Pharmacy Drug Policy & Procedure

Policy Name:	Spinraza (nusinersen)	Policy #:	2609P

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 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	

HCPCS Codes	
J2326	Injection, nusinersen, 0.1mg

References

1. Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen; April 2024.
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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