SPINRAZA®
(nusinersen) injection
12 mg/5 mL

GUIDE TO PRIOR AUTHORIZATION SUBMISSIONS

INDICATION

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

SELECTED 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.

Please see additional Important Safety Information on page 10 and accompanying full Prescribing Information.

INTRODUCTION TO PRIOR AUTHORIZATIONS

Your practice or facility may need to obtain prior approval from a health plan before it will cover SPINRAZA® (nusinersen). This request for approval is referred to as prior authorization (PA), precertification, or coverage determination.

PAs are very common for orphan drugs, such as SPINRAZA, that treat rare diseases because they enable health plans to monitor costs and ensure that drugs are being used for appropriate patients only.

For many drugs that treat rare diseases, health plans may require a PA renewal (reauthorization) after a certain period of time. For many plans than cover SPINRAZA, this period is 6 months to 1 year. This is true regardless of whether the patient is remaining on the same treatment or transitioning to another treatment.

HOW THIS GUIDE CAN HELP WITH PA SUBMISSIONS

To help you in understanding the submission process for a PA for SPINRAZA, this guide will provide information on

KEY STEPS IN THE PA PROCESS

FIELDS TO COMPLETE ON A PA FORM

HANDLING A DENIED PA REQUEST

SMA360™ Support services from Biogen

Biogen can help your practice or facility understand the PA requirements for individual health plans in your area. Contact your Biogen representative or call SMA360° at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, from 8:30 AM to 8:00 PM ET.

SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA and have submitted a SPINRAZA Start Form. SMA360° is intended for US residents only.

SELECTED IMPORTANT SAFETY INFORMATION

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.

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KEY STEPS IN THE PA PROCESS FOR SPINRAZA® (nusinersen)

The following steps illustrate how to complete a PA.

Step 1: COMPLETE THE BENEFITS INVESTIGATION

The Benefits Investigation will determine whether your patient has insurance coverage for SPINRAZA. For more information about this process and important considerations for your practice or facility, refer to the **Guide to Benefits Investigations**, available at **spinraza-hcp.com**.

Step 2: COMPLETE THE PA REQUEST

- Make sure you have the proper PA form for that payer. PAs can be denied simply because the wrong form has been submitted
- Remember to fill out the form completely. PAs are often denied because the form is missing information
- Include a letter of medical necessity, if needed, to strengthen the request
  - Refer to the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA**, available at **spinraza-hcp.com**, for support
- Prepare supplemental documentation, which can increase the chance that your patient can start therapy efficiently. Each health plan is unique, so it is essential to identify the specific documents you will need. These documents may include
  - Relevant clinical studies supporting the use of SPINRAZA. Refer to the **SPINRAZA Clinical Overview**, available for download at **spinraza-hcp.com**
  - Clinical patient notes and relevant patient medical history
- If you need additional assistance with a PA submission, contact your Biogen representative

How long does a PA take?

The PA process can sometimes take longer than expected. If you have questions about how long the insurance approval process is taking, contact your Biogen representative.

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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KEY STEPS IN THE PA PROCESS FOR SPINRAZA® (nusinersen) (*cont'd*)

Step 3: SUBMIT THE PA REQUEST

- Determine whether the information should be phoned in, faxed, emailed, or submitted via the health plan's website. This information is often listed on the actual form. Include supplemental documents in your submission
- For future reference, you may want to add health plan contact information, proper submission requirements, and other tips to the **Health Plan Reference Sheet**, available for download at **spinraza-hcp.com**
- Keep a copy of everything your practice or facility submits with the request. You may need to reference these documents for many reasons, including if your patient needs financial assistance services from SMA360°™* later on

Step 4: TRACK THE STATUS OF THE REQUEST

- It is important to keep a thorough log of the PA submissions and denials for each patient. This information will be needed if the patient wishes to apply for financial support services from SMA360°

Step 5: FOLLOW UP AS NEEDED

- If additional documentation is requested at any point, make sure to provide it as soon as possible

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

If a PA is denied, it may be necessary to submit an appeal. For information about appeals, refer to page 9 and the **Guide to Requesting Medical Exceptions and Appealing Denials**, available at **spinraza-hcp.com**.

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.

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HOW TO FILL OUT A PA FORM

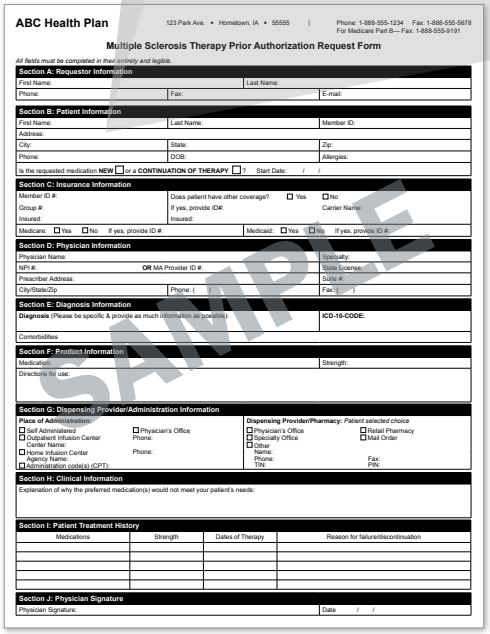
This sample form is meant to guide you as you complete a PA form. It cannot be submitted. PA forms vary by health plan and may require more documentation than what is listed on this sample. Please contact the specific health plan to obtain the correct PA form.

The first section of the PA form is typically where the sender includes all relevant contact information.

PATIENT AND INSURANCE INFORMATION

Section B: Patient Information		
First Name:	Last Name:	Member ID:
Address:		
City:	State:	Zip:
Phone:	DOB:	Allergies:
Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /		

Section C: Insurance Information		
Member ID #:	Does patient have other coverage? ☐ Yes ☐ No	
Group #:	If yes, provide ID#:	Carrier Name:
Insured:	Insured:	
Medicare: ☐ Yes ☐ No If yes, provide ID #:	Medicaid: ☐ Yes ☐ No If yes, provide ID #:	



ABC Health Plan

123 Park Ave. • Hometown, IA • 55555 | Phone: 1-888-555-1234 Fax: 1-888-555-5678
For Medicare Part B— Fax: 1-888-555-9191

Multiple Sclerosis Therapy Prior Authorization Request Form

All fields must be completed in their entirety and legible.

Section A: Requestor Information
First Name: | Last Name:
Phone: | Fax: | E-mail:

Section B: Patient Information
First Name: | Last Name: | Member ID:
Address:
City: | State: | Zip:
Phone: | DOB: | Allergies:
Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /

Section C: Insurance Information
Member ID #: | Does patient have other coverage? ☐ Yes ☐ No
Group #: | If yes, provide ID#: | Carrier Name:
Insured: | Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: | Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information
Physician Name: | Specialty:
NPI #: **OR** MA Provider ID #: | State License:
Prescriber Address: | Suite #:
City/State/Zip | Phone: ( ) | Fax: ( )

Section E: Diagnosis Information
Diagnosis (Please be specific & provide as much information as possible): | **ICD-10-CODE:**
Comorbidities

Section F: Product Information
Medication: | Strength:
Directions for use:

Section G: Dispensing Provider/Administration Information
Place of Administration:
☐ Self Administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone:
Center Name:
☐ Home Infusion Center Phone:
Agency Name:
☐ Administration code(s) (CPT):

Dispensing Provider/Pharmacy: *Patient selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Office ☐ Mail Order
☐ Other
Name:
Phone: Fax:
TIN: PIN:

Section H: Clinical Information
Explanation of why the preferred medication(s) would not meet your patient's needs:

Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature
Physician Signature: | Date / /

SAMPLE

- Include all relevant patient information and ensure that you are using the correct insurance card. Please note that in some instances, the patient may have separate medical benefit and pharmacy benefit cards
  - SPINRAZA is typically covered under the medical benefit (ie, the same card you would use to charge for the office visit)
- List the patient's name exactly as it appears on the insurance card. It is important to check for possible name changes and make sure all of the documents match
- Check the appropriate box to distinguish between a new medication and a continuation of therapy

THIS IS A SAMPLE PA FORM FOR ILLUSTRATIVE PURPOSES ONLY.

A successful PA begins with an accurate and complete form. Remember to fill out the health plan's PA form(s) properly and completely. Failure to do so could delay your patient's treatment. Keep copies of all PA request documents and correspondence for your records.

SELECTED IMPORTANT SAFETY INFORMATION

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.

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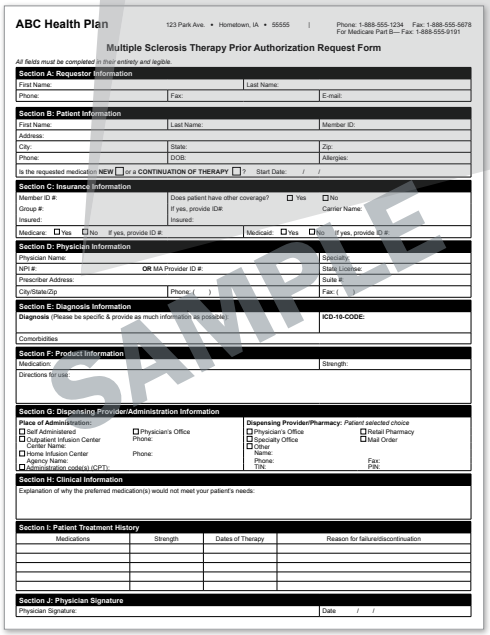
HOW TO FILL OUT A PA FORM (*cont'd*)

PRESCRIBING PHYSICIAN, DIAGNOSIS, AND PRODUCT INFORMATION

Section D: Physician Information		
Physician Name:		Specialty:
NPI #:	**OR** MA Provider ID #:	State License:
Prescriber Address:		Suite #:
City/State/Zip	Phone: ( )	Fax: ( )
Section E: Diagnosis Information		
Diagnosis (Please be specific & provide as much information as possible):		**ICD-10-CODE:**
Comorbidities		
Section F: Product Information		
Medication:		Strength:
Directions for use:		



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Section A: Requestor Information
First Name: | Last Name:
Phone: | Fax: | E-mail:

Section B: Patient Information
First Name: | Last Name: | Member ID:
Address:
City: | State: | Zip:
Phone: | DOB: | Allergies:
Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /

Section C: Insurance Information
Member ID #: | Does patient have other coverage? ☐ Yes ☐ No
Group #: | If yes, provide ID#: | Carrier Name:
Insured: | Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: | Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information
Physician Name: | Specialty:
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Prescriber Address: | Suite #:
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Medication: | Strength:
Directions for use:

Section G: Dispensing Provider/Administration Information
Place of Administration:
☐ Self Administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone:
Center Name:
☐ Home Infusion Center Phone:
Agency Name:
☐ Administration code(s) (CPT):
Dispensing Provider/Pharmacy: *Patient selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Office ☐ Mail Order
☐ Other
Name:
Phone: Fax:
TIN: PIN:

Section H: Clinical Information
Explanation of why the preferred medication(s) would not meet your patient's needs:

Section I: Patient Treatment History

Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature
Physician Signature: | Date / /

SAMPLE

- Complete the physician information section. Be sure to include all identification and/or licensing information
- Provide a detailed diagnosis and ICD-10 code so the health plan understands why SPINRAZA is being requested. Refer to the **Relevant Code and Sample Claim Form Guide**, available for download at **spinraza-hcp.com**, for the appropriate code
  - Ensure that the ICD-10 code and the language used to describe the diagnosis match the FDA-approved indication for SPINRAZA
- It is important to list any comorbidities, as this may help provide medical rationale for SPINRAZA
- Include the SPINRAZA name and the dosage you are prescribing for your patient

THIS IS A SAMPLE PA FORM FOR ILLUSTRATIVE PURPOSES ONLY.

FDA=US Food and Drug Administration; ICD-10=*International Classification of Diseases, Tenth Revision.*

SELECTED IMPORTANT SAFETY INFORMATION

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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HOW TO FILL OUT A PA FORM (*cont'd*)

PLACE OF ADMINISTRATION, DISPENSING PROVIDER/PHARMACY, AND CLINICAL INFORMATION

Section G: Dispensing Provider/Administration Information

Place of Administration:

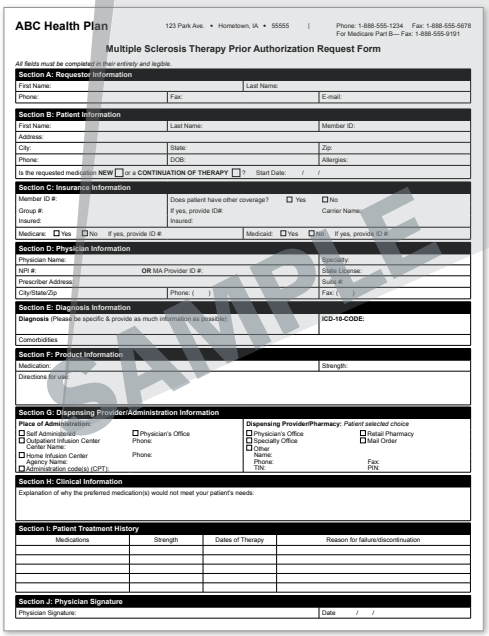
- ☐ Self Administered
- ☐ Outpatient Infusion Center
  Center Name:
- ☐ Home Infusion Center
  Agency Name:
- ☐ Administration code(s) (CPT):
- ☐ Physician's Office
  Phone:
- Phone:

Dispensing Provider/Pharmacy: *Patient selected choice*

- ☐ Physician's Office
- ☐ Specialty Office
- ☐ Other
  Name:
  Phone:
  TIN:
- ☐ Retail Pharmacy
- ☐ Mail Order
- Fax:
- PIN:

Section H: Clinical Information

Explanation of why the preferred medication(s) would not meet your patient's needs:



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Phone: | Fax: | E-mail:

Section B: Patient Information
First Name: | Last Name: | Member ID:
Address:
City: | State: | Zip:
Phone: | DOB: | Allergies:
Is the requested medication **NEW** ☐ or a **CONTINUATION OF THERAPY** ☐? Start Date: / /

Section C: Insurance Information
Member ID #: | Does patient have other coverage? ☐ Yes ☐ No | Carrier Name:
Group #: | If yes, provide ID#: |
Insured: | Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: | Medicaid: ☐ Yes ☐ No If yes, provide ID #:

Section D: Physician Information
Physician Name: | Specialty:
NPI #: **OR** MA Provider ID #: | State License:
Prescriber Address: | Suite #:
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Section E: Diagnosis Information
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Section F: Product Information
Medication: | Strength:
Directions for use:

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Phone:
Phone:
Dispensing Provider/Pharmacy: *Patient selected choice*
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Section J: Physician Signature
Physician Signature: | Date / /

- Fill in the Place of Administration. If your practice or facility is not listed, you should write it in
- For the Dispensing Provider/Pharmacy section, make sure to use the information from the Benefits Investigation to ensure that you are listing an in-network specialty pharmacy
- If SPINRAZA is Not Preferred or Not Covered on the health plan's formulary, provide a detailed explanation describing why the preferred formulary medications are not appropriate for your patient
  - Use the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA**, available at spinraza-hcp, to help with your explanation
  - You may need to provide additional documentation, such as medical literature and the patient's medical history

THIS IS A SAMPLE PA FORM FOR ILLUSTRATIVE PURPOSES ONLY.

SELECTED IMPORTANT SAFETY INFORMATION

The most common adverse reactions (≥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.

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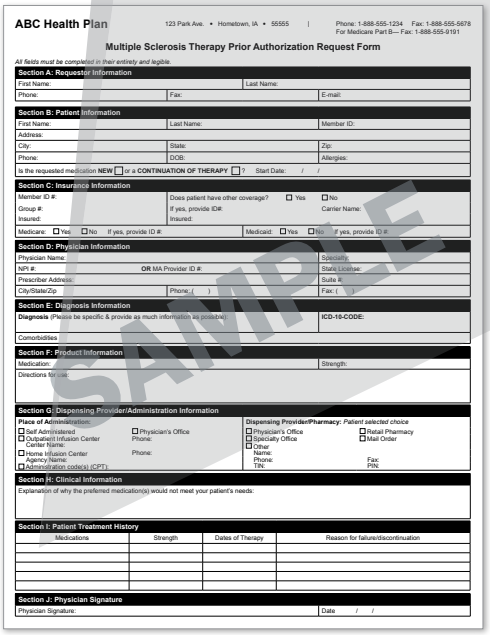
HOW TO FILL OUT A PA FORM (*cont'd*)

PATIENT TREATMENT HISTORY AND PHYSICIAN SIGNATURE

Section I: Patient Treatment History			
Medications	Strength	Dates of Therapy	Reason for failure/discontinuation

Section J: Physician Signature	
Physician Signature:	Date / /



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Group #: | If yes, provide ID#:
Insured: | Insured:
Medicare: ☐ Yes ☐ No If yes, provide ID #: | Medicaid: ☐ Yes ☐ No If yes, provide ID #:

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- List any medications the patient has used for treatment. If there are no prior treatments, write "none"
- Review the patient's Benefits Investigation. If the request is outside of the health plan's policy, a letter of medical necessity may be required
- Be sure to sign all documentation where required

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Submission of inaccurate or incomplete forms is the primary reason denials occur. Make sure to read and complete the PA form carefully before submitting.

SELECTED IMPORTANT SAFETY INFORMATION

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IN THE EVENT THAT A PA IS DENIED

There could be several reasons that an authorization may be denied. One of the main reasons PA requests are denied is incomplete or inaccurate information on the PA form. Check to ensure all information is complete and accurate. Resubmit the form if necessary. If the denial was for clinical reasons, determine what additional information may be required to demonstrate the medical necessity of SPINRAZA for the patient.

In some cases, a letter of medical necessity may be required when the PA is being resubmitted. Review the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA**, available for download at **spinraza-hcp.com**.

In the event that the PA request has been denied, the physician can appeal the decision by contacting the health plan directly to have a peer-to-peer discussion regarding the patient, the clinical issues, and the reasons for requesting a specific drug. If a phone call is not possible, you may submit a medical exception request. Refer to the **Guide to Requesting Medical Exceptions and Appealing Denials**, available for download at **spinraza-hcp.com**, for additional guidance.

If you work with a specific individual at the health plan to handle denials of PA requests, you may want to include his or her contact information on the **Health Plan Reference Sheet**, available at **spinraza-hcp.com**. You can also use the sheet to keep track of PA requirements for each health plan.

SMA360™
Support services from Biogen

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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 (≥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.

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