{{PANUMCODE}}
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{{PACDESCRIPTION}}

This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to {{COMPANY_NAME}} at {{CLIENT_PAG_FAX}}. Please contact {{COMPANY_NAME}} at {{CLIENT_PAG_PHONE}} with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of {{DRUGNAME}}.

Patient's Name: {{MEMFIRST}} {{MEMLAST}} Date: {{TODAY}}
Patient's ID: {{MEMBERID}} Patient's Date of Birth: {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}} Patient Phone: <<MEMPHONE>>
Specialty: _____ NPI#: _____
Physician Office Telephone: {{PHYSICIANPHONE}} Physician Office Fax: {{PHYSICIANFAX}}
Physician Office Address: <<PHYADDRESS1>> <<PHYADDRESS2>> <<PHYCITY>>, <<PHYSTATE>> <<PHYZIP>>
Drug Name: {{DRUGNAME}}

Quantity: _____ Frequency: _____ Strength: _____
Route of Administration: _____ Expected Length of Therapy: _____
Diagnosis: <<DIAGNOSIS>> ICD Code: <<ICD9>>

1. What is the diagnosis?
   - ❑ Spinal muscular atrophy
   - ❑ Other _____
2. What is the ICD-10 code? _____
3. Please indicate the patient's weight: _____ kg
4. Please indicate the daily dose (in milligrams) being prescribed: _____ mg
5. Which type of spinal muscular atrophy does the patient have?
   - ❑ Type 0
   - ❑ Type 1
   - ❑ Type 2
   - ❑ Type 3
   - ❑ Type 4
   - ❑ Unknown
6. 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 use of non-invasive ventilation beyond naps and nighttime sleep
7. Is the requested drug prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy? ❑ Yes ❑ No
8. Will the requested drug be used concomitantly with Spinraza? ❑ Yes ❑ No
9. Is the patient currently receiving treatment with the requested drug? ❑ Yes ❑ No *If No, skip to #20*

10. Was the patient previously established and is re-starting therapy with the requested drug after administration of gene replacement therapy for SMA (e.g., Zolgensma)? *If Yes, skip to #20* ❑ Yes ❑ No

11. 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, 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)
    ❑ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *skip to #14*
    ❑ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *skip to #15*
    ❑ Yes - MFM32, *skip to #16*
    ❑ Yes - BSID-III, *skip to #17*
    ❑ No, *skip to #18*

12. 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
    ❑ 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
    ❑ None of the above, *skip to #18*

13. Has the patient experienced any of the following per the most recent HINE-2 assessment (less than 1 month prior to continuation request)? *If Yes, no further questions*
    ❑ 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, *skip to #18*

14. Has the patient experienced any of the following per most the recent HFMSE assessment (less than 1 month prior to continuation request)? *If Yes, no further questions*
    ❑ 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 #18*

15. Has the patient experienced any of the following per the most recent CHOP-INTEND assessment (less than 1 month prior to continuation request)? *If Yes, no further questions*
    ❑ 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, *skip to #18*

16. Has the patient experienced an increase in their 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)? *If Yes, no further questions* ❑ Yes ❑ No *If No, skip to #18.*

17. Has the patient exhibited the ability to sit without support for at least 5 seconds after 12 months of treatment per most recent BSID-III (less than 1 month prior to continuation request)? ❑ Yes ❑ No

18. Was the patient prescribed the requested drug due to clinical worsening after receiving gene replacement therapy (e.g., Zolgensma)? ❑ Yes ❑ No

19. 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 and no further questions.*** ❑ Yes ❑ No

20. 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

21. 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, CHOP-INTEND, MFM32 or Bayley Scales of Infant and Toddler Developement-Third Edition (BSID-III) assessment tools.***
    ❑ Yes - Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    ❑ Yes - Hammersmith Functional Motor Scale Expanded (HFMSE)
    ❑ Yes - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    ❑ Yes - MFM32 (Motor Function Measure 32)
    ❑ Yes - Bayley Scales of Infant and Toddler Developement-Third Edition (BSID-III)
    ❑ No

22. What is the patient's age at initiation of the requested drug? _____ years _____ months

23. Has the patient previously received gene replacement therapy for spinal muscular atrophy (e.g., Zolgensma)?
    ❑ Yes ❑ No *If No, skip to #28*

24. 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 or baseline on one of the following exams (based on member age and motor ability and specific exam)?
    ❑ Yes - Hammersmith Infant Neurological Exam Part 2 (HINE-2)
    ❑ Yes - Hammersmith Functional Motor Scale Expanded (HFMSE)
    ❑ Yes - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    ❑ Yes - MFM32 (Motor Function Measure 32)
    ❑ Yes - Bayley Scales of Infant and Toddler Developement-Third Edition (BSID-III)
    ❑ No

25. Has the patient experienced any of the following since receiving gene replacement therapy?
    ❑ 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
    ❑ A decline of at least 3 points from highest score achieved on HFMSE
    ❑ A decline of at least 4 points from highest score achieved on CHOP-INTEND
    ❑ None of the above

26. Has the patient experienced a decline from baseline since receiving gene replacement therapy?
    If Yes, no further questions ❑ Yes ❑ No

27. 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? *If Yes, no further questions* ❑ Yes ❑ No

28. Has the patient received Spinraza previously? ❑ Yes ❑ No ***Date of last dose***: _____

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

_____

Prescriber (Or Authorized) Signature and Date