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* ❑ *Inpatient Hospital* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

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

Criteria Questions:

1. What is the diagnosis?
   ❑ Spinal muscular atrophy ❑ Other _____
2. What is the ICD-10 code? _____
3. Which type of spinal muscular atrophy does the patient have?
   ❑ Type 0 ❑ Type 1 ❑ Type 2 ❑ Type 3 ❑ Type 4 ❑ Unknown
4. Is the patient dependent on either of the following?
   ❑ Invasive ventilation or tracheostomy
   ❑ Use of non-invasive ventilation beyond naps and nighttime sleep
   ❑ 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 Spinraza after administration of gene 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', 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', submit medical records (e.g., chart notes) documenting baseline assessment using the HINE-2, HFMSE, or CHOP-INTEND assessment tools.***
    ❑ Yes ❑ No
    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)
11. What is the patient's age at initiation of the requested drug? _____ years
12. Has the patient previously received gene 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 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 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 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 therapy? ❑ Yes ❑ No
17. Has the patient received the loading doses? ❑ Yes ❑ No

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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 Spinraza since pretreatment baseline documented by one of the following assessments? ***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, or CHOP-INTEND assessments.***
    ❑ Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    ❑ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *skip to #22*
    ❑ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *skip to #22*
    ❑ No

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)
    ❑ 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

22. Has the patient experienced any of the following per most the recent HFMSE or CHOP-INTEND 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 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
    ❑ Patient exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score
    ❑ None of the above

23. Will the maintenance dose exceed 12 mg (5 mL) every 4 months? ❑ Yes ❑ No

24. Was the patient prescribed Spinraza due to clinical worsening after receiving gene therapy? ❑ Yes ❑ No

25. Has there been stabilization or improvement in clinical status with Spinraza therapy (e.g., impact on motor milestones)? ***ACTION REQUIRED: If 'Yes', submit medical records (e.g., chart notes) documenting the impact of Spinraza therapy.*** ❑ 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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