Neurological Exam (HINE) (infant to early childhood);
   b) Hammersmith Functional Motor Scale Expanded (HFMSE);
   c) Upper Limb Module (ULM) Test (Non ambulatory);
   d) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND); AND
5. Member's gestational age is 37 to 42 weeks for singleton births or 34 to 42 weeks for twins; AND
6. Member's documented oxygen saturation is ≥ 92% (awake or asleep) without any supplemental oxygen or respiratory support; AND
7. Member does not have shunt or central nervous system (CNS) catheter; AND
8. Member has no history of bacterial meningitis or viral encephalitis; AND
9. Medication must not be concomitantly used with Zolgensma (discontinuation of Spinraza prior to Zolgensma therapy is required and Spinraza will not be reauthorized after Zolgensma infusion).

10. **Dosage allowed:** Initiate Spinraza treatment with 4 loading doses (12 mg (5 mL) per administration). 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. A maintenance dose should be administered once every 4 months thereafter.

If member meets all the requirements listed above, the medication will be approved 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member has documentation of positive clinical improvement from pretreatment baseline status in spinal muscular atrophy-associated symptoms or maintenance (not worsening) of the disease state (e.g., decreased decline in motor function, increased ability to kick, increased in the motor milestones of head control, rolling, sitting, crawling, standing, or walking, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Spinraza (nusinersen) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/05/2017	New policy for Spinraza created.
06/11/2019	Concomitant used of Spinraza with Zolgensma will not be authorized. Spinraza must be discontinued before Zolgensma infusion. Spinraza will not be reauthorized after Zolgensma infusion.

References:

1. Spinraza [package insert]. Cambridge, MA; Biogen Inc.; December, 2016.
2. Markowitz JA, Singh P, Darras BT. Spinal Muscular Atrophy: A Clinical and Research Update. Pediatric Neurology 46 (2012) 1-12.
3. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants With Spinal Muscular Atrophy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Available from: https://clinicaltrials.gov/show/NCT02193074. NLM Identifier: NCT02193074.
4. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Patients With Later-onset Spinal Muscular Atrophy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000. Available from: https://clinicaltrials.gov/show/NCT02292537. NLM Identifier: NCT02292537.
5. Finkel RS, Chiriboga CA, Vajsar J, et al. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. Lancet. 2017 Dec 17;388(10063):3017-3026.

Effective date: 09/26/2019
Revised date: 06/11/2019