Spinraza

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4**.**

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 (POS Code 24)*
❑ *Home (POS Code 12)*
❑ *Off Campus Outpatient Hospital (POS Code 19)*
❑ *On Campus Outpatient Hospital (POS Code 22)*
❑ *Office (POS Code 11)*

Drug Information:

*Strength/Measure*_____ *Units* ❑ ml ❑ Gm ❑ mg ❑ ea ❑ Un
*Directions(sig)*_____ *Route of administration*_____
*Dosing frequency*_____

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 _____, *Continue to 3*
❒ Unknown, *Continue 3*

Send completed form to: Priority Partners Fax: 1-866-212-4756

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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 19*

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.

❒ 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. What is the patient's age at initiation of the requested drug?

_____years, *Continue to 11*

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

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Priority Partners ● 7231 Parkway Drive Suite 100 ● Hanover, MD 21076

Phone: 888-819-1043 ● Fax: 1-866-212-4756 ● www.hopkinshealthplans.org

❒ Yes, *Continue to 12*
❒ No, *Continue to 16*

12. 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 13*

❒ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *Continue to 14*
❒ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *Continue to 15*

❒ No, *Continue to 16*

13. 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 16*
❒ No, *Continue to 16*

14. 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 16*
❒ No, *Continue to 16*

15. 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 16*
❒ No, *Continue to 16*

16. Has the patient received the loading doses?
❒ Yes, *Continue to 26*
❒ No, *Continue to 17*

17. Will the loading doses be dosed at 12 mg (5 mL) on Day 0, 14, 28 and 58 of treatment?
❒ Yes, *Continue to 18*
❒ No, *Continue to 18*

18. Will the maintenance dose exceed 12 mg (5 mL) every 4 months?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

19. 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 20*
❒ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE) ***ACTION REQUIRED****: Submit supporting documentation, Continue to 22*

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❒ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ***ACTION REQUIRED***: *Submit supporting documentation, Continue to 23*

❒ No, *Continue to 24*

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 of at least a 2 point (or maximal score) increase in ability to kick, *Continue to 21*
❒ 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 21*

❒ None of the above, *Continue 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)?
❒ Patient exhibited improvement or maintenance of previous improvement in more HINE-2 motor milestones than worsening (net positive improvement), *Continue 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), *Continue to 26*

❒ None of the above, *Continue 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)?
❒ Patient exhibited improvement or maintenance of previous improvement of at least a 3-point increase in score, *Continue to 26*
❒ Patient achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 26*

❒ None of the above, *Continue to 24*
23. 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 26*
❒ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so, *Continue to 26*

❒ None of the above, *Continue to 24*

24. Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy?
❒ Yes, *Continue to 25*
❒ No, *Continue to 25*

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, attach medical records (e.g., chart notes) documenting the impact of therapy with the requested drug.
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

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26. 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 Priority Partners.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

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