



Spinraza

CareFirst 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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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:

- | | | |
|--------------------------------------------------------|---------------------------------|---------------------------------------------------------|
| <input type="checkbox"/> Ambulatory Surgical | <input type="checkbox"/> Home | <input type="checkbox"/> Off Campus Outpatient Hospital |
| <input type="checkbox"/> On Campus Outpatient Hospital | <input type="checkbox"/> Office | <input type="checkbox"/> Pharmacy |

What is the ICD-10 code? _____

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Spinraza SGM 1834-A – 11/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062
Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Criteria Questions:

1. What is the diagnosis?

☐ Spinal muscular atrophy, *Continue to 2*

☐ Other, please specify. _____, *Continue to 2*

2. Which type of spinal muscular atrophy does the patient have?

☐ Type 0, *Continue to 3*

☐ Type 1, *Continue to 3*

☐ Type 2, *Continue to 3*

☐ Type 3, *Continue to 3*

☐ Type 4, *Continue to 3*

☐ Unknown, *Continue to 3*

3. Is the patient dependent on either of the following?

☐ Invasive ventilation or tracheostomy, *Continue to 4*

☐ Use of non-invasive ventilation beyond naps and nighttime sleep, *Continue to 4*

☐ Patient is not dependent on invasive ventilation, tracheostomy, or non-invasive ventilation support beyond naps and nighttime sleep, *Continue to 4*

4. Is the requested drug prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy?

☐ Yes, *Continue to 5*

☐ No, *Continue to 5*

5. Will the requested drug be used concomitantly with Evrysdi (risdiplam)?

☐ Yes, *Continue to 6*

☐ No, *Continue to 6*

6. Is the patient currently receiving treatment with the requested drug?

☐ Yes, *Continue to 7*

☐ No, *Continue to 8*

7. Was the patient previously established and is re-starting therapy with the requested drug after administration of gene replacement therapy?

☐ Yes, *Continue to 8*

☐ No, *Continue to 18*

8. 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, attach a copy of the laboratory report with SMN1 allele genetic test results.

☐ Yes, *Continue to 9*

☐ No, *Continue to 9*

9. 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, attach medical records (e.g., chart notes) documenting baseline assessment using the HINE-2, HFMSE, or CHOP-INTEND assessment tools.

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Spinraza SGM 1834-A – 11/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

- ☐ Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 10*
- ☐ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 10*
- ☐ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 10*

☐ No, *Continue to 10*

10. Has the patient previously received gene replacement therapy for spinal muscular atrophy?

☐ Yes, *Continue to 11*

☐ No, *Continue to 15*

11. 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), *Continue to 12*

☐ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *Continue to 13*

☐ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *Continue to 14*

☐ No, *Continue to 15*

12. 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?

☐ Yes, *Continue to 15*

☐ No, *Continue to 15*

13. Has the patient experienced a decline of at least 3 points from highest score achieved on HFMSE since receiving gene replacement therapy?

☐ Yes, *Continue to 15*

☐ No, *Continue to 15*

14. Has the patient experienced a decline of at least 4 points from highest score achieved on CHOP-INTEND since receiving gene replacement therapy?

☐ Yes, *Continue to 15*

☐ No, *Continue to 15*

15. Has the patient received the loading doses?

☐ Yes, *Continue to 25*

☐ No, *Continue to 16*

16. Will the loading doses be dosed at 12 mg (5 mL) on Day 0, 14, 28 and 58 of treatment?

☐ Yes, *Continue to 17*

☐ No, *Continue to 17*

17. Will the maintenance dose exceed 12 mg (5 mL) every 4 months?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Spinraza SGM 1834-A – 11/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

18. 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, attach medical records (e.g., chart notes) documenting 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) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 19*

☐ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 21*

☐ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **ACTION REQUIRED:** Submit supporting documentation, *Continue to 22*

☐ No, *Continue to 23*

19. 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 least a 2 point (or maximal score) increase in ability to kick, *Continue to 20*

☐ 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, *Continue to 20*

☐ None of the above, *Continue to 23*

20. 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), *Continue to 25*

☐ Patient achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk), *Continue to 25*

☐ None of the above, *Continue to 23*

21. 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, *Continue to 25*

☐ Patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 25*

☐ None of the above, *Continue to 23*

22. 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, *Continue to 25*

☐ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 25*

☐ None of the above, *Continue to 23*

23. Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy?

☐ Yes, *Continue to 24*

☐ No, *Continue to 24*

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Spinraza SGM 1834-A – 11/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

24. Has there been stabilization or improvement in clinical status with the requested drug therapy (e.g., impact on motor milestones)? **ACTION REQUIRED:** If Yes, attach medical records (e.g., chart notes) documenting the impact of therapy with the requested drug.

☐ Yes, *Continue to 25*

☐ No, *Continue to 25*

25. Will the maintenance dose exceed 12 mg (5 mL) every 4 months?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

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)

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Spinraza SGM 1834-A – 11/2024.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com