Evrysdi

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 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** 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:** _____
Request Initiated For: _____

1. What is the diagnosis? ❑ Spinal muscular atrophy ❑ Other _____
2. What is the ICD-10 code? _____
3. Coverage for the requested drug is provided when the patient has tried and had a treatment failure with all or at least three of the formulary medications. The formulary alternatives for the requested drug are Spinraza. Can the patient's treatment be switched to a formulary alternative? ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.***
   ❑ Yes - Spinraza
   ❑ No - continue request for Evrysdi
4. Has the patient tried and had a documented inadequate response or intolerable adverse reaction to all or at least three of the formulary alternative(s)? Note: Formulary medications should be prescribed first unless the patient is unable to use or receive treatment with the alternative.
   Formulary alternative(s): Spinraza
   ACTION REQUIRED: If Yes, indicate drug name and reason for treatment failure and submit chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment and skip to #6. ❑ Yes ❑ No

   Drug Name: _____ Reason for treatment failure: _____
5. Does the patient have a documented contraindication to all of the formulary alternative(s): Spinraza
   ACTION REQUIRED: If Yes, indicate drug name and contraindication and submit chart note(s) or other documentation indicating contraindication to formulary alternatives. ❑ Yes ❑ No

   Drug Name: _____ Contraindication: _____
6. Has chart note(s) or other documentation supporting the inadequate response, intolerable adverse reaction or contraindication to the necessary number of formulary alternatives been submitted? ***ACTION REQUIRED: Submit chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.***
   ❑ Yes ❑ No

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7. Which type of spinal muscular atrophy does the patient have?
   ❑ Type 0 ❑ Type 1 ❑ Type 2 ❑ Type 3 ❑ Type 4 ❑ Unknown

8. 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

9. Is the requested drug prescribed by or in consultation with a physician who specializes in treatment of spinal muscular atrophy? ❑ Yes ❑ No

10. Will the requested drug be used concomitantly with Spinraza? ❑ Yes ❑ No

11. Is the patient currently receiving treatment with the requested drug? ❑ Yes ❑ No *If No, skip to #21*

12. Was the patient previously established and is re-starting therapy with Evrysdi after administration of gene therapy? *If Yes, skip to #21* ❑ Yes ❑ No

13. Has the patient experienced a positive clinical response with Evrysdi 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, or MFM32 assessments.***
   ❑ Yes, Hammersmith Infant Neurological Exam Part 2 (HINE-2)
   ❑ Yes, Hammersmith Functional Motor Scale Expanded (HFMSE), *skip to #16*
   ❑ Yes, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), *skip to #17*
   ❑ Yes - MFM32, *skip to #18*
   ❑ None of the above, *skip to #19*

14. 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 #19*

15. 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 #19*

16. 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 #19*

17. 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 #19*

18. 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

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

20. Has there been stabilization or improvement in clinical status with Evrysdi therapy (e.g., impact on motor milestones)? ***ACTION REQUIRED: If Yes, submit medical records (e.g., chart notes) documenting the impact of Evrysdi therapy and no further questions.*** ❑ Yes ❑ No

21. 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

22. 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, or MFM32 assessment tools.***
    ❑ 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)
    ❑ MFM32
    ❑ None of the above

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

24. Has the patient previously received gene therapy for spinal muscular atrophy? ❑ Yes ❑ No *If No, skip to #27*

25. 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)
    ❑ Yes - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    ❑ None of the above

26. Has the patient experienced any of the following since receiving gene 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

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

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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