HUSKY Health Program Spinraza® (nusinersen)
Prior Authorization Request Form
Phone: 1.800.440.5071

THIS FORM IS TO BE COMPLETED BY THE ORDERING PROVIDER AND FAXED WITH CLINICAL DOCUMENTATION TO 203.265.3994

Member Information				
Member ID #:		Member Name (Last, First):		DOS:
DOB:	Sex:	Primary Diagnosis Code:	HCPCS Code:	
Address:		City, State, Zip:		

ALL Authorization Requests:
Please fill out completely for **all initial and reauthorization** requests.

□ Initial Request □ First Reauthorization Request □ Subsequent Reauthorization Request

1. Please indicate the patient's SMA Diagnosis:
   - □ Pre-Symptomatic SMA
   - □ Symptomatic SMA:
     - □ Type 1 □ Type 2 □ Type 3

Note: The use of Spinraza (nusinersen) is considered investigational in the treatment of SMA Types 0 and 4.

2. Has Spinraza been ordered by, or in consultation with, a physician experienced in the treatment of SMA?	○ Yes	○ No
3. Is the patient dependent on permanent ventilatory support (defined as tracheostomy or non-invasive ventilator support for at least 16 hours per day for > 21 days in the absence of an acute reversible event)?	○ Yes	○ No
4. Will the administration follow the current FDA Spinraza labeling for dosing protocol?	○ Yes	○ No

INITIAL Authorization Requests:
Please fill out completely for all **initial authorization** requests.

1. Has genetic testing been performed, and confirmed a homozygous deletion, homozygous mutation, or compound heterozygous mutations of the SM1 gene on chromosome 5q?	○ Yes	○ No
2. Has a description of the benefits, risks, and treatment expectations been provided to the individual, parent, or guardian?	○ Yes	○ No
3. Previous treatment with gene replacement therapy: a. Has the patient previously received gene replacement therapy (onasemnogene abeparvovec) for SMA? b. If yes to (a), and the patient has symptomatic SMA, has the patient experienced a decline in clinical status?	○ Yes ○ Yes	○ No ○ No
4. Is the patient on concurrent gene-based SMA therapy (e.g., risdiplam)?	○ Yes	○ No
5. Has a **baseline** motor exam been completed by a physician or physical therapist (specializing in SMA motor exam evaluations and supervised by a neurologist or physiatrist) experienced in treating SMA?	○ Yes	○ No

6. Please indicate the motor exam used and provide the baseline score:
   - □ Hammersmith Infant Neurological Exam, Section 2 (HINE-2)
   - □ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
   - □ Hammersmith Functional Motor Scale Expanded (HFMSE)
   - □ Revised Upper Limb Module (RULM)
   - □ Other

   If other, ***please provide test name***: _____

   Baseline Pre-Treatment Exam Score:_____ Date of Exam:_____

FIRST Reauthorization for Pre-Symptomatic SMA:
Please fill out completely.

1. Has the individual continued to have appropriate developmental gains in motor functions, and continued to attain motor milestones?	○ Yes	○ No
2. Has the individual received gene replacement therapy (e.g., onasemnogene abeparvovec) since Spinraza therapy was originally approved?	○ Yes	○ No
3. Is the individual on concurrent gene-based SMA therapy (e.g., risdiplam)?	○ Yes	○ No
4. Has the individual remained asymptomatic? **If the individual has developed symptoms and there is a worsening in motor ability, please attach the following documentation to this request: a letter from the treating physician explaining why the medication should be continued, and articles/studies from evidence-based, peer-reviewed medical literature supporting the treating physician's recommendation to continue treatment.**	○ Yes	○ No
5. Does documentation show that the benefits of treatments continue to outweigh the risks (i.e., continued intrathecal injections)? ***Please describe:***	○ Yes	○ No

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FIRST Reauthorization for <u>Symptomatic SMA Type 1, 2, or 3</u> Please fill out completely to document response to treatment.		
1. Has a re-examination been performed by the same examiner as the baseline exam, or if not possible, has a re-examination been performed by another physician or physical therapist (specializing in SMA motor exam evaluations and supervised by a neurologist or physiatrist) experienced in treating SMA?	◯ Yes	◯ No
2. Has the individual responded to the treatment by demonstrating an improved motor ability in repeat motor testing? **If no clear response is noted, a letter from the treating physician explaining why the medication should be continued, along with supporting documentation from the medical literature, must be attached to this request.**	◯ Yes	◯ No
3. Please indicate the motor exam used, and provide the post-treatment score and change from the baseline: □ Hammersmith Infant Neurological Exam, Section 2 (HINE-2) □ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) □ Hammersmith Functional Motor Scale Expanded (HFMSE) □ Revised Upper Limb Module (RULM) □ Other If other, ***please provide test name***: _____ Post-Treatment Exam Score:_____ Change from Baseline Score: _____ Date of Exam:_____		
4. Has the individual received gene replacement therapy (e.g., onasemnogene abeparvovec) since Spinraza therapy was initially approved?	◯ Yes	◯ No
5. If the individual was prescribed Spinraza due to clinical worsening after receiving gene replacement therapy (e.g., onasemnogene abeparvovec), is there documentation of stabilization or improvement in clinical status with Spinraza therapy (e.g., impact on motor milestones)?	◯ Yes	◯ No
6. Is the individual on concurrent gene-based SMA therapy (e.g., risdiplam)?	◯ Yes	◯ No
7. Does documentation show that the benefits of treatments continue to outweigh the risks (i.e., continued intrathecal injections)? ***Please describe:***	◯ Yes	◯ No

SUBSEQUENT Reauthorizations for both Pre-Symptomatic and Symptomatic SMA: Please fill out completely.		
1.Does documentation show that the benefits of treatments continue to outweigh the risks (i.e., continued intrathecal injections)? ***Please describe:***	◯ Yes	◯ No
2. Has the individual received gene replacement therapy (onasemnogene abeparvovec) since Spinraza therapy was originally approved?	◯ Yes	◯ No
3. If the individual was prescribed Spinraza due to clinical worsening after receiving gene replacement therapy (e.g., onasemnogene abeparvovec), is there documentation of stabilization or improvement in clinical status with Spinraza therapy (e.g., impact on motor milestones)?	◯ Yes	◯ No
4. Is the individual on concurrent gene-based SMA therapy (e.g., risdiplam)?	◯ Yes	◯ No

Billing Provider Information	
Medicaid Billing Number:	Billing Provider Name:
Street Address:	City, State, Zip:
Contact Name:	Contact Telephone Number:
Contact Fax Number:	
Ordering Provider Information	
Medicaid Billing Number:	Ordering Provider Name:
Street Address:	City, State, Zip:
Contact Name:	Contact Telephone Number:
Contact Fax Number:	Provider Specialty:

Certification Statement: This is to certify that the requested medication is medically indicated and is reasonable and necessary for the treatment of this patient, and that a prescribing practitioner signed order is on file. This form, and any statement on my letterhead attached hereto, has been completed by me or by my employee, and reviewed by me. The foregoing information is true, accurate, and complete, and I understand that any falsification, omission, or concealment of material fact may subject me to civil and criminal liability.

Provider Signature:	Date: