Spinraza™ (nusinersen)

Humana

Pharmacy Coverage Policy

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Line of Business: Medicare, Exchanges, Puerto Rico, Commercial, Medicaid
Policy Type: Prior Authorization

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Description

Spinraza (nusinersen) is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide.

Spinraza (nusinersen) is designed to alter splicing of SMN2 mRNA to increase full-length SMN protein production.

Spinraza (nusinersen) is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Nusinersen is available as Spinraza 12 mg/5 mL injection solution in a single-dose vial.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of

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the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Spinraza (nusinersen) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Spinal Muscular Atrophy (SMA)

- The member must have a diagnosis of spinal muscular atrophy documented by:
  - SMN1 gene deletion, **OR**
  - 5q SMA homozygous gene deletion, homozygous mutation, or compound heterozygote; **AND**
- The member has no more than two copies of SMN2, **AND**
- The member has an onset of clinical signs and symptoms consistent with SMA at ≤ 6 months

Continuation of Therapy

- The member is responding to therapy, defined as:
  - Improvement in motor milestones by the Hammersmith Infant Neurological Examination (HINE) from predicted natural disease progression (e.g. head control, independent sitting, ability to kick in supine position, rolling, crawling), **OR**
  - Prevention of permanent ventilation (≥ 16 hours ventilation/day continuously for > 21 days in absence of an acute reversible event or tracheostomy)

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- Recommended dosing: 12 mg (5mL) per intrathecal administration
  - **Loading doses**: first three loading doses should be administered at 14 day intervals; fourth loading dose should be administered 30 days after the third dose
  - **Maintenance doses:** administered once every 4 months thereafter

- Approval duration
  - **Initial approval:** 6 months
  - **Continuation of therapy approval:** 6 months

Coverage Limitations

Spinraza (nusinersen) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Spinraza (nusinersen):

- Spinal muscular atrophy (SMA) is an autosomal recessive neuromuscular disease characterized by degeneration of motor neurons that leads to atrophy of the voluntary muscles of the limbs and trunk. SMA is caused by low levels of SMN protein due to deletions or loss-of-function mutations in the SMN1 gene. With an estimated prevalence of 9.1 to 10.0 per 100,000 live births, SMA is one of the more common rare diseases and is the leading genetic cause of infant mortality. SMA is classified into types I – IV based on age of symptom onset and highest motor function achieved. Generally, the earlier the disease onset, the more severe the prognosis is. Type I, called Werdnig-Hoffman disease, is of the severest severity, with age of onset under 6 months and life expectancy under 2 years.
- Spinraza (nusinersen) requires lab monitoring of platelet count, prothrombin time or activated partial thromboplastin time, and quantitative spot urine protein testing at baseline, prior to each dose of nusinersen, and as clinically needed.

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Provider Claims Codes

There are no provider claim codes associated with this policy.

Medical Terms

Spinraza; nusinersen; spinal muscular atrophy; intrathecal;

References

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6. New Data Show SPINRAZA™ (nusinersen) Significantly Reduces Risk of Death or Permanent Ventilation in Infantile-Onset Spinal Muscular Atrophy. http://pipelinereview.com/index.php/2017011463622/DNA-RNA-and-Cells/New-Data-Show-SPINRAZA-nusinersen-Significantly-Reduces-Risk-of-Death-or-Permanent-Ventilation-in-Infantile-Onset-Spinal-Muscular-Atrophy.html. Published January 14, 2016. Accessed January 17, 2017.
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Spinal Muscular Atrophy. J Child Neurol. 2007;22(8):1027-49.

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