NHP Criteria

1. Patient Population
   NHP 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


