



Evrysdi

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.

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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

What is the ICD-10 code? _____

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

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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 use of non-invasive ventilation 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. What is the patient's age (in years)?

- Any age; please specify. _____, *Continue to 6*

6. What is the patient's weight (in kilograms)?

- Any weight; please specify. _____ kg, *Continue to 7*

7. What is the daily dose (in milligrams) being prescribed?

- Any dose; please specify. _____ mg, *Continue to 8*

8. Does the daily dose exceed the recommended dose based on patient's age and weight: a) Less than 2 months of age: 0.15 mg/kg, b) 2 months to less than 2 years of age: 0.2 mg/kg, c) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg, d) 2 years of age and older weighing 20 kg or more: 5 mg?

- Yes, *Continue to 9*
 No, *Continue to 9*

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

- Yes, *Continue to 10*
 No, *Continue to 11*

10. Was the patient previously established and is re-starting therapy with the requested drug after administration of gene replacement therapy for spinal muscular atrophy (e.g., Zolgensma)?

- Yes, *Continue to 11*
 No, *Continue to 22*

11. Was the diagnosis of spinal muscular atrophy (SMA) 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. **ACTION REQUIRED:** Submit supporting documentation

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- Yes, *Continue to 12*
- No, *Continue to 12*

12. 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: a) Hammersmith Infant Neurological Exam Part 2 (HINE-2), b) Hammersmith Functional Motor Scale Expanded (HFMSE), c) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), d) MFM32 (Motor Function Measure 32), e) Bayley Scales of Infant and Toddler Development- Third Edition (BSID-III)? **ACTION REQUIRED:** If Yes, submit medical records (e.g., chart notes) documenting baseline assessment using the HINE-2, HFMSE, CHOP-INTEND, MFM32 or Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III) assessment tools.

- Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- Yes, Hammersmith Functional Motor Scale Expanded (HFMSE) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- Yes, Motor Function Measure 32 (MFM32) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- Yes, Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III) **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- No, *Continue to 13*

13. Has the patient previously received gene replacement therapy for spinal muscular atrophy (e.g., Zolgensma)?

- Yes, *Continue to 14*
- No, *Continue to 20*

14. Has the patient experienced a worsening in clinical status since receiving gene replacement therapy as demonstrated by a decline of minimally clinically important difference from highest score achieved or baseline on one of the following exams (based on member age and motor ability and specific exam): a) Hammersmith Infant Neurological Exam Part 2 (HINE-2), b) Hammersmith Functional Motor Scale Expanded (HFMSE), c) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), d) MFM32 (Motor Function Measure 32), e) Bayley Scales of Infant and Toddler Development- Third Edition (BSID-III)?

- Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2), *Continue to 15*
- Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *Continue to 16*
- Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *Continue to 17*
- Yes, Motor Function Measure 32 (MFM32), *Continue to 18*
- Yes, Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III), *Continue to 19*
- No, *Continue to 20*

15. 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 20*
- No, *Continue to 20*

16. 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 20*
- No, *Continue to 20*

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

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- Yes, *Continue to 20*
- No, *Continue to 20*

18. Has the patient experienced a decline from baseline since receiving gene replacement therapy?

- Yes, *Continue to 20*
- No, *Continue to 20*

19. Does the patient have the inability to sit without support for more than 5 seconds per item 22 of test since receiving gene replacement therapy?

- Yes, *Continue to 20*
- No, *Continue to 20*

20. Will the requested drug be used concomitantly with Spinraza?

- Yes, *Continue to 21*
- No, *Continue to 21*

21. Has the patient received Spinraza previously? If Yes, please indicate date of last dose.

- Yes, please specify date last dose was received on: _____ MM/DD/YYYY, *No Further Questions*
- No, *No Further Questions*

22. Has the patient experienced a positive clinical response with the requested drug since pretreatment baseline documented by one of the following assessments: a) Hammersmith Infant Neurological Exam Part 2 (HINE-2), b) Hammersmith Functional Motor Scale Expanded (HFMSE), c) Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), d) MFM32 (Motor Function Measure 32), e) Bayley Scales of Infant and Toddler Development- Third Edition (BSID-III)? ***ACTION REQUIRED:*** If Yes, 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, CHOP-INTEND, MFM32, or BSID-III assessments.

- Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2) ***ACTION REQUIRED:*** *Submit supporting documentation, Continue to 23*
- Yes, Hammersmith Functional Motor Scale Expanded (HFMSE) ***ACTION REQUIRED:*** *Submit supporting documentation, Continue to 25*
- Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ***ACTION REQUIRED:*** *Submit supporting documentation, Continue to 26*
- Yes, Motor Function Measure 32 (MFM32) ***ACTION REQUIRED:*** *Submit supporting documentation, Continue to 27*
- Yes, Bayley Scales of Infant and Toddler Development- Third Edition (BSID-III) ***ACTION REQUIRED:*** *Submit supporting documentation, Continue to 28*
- No, *Continue to 29*

23. Has the patient experienced either of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request): a) Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick, b) 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?

- Yes, patient exhibited improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick, *Continue to 24*
- Yes, 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 24*
- No, none of the above, *Continue to 29*

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24. Has the patient experienced either of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request): a) Improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement), b) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit or stand unassisted, walk)?

Yes, patient exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement), *Continue to 31*

Yes, 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 31*

No, none of the above, *Continue to 29*

25. Has the patient experienced either of the following per most the recent HFMSE assessment (less than 1 month prior to continuation request): a) Improvement or maintenance of previous improvement of at least a 3-point increase in score, b) Achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so?

Yes, patient exhibited improvement or maintenance of previous improvement of at least a 3-point increase in score, *Continue to 31*

Yes, patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 31*

No, none of the above, *Continue to 29*

26. Has the patient experienced either of the following per the most recent CHOP-INTEND assessment (less than 1 month prior to continuation request): a) Improvement or maintenance of previous improvement of at least a 4-point increase in score, b) Achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so?

Yes, patient exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score, *Continue to 31*

Yes, patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 31*

No, none of the above, *Continue to 29*

27. Has the patient experienced an increase in their Motor Function Measure 32 (MFM32) score from baseline and that increase correlates with a clinically significant functional improvement per most recent MFM32 assessment (less than 1 month prior to continuation request)?

Yes, *Continue to 31*

No, *Continue to 29*

28. Has the patient exhibited the ability to sit without support for at least 5 seconds after 12 months of treatment per most recent Bayley Scales of Infant and Toddler Development-Third Edition (BSID-III) (less than 1 month prior to continuation request)?

Yes, *Continue to 31*

No, *Continue to 29*

29. Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma)?

Yes, *Continue to 30*

No, *Continue to 30*

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

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- Yes, *Continue to 31*
- No, *Continue to 31*

31. Will the requested drug be used concomitantly with Spinraza?

- 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)

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