Nusinersen (Spinraza)
Coverage Criteria

Description:

Nusinersen (Spinraza) is a medication used to treat certain types of spinal muscular atrophy (SMA), a rare genetic disorder that affects motor function. Spinraza is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of SMA in pediatric and adult patients. It is given by intrathecal (IT) injection directly in to the spinal column.

Policy:

The intent of this policy is to define clinical characteristics to identify patients who qualify for Nusinersen (Spinraza) require a prior authorization and will be covered when the criteria have been met.

Nusinersen (Spinraza) will be covered through Amida Care's medical benefit.

Prior Authorization Criteria:

Nusinersen (Spinraza) may be considered medically necessary in patients when there is clinical documentation (including, but not limited to chart notes) confirming diagnosis of:

Spinal Muscular Atrophy and the following criteria is met:

- Member (pediatric or adult) must have presymptomatic or symptomatic with a confirmed diagnosis of **SMA Types I, II, or III** by submission of laboratory testing demonstrating corresponding mutations or deletions in **chromosome 5q13** that lead to survival motor neuron (SMN) protein deficiency
- Medication must be prescribed by or in consultation with a neurologist or pediatric neurologist.
- The provider attests that the following laboratory tests will be performed at baseline, prior to each dose of Spinraza, and as clinically needed:
    - Platelet Count
    - Prothrombin time; activated partial thromboplastin time
    - Quantitative spot urine protein testing
- Member has documentation of a baseline evaluation, including at least one of the following standardized assessment of motor function such as:
    - Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Hammersmith Infant Neurologic Exam (HINE)
    - Upper limb module (ULM) score
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
    - Six-minute walk test

Spinraza is not proven or medically necessary for SMA without chromosome 5q mutations or deletions.

Spinraza is not proven or medically necessary for routine concomitant treatment of SMA in patients who have previously received gene replacement therapy such as abeparvovec (Zolgensma).

Administration and Authorization Period

I. Nusinersen (Spinraza) must be administered in a healthcare facility or provider officer. Spinraza is not considered to be a self-administered medication.

II. When pre-authorization is approved, nusinersen (Spinraza) may be authorized for up to twelve months, for a maximum of 4 doses (12 mg per dose) in a 64-day period, based on loading doses on Days 1, 15, 29, 59, then a maximum of 1 dose (12 mg per dose) in a 4-month period (based on dosing on days 179 and 299), for a **total of 6 doses in a 299-day period**

III. After initial authorization, nusinersen (Spinraza) may be reauthorized for a maximum of **three doses (12 mg per dose) every 12 months** [based on dosing of 12 mg every 4 months]. Authorization shall be reviewed at least every 12 months when criteria **A** and **B** are met:

   A. Documentation (including, but not limited to chart notes) is provided showing current medical necessity criteria are met, including comprehensive care by, or in consultation with, a pediatric neuromuscular specialist.

   B. Documentation (including, but not **limited** to chart notes) is provided showing that the medication is effective, including documentation of clinically significant improvement of motor function or stabilization of motor function loss, which must include clinical documentation of a physical assessment, motor function function-based testing, and need for medical intervention related to SMA symptoms, relative to baseline (and/or previous authorization period). Overall motor function must be improved/superior relative to that projected for the natural course of SMA.

References:

1. Spinraza (nusinersen) injection for intrathecal use [package insert]. Cambridge, MA: Biogen, Inc; October 2018
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3. Bodamer, OA. Spinal muscular atrophy (SMA). Last updated Dec. 13, 2016. In: Nordli DR, Firth, H.V., Martin, R. UpToDate, Waltham, MA, 2016.
4. Product dossier: Spinraza (nusinersen) – April 13, 2017. Cambridge, MA: Biogen; Data reviewed May 2017.
5. FDA Center for Drug Evaluation and Research (CDER). Medical Review. NDA 209531; Spinraza (nusinersen). 12/23/2016. [cited 1/25/2017]; Available from: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/209531Orig1s000TOC.cfm
6. Wang, CH, Finkel, RS, Bertini, ES, et al. Consensus statement for standard of care in spinal muscular atrophy. Journal of child neurology. 2007 Aug;22(8):1027-49. PMID: 17761659