



**Spinraza (Nusinersen) Medication
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange**

Document Number: 044

	Commercial and Qualified Health Plans	MassHealth
Authorization required for administration in all settings of care: • Acute inpatient • Surgical Day Center, office • Outpatient	X	X
Not covered		

Approval Criteria

1. Patient Population

AllWays Health Partners may authorize coverage of Spinraza (nusinersen) for members, when ALL of the following criteria are met:

- Members have a documented diagnosis of spinal muscular atrophy (SMA) type 1, 2, or 3 confirmed by molecular genetic testing
- Clinical documentation of baseline (pre-treatment) motor function skills has been submitted
- Members have already established care with a SMA multidisciplinary care center
- Members have none of the following: hospitalization for surgery or pulmonary event within past 2 months, active infection, brain or spinal cord disease, meningitis, implanted CSF shunt, treatment with another investigational drug <1 month of evaluation

2. Prescribing

- Prescribed by neurologist with expertise in the management of SMA

3. Dosing and Administration

- 4 loading doses: First 3 loading doses at 14 day intervals, 4th loading dose 30 days after 3rd dose
- Maintenance dose every 4 months after the 4th loading dose
- Dose: 12 mg (5 mL) given intrathecally as bolus injection over 1-3 minutes using a spinal anesthesia needle
- Prior to administration, remove 5 mL of cerebral spinal fluid (CSF)
- Administered by attending neurologist experienced in administering intrathecal injections

4. Monitoring

- At baseline and prior to each dose, obtain a platelet count, coagulation test (i.e., prothrombin time, activated partial thromboplastin time) and quantitative spot urine protein test
 - At each visit, assessment for improvement in clinical outcomes via motor function using HINE, CHOP-INTEND, HFMSE or other age-appropriate motor function scales
5. Duration of Therapy
- May be continued until disease progression or unacceptable toxicity (may require several months to a year for improvement in motor function to be seen)
 - Discontinuation of drug to be determined based on age-appropriate performance on motor function and patient reported outcome scales using standardized instrument(s)
6. Approval Duration:
- Initial approval x 1 year
7. Reauthorizations
- Documentation of assessment of improvement in clinical outcomes via motor function using HINE, CHOP-INTEND, HFMSE or other age-appropriate motor function scale
 - Reauthorization x 1 year

Reviewed by Clinical Experts

February 2017

Approved by NHP P&T Committee

Revised

August 2017; P&T approval

References

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