

Policy Name:	Spinraza (nusinersen)	Policy #:	2609P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Spinraza.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Spinraza under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of Spinal Muscular Atrophy (SMA) types I, II, or III
- 1.2 Documentation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote
- 1.3 Ordered by a Geneticist or provider specializing in the treatment of SMA
- 1.4 Member is 15 years of age or younger at initiation of treatment
- 1.5 Documented baseline motor milestone scores according to one of the following age-appropriate assessments:
 - Hammersmith Infant Neurologic Exam (HINE)
 - Modified Hammersmith Functional Motor-Scale
 - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP –INTEND)
 - Bayley Scales of Infant and Toddler Development (BSID-III)
 - Motor Function Measure 32 (MFM-32)
- 1.6 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Spinraza by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Spinraza will not be covered after treatment with Zolgensma because its use following Zolgensma infusion has not been studied and is considered experimental/investigational
 - Note: Patients in the clinical trials that received Zolgensma before the age of 2 were followed up to 5 years post-treatment and did not require additional medications
- 2.2 Spinraza will not be covered in combination with Evrysdi because the concomitant use of these two drugs has not been studied and is considered experimental/investigational

3. Approval Period

- 3.1 Initial Approval: 6 administrations within a 12 month approval duration

- 3.2 Subsequent Approvals: 12 months, with documented improvement of motor milestone scores according to Hammersmith Infant Neurologic Exam (HINE), Modified Hammersmith Functional Motor-Scale, or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP - INTEND)

CPT Codes

96365 – 96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

HCPCS Codes

J2326	Injection, nusinersen, 0.1mg
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References

1. Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen; February 2023.
2. Finkel RS, Mercuri E, Meyer OH, et al; SMA Care group. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. *Neuromuscul Disord*. 2018 Mar;28(3):197-207.
3. Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. *N Engl J Med* 2017; 377:1723.
4. Hagenacker T, Wurster CD, Günther R, et al. Nusinersen in adults with 5q spinal muscular atrophy: a non-interventional, multicentre, observational cohort study. *Lancet Neurol* 2020; 19:317.
5. Pechmann A, Behrens M, Dörnbrack K, et al. Effect of nusinersen on motor, respiratory and bulbar function in early-onset spinal muscular atrophy. *Brain* 2023; 146:668.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web.

Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.