MARYLAND DEPARTMENT OF HEALTH
Medicaid Pharmacy Program

SPINRAZA PRIOR AUTHORIZATION FORM
Incomplete forms will be returned
1-800-492-5231-Option 3
Fax form to 410-333-5398

Please attach copies of the patient's medical history summary, lab and genetic test reports to the State.
****Please review our clinical criteria before submitting this form. ****

Patient Information:

NAME: DOB:

Recipient's Maryland Medicaid Number: SEX: ❑ M ❑ F

Name of Facility/Clinic:

Prescriber Information:

NAME: NPI #

Phone # Fax #

Contact Person for this Request:

NAME: Phone # Fax #

Billing: (Choose one)

☐ Dispensed and billed by the Pharmacy Program.
☐ Furnished and billed directly by the Prescriber.

Has patient received previous treatment with Spinraza? Yes___ No ___

If yes, what was the start date? _____ and how many doses has patient received? ____

Is patient enrolled in a clinical trial? Yes____ No ____

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 I, II or III;
❑ 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 beyond use for naps and nighttime sleep;
❑ If patient has Type II or III SMA, patients must have some functional upper extremity use;

AND

❑ Spinraza has been prescribed by a neurologist experienced in treating SMA;
❑ Spinraza will be given according to the current FDA labelling guidelines for dosage and timing;
❑ Spinraza will 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 (HFMSE)

  Remove space here

  - ❑ Upper Limb Module Test (non-ambulatory)
  - ❑ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

Note: Initially, Spinraza will be 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:

1. **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;
2. **HFMSE**
   - ❑ Improvement or maintenance of improvement of at least a 3 point increase in score;
3. **ULM**
   - ❑ Improvement or maintenance of previous improvement of at least 2 point increase in score;
4. **CHOP-INTEND**
   - ❑ Improvement or maintenance of previous improvement of at least 4 point increase in score.

I certify that benefit of treatment for this patient outweigh the risks and verify that the information provided on this form is true and accurate to the best of my knowledge.

Prescriber's Signature_____ Date_____

Fax completed form to 410-333-5398