Spinraza® (nusinersen) Injectable Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Phone: 1-866-503-0857
FAX: 1-844-268-7263

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	E-mail:	

Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:		Last Name: *(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.			
Address:		City:	State:	ZIP:	
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:		Office Contact Name:		Phone:	

Specialty *(Check one):* ☐ **Neurologist** ☐ **Pediatrician** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for Spinraza (nusinersen): Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

For All Requests (Clinical documentation must be submitted with request):

Please provide the name of the gene therapy designated center the requested drug will be administered at:
Name: _____

☐ Yes ☐ No Does the patient have a documented diagnosis of spinal muscular atrophy (SMA)?
→ Please confirm the type of SMA: ☐ SMA Type 1 ☐ SMA Type 2 ☐ SMA Type 3 ☐ SMN Type 4 ☐ Unknown
☐ Yes ☐ No Is the medication prescribed by or in consultation with a physician who specializes in treatment of SMA?
☐ Yes ☐ No Is the patient dependent on invasive ventilation or tracheostomy?
☐ Yes ☐ No Is the patient dependent on use of non-invasive ventilation support beyond naps and nighttime sleep?
☐ Yes ☐ No Will the requested drug be used concomitantly with Evrysdi (risdeplam)?
☐ Yes ☐ No Has the patient received loading doses?
→ ☐ Yes ☐ No Will the loading doses be dosed at 12 mg (5mL) on day 0, 14, 28 and 58 of treatment?
☐ Yes ☐ No Will the maintenance dose exceed 12 mg (5mL) every 4 months?

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For Initiation of Therapy (patient is NOT currently receiving the requested drug):

☐ Yes ☐ No Was the diagnosis of spinal muscular atrophy confirmed by genetic confirmation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote?

☐ Yes ☐ No Has a baseline assessment been completed using one of the following assessment tools (based on patient age and motor ability) to establish baseline motor ability? Date completed: ____/____/____

→ ☐ Hammersmith Infant Neurological Exam Part 2 (HINE-2): Please indicate the score: ____

☐ Hammersmith Functional Motor Scale Expanded (HFMSE): Please indicate the score: ____

☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND): Please indicate the score: ____

☐ Yes ☐ No Has the patient previously received gene replacement therapy for spinal muscular atrophy (e.g., Zolgensma)?

→ ☐ Yes ☐ No Has the patient experienced a worsening in clinical status since receiving gene replacement therapy as demonstrated by a decline of minimally clinical important difference from highest score achieved on one of the following exams (based on member age and motor ability)? Date completed: ____/____/____

☐ Hammersmith Infant Neurological Exam Part 2 (HINE-2)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 2 points on kicking and 1 point of any other milestone excluding voluntary grasp) from the highest score achieved on HINE-2 since receiving gene therapy? Please indicate the score: ____

☐ Hammersmith Functional Motor Scale Expanded (HFMSE)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 3 points from highest score achieved on HFMSE since receiving gene therapy? Please indicate the score: ____

☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 4 points from highest score achieved on CHOP-INTEND since receiving gene therapy? Please indicate the score: ____

For patients re-starting therapy with the requested drug after administration of gene therapy:

Please indicate the patient's age at initiation of the requested drug therapy: ____

☐ Yes ☐ No Was the diagnosis of spinal muscular atrophy confirmed by genetic confirmation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote?

☐ Yes ☐ No Has a baseline assessment been completed using one of the following assessment tools (based on patient age and motor ability) to establish baseline motor ability? Date completed: ____/____/____

→ ☐ Hammersmith Infant Neurological Exam Part 2 (HINE-2): Please indicate the score: ____

☐ Hammersmith Functional Motor Scale Expanded (HFMSE): Please indicate the score: ____

☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND): Please indicate the score: ____

☐ Yes ☐ No Has the patient experienced a worsening in clinical status since receiving gene replacement therapy as demonstrated by a decline of minimally clinical important difference from highest score achieved on one of the following exams (based on member age and motor ability)?

→ Date completed: ____/____/____

☐ Hammersmith Infant Neurological Exam Part 2 (HINE-2)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 2 points on kicking and 1 point of any other milestone excluding voluntary grasp) from the highest score achieved on HINE-2 since receiving gene therapy? Please indicate the score: ____

☐ Hammersmith Functional Motor Scale Expanded (HFMSE)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 3 points from highest score achieved on HFMSE since receiving gene therapy? Please indicate the score: ____

☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

→ ☐ Yes ☐ No Has the patient experienced a decline of at least 4 points from highest score achieved on CHOP-INTEND since receiving gene therapy? Please indicate the score: ____

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For Continuation Requests (patient is currently receiving the requested drug):

Please indicate the patient's age at initiation of the requested drug therapy: _____

☐ Yes ☐ No Has the patient experienced a positive clinical response with the requested drug since pretreatment baseline documented by one of the following assessments? Date completed: ____/____/____

→ ☐ Hammersmith Infant Neurological Exam Part 2 (HINE-2)

→ ☐ Yes ☐ No Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request)?

→ ☐ Patient exhibited improvement or maintenance of previous improvement of at l least a 2 point (or maximal score) increase in ability to kick. Please indicate the score: _____

☐ Patient exhibited improvement or maintenance of previous improvement of at l least a 1 point (or maximal score) increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, standing, or walking) excluding voluntary grasp. Please indicate the score: _____

☐ None of the above

→ ☐ Yes ☐ No Was the patient prescribed the requested drug due to clinical worsening after receiving gene therapy?

☐ Yes ☐ No Has there been stabilization or improvement in clinical status with the requested drug therapy (e.g., impact on milestones)?

☐ Yes ☐ No Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request)?

→ ☐ Patient exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement).

☐ Patient achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk)

☐ None of the above

→ ☐ Yes ☐ No Was the patient prescribed the requested drug due to clinical worsening after receiving gene therapy?

☐ Yes ☐ No Has there been stabilization or improvement in clinical status with the requested therapy (e.g., impact on milestones)?

☐ Hammersmith Functional Motor Scale Expanded (HFMSE)

→ ☐ Yes ☐ No Has the patient experienced any of the following per most the recent HFMSE assessment (less than 1 month prior to continuation request)?

→ ☐ Patient exhibited improvement or maintenance of previous improvement of at least a 3- point increase in score. Please indicate the score: _____

☐ Patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so.

☐ None of the above

→ ☐ Yes ☐ No Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma)?

☐ Yes ☐ No Has there been stabilization or improvement in clinical status with the requested drug therapy (e.g., impact on milestones)?

☐ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

→ ☐ Yes ☐ No Has the patient experienced any of the following per the most recent CHOP-INTEND assessment (less than 1 month prior to continuation request)?

→ ☐ Patient exhibited improvement or maintenance of previous improvement of at least a 4- point increase in score. Please indicate the score: _____

☐ Patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so.

☐ None of the above

→ ☐ Yes ☐ No Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma)?

☐ Yes ☐ No Has there been stabilization or improvement in clinical status with the requested drug therapy (e.g., impact on milestones)?

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H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required):* _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.