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

Document Number: 044

<table>
<thead>
<tr>
<th>Authorization required for administration in all settings of care:</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
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</thead>
<tbody>
<tr>
<td>• Acute inpatient</td>
<td>X</td>
<td>X</td>
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<td>• Surgical Day Center, office</td>
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<td>• Outpatient</td>
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<tr>
<td>Not covered</td>
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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 AllWays Health Partners P&T Committee

Revised
August 2017; P&T approval

References


6. FDA summary review.  


