



GUIDE TO REQUESTING MEDICAL EXCEPTIONS AND APPEALING DENIALS

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.

Please see additional Important Safety Information on page 8 and accompanying full [Prescribing Information](#).

REQUESTING A MEDICAL EXCEPTION FOR SPINRAZA® (nusinersen)

There are occasions when a Benefits Investigation determines that SPINRAZA is not covered by a health plan or coverage is denied for a certain patient. Under these circumstances, it may be necessary to request a medical exception (ME). An ME communicates a physician's request to use a medication (citing the patient's individual circumstances) that is nonpreferred or not covered by the patient's health plan.

Step 1: COMPLETE THE MEDICAL EXCEPTION REQUEST WITH A LETTER OF MEDICAL NECESSITY FOR SPINRAZA, AS NEEDED

- The ME request may include a form from the health plan or a separate letter from your office
- Provide any additional information and documentation. Use the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA** for support and information you may want to include with the ME request

An effective letter of medical necessity is tailored to your patient's needs

Be clear about your patient's individual circumstance. The following are key considerations when writing a letter of medical necessity:

Background on your patient's condition

- Summarize his or her clinical status citing diagnostic evidence of spinal muscular atrophy (SMA), including baseline functional exam results and genetic testing results
- If appropriate, list current supportive care management and provide clinical evidence of the patient's disease progression despite supportive care

Why SPINRAZA is, in your opinion, the appropriate treatment choice for your patient

- Provide a clinical justification supporting SPINRAZA treatment for your patient and cite any relevant literature
- State any patient-specific reasons for the treatment choice, such as expected effect of treatment
- 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 or she does not meet

Providing additional documentation that supports your decision may strengthen your request

- General medical history listing comorbidities and any medication history, if appropriate
- Letters from other healthcare professionals (such as physical therapists or nurses) that support your treatment choice
- Clinical information regarding your treatment choice, such as the Prescribing Information for SPINRAZA. Additional information about SPINRAZA can be found in the **SPINRAZA Clinical Overview**
- Other relevant patient information, as appropriate

A common reason that MEs are denied is that information is missing from or incorrect on the form. This may delay treatment for your patient. Remember to carefully and accurately complete the ME request form.

SELECTED IMPORTANT SAFETY INFORMATION

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%).

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REQUESTING A MEDICAL EXCEPTION FOR SPINRAZA® (nusinersen) (cont'd)

Step 2: SUBMIT AND TRACK YOUR MEDICAL EXCEPTION REQUEST

- Determine whether the ME needs to be phoned in, faxed, emailed, or submitted via the health plan's website
- Determine the appropriate individual to contact regarding the ME request



Some states have legislation that requires health plans to respond to ME requests within a certain period of time. Contact your Biogen representative to learn whether this applies in your state.

If the ME is denied

There are several reasons that an ME may be denied. Review the following considerations to determine your course of action.

Denied due to inaccurate or incomplete information

- Carefully review the request to ensure that the information is correct and that no information has been omitted. If reasons for the denial are not provided, consider calling the health plan for details
- Resubmit the request if necessary, with all of the required information
- Remember, your Biogen representative can help you understand the process for handling an ME denial. Be sure to keep a copy of all pages of the denial letter so he or she can help more quickly

Denied due to clinical reasons

- Arrange for the prescribing physician to contact the health plan directly to speak with a clinical representative or medical director for a peer-to-peer discussion. The physician can request an individual with a similar specialty (eg, a neurologist, pulmonologist, or neuromuscular specialist). A peer-to-peer discussion should include detailed information about the patient's medical history and clinical considerations, as well as the reason for the requested treatment. This discussion may help the health plan understand the concerns for your patient and why there is an ME request for your treatment of choice



If the peer-to-peer discussion does not result in an approval of treatment, the next step is to consider an appeal (see page 4).

SELECTED IMPORTANT SAFETY INFORMATION

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 additional Important Safety Information on page 8 and accompanying full Prescribing Information.



APPEALING A HEALTH PLAN'S DENIAL OF SPINRAZA® (nusinersen)

Sometimes, even if treatment with SPINRAZA is medically necessary, coverage may be denied. In the event that a health plan denies a prior authorization (PA), ME, or request for reauthorization, your patient has the right to appeal the decision. You may be asked to submit the appeal to the patient's health plan.

The information in this section will help guide you through submitting an appeal for SPINRAZA on behalf of your patient.

Step 1: UNDERSTAND THE REASON FOR THE DENIAL

There can be several reasons that a PA or ME for SPINRAZA was denied. Therefore, you should read the denial letter carefully to understand why. You may also call and speak with the health plan. This may help you to better understand the reason for the denial and find a way to quickly resolve the matter.¹

- One of the main reasons that PA or ME requests are denied is incomplete or inaccurate information on the form
- Check to ensure all information is complete and accurate. Resubmit the form and required information



If SPINRAZA is denied, the health plan is required to notify you and your patient in writing and provide an explanation for the denied claim within²

- 15 days for a PA
- 30 days for medical services already provided
- 72 hours for urgent care cases

When submitting an appeal, timing is critical. Refer to the denial letter to find out the timelines for submitting your appeal.

SELECTED IMPORTANT SAFETY 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.

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APPEALING A HEALTH PLAN'S DENIAL OF SPINRAZA® (nusinersen) (cont'd)

Step 2: APPEAL THE DENIAL

It's important to follow the health plan's guidelines and time frames when requesting an appeal. Be sure to contact the health plan with any questions and to obtain a written description of its appeals process. The appeals process may vary depending on the health plan.

- Health plans may have their own appeal request forms. Be sure all information is complete and accurate. Forms are usually available at the health plan's website^{3,4}
- Use the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA** for support and information you may want to include with the appeal request

A letter of appeal is a critical component of your request

An effective letter of appeal may include the following elements:

- Patient information such as name, policy number, and case or claim number¹
- Reason for the denial as listed in the denial letter^{1,3}
- The patient's medical history and current condition^{1,3}
- The reason you disagree with the denial^{1,3}
- Explanation of the medical necessity for SPINRAZA¹
- Patient-specific reasons for choosing SPINRAZA, such as expected effect of treatment¹
- Indication for SPINRAZA
- Additional information to support your treatment decision¹

Providing additional documentation may help justify the use of SPINRAZA^{1,3}

Additional information to help strengthen your patient's appeal includes

- The patient's medical records
- Appropriate laboratory test results, including genetic testing results
- Pertinent or relevant office notes
- Letters from other healthcare professionals and members of the care team, including but not limited to physical therapists, occupational therapists, respiratory therapists, and dietitians who support your treatment choice
- Published clinical studies documenting the effectiveness of SPINRAZA
- Additional real-world observational information about SPINRAZA use in adult patients
- Examples of other health plan policies in which the patient would be approved for SPINRAZA



It may be helpful to contact the health plan directly to have a peer-to-peer discussion regarding the patient, clinical issues, and the reasons for prescribing SPINRAZA. This may help the health plan to better understand your treatment decision and appeal.

SELECTED IMPORTANT SAFETY INFORMATION

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.

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APPEALING A HEALTH PLAN'S DENIAL OF SPINRAZA® (nusinersen) (cont'd)

Step 3: MONITOR THE APPEAL

Follow up with the health plan to confirm that your request was received and to check the status of its decision. Notify the patient of instances for which your office may need his or her involvement.

Generally, health plans are required to complete an internal appeal within²

- 30 days for a PA
- 60 days for medical services already provided

Check with patient's health plan and state board of insurance for the timelines pertinent to your case.



As a reminder, Biogen's SMA360° support provides certain services that address nonmedical barriers to access.* These include support for PAs, MEs, and in the event of denied insurance claims. A complete list of SMA360° offerings can be found at spinraza-hcp.com/support. SMA360° can be reached at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, 8:30 AM to 8:00 PM ET. You can also contact your Biogen representative for assistance navigating the health plan approval process.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.

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If the appeal is denied

At the end of the internal appeals process, the health plan must provide you and your patient with a written decision.

If coverage for SPINRAZA is still denied, your patient can ask for an independent external review. This is helpful for people with SMA because it means their health plan will no longer have the final say regarding their coverage.^{1,5}



The external review process

An independent, accredited medical professional will review your patient's case. The reviewer does not receive any financial incentives to perform the review. The health plan is required by law to accept the reviewer's decision.^{1,6}

To request an external review, your patient must file a written request within 60 days of the health plan's final determination. Some plans may allow more time to file the request. The letter sent to you and your patient should describe how to request an external review.⁶

External review decisions are made as soon as possible, but generally take no longer than 60 days from receipt of request.



Expedited reviews

In urgent situations, your patient may request an external review at the same time as an internal review to speed up the process. An expedited appeal may be granted if your patient is currently receiving or prescribed treatment and you believe a delay would risk his or her life, affect his or her ability to regain maximum function, or subject him or her to severe pain.

The request for an expedited appeal may be made verbally. The health plan must make a decision within 4 business days after your patient's request is received.^{1,2}



Secondary health plan option

If your patient has secondary insurance coverage, you should submit to the secondary health plan for coverage after attempts with the primary health plan have been exhausted. Use the **Letter of Medical Necessity/Appeal Template** for support to build the request for coverage.

SELECTED IMPORTANT SAFETY INFORMATION

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 **SPINRAZA**[®]
(nusinersen) injection
12 mg/5 mL

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References: **1.** The Patient Advocate Foundation. *A Patient's Guide to Navigating the Insurance Appeals Process*. <https://www.patientadvocate.org/wp-content/uploads/Navigating-the-insurance-appeals-guide-pages.pdf>. Accessed April 4, 2018. **2.** Appealing a health plan decision. Internal appeals. HealthCare.gov website. <https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/>. Accessed April 4, 2018. **3.** Disputes & appeals overview. Aetna website. <https://www.aetna.com/health-care-professionals/disputes-appeals/disputes-appeals-overview.html>. Accessed April 4, 2018. **4.** Claim adjustment & appeals guidelines. Cigna website. <https://www.cigna.com/healthcare-professionals/resources-for-health-care-professionals/clinical-payment-and-reimbursement-policies/claim-policies-procedures-and-guidelines/claim-adjustment>. Accessed April 4, 2018. **5.** Appealing a health plan decision. How to appeal an insurance company decision. HealthCare.gov website. <https://www.healthcare.gov/appeal-insurance-company-decision/appeals/>. Accessed April 4, 2018. **6.** Appealing a health plan decision. External review. HealthCare.gov website. <https://www.healthcare.gov/appeal-insurance-company-decision/external-review/>. Accessed April 4, 2018.