

Sample Letter of Medical Necessity/ Appeal Template Cover Letter

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

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 and later-onset SMA, 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.

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 the sham-controlled studies for patients with infantile-onset and later-onset SMA, 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.

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 ($\geq 20\%$ of SPINRAZA-treated patients and $\geq 5\%$ 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.

Please click here for 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/Appeal] Template for SPINRAZA[®] (nusinersen)

[Note: When preparing the actual letter, use professional/personal 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]

RE: [Reason for letter]

Dear [Contact name]:

I am writing this letter of [medical necessity/appeal] in support of my request to [initiate treatment/continue treatment] for [patient name] with SPINRAZA[®] (nusinersen), a United States Food and Drug Administration (FDA)–approved treatment for spinal muscular atrophy (SMA) in pediatric and adult patients.¹

As a board-certified [field of certification] ([National Provider Identifier]) with [#] years of experience caring for patients with SMA, I believe that treatment with SPINRAZA at this time is warranted, appropriate, and medically necessary for this patient based on my clinical judgment and expertise. [I have been treating [patient name] for [#] years.] Below, this letter outlines [patient name]'s medical history and prognosis, and the rationale for treatment with SPINRAZA.

1. Summary of Patient's Medical History [You may want to include]:

- [Patient's diagnosis and current condition/ICD-10 code(s)]
- 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 (if applicable)
- Overview of the patient's current abilities and level of mobility, if applicable
 - Consider including relevant functional assessment scores prior to treatment and, if applicable, during]

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2. Patient-Specific Rationale for Treatment

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

In brief, based on the clinical data available to date, it is my medical opinion that **[initiating/continuing/re-initiating]** treatment with SPINRAZA for **[patient name]** is warranted, appropriate, and medically necessary, and the procedures required for its administration are services that should be covered and reimbursed.

3. About SPINRAZA

SPINRAZA is an FDA-approved treatment indicated for SMA in pediatric and adult patients. SPINRAZA has been studied across multiple clinical trials in a broad range of patients with SMA, including presymptomatic and symptomatic infantile-onset and later-onset SMA.¹

[Healthcare professionals (HCPs) to include relevant clinical trial/real-world observational information to justify use of SPINRAZA for this patient specific to his or her medical condition and criteria (eg, age and type of SMA). For additional information, refer to the SPINRAZA Prescribing Information.]

4. Concluding Remarks

[HCP to insert information relevant to 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 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 [treatment/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).]***

Reference: 1. SPINRAZA [Prescribing Information]. Cambridge, MA: Biogen.

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