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* ❑ *Home* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office*

Drug Information:

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

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

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Priority Partners ● 7231 Parkway Drive Suite 100 ● Hanover, MD 21076
Phone: 888-819-1043 ● Fax: 1-866-212-4756 ● www.jhhc.com

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-invasiveventilation 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 the requested drug after administration of gene replacement 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, please 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, please 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 replacement 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 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)
    ❑ 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 replacement 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 replacement 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 replacement therapy? ❑ Yes ❑ No
17. Has the patient received the loading doses? *If Yes, skip to #19* ❑ 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 the requested drug since pretreatment baseline documented by one of the following assessments? ***ACTION REQUIRED: If Yes, please 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 #23*
    - ❑ No, *skip 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)? ***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), *skip 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), *skip to #26*
    - ❑ None of the above, *skip 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)? *If Yes, indicate below and skip to #26.*
    - ❑ 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
    - ❑ None of the above, *skip to #24*

23. Has the patient experienced any of the following per most the recent CHOP-INTEND assessment (less than 1 month prior to continuation request)? *If Yes, indicate below and skip to #26.*
    - ❑ Patient exhibited improvement or maintenance of previous improvement of at least a 4-point increase in score
    - ❑ Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so
    - ❑ None of the above

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

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, please submit medical records (e.g., chart notes) documenting the impact of therapy with the requested drug.*** ❑ Yes ❑ No

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

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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