Spinraza

HMSAMCD - 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 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** 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:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

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

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient hospital ❑ Office
❑ Outpatient Hospital ❑ Pharmacy

What is the ICD-10 code? _____

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

 Spinraza HMSAMCD C18217-A – 10/2025.

Criteria Questions:

1. What is the diagnosis?

❒ Spinal muscular atrophy, *Continue to #2*

❒ Other, *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 either invasive ventilation or tracheostomy or noninvasive 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. Does the patient have any of the following exclusion criteria?

- Invasive or noninvasive ventilation support is required beyond naps and nighttime sleep
- Gastric tube feeding is required for the majority of feeds
- Severe contractures or scoliosis
- History of bacterial meningitis
- History of brain or spinal cord disease, including tumors, or abnormalities by MRI or CT that would interfere with the lumbar puncture procedure or cerebrospinal (CSF) circulation
- Presence of an implanted shunt for the drainage of CSF or an implanted CNS catheter

❒ Yes, *Continue to #6*

❒ No, *Continue to #6*

6. Will the patient receive Evrysdi concomitantly with Spinraza?

❒ Yes, *Continue to #7*

❒ No, *Continue to #7*

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

❒ Yes, *Continue to #201*

❒ No, *Continue to #101*

INITIAL THERAPY

101. 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 #102*

❒ No, *Continue to #102*

102. 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?

- Hammersmith Infant Neurological Exam Part 2 (HINE-2)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)

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, *Continue to #103*

❒ No, *Continue to #103*

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

❒ Yes, *Continue to #104*

❒ No, *Continue to #108*

104. 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), *Continue to #105*

❒ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *Continue to #106*

❒ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *Continue to #107*

❒ No, *No Further Questions*

105. 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?

❒ Yes, *Continue to #108*

❒ No, *Continue to #108*

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

❒ Yes, *Continue to #108*

❒ No, *Continue to #108*

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

❒ Yes, *Continue to #108*

❒ No, *Continue to #108*

Dosing

108. Has the patient received the loading doses?

❒ Yes, *Continue to #208*

❒ No, *Continue to #109*

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

❒ Yes, *Continue to #110*

❒ No, *Continue to #110*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

CONTINUATION

201. 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), *Continue to #202*

❒ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *Continue to #204*

❒ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *Continue to #205*

❒ No, *Continue to #206*

202. Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 4 months 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 #203*

❒ 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 #203*

❒ None of the above, *Continue to #206*

203. Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 4 months 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 #207*

❒ 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 #207*

❒ None of the above, *Continue to #206*

204. Has the patient experienced any of the following per most the recent HFMSE assessment (less than 4 months prior to continuation request)?
❒ Patient exhibited improvement or maintenance of previous improvement of at least a 3-point increase in score, *Continue to #207*
❒ Patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to #207*
❒ None of the above, *Continue to #206*

205. Has the patient experienced any of the following per the most recent CHOP-INTEND assessment (less than 4 months prior to continuation request)?
❒ Patient exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score, *Continue to #207*
❒ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to #207*
❒ None of the above, *Continue to #206*

206. Was the patient prescribed Spinraza due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma)?
❒ Yes, *Continue to #207*
❒ No, *Continue to #207*

207. 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, *Continue to #208*
❒ No, *Continue to #208*

Dosing

208. 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)**