



Securing Access to SPINRAZA

This high-level overview outlines the key steps involved in securing access to SPINRAZA. For patients transitioning to the High Dose Regimen of SPINRAZA from the Low Dose Regimen, note that coverage requirements may differ between the regimens, and a new prior authorization may be required.

Step 1 Complete the Start Form and conduct a Benefits Investigation

- Complete appropriate Start Form for your patient.** Start Forms for the High Dose Regimen and Low Dose Regimen of SPINRAZA are available [here](#)
- Confirm** with the patient's health plan if SPINRAZA:
 - Is covered under the pharmacy or medical benefit
 - Must be procured through a Specialty Pharmacy (SP) or Specialty Distributor (SD)
- Check** if any specific documentation is required and for coding and billing requirements. Relevant coding information can be found in the **SPINRAZA Product Fact Sheet** available [here](#)
- Determine** the patient's financial responsibilities

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.

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

Securing Access to SPINRAZA (cont'd)

Step 2 Complete and submit the prior authorization (PA) request



Access and reimbursement can be complex, so it is recommended to contact your **Rare Disease Reimbursement Manager**.

- Fill out the appropriate PA form** and include payer-required documentation, such as:
 - Rationale for why SPINRAZA is medically necessary for your patient
 - Recent motor function tests showing improvements or stabilization of disease (addressing motor tests listed in the medical policy criteria)

Note that new motor tests may be necessary if they:

 - Differ from the type or number of tests listed in the PA criteria
 - Do not meet the minimum achievements for each test as listed in the PA or health plan policy
 - Were completed outside the required time frame (often needed within 30 days of PA submission)- A letter of medical necessity, when appropriate



SPINRAZA Sample Letter of Medical Necessity/Appeal template can be found [here](#).

- Note that a separate PA may be required for the High Dose Regimen of SPINRAZA in patients currently receiving the Low Dose Regimen, so be sure to check with the patient's health plan policy
 - J2326 (injection, nusinersen, 0.1 mg) is the HCPCS code to report both the Low Dose and High Dose Regimens of SPINRAZA
 - Be sure to include the number of J2326 billing units you are requesting to submit to the payer for the duration of the authorization period
 - Ensure both the correct NDC numbers and the vial count per NDC number is included with a pharmacy benefit PA
- Submit the PA form** and payer-required documentation via the preferred method of the patient's health plan

IMPORTANT SAFETY INFORMATION (cont'd)

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%).

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

Securing Access to SPINRAZA (cont'd)

Step 3 Track the status of the PA request

- Maintain a log** of the PA submissions and payer responses for each patient
- Follow up as needed** and provide any requested materials as soon as possible
 - For patients who qualify, financial support services may be available through SMA360[®]™

 **If approved: Go to Step 4**

 **If coverage is not initially approved:**

- Appeal** the denial
 - Complete the health plan's appeal request form and follow important guidelines and time frames
 - Include a letter of medical appeal to strengthen the request
- Monitor** the appeal
 - Follow up with the health plan to confirm your request was received and to check the status of its decision



Refer to the **SPINRAZA Sample Letter of Medical Necessity/Appeal template** available [here](#), for information you may want to include in your appeal request.



Access and reimbursement can be complex, so it is recommended to contact your **Rare Disease Reimbursement Manager**.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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

Securing Access to SPINRAZA (cont'd)

Step 4 Order SPINRAZA and treat the patient

SPINRAZA is available through CuraScript SD by Evernorth and Accredo[®] Specialty Pharmacy.

CuraScript SD by Evernorth:

- Contact CuraScript SD by Evernorth** to confirm you have an active account and to obtain the SPINRAZA order form from them
 - Complete the SPINRAZA order form and place the order with CuraScript SD by Evernorth by emailing the order form to WholesaleSpinraza@curascript.com, faxing the order form to 1-888-538-9781, or calling 1-855-778-1510
 - Place the order no later than 5 business days before the scheduled administration to ensure the product is on hand for the procedure (orders received Monday through Thursday prior to 5 PM ET will ship within 24 hours)

Accredo:

- Provide Accredo** with a prescription or SPINRAZA referral form
 - Fax the prescription or referral form to 1-888-454-8488 or call 1-855-778-1510
 - Accredo may contact your institution to obtain any additional information required for the PA
 - Accredo will call to confirm shipment date and location with the administration site (shipment will not go out until verbal confirmation is made)
- Understand the dosing schedule for SPINRAZA** and treat the patient
 - There are 2 dosing regimen options for SPINRAZA. For dosing guidance, click [here](#)



For additional information, refer to the **SPINRAZA Resource Guide for Practices and Facilities** available [here](#) and reach out to your Rare Disease Reimbursement Manager.

IMPORTANT SAFETY INFORMATION (cont'd)

The most common adverse reactions in the Low Dose Regimen ($\geq 20\%$ 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.

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

Indication and Important Safety Information

INDICATION

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

IMPORTANT SAFETY INFORMATION

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The most common adverse reactions in the Low Dose Regimen ($\geq 20\%$ 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.

The most common adverse reactions in the High Dose Regimen ($\geq 10\%$ of SPINRAZA-treated patients and $\geq 5\%$ 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](#).