blue california
Promise Health Plan

nusinersen (Spinraza)

Medical Benefit Drug Policy

Place of Service

Hospital Administration
Office Administration
Outpatient Facility Infusion Administration
Infusion Center Administration
Home Infusion

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: antisense oligonucleotide shown in in vitro assays and studies in transgenic animal models of SMA to increase exon 7 inclusion in SMN2 messenger ribonucleic acid (mRNA) transcripts and production of f
HCPCS:
J2326:Injection, nusinersen, 0.1 mg
How Supplied:
12 mg (single-dose vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Spinal Muscular Atrophy (SMA)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Spinal Muscular Atrophy (SMA)
Meets medical necessity if all the following are met:
1. Prescribed by or in consultation with a neurologist
2. Diagnosis of SMA confirmed by genetic testing demonstrating bi-allelic mutations in the survival motor neuron 1 (SMN1) gene by one of the following (a or b):

   a. Deletion of both copies of the SMN1 gene
   b. Identification of pathogenic variant(s) in both copies of the SMN1 gene
3. Genetic documentation of 4 or fewer copies of SMN2
4. Either of the following:
   a. Provider attestation that patient has not received prior therapy with Zolgensma
   b. Provider attestation that patient had an inadequate response with Zolgensma
5. Not being used as an initial combination regimen with Evrysdi
6. Not being used as an initial combination regimen in combination with Zolgensma

Covered Doses:

- Initial: 1 vial (12 mg) administered intrathecally every 2 weeks x 3; followed by 1 vial one month later; then 1 vial every 4 months thereafter
- Maintenance: 1 vial every 4 months

Coverage Period:

- Initial: one year
- Reauthorization: Yearly based upon documentation of stabilization or improvement of continued motor function relative to projected natural course of SMA

ICD-10:

G12.0, G12.1

References

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2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Finkel RS, Mercuri E, Meyer OH, et al. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. Neuromuscul Disord NMD. 2018;28(3):197-207. doi:10.1016/j.nmd.2017.11.004
4. Glascock J, Sampson J, Connolly AM, et al. Revised recommendations for the treatment of infants diagnosed with spinal muscular atrophy via newborn screening who have 4 copies of SMN2. J Neuromuscul Dis 2020; 7:97-100.
5. Institute for Clinical and Economic Review (ICER), Spinraza® and Zolgensma® for Spinal Muscular Atrophy: Effectiveness and Value. Final Evidence Report. April 3, 2019 (Updated May 24, 2019). Available from: https://icer-review.org/wp-content/uploads/2018/07/ICER_SMA_Final_Evidence_Report_052419.pdf. Accessed: May 24, 2019.
6. Mercuri, E, Bertini, E, Iannaccone, S. Childhood spinal muscular atrophy: controversies and challenges. Lancet Neurol 2012; 11(5): 443-452.

7. Mercuri E, Finkel R, Kirschner J et al. Efficacy and safety of nusinersen in children with later-onset spinal muscular atrophy (SMA): end of study results from the phase 3 CHERISH study. Neuromuscular Disord 2017; 27(Suppl 2):S210.
8. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. Neuromuscul Disord NMD. 2018;28(2):103-115.
9. Michelson D, Ciafaloni E, Ashwal S, et al. Evidence in focus: Nusinersen use in spinal muscular atrophy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018;91(20):923-933.
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Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee