



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Dennis R. Schrader, Secretary

MARYLAND MEDICAL ASSISTANCE PROGRAM

Hospital Transmittal No. 250

Physician Transmittal No. 142

Pharmacy Transmittal No. 204

June 23, 2017

TO: Hospital Administrators
Neurologists
Pharmacies

FROM: Susan J. Tucker, Executive Director
Office of Health Services

RE: Preauthorization Guidelines and Coverage Criteria for Spinraza® (Nusinersen)

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this memorandum.

For dates of service on or after July 1, 2017, Maryland Medicaid will cover the drug Spinraza®, which can be used for the treatment of spinal muscular atrophy in patients when certain criteria is met and the treatment is determined to be medically necessary. Attached are the coverage criteria and preauthorization requirements for Spinraza®. Spinraza® will be reimbursed using the HCPCS code of J3490 with the modifier KX, and the National Drug Code (NDC) 64406-058-01. Maryland Medicaid considers Spinraza® experimental and not medically necessary when the criteria are not met.

In order to be reimbursed for initial and continuing therapy, Spinraza® must be preauthorized by Maryland Medicaid.

- If the drug is administered in a physician’s office, please follow the preauthorization process that is already in place for the Physicians’ Services Program. Please see the link to the physician’s preauthorization form in the next bullet.
- If the drug is administered in the hospital, the rendering physician must follow the preauthorization process in place with the Physicians’ Services Program. The preauthorization form may be found at:
<https://mmcp.health.maryland.gov/Documents/Physician%20Services%20Preauthorization%20Request%20Form.pdf>.

- If the drug is purchased by a pharmacy and obtained by the hospital for administration of the drug, preauthorization must be requested by the pharmacy through the preauthorization process already in place for the Pharmacy Program. In this situation, the Department will reimburse the pharmacy for the drug and the hospital for the administration of the drug if all criteria for coverage are met.

For questions regarding the preauthorization process through the Physician Program, please contact Christa Smith at 410-767-1462 or christa.smith@maryland.gov.

For questions regarding the preauthorization process for the Pharmacy Program, please contact Dixit Shah at 410-767-1456 or dixit.shah@maryland.gov.

For questions regarding the coverage criteria for Spinraza®, please contact Jamie Perry, MD at 410-767-9865 or jamie.perry@maryland.gov.

Coverage Criteria for Spinraza® (Nusinersen)

Maryland Medicaid considers Spinraza® medically necessary for the treatment of spinal muscular atrophy (SMA) in patients when **ALL** of the following criteria are met:

- Diagnosis of SMA Type 1 with symptom onset at < 6 months of age;
- Diagnosis by a neurologist with expertise in the diagnosis of SMA;
- Genetic testing confirming both:
 - 5q SMA homozygous gene deletion, homozygous gene mutation, or compound heterozygous mutation; **AND**
 - At least 2 copies of SMN2

AND

- Patient is not dependent on invasive ventilation or tracheostomy;
- Patient is not dependent on non-invasive ventilation for greater than 12 hours in a 24 hour period

AND

- Spinraza® must be prescribed by a neurologist experienced in treating SMA;
- Spinraza® must be given according to the current FDA labelling guidelines for dosage and timing;
- Spinraza® must be administered intrathecally by a physician or other healthcare professional experienced in performing lumbar punctures

For Initial Therapy:

- Medical records must be submitted documenting all of the above criteria;
- Medical records must be submitted documenting a baseline motor examination utilizing at least one of the following exams (based on patient age and motor ability) to establish baseline motor ability:
 - Hammersmith Infant Neurological Exam (HINE);
 - Hammersmith Functional Motor Scale Expanded (HFMSSE);
 - Upper Limb Module Test (non-ambulatory); or
 - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); and
- Spinraza® will be initially preauthorized for 4 loading doses when criteria are met.

For Continuing Therapy:

- Each Spinraza® maintenance dose must be preauthorized;
- All of the criteria for initial therapy must be met;
- Medical records must be submitted that document repeat motor testing since the most recent Spinraza® dose (and not more than 1 month prior to the next scheduled dose) using the same motor test done to establish baseline motor ability, unless it is determined that the original test is no longer appropriate;
- Repeat motor testing must document a response to treatment as defined by the following:

- HINE:
 - Improvement or maintenance of previous improvement of at least 2 points (or max score of 4) in ability to kick (improvement in at least 2 milestones); **OR**
 - Improvement or maintenance of previous improvement of at least 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing or walking (consistent with improvement by at least 1 milestone); **AND**
 - Improvement or maintenance of previous improvement in more HINE motor milestones than worsening;

- HFMSE:
 - Improvement or maintenance of improvement of at least a 3 point increase in score;

- ULM:
 - Improvement or maintenance of previous improvement of at least 2 point increase in score;

- CHOP-INTEND:
 - Improvement or maintenance of previous improvement of at least 4 point increase in score.

Maryland Medicaid considers Spinraza® investigational and not medically necessary when the criteria above are not met and for all other indications.