Sample Letter of Medical Necessity for Continuation of Care Cover Letter

The following pages are a template that may be customized to use as a letter of medical necessity for your patients who are changing health plans. Please note that the Important Safety Information does not need to be included as part of your letter.

The following sample letter is intended to be used as a guide; therefore, it is important to tailor the letter to the specific needs of your patients and address the reason(s) why SPINRAZA® (nusinersen) is the appropriate treatment for your patient to continue to use after changing health plans. You should always include pertinent clinical information that supports your decision to prescribe SPINRAZA.

Please see below for considerations when writing a letter of medical necessity:

- Review the health plan's medical policy criteria and point out the criteria that your patient meets. Explain why your patient should be excluded from any criteria that he/she/they do(es) not meet
- Provide background on your patient's condition and clearly state your patient's individual circumstances to justify why the prescribed therapy is the appropriate choice
- Provide clinical justification and include copies of relevant clinical data to support your decision (eg, chart notes, clinical data)
- Submit the letter as required by the health plan and state guidelines. It is important that you understand the process for each health plan, including how to submit the request (fax, phone, email, the company's website, etc) as well as how and when the decision will be communicated
- Track the status of your request and follow-up with the health plan as needed

INDICATION
SPINRAZA® (nusinersen) is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

IMPORTANT SAFETY INFORMATION
Coagulation abnormalities and thrombocytopenia, including acute severe thrombocytopenia, have been observed after administration of some antisense oligonucleotides. Patients may be at increased risk of bleeding complications.

In the sham-controlled studies for patients with infantile-onset (Study 1) and later-onset (Study 2) SMA who received Low Dose Regimen (12 mg loading doses/12 mg maintenance doses), 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two SPINRAZA-treated patients developed platelet counts <50,000 cells per microliter, with the lowest level of 10,000 cells per microliter recorded on study day 28. In patients who received High Dose Regimen (50 mg loading doses/28 mg maintenance doses), decreases in platelet counts were also observed.

Renal toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. SPINRAZA is present in and excreted by the kidney. In Study 1 and Study 2, 71 of 123 SPINRAZA-treated patients (58%) had elevated urine protein, compared to 22 of 65 sham-controlled patients (34%).

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Please see Important Safety Information continued on next page and full Prescribing Information.

Cases of rash were reported in patients treated with SPINRAZA.

SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

The most common adverse reactions in the Low Dose Regimen (≥20% of SPINRAZA-treated patients and ≥5% more frequently than in control patients) that occurred in the infantile-onset controlled study were lower respiratory infection and constipation. Serious adverse reactions of atelectasis were more frequent in SPINRAZA-treated patients (18%) than in control patients (10%). Because patients in this controlled study were infants, adverse reactions that are verbally reported could not be assessed. The most common adverse reactions that occurred in the later-onset controlled study were pyrexia, headache, vomiting, and back pain. Post-lumbar puncture syndrome has also been observed after the administration of SPINRAZA.

The most common adverse reactions in the High Dose Regimen (≥10% of SPINRAZA-treated patients and ≥5% more frequently than control patients from Study 1) that occurred in patients with infantile-onset SMA were pneumonia, COVID-19, pneumonia aspiration, and malnutrition. COVID-19 was not discovered at the time of Study 1.

Please see full Prescribing Information.

This sample letter is for informational purposes only, providing an example of language that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

Letter of Medical Necessity Template for SPINRAZA® (nusinersen)

[Note: When preparing the letter, considering using professional letterhead.]

[Date]
[Health plan contact name]
[Health plan name]
[Address]
[City, State, ZIP code]

Patient: [First and last name]
Policy number: [Number]
Group number: [Number]
[Claim number: Number if relevant to request]

Dear **[Health Plan Contact Name],**

I am writing this letter of medical necessity in support of my request to continue treatment for SPINRAZA® (nusinersen) for my patient, **[patient name]**, who may be a new member of your health plan. SPINRAZA is a US Food and Drug Administration (FDA)–approved treatment for spinal muscular atrophy (SMA) in pediatric and adult patients.

[Patient name] has been treated with SPINRAZA for a total of **[[#] months/years]** and in my care at **[institution name]** for **[#] months/years, from [month, year] to [month, year]**. As a board-certified **[field of certification] ([National Provider Identifier])** with **[#]** years of experience caring for patients with SMA, I believe that the continuation of treatment for **[patient name]** with SPINRAZA at this time is warranted, appropriate, and medically necessary for this patient based on my clinical judgment and expertise. Discontinuation or delay in receiving SPINRAZA can result in harm and disease progression for my patient. Below, this letter outlines **[patient name]**'s medical history and prognosis and the rationale for continued treatment with SPINRAZA.

1. Summary of Patient's Medical History

[Note: Exercise your medical judgment and discretion when providing characterization of the patient's history of treatment with SPINRAZA. Provide your clinical rationale for continued treatment while considering the health plan's medical policy criteria for SPINRAZA.]

- ***[Patient's age, date of diagnosis, and current condition/*International Classification of Diseases, Tenth Revision *(ICD-10) code(s)]***
- ***[Patient's health plan member ID and case reference number for the prior authorization]***
- ***[Relevant medical history]***
- ***[Information pertaining to survival motor neuron 2 gene copy number, baseline testing, and genetic testing]***
- ***[Previous treatments/therapies (if any) and patient's response to these treatments/therapies, including reason for treatment failure, discontinuation, or contraindication (if applicable)]***
- ***[Overview of the patient's current abilities and level of mobility, if applicable***
    - ***Consider including relevant functional assessment scores prior to and during treatment]***
- ***[Length of time on SPINRAZA, date of last infusion, and where it was administered]***
- ***[Any improvement or stabilization of motor function: [indicate the specific motor assessments listed in the medical policy criteria, if possible; assessments may include the Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Hammersmith Functional Motor Scale—Expanded (HFMSE), Hammersmith Infant Neurological Examination (HINE), Hammersmith Infant Neurological Examination Section 2 (HINE-2), Revised Upper Limb Module (RULM), and Upper Limb Module (ULM)]***

- ***[Indicate specific examples of disease progression that you foresee for your patient if treatment does not continue, such as progressive muscle weakness and respiratory insufficiency, progressive worsening of basic motor functions, reduction in the probability of ambulation, and expected muscle loss]***

2. Patient-Specific Rationale for Continued Treatment

[Insert the reason(s) for recommendation to continue to use SPINRAZA, which may include:]

- ***[Reason(s) SPINRAZA is most appropriate for this patient, such as efficacy profile, clinical trial and real-world observational information, safety and tolerability profile of this product, pharmacokinetic profile, dosage, and/or route of administration]***
- ***[Relevant information about SPINRAZA (Note: You may wish to include relevant background information about SPINRAZA in the letter. For additional information, please refer to the SPINRAZA Prescribing Information)]***
- ***[Additional reason(s) why SPINRAZA is the most appropriate treatment for this patient based on relevant medical history, genetic testing, previous treatments/therapies and patient's response to these treatments/therapies (if applicable), and/or patient's current abilities and level of mobility, if applicable]***

3. Concluding Remarks

[Healthcare provider to insert information relevant to the particular case (eg, Given the patient's history, his/her current condition, and the emerging data of the effects of SPINRAZA in patients with SMA, I believe that the continued treatment of [patient name] with this product is warranted, appropriate, and medically necessary. The totality of the data available to date supports the potential benefit of continuing treatment with SPINRAZA).]

Please call my office at **[telephone number]** for any additional information. I look forward to receiving your timely response and approval of this claim.

Sincerely,
[Physician name, National Provider Identifier]

Attachments: ***[Copy of patient's health plan card(s); SPINRAZA Prescribing Information; additional relevant information such as chart notes, laboratory results, and functional assessment results; original claim form; and previous communications with the health plan/denial letters (if relevant).]***