



## Spinraza

### Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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**Patient's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Patient's ID:** \_\_\_\_\_ **Patient's Date of Birth:** \_\_\_\_\_  
**Physician's Name:** \_\_\_\_\_  
**Specialty:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Physician Office Telephone:** \_\_\_\_\_ **Physician Office Fax:** \_\_\_\_\_

**Referring Provider Info:**  Same as Requesting Provider

**Name:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Fax:** \_\_\_\_\_ **Phone:** \_\_\_\_\_

**Rendering Provider Info:**  Same as Referring Provider  Same as Requesting Provider

**Name:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Fax:** \_\_\_\_\_ **Phone:** \_\_\_\_\_

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.*

**Required Demographic Information:**

*Patient Weight:* \_\_\_\_\_ kg

*Patient Height:* \_\_\_\_\_ cm

*Please indicate the place of service for the requested drug:*

- Ambulatory Surgical       Home       Off Campus Outpatient Hospital  
 On Campus Outpatient Hospital       Office       Pharmacy

**Criteria Questions:**

- What is the diagnosis?  
 Spinal muscular atrophy  
 Other, please specify \_\_\_\_\_
- What is the ICD-10 code? \_\_\_\_\_
- Which type of spinal muscular atrophy does the patient have?  
 Type 0    Type 1    Type 2    Type 3    Type 4    Unknown
- Is the patient dependent on either of the following?  
 Invasive ventilation or tracheostomy  
 Use of non-invasive ventilation beyond naps and nighttime sleep

**Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720**

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- Patient is not dependent on invasive ventilation, tracheostomy, or non-invasive ventilation support beyond naps and nighttime sleep
5. Is the requested drug prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy?  Yes  No
  6. Will the requested drug be used concomitantly with Evrysdi (risdiplam)?  Yes  No
  7. Is the patient currently receiving treatment with the requested drug?  Yes  No *If No, skip to #9*
  8. Was the patient previously established and is re-starting therapy with the requested drug after administration of gene replacement therapy?  Yes  No *If No, skip to #20*
  9. Was the diagnosis of spinal muscular atrophy confirmed by genetic confirmation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote? **ACTION REQUIRED: If Yes, please attach a copy of the laboratory report with SMN1 allele genetic test results.**  Yes  No
  10. 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? **ACTION REQUIRED: If Yes, please submit medical records (e.g., chart notes) documenting baseline assessment using the HINE-2, HFMSE, or CHOP-INTEND assessment tools.**
    - Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    - Yes, Hammersmith Functional Motor Scale Expanded (HFMSE)
    - Yes, Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    - No
  11. What is the patient’s age at initiation of the requested drug? \_\_\_\_\_ years
  12. Has the patient previously received gene replacement therapy for spinal muscular atrophy?  Yes  No *If No, skip to #17*
  13. 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)?
    - Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    - Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *skip to #15*
    - Yes, Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *skip to #16*
    - No
  14. Has the patient experienced a decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp) from the highest score achieved on HINE-2 since receiving gene replacement therapy? *If Yes, skip to #17*  Yes  No
  15. Has the patient experienced a decline of at least 3 points from highest score achieved on HFMSE since receiving gene replacement therapy? *If Yes, skip to #17*  Yes  No
  16. Has the patient experienced a decline of at least 4 points from highest score achieved on CHOP-INTEND since receiving gene replacement therapy?  Yes  No
  17. Has the patient received the loading doses? *If Yes, skip to #19*  Yes  No
  18. Will the loading doses be dosed at 12 mg (5 mL) on Day 0, 14, 28 and 58 of treatment?  Yes  No
  19. Will the maintenance dose exceed 12 mg (5 mL) every 4 months?  Yes  No *No further questions*
  20. Has the patient experienced a positive clinical response with the requested drug since pretreatment baseline documented by one of the following assessments? **ACTION REQUIRED: If Yes, please submit medical records (e.g., chart notes) of the most recent (less than 1 month prior to continuation request) assessment using the HINE-2, HFMSE, or CHOP-INTEND assessments.**
    - Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    - Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *skip to #22*

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- Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *skip to #23*  
 No, *skip to #24*
21. Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request)? **Indicate ALL that apply.**
- Patient exhibited improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
  - Patient exhibited improvement or maintenance of previous improvement of at 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
  - Patient exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement), *skip to #26*
  - Patient achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk), *skip to #26*
  - None of the above, *skip to #24*
22. Has the patient experienced any of the following per most the recent HFMSE assessment (less than 1 month prior to continuation request)? *If Yes, indicate below and skip to #26.*
- Patient exhibited improvement or maintenance of previous improvement of at least a 3-point increase in 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, *skip to #24*
23. Has the patient experienced any of the following per most the recent CHOP-INTEND assessment (less than 1 month prior to continuation request)? *If Yes, indicate below and skip to #26.*
- Patient exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score
  - Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
  - None of the above
24. Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy?  
 Yes  No
25. Has there been stabilization or improvement in clinical status with the requested drug therapy (e.g., impact on motor milestones)? **ACTION REQUIRED: If Yes, please submit medical records (e.g., chart notes) documenting the impact of therapy with the requested drug.**  Yes  No
26. Will the maintenance dose exceed 12 mg (5 mL) every 4 months?  Yes  No

***I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.***

X \_\_\_\_\_

**Prescriber or Authorized Signature**

**Date (mm/dd/yy)**

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