Louisiana ~~Fee-for-Service~~ Medicaid
Nusinersen (Spinraza®)

The ~~Nusinersen (Spinraza®) requires clinical authorization. The~~ *Nusinersen (Spinraza®) Clinical ~~Louisiana Uniform Prescription Drug Prior~~ Authorization Form* should be utilized to request clinical authorization for nusinersen (Spinraza®).

Approval Criteria~~Requests for nusinersen will be considered for initial approval if all of the following criteria are met~~

~~:~~

- The recipient has a diagnosis of spinal muscular atrophy (SMA):
  - Type I, also known as infantile-onset or Werdnig-Hoffmann disease (ICD-10-CM G12.0), symptoms are present at birth or by 6 months of age, unable to sit without assistance; **OR**
  - Type II (ICD-10-CM G12.1), symptoms develop between 6 months and 12 months of age, able to sit unassisted but unable to stand or walk independently; **OR**
  - Type III, also known as Kugelberg-Welander disease (ICD-10-CM G12.1), usually diagnosed between early childhood and early adolescence, able to stand and walk independently but may lose this ability later in life; **AND**
- The diagnosis of SMA is confirmed with genetic testing~~ and the results are noted on the request~~; **AND**
- The recipient is 1~~6~~5 years of age or younger at the initiation of treatment; **AND**
- The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of spinal muscular atrophy; **AND**
- **ONE** of the following motor milestone tests have been performed and the results are noted on the request form:
  - For recipients < 2 years of age: Hammersmith Infant Neurological Examination Section 2 (HINE-2); **OR**
  - For ambulatory recipients ≥3 years of age: Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
  - For non-ambulatory recipients >3 years of age: Revised Upper Limb Module (RULM); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states; **AND**
  - The recipient does not have a coexisting terminal condition or a condition with which the risk of nusinersen treatment outweighs the potential benefits.

Reauthorization Criteria~~quests to continue treatment with nusinersen will be considered for approval if all of the following criteria are met:~~

- Recipient continues to meet initial approval criteria; **AND**
- The prescriber states on the request that there has been a positive clinical benefit from nusinersen therapy as evidenced by:
    - improvement or maintenance of motor skills or ability to sit, crawl, stand or walk, or new motor milestone; **AND**

~~1. is clinically significant improvement with:~~

~~2. 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); **AND**~~

- when considering all categories of motor milestones, the number of categories which show improvement is greater than the number that shows worsening.

Duration of initial authorization: 6 months

Duration of reauthorization~~, both initial and reauthorization~~: 12 months

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

References:

Spinraza (nusinersen) [package insert]. Cambridge, MA: Biogen; June 2019~~May 2018~~. Retrieved from https://www.spinraza-hcp.com/content/dam/commercial/specialty/spinraza/hcp/en_us/pdf/spinraza-prescribing-information.pdf

U.S. National Library of Medicine. Genetics Home Reference. (2018, September 25). Spinal Muscular Atrophy. Retrieved from https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy

Revision	Date
Added requirement for motor milestone testing and modified reauthorization criteria to remove point-related increases in motor milestones	September 2019
Modified age to reflect updated prescribing information	September 2019