PHARMACY POLICY STATEMENT
TRICARE

DRUG NAME	Spinraza (nusinersen)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Spinraza is a survival of motor neuron 2 (SMN2) splicing modifier initially approved by the FDA in 2020. It is indicated for the treatment of pediatric and adult patients with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron (SMN1) gene.
Spinal muscular atrophy (SMA) is a genetic, autosomal recessive neuromuscular disorder caused by a defect in the survival of the motor neuron 1 (*SMN1*) gene. SMA is the leading genetic cause of infant mortality and affects approximately 1 in every 10,000 infants. There are multiple types of SMA, and the age of onset and severity of the disease varies with each type.

Spinraza (nusinersen) will be considered for coverage when the following criteria are met:

Spinal Muscular Atrophy (SMA)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with a neurologist; AND
2. Member has a diagnosis of SMA confirmed by genetic testing showing any of the following:
   a) Homozygous gene deletion of the survival motor neuron 1 (SMN1) gene (e.g., absence of SMN1 gene)
   b) Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7)
   c) Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]); AND
3. Member has documentation in chart notes of the following:
   a) 2 to 4 copies of SMN2;
   b) Coagulation lab tests (prothrombin time, activated partial prothrombin time, etc.);
   c) Platelet counts;
   d) Quantitative spot protein urine testing; AND
4. Member does **NOT** have any of the following:
   a) Prior treatment with gene therapy;
   b) Advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence); AND
   c) Concomitant use with other SMA disease modifying treatment (such as Evrysdi)
5. **Dosage allowed/Quantity limit:** administer a total of four 12 mg loading doses. 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. Administer a 12 mg maintenance dose every 4 months thereafter. Quantity limit: 1 vial per 16 weeks

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes demonstrate improvement or stabilization of signs and symptoms such as decreased decline in motor function, increased ability to kick, increased head control, rolling, sitting, crawling, standing, or walking, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Scenarios that do not meet the above requirements may be considers Spinraza (nusinersen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
07/11/2022	Transferred to new format. Updated references. Removed SMA typing. Removed baseline motor ability assessment scores.
01/13/2026	Updated references; removed gestational age requirement; removed oxygen saturation requirement; removed shunt or CNS catheter contraindication; removed history of bacterial meningitis or viral encephalitis contraindication; replaced no prior use of Zolgensma with gene therapy; lengthened initial authorization from 6 months to 12 months; replaced no concomitant use of Evrysdi with no concomitant use of SMA disease modifying treatment; added requirement member does not have advanced SMA

References:

1. Spinraza [package insert]. Biogen Inc.; 2024.
2. Finkel RS et al. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. *Lancet*. 2016 Dec 17;388(10063):3017-3026.
3. Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. *N Engl J Med.* 2018;378(7):625-635. doi:10.1056/NEJMoa1710504
4. Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. *N Engl J Med*. 2017;377(18):1723-1732. doi:10.1056/NEJMoa1702752
5. 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(2):97-100. doi:10.3233/JND-190468
6. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. *J Neuromuscul Dis*. 2018;5(2):145-158. doi:10.3233/JND-180304
7. Schroth M, Deans J, Arya K, et al. Spinal Muscular Atrophy Update in Best Practices: Recommendations for Diagnosis Considerations. *Neurol Clin Pract.* 2024;14(4):e200310. doi:10.1212/CPJ.0000000000200310
8. Schroth MK, Deans J, Bharucha Goebel DX, et al. Spinal Muscular Atrophy Update in Best Practices: Recommendations for Treatment Considerations. *Neurol Clin Pract.* 2025;15(1):e200374. doi:10.1212/CPJ.0000000000200374

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