Individual results may vary based on several factors, including severity of disease, initiation of treatment, and duration of therapy.

SPINRAZA Resource Guide for Practices and Facilities

For Coverage & Continued Treatment With SPINRAZA

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.

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 the next page and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INDICATION AND IMPORTANT SAFETY INFORMATION

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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 (≥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.

Please see full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

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Biogen is committed to SPINRAZA® (nusinersen) patients, their families, and the healthcare providers (HCPs) that care for SPINRAZA patients. The purpose of this resource is to highlight best practices and provide potential solutions to help clinics and administration sites that participate in spinal muscular atrophy (SMA) patient care, maximize SPINRAZA access, and improve the overall patient experience.

SMA360™ Support services from Biogen

Questions about support or treatment logistics?

Contact your Biogen Family Access Manager or call **1-844-4SPINRAZA (1-844-477-4672)**

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

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Biogen Care Team

BIOGEN CARE TEAM

Your SPINRAZA® (nusinersen) team members are available to provide clinical trial and nonclinical information to help navigate SPINRAZA access.

RARE DISEASE ACCOUNT EXECUTIVE (RDAE)

The RDAE is your primary point of contact who can help answer your questions about SPINRAZA. Your RDAE can:

- Share clinical information about SPINRAZA
- Educate and assist your staff on how they may be able to support access to treatment

RARE DISEASE REIMBURSEMENT MANAGER (RDRM)

The RDRM is responsible for helping you and your staff navigate the reimbursement process for SPINRAZA. Your RDRM can:

- Educate your staff on SPINRAZA procurement methods
- Provide enhanced education on claim forms and coding/billing
- Support your interactions with health plans

FAMILY ACCESS MANAGER (FAM)

The FAM is the primary contact for patients/caregivers, helping patients get access to SPINRAZA. Your FAM can:

- Educate your staff on the prior authorization (PA) process
- Support your staff in the event of specific patient escalations around dosing schedule, PAs, and reauthorization

LEAD CASE MANAGER (LCM)

The LCM is responsible for case managing all patient information to assist in a smooth patient journey. Your LCM can:

- Support your staff by monitoring for PAs and reauthorizations of existing patients, proactively alerting them of any obstacles, and confirming product shipment
- Help educate and support providers and patients with the Biogen Support Services offerings

Please see Important Safety Information on page 2 and full Prescribing Information.

Product Fact Sheet

PRODUCT FACT SHEET

COMPANY: Biogen

PRODUCT TRADE NAME: SPINRAZA®

GENERIC NAME: nusinersen

INDICATION: SPINRAZA is a survival motor neuron-2 (*SMN2*)-directed antisense oligonucleotide indicated for the treatment of SMA in pediatric and adult patients.

DOSING: The recommended dosage is 12 mg (5 mL) per administration. Initiate SPINRAZA treatment with 4 loading doses. The first 3 loading doses should be administered at 14-day intervals. The fourth loading dose should be administered 30 days after the third dose. A maintenance dose should be administered once every 4 months thereafter.[1]

Not shown actual size

STORAGE REQUIREMENTS: Store in a refrigerator between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. See product packaging and Prescribing Information for complete list of instructions.[1]

How supplied[1]	12-mg/5-mL injection
Packaging[1]	Single-dose glass vial
Carton dimensions	2.28" x 3.15" x 2.56"
Shipping case dimensions	11.25" x 9.5" x 8" or 11.25" x 9.5" x 10.75"
National Drug Code (NDC) number[1]	64406-058-01
J-code[1,2]	J2326, Injection, nusinersen, 0.1 mg **Note:** 1 dose=120 billing units.
Example International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes[3]	**G12.0** - Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann] **G12.1** - Other inherited spinal muscular atrophy Adult form spinal muscular atrophy Childhood form, type II spinal muscular atrophy Distal spinal muscular atrophy Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander] **Note:** Be sure to use the appropriate code for SMA diagnosis so it will be accepted on the claim form by the health plan. Using codes G12.8 (other SMAs and related syndromes) or G12.9 (SMA, unspecified) may result in a claim denial because SMA type is not specified.

References: 1. SPINRAZA Prescribing Information. Cambridge, MA: Biogen. **2.** HCPCS.codes. J2326. https://hcpcs.codes/j-codes/J2326/. Accessed May 24, 2024. **3.** Centers for Medicare & Medicaid Services. 2020 ICD-10-CM. Updated September 6, 2023. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Accessed May 24, 2024.

Please see Important Safety Information on page 2 and full Prescribing Information.

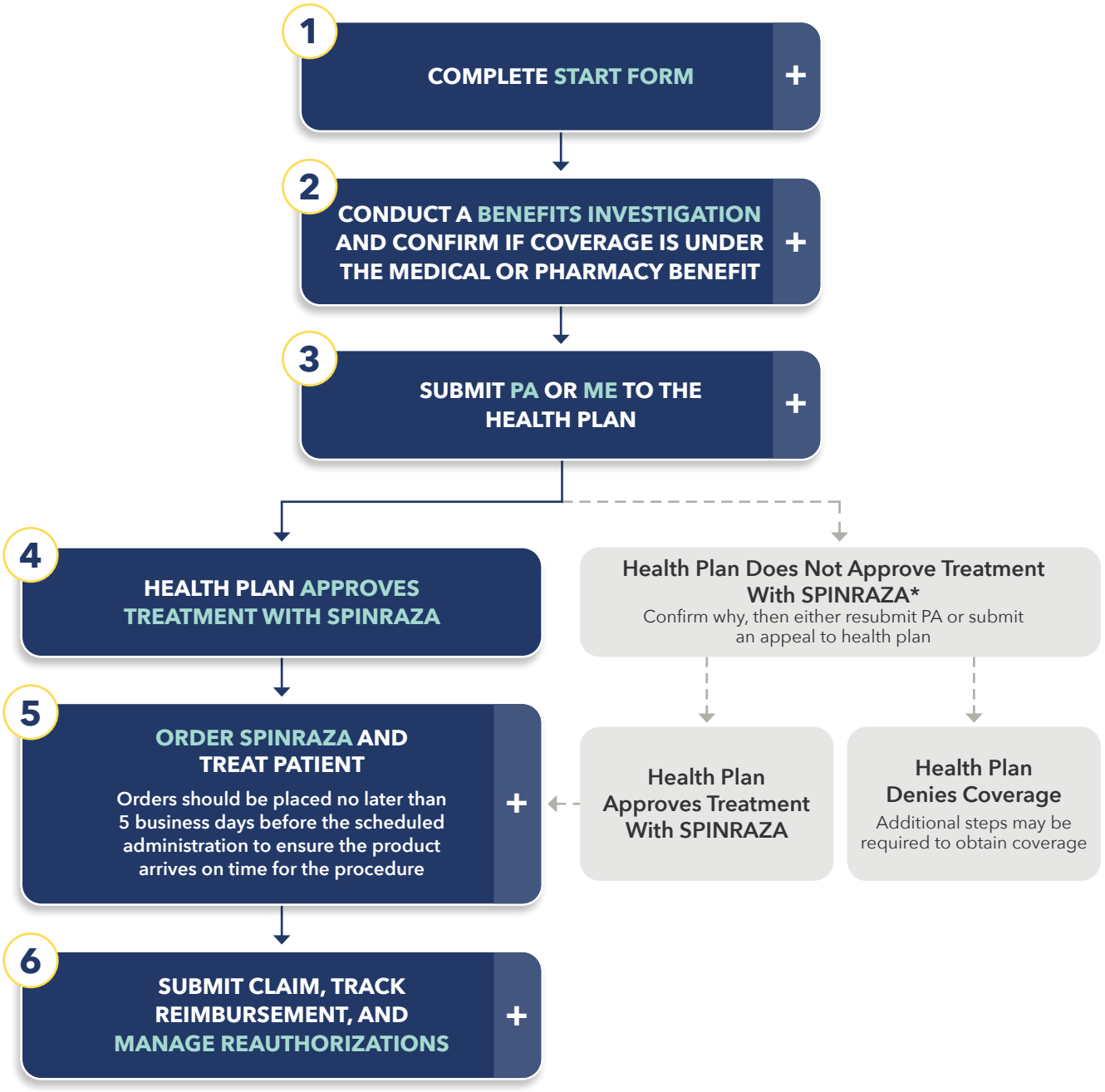
SPINRAZA® (nusinersen) injection 12 mg/5 mL

Navigating Payer Coverage

Ask your RDRM for more information about prior authorizations (PAs), medical exceptions (MEs), and appeals for SPINRAZA® (nusinersen)

STEPS TO PRODUCT ACCESS

This flow provides a general overview of the process for getting patients started on SPINRAZA® (nusinersen).



*Missing or inaccurate information on the PA or ME submission may have caused the denial. If so, correct or complete all information and resubmit. If all information was accurate and the approval to treat was denied for other reasons, consider an appeal.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA® (nusinersen) START FORM

Once you have determined that SPINRAZA is the appropriate treatment for your patient, submit the SPINRAZA Start Form, which will initiate your patient's enrollment in SMA360°™ support services.*

1. **Ask your patient** to complete the patient sections of the Start Form, including Consent Information

2. **Complete the Healthcare Provider section** of the Start Form. Partially completed forms may delay access to Biogen services
   - If you plan to acquire SPINRAZA through Accredo, the exclusive specialty pharmacy (SP) for SPINRAZA, remember to complete the prescription section of the Start Form so that SPINRAZA can be filled by Accredo. Submitting the Start Form will also ensure your patient is enrolled in SMA360°

3. **Make a photocopy** of both sides of the covered individual's medical insurance card and pharmacy benefit card, if available

4. **Give the patient** or parent/guardian the instructions and consent information pages to take home

5. **Send the completed Start Form** and copies of medical and pharmacy benefit cards to Biogen
   - Fax to **1-888-538-9781** or email as an attachment to **StartForm@biogen.com** (this email address is an unattended inbox and is for Start Forms only). For questions, please contact your Biogen RDAE at **1-844-477-4672**

Please click here for the **SPINRAZA START FORM (English)**

*The Start Form is not a requirement to begin treatment. It is only required to receive support services for which you are eligible. SMA360° can help address nonmedical access barriers, but you will still need a prescription before you can begin treatment with SPINRAZA.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BENEFITS INVESTIGATION

Once a patient is prescribed SPINRAZA® (nusinersen), the practice or facility should conduct a Benefits Investigation to determine the patient's health plan requirements. For SPINRAZA, the practice or facility will need to know how the patient's health plan covers both the drug and the administration components.

If ordering SPINRAZA through Accredo SP,* Accredo will manage the Benefits Investigation process and follow up with the health plan. As soon as the SP procurement pathway has been determined, provide Accredo with the prescription or SPINRAZA referral form.

It is important to determine your patient's level of coverage before each administration of SPINRAZA because health plan coverage can vary and change over time.

BENEFITS INVESTIGATION CHECKLIST

Determine the following information:

Confirm the patient's demographics are accurate and up to date

- Ensure the appropriate health plan information is on file and accurate drug and procedure codes are noted for each patient's individual health plan(s)

Determine if SPINRAZA is covered under the patient's pharmacy or medical benefit

- SPINRAZA will most often be covered under the medical benefit

Identify if the patient's health plan has a requirement that SPINRAZA be dispensed through an SP or procured through buy-and-bill

Determine PA requirements and submission timelines

- Identify health plan–specific requirements for prior authorization and/or sites of care for each health plan the patient has coverage through (eg, in-network, treatment in same state policy was issued, etc)

Identify patient financial responsibility

- Determine key elements of the health plan's cost-sharing structure (out-of-pocket (OOP) costs, deductibles, copays, coinsurance, in-/out-of-network benefits)

*Accredo SP is the exclusive specialty pharmacy of SPINRAZA.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BENEFITS INVESTIGATION (cont'd)

Important considerations for conducting a Benefits Investigation/verification.

Out-of-network and/or out-of-state restrictions

Some patients who receive SPINRAZA® (nusinersen) may face restrictions from their commercial and/or Medicaid health plans because the provider and/or facility is out of network or out of state. However, in these instances, waivers or exceptions can be granted on the grounds of medical necessity

- Investigate and record the patient OOP cost implications for out-of-network and/or out-of-state providers. OOP costs may be higher for patients seeking treatment through these providers
- Find out if there is an exception process for patients seeking care out of network and/or out of state

Coordination of benefits between multiple health plans

There may be cases where your patient has multiple health plans that provide benefit coverage, such as a commercial health plan and Medicaid

- In the case of multiple health plans, it is important to establish during the Benefits Investigation which health plan is primary, which is secondary, and which is tertiary. Patients may need to be contacted to confirm coordination of benefits with each insurer
- Once you have established the order of benefits, follow the instructions from each health plan regarding coordination of benefits

Coding and claims submission details

Specific coding and billing requirements may vary by health plan

- Clarify the requirements for reporting an National Drug Code (NDC) number in a medical claim
- Check if any specific documentation is required to be submitted with the claim (eg, clinical records, drug invoice)

Coordinate with Biogen's FAM or LCM, who advocates on behalf of patients, or RDRMs who can support access to treatment (including insurance coverage, reimbursement, financial limitations, site-of-care logistics, and procurement and distribution issues).

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

COVERAGE CONSIDERATIONS

There are different types of health plan options that may help cover some or most of the cost of SPINRAZA® (nusinersen). Health plans may provide different levels of coverage and work in different ways.

The 2 main types of health insurance available in the United States include:

Private Health Insurance (Commercial)[1]	Public Health Insurance[1,2]
Includes plans provided by an entity other than the government	Includes coverage offered through programs funded by the state or federal government, such as Medicare, Medicaid, Children's Health Insurance Program (CHIP), CHAMPVA,* and VA coverage

	Private (Commercial)[1]	Medicare[1,3,†,‡,§]	Medicaid[4,5]
Who Funds It?	Funded by employers, unions, trade organizations, and/or individuals and families	Funded only by the government	Funded by the federal government and/or the state
How Does Coverage Work?	Coverage is based on the benefits package provided by the employer or the individual/family health plan	Medicare provides coverage through 4 parts: Part A: hospital insurance Part B: medical insurance Part C: Medicare Advantage Part D: prescription drug	Under federal law, states are mandated to provide certain benefits and have the choice to cover optional benefits
Who Is Eligible?	Everyone (primarily through employer-sponsored or Health Insurance Marketplace plans)	All people aged 65 years or older and people younger than 65 years who have received Social Security Disability Insurance (SSDI) benefits for at least 2 years (24 months)	Eligible low-income individuals/families, pregnant women and children, and people with disabilities

*Please note that Maryland follows the terms of the Maryland All-Health Plan Model and some of the information below may not apply.
†Medicare providers and suppliers are not permitted to bill people enrolled in the Qualified Medicare Beneficiary program for items such as Medicare copays, deductibles, or coinsurance.
‡State-based qualification parameters also apply.
CHAMPVA=Civilian Health and Medical Program of the Department of Veterans Affairs; VA=Veterans Affairs.

References: 1. United States Census Bureau. Health insurance glossary. https://www.census.gov/topics/health/health-insurance/about/glossary.html. Accessed April 19, 2024. **2.** Centers for Medicare & Medicaid Services. Children's Health Insurance Program (CHIP). https://www.cms.gov/training-education/partner-outreach-resources/american-indian-alaska-native/chip. Accessed April 19, 2024. **3.** Centers for Medicare & Medicaid Services. Medicare & You 2024. https://www.medicare.gov/publications/10050-Medicare-and-You.pdf. Accessed April 2, 2024. **4.** Medicaid.gov. Mandatory & optional Medicaid benefits. https://www.medicaid.gov/medicaid/benefits/mandatory-optional-medicaid-benefits/index.html. Accessed April 19, 2024. **5.** Medicaid.gov. Medicare eligibility. https://www.medicaid.gov/medicaid/eligibility/index.html. Accessed April 19, 2024.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

MEDICARE CONSIDERATIONS FOR PATIENTS WITH SMA

MEDICARE COVERS ABOUT 1 IN 4 ADULTS WITH SMA (AGED 18 YEARS AND OLDER)

Enrollment

For patients with SMA who receive SSDI benefits, enrollment is automatic after 24 months of receiving benefits[1]

If a patient is eligible for Medicare, you may help them sign up in the following ways:

1. Calling Social Security at **1-800-772-1213**
2. Signing up online at **https://www.ssa.gov/benefits/medicare**

Important Considerations

- Children who were receiving benefits as a minor child on a parent's Social Security record (via Supplementary Security Income [SSI]) may be eligible to continue receiving benefits on that parent's record upon reaching age 18 if they are disabled[1]
  – Marriage of the disabled "adult child" may affect eligibility for this benefit
- SMA types 0 and 1 qualify as compassionate allowances for Social Security disability (1 of more than 200 conditions)[2]
- Patients who receive SSDI get Part A at no cost but may have to pay a premium for Parts B and D

Medigap Policies

- Medicare Supplement Insurance policies, also known as Medigap policies, can help pay some of the costs Original Medicare does not. This includes copayments, coinsurance, and deductibles. Medigap policies are sold by private insurance companies. They must follow federal and state laws[3]
- Patients must have Medicare Part A and Part B to have a Medigap Policy[3]

Continuing SPINRAZA® (nusinersen) Treatment When Insurance Changes

It is important to track and understand changes in health insurance for your patients with SMA, including primary and secondary insurance plans.

- For example, patients with SMA may transition to Medicare from Medicaid; Medicare becomes the primary insurer, and Medicaid is the secondary insurer
- Patients with SMA may require authorization for treatment due to the change in health insurance
- Insurance claims submitted to the wrong primary insurer will likely be rejected and will need to be resubmitted to the correct insurer, causing a significant delay in reimbursement

References: 1. Social Security Administration. Benefits for children with disabilities. Published March 2024. https://www.ssa.gov/pubs/EN-05-10026.pdf. Accessed March 21, 2024. **2.** Social Security Administration. Compassionate allowances conditions. https://www.ssa.gov/compassionateallowances/conditions.htm. Accessed March 21, 2024. **3.** Centers for Medicare & Medicaid Services. Medicare & You 2024. https://www.medicare.gov/publications/10050-Medicare-and-You.pdf. Accessed March 21, 2024.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

FUNCTIONAL ASSESSMENTS IN SMA

DOCUMENTING FUNCTIONAL BASELINES AND IMPROVEMENTS

Health plans generally require documentation of a patient's motor assessments in PAs, MEs, appeals, and reauthorizations to evaluate a patient's outcomes with SPINRAZA® (nusinersen).

- A patient's baseline motor score should be recorded at the start of treatment
- If a health plan requires a demonstration of efficacy of SPINRAZA over the course of treatment, this is typically documented in terms of maintenance of, or improvements in, motor milestones as measured in functional exam testing
- Confirm if the patient's health plan specifies which motor function test should be used to demonstrate an improvement in motor milestones or demonstrating that existing motor milestones have not been lost

There are a variety of functional tests that can be used to assess patients with SMA. Because motor milestones in infants and children with SMA vary significantly, there is not one standardized functional assessment used in clinical practice.

The following tests evaluate a range of motor functions and are appropriate for different populations with SMA.

The Hammersmith Infant Neurological Examination Section 2 (HINE-2)
Age 2 months to 24 months

The Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
Non-sitters

The Revised Upper Limb Module (RULM)
Age >30 months

The Hammersmith Functional Motor Scale–Expanded (HFMSE)
Sitters and walkers

6-Minute Walk Test (6MWT)
Ambulatory patient

FUNCTIONAL TESTING FREQUENCY

- Functional testing information is extremely important to include with all requests for authorizations and reauthorizations
- Requirements vary by health plan in duration and assessment. Please refer to the health plan's medical policy for functional test requirements

Reference: Pierzchlewicz K, et al. *Child Neurol Open*. 2021;8:2329048X211008725.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

PRIOR AUTHORIZATION SUBMISSIONS

PAs are very common for orphan drugs that treat rare diseases, such as SPINRAZA® (nusinersen), because they enable health plans to monitor costs and ensure that drugs are being used for appropriate patients only. Dedicating staff to manage/oversee the authorization process can reduce administrative denials.

AFTER COMPLETING THE BENEFITS INVESTIGATION, IF YOU FIND THAT A PA IS REQUIRED:

Step 1: Complete and submit the PA request

- Identify, review, and document any health plan–specific requirements for authorization requests
- Fill out the appropriate PA form for that health plan and include supplemental documents to strengthen the request
  - May include: confirmatory genetic test, baseline motor ability assessment, chart notes, and a letter of medical necessity
  - Prepare supplemental documentation. Each health plan is unique, so it is essential to identify the specific documents you will need (eg, clinical patient notes and relevant patient medical history)
  - Reminder to include the **tax ID number (11-3358535)** for Accredo, the sole SP provider for SPINRAZA, on the PA form. The **National Provider Identifier (NPI)** may also be required
  - **Your FAM can assist in confirming which electronic prior authorization (ePA) option is available based on the Benefits Investigation. Most health plan websites list and encourage utilization of ePAs***

Step 2: Track the status of the request

- Maintain a thorough log of the PA submissions and denials for each patient, as this information will be needed if the patient wishes to apply for financial support services from SMA360°™
- ePA requests typically receive a determination within 2-3 business days when all proper documentation is completed whereas faxed PA submissions may take several weeks. In either instance, it is important to continue to check on the status of the PA[1,2]

Step 3: Follow up as needed

- If additional documentation is requested at any point, make sure to provide it as soon as possible
- If authorization is granted, document any health plan or plan-specific requirements outlined in the authorization or plan policy, including but not limited to:
  - Duration of authorization and requirements/timing for authorization renewal

One of the main reasons PA requests are denied is incomplete or inaccurate information on the PA form. Reach out to your RDRM or FAM to help ensure a completed PA packet is submitted to the health plan based on their requirements.

*If the patient's health plan does not accept ePAs, please follow up with them for instructions on how to complete a paper form of the PA via fax, mail, or telephone.

References: 1. CoverMyMeds. 2020 electronic prior authorization report. https://assets.ctfassets.net/2in405srp47m/4uzia8m4YQy3mBplpyBuqF/9af9cefa63bba76566aa3e8595751e45/CMM_36664_ePAExecutiveSummary_Digital.pdf. Accessed March 21, 2024. **2.** DeMarzo A. What is prior authorization? Accreditation Council for Medical Affairs website. Published December 15, 2020. https://www.priorauthtraining.org/prior-authorization/. Accessed March 21, 2024.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

MEDICAL EXCEPTIONS

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 ME request with a letter of medical necessity for SPINRAZA® (nusinersen), as needed

- Find out if the health plan has its own ME request form or will accept a separate letter from your office
- Provide background on your patient's condition:
  - Summarize their clinical status citing diagnostic evidence of SMA
  - 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
  - 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 they do 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
- Refer to the **Sample Letter of Medical Necessity/Appeal Template for SPINRAZA**, available at **SPINRAZA-hcp.com**, for information you may want to include with your ME request

Step 2: Submit and track your ME request

- Submit the ME via phone, fax, email, or the company's website. Then, identify the appropriate individual to contact regarding the progress of the ME request

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.

APPEALS

Sometimes, even if treatment with SPINRAZA® (nusinersen) is medically necessary, coverage may still be denied. An appeal is a request to your patient's health plan to reverse its decision and approve SPINRAZA.

Step 1: Understand the reason for the denial

- Identify the reason that treatment was denied and contact the health plan to find a way to resolve the matter
  - If denied for nonclinical reasons, the PA or ME should be resubmitted with the required or corrected information
  - If denied for clinical reasons, verify the appeals process with the health plan and complete the appeal fully and accurately

Step 2: Appeal the denial

- Complete the health plan's appeal request form and follow important guidelines and time frames
- Refer to the **Sample Letter of Medical Necessity/Appeal Template for SPINRAZA**, available at **SPINRAZA-hcp.com**, for information you may want to include with your appeal request
- **Your RDRM and/or FAM can assist you in preparing an appeal**

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 their involvement

In the event the appeal is denied:

- Your patient can ask for an external review (by an independent, accredited medical professional) or a peer review. This can be helpful because the health plan will no longer have the final say regarding their coverage
- If all attempts at coverage are denied by the primary health plan, you may appeal to a secondary health plan

Please click here for the **Sample Letter of Medical Necessity/Appeal Template**.

SMA360 Support services from Biogen

Work with your SMA360°™ team to explore other options.

SMA360° insurance and financial assistance programs are available to help patients and providers navigate the SPINRAZA treatment process. Contact SMA360° support services at 1-844-4SPINRAZA (1-844-477-4672), Monday through Friday, from 8:30 AM to 8 PM ET.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

REAUTHORIZATIONS

Reauthorizations are required for patients continuing on therapy. Health plans vary widely in their requirements for reauthorization but generally include documentation similar to what was submitted with the initial PA, such as diagnostic criteria and demonstration of efficacy.

- A diagnosis of SMA types 1, 2, 3, or 4, which would also include genetic testing confirming the diagnosis
- Demonstration of efficacy of SPINRAZA® (nusinersen) over the course of treatment, which is typically documented in terms of maintenance of, or improvements in, motor milestones as measured in functional exam testing
  - Functional testing information is extremely important to include with all requests for reauthorizations
  - If changes are not documented, reauthorization may be denied because lower, undetected baseline scores could make the patient's progress appear inadequate according to the plan's minimum efficacy standard

Medical plans may have different intervals for reauthorizations. It is important to become familiar with the medical policy for SPINRAZA at your patient's health plan. To start the reauthorization process, see the steps below and be mindful of the duration of coverage at the health plan and the patient's start date.

Step 1:

- **Contact the health plan** to find out the specific requirements for reauthorization, such as required forms. Reference the health plan's most current medical policy for SPINRAZA

Step 2:

- **Determine the supporting documentation** that may be required, such as patient notes and results of functional assessments

Step 3:

- **Submit documentation** according to the health plan's policy
  - **Best Practice:** Timing is everything—if possible, start preparing documents several months before reauthorization is needed and set a reauthorization target date. It may be helpful to create a patient tracking system to manage PA effective date, last functional assessment, etc
  - **Your RDRM or FAM can assist with building out a tracking system template, if needed**

Your FAM can help you identify the appropriate documents for a reauthorization and address timing concerns.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

REAUTHORIZATIONS (cont'd)

THE DOSING SCHEDULE FOR SPINRAZA® (nusinersen): IMPLICATIONS FOR REAUTHORIZATION

SPINRAZA is administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures. Patients treated with SPINRAZA are given 4 initial loading doses and a maintenance dose every 4 months thereafter.

The recommended dosage of SPINRAZA is 12 mg (5 mL) per administration.

For plans requiring renewal every **6 MONTHS,** initial approval coverage may end **before maintenance dosing begins**

For plans requiring renewal every **12 MONTHS,** initial approval coverage may end **while patient is between maintenance doses**

At baseline and prior to each dose, obtain a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing.

Because each medical plan may have different intervals for reauthorizations, it is important to become familiar with the medical policy for SPINRAZA at your patient's health plan. If reauthorization is not achieved in time, the patient's coverage for SPINRAZA can be put at risk.

Reference: SPINRAZA Prescribing Information. Cambridge, MA: Biogen.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ON-TIME DOSING

On-time dosing is important because delayed dosing may reduce efficacy of SPINRAZA® (nusinersen) for your patient. Missed dosing may contribute to additional administrative costs for your practice and may have high-cost implications to health plan coverage and reimbursement.

IN CASES WHERE A PATIENT HAS MISSED DOSES:

- **Several doses may be required in a short time frame to return to maintenance dosing**
  - Inform the patient of the number of subsequent doses and administration procedures required as well as the potential financial responsibilities
- **Health plans may require a new authorization**
  - Consider including the rationale for the missed dose within the PA submission and reiterate the need for an expedited review to avoid gaps in care and subsequent increases in costs associated with delays in treatment
  - If a dose is significantly delayed, your patient may demonstrate disease worsening in motor tests. In the new authorization request, be sure to sufficiently explain disease worsening as the result of delayed or missed dosing so it is not misinterpreted as a lack of efficacy

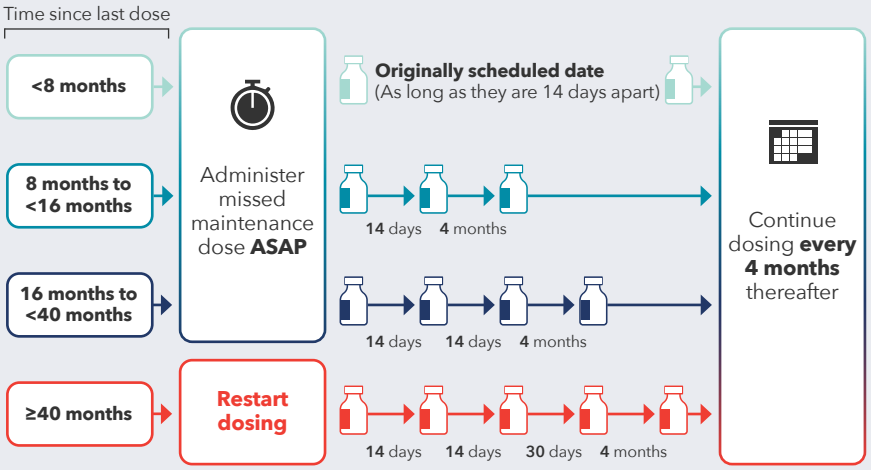
If your patient misses a dose, administer the missed dose as soon as possible. The schedule of subsequent doses will vary according to the table below.

MISSED LOADING DOSE

Administer missed dose **ASAP**

Adjust date for subsequent doses to maintain the recommended interval between doses

MISSED MAINTENANCE DOSE*



Missed doses should be administered ASAP because patients may experience disease worsening.

*Missed maintenance dosing guidance was added to the SPINRAZA Prescribing Information in February 2023.

Reference: SPINRAZA Prescribing Information. Cambridge, MA: Biogen.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Relevant Codes and Sample Claim Forms

Ask your RDRM for more information about the reimbursement process for SPINRAZA® (nusinersen), including codes and sample claim forms

REIMBURSEMENT PROCESS OVERVIEW

This section provides an overview of best practices to assist with coding for procedures related to SPINRAZA® (nusinersen) administration and ancillary services (if needed). It also provides examples of claim forms and guidance on how to complete them.

Overview of the Reimbursement Process for SPINRAZA

1. Benefits Investigation and authorization

2. Financial assistance and insurance counseling

3. Patient treatment scheduling

4. SPINRAZA administration and claim submission

ALWAYS CHECK YOUR PATIENT'S PLAN FOR COVERAGE AND CODING GUIDANCE

Remember, coding and billing recommendations may vary by health plan. Your practice or facility should check directly with the patient's health plan(s) for guidance on the appropriate codes to use to facilitate claim processing for SPINRAZA, its administration, and any ancillary services. Biogen field representatives are available to answer questions and further support the reimbursement process.

RELEVANT CODES FOR SPINRAZA® (nusinersen)

ICD-10-CM CODE EXAMPLES

ICD-10-CM Code[1]	Description[1]
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]
G12.1	Other inherited spinal muscular atrophy Adult form spinal muscular atrophy Childhood form, type II spinal muscular atrophy Distal spinal muscular atrophy Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander]
REMEMBER: Make sure to use the appropriate code for SMA diagnosis so it will be accepted on the claim form by the health plan. Using codes G12.8 (other spinal muscular atrophies and related syndromes) or G12.9 (spinal muscular atrophy, unspecified) may result in a claim denial because SMA type is not specified.	

HCPCS CODE

HCPCS Code[2]	Description[2]
J2326	Injection, nusinersen, 0.1 mg (120 billable units=1 vial)

340B AND DRUG WASTAGE MODIFIERS

Modifiers[3,4]	Description[3,4]
JZ	Indicates zero wastage/not administered to any patient
TB*	340B-acquired drug (mandatory use effective 1/1/25)
JG	340B-acquired drug (voluntary use)

NDC NUMBER

NDC Number[5]		Description[5]
10-digit format	11-digit format	
64406-058-01	64406-0058-01	12-mg/5-mL single-dose vial (contains 12 mg of nusinersen solution for intrathecal injection)

*The 340B Program allows certain hospitals to buy outpatient drugs at discounted prices. Starting January 1, 2025, if you are a 340B-covered entity, you must report the "TB" modifier on Medicare claims, even if you are using the "JG" modifier.

References: 1. Centers for Medicare & Medicaid Services. 2020 ICD-10-CM. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Accessed May 24, 2024. **2.** HCPCS.code. J2326. https://hcpcs.codes/j-codes/J2326/. Accessed May 24, 2024. **3.** CMS.gov. Billing and coding: JW and JZ modifier billing guidelines. Updated March 21, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932. Accessed March 21, 2024. **4.** CMS.gov. Billing 340B modifiers under the Hospital Outpatient Prospective Payment System (OPPS). Published March 3, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf. Accessed March 21, 2024. **5.** SPINRAZA Prescribing Information. Cambridge, MA: Biogen.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

RELEVANT CODES FOR SPINRAZA® (nusinersen) (cont'd)

CURRENT PROCEDURAL TERMINOLOGY (CPT)® CODE EXAMPLES

Procedure Type	CPT® Code	Description
Drug Administration & Imaging Procedure/ Guidance	96450	Chemotherapy administration, into central nervous system (CNS) (eg, intrathecal), requiring spinal puncture
	62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
	62329	With fluoroscopic or computed tomography (CT) guidance
	77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (eg, epidural or subarachnoid)
	76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77012	CT guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
Anesthesia	00635	Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)
	99100	Anesthesia for patient of extreme age, younger than 1 year and older than 70 years (list separately in addition to code for primary anesthesia procedure)
Moderate (Conscious) Sedation	99151-99153, 99155-99157	Drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Coding is based on total intra-service time and the healthcare professional who is performing the procedure. For descriptions of individual codes, refer to the current CPT® Professional Edition

Reference: American Medical Association. *CPT® 2021 Professional Edition*. American Medical Association; 2020.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

RELEVANT CODES FOR SPINRAZA® (nusinersen) (cont'd)

CPT® CODE EXAMPLES (CONT'D)

Procedure Type[1]	CPT® Code[1]	Description[1]
Outpatient Hospital Observation Status	99217	Observation care discharge day management (this code is to be utilized to report all services provided to a patient on discharge from outpatient hospital observation status if the discharge is on a day other than the initial date of observation status)
	99218-99220	Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: a detailed or comprehensive history; a detailed or comprehensive examination; and varying levels of medical decision-making complexity
	99234-99236	Observation or inpatient hospital care, for the evaluation and management of a patient, including admission and discharge on the same date, which requires these 3 key components: a detailed or comprehensive history; a detailed or comprehensive examination; and varying levels of medical decision-making complexity
Modifiers	22	Increased procedural services
	23	Unusual anesthesia services
	25	Significant, separately identifiable evaluation and management service by the same physician or other qualified HCP on the same day of procedure or other service
	51	Multiple procedures
	52	Reduced services
	53	Discontinued procedure
	59	Distinct procedural service

REVENUE CODE EXAMPLES FOR OUTPATIENT HOSPITAL-BASED FACILITIES*

Service Type[2]	Revenue Code[2]	Description[2]
Drug Administration, Surgical Procedure, Recovery, and Observation	0710	Recovery room permits identification of particular services, if necessary
Anesthesia Services	0370	Anesthesia (ie, general classification)

*Including off-campus clinic, on-campus facility, hospital-based ASC, and other outpatient outlets operated by a hospital.

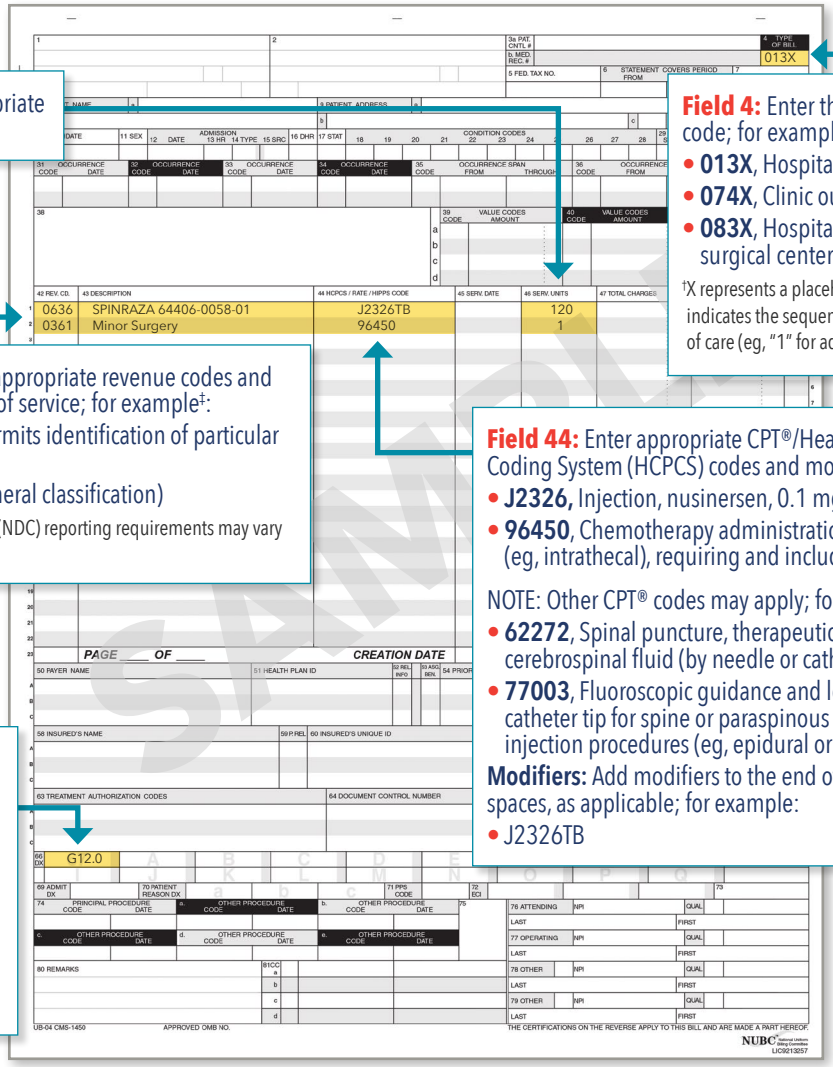
References: 1. American Medical Association. *CPT® 2021 Professional Edition*. American Medical Association; 2020. **2.** CMS.gov. CMS manual system. Published July 10, 2009. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1767CP.pdf. Accessed March 21, 2024.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SAMPLE CMS-1450/UB-04 CLAIM FORM

FOR OUTPATIENT HOSPITAL-BASED FACILITIES*



Field 46: Enter the appropriate number of units of service.

Field 4: Enter the appropriate type of bill code; for example†:

- **013X**, Hospital outpatient
- **074X**, Clinic outpatient physical therapy (OPT)
- **083X**, Hospital outpatient ambulatory surgical center (ASC)

†X represents a placeholder for the fourth digit, which indicates the sequence of this bill in this particular episode of care (eg, "1" for admit through discharge claim).

Fields 42 and 43: Enter appropriate revenue codes and corresponding description of service; for example‡:

- **0710**, Recovery room permits identification of particular services, if necessary
- **0370**, Anesthesia (ie, general classification)

‡For Field 43, National Drug Code (NDC) reporting requirements may vary by health plan.

Field 44: Enter appropriate CPT®/Healthcare Common Procedure Coding System (HCPCS) codes and modifiers; for example:

- **J2326,** Injection, nusinersen, 0.1 mg
- **96450**, Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture

NOTE: Other CPT® codes may apply; for example:

- **62272**, Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
- **77003**, Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (eg, epidural or subarachnoid)

Modifiers: Add modifiers to the end of the CPT/HCPCS code without spaces, as applicable; for example:

- J2326TB

Field 66: Enter the appropriate primary International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code; for example:

- **G12.0**, Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]

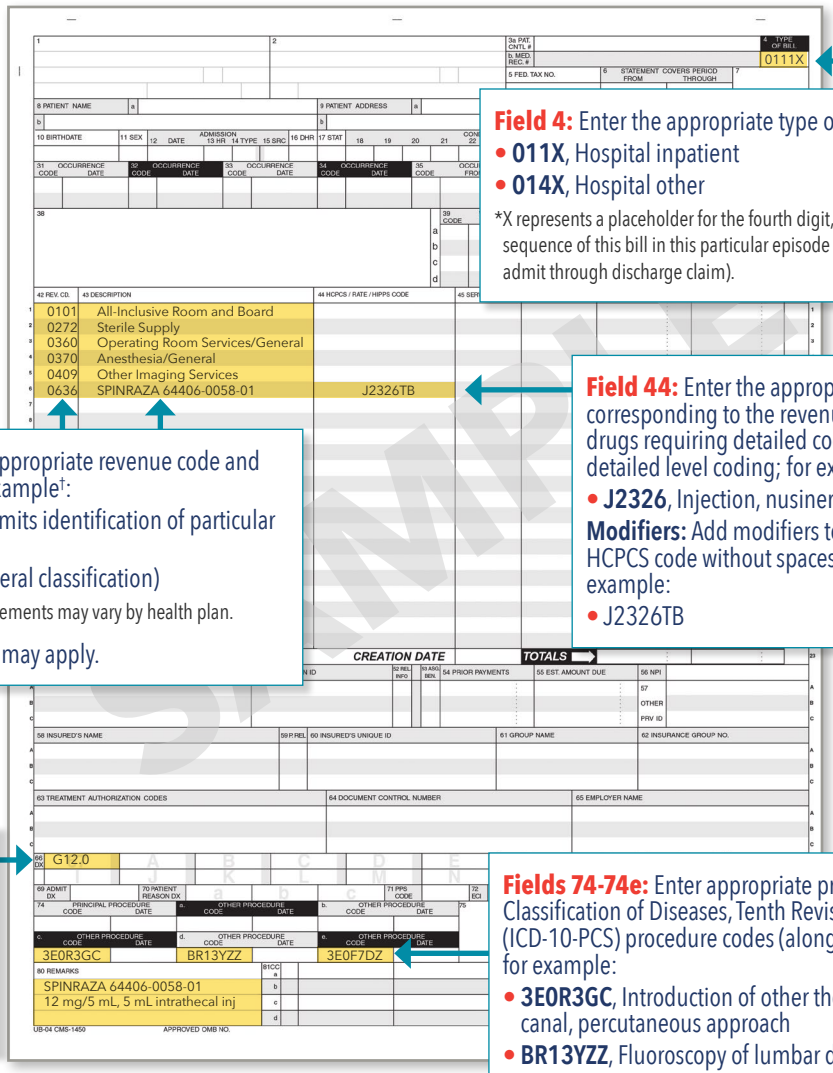
*Including off-campus clinic, on-campus facility, hospital-based ASC, and other outpatient outlets operated by a hospital.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SAMPLE CMS-1450/UB-04 CLAIM FORM (cont'd)

FOR INPATIENT HOSPITAL FACILITIES



Field 4: Enter the appropriate type of bill code; for example*:

- **011X**, Hospital inpatient
- **014X**, Hospital other

*X represents a placeholder for the fourth digit, which indicates the sequence of this bill in this particular episode of care (eg, "1" for admit through discharge claim).

Fields 42 and 43: Enter appropriate revenue code and description of service; for example†:

- **0710**, Recovery room permits identification of particular services, if necessary
- **0370**, Anesthesia (ie, general classification)

†For Field 43, NDC reporting requirements may vary by health plan.

NOTE: Other revenue codes may apply.

Field 44: Enter the appropriate HCPCS code corresponding to the revenue code 0636 (Pharmacy: drugs requiring detailed coding) in order to provide detailed level coding; for example:

- **J2326**, Injection, nusinersen, 0.1 mg

Modifiers: Add modifiers to the end of the CPT/HCPCS code without spaces, as applicable; for example:

- J2326TB

Field 66: Enter the appropriate primary ICD-10-CM diagnosis code; for example:

- **G12.0**, Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]

Fields 74-74e: Enter appropriate principal and other International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) procedure codes (along with corresponding dates); for example:

- **3E0R3GC**, Introduction of other therapeutic substance into spinal canal, percutaneous approach
- **BR13YZZ**, Fluoroscopy of lumbar disc(s) using other contrast
- **3E0F7DZ**, Introduction of inhalation anesthetic into respiratory tract, via natural or artificial opening

NOTE: Other ICD-10-PCS procedure codes may apply; for example:

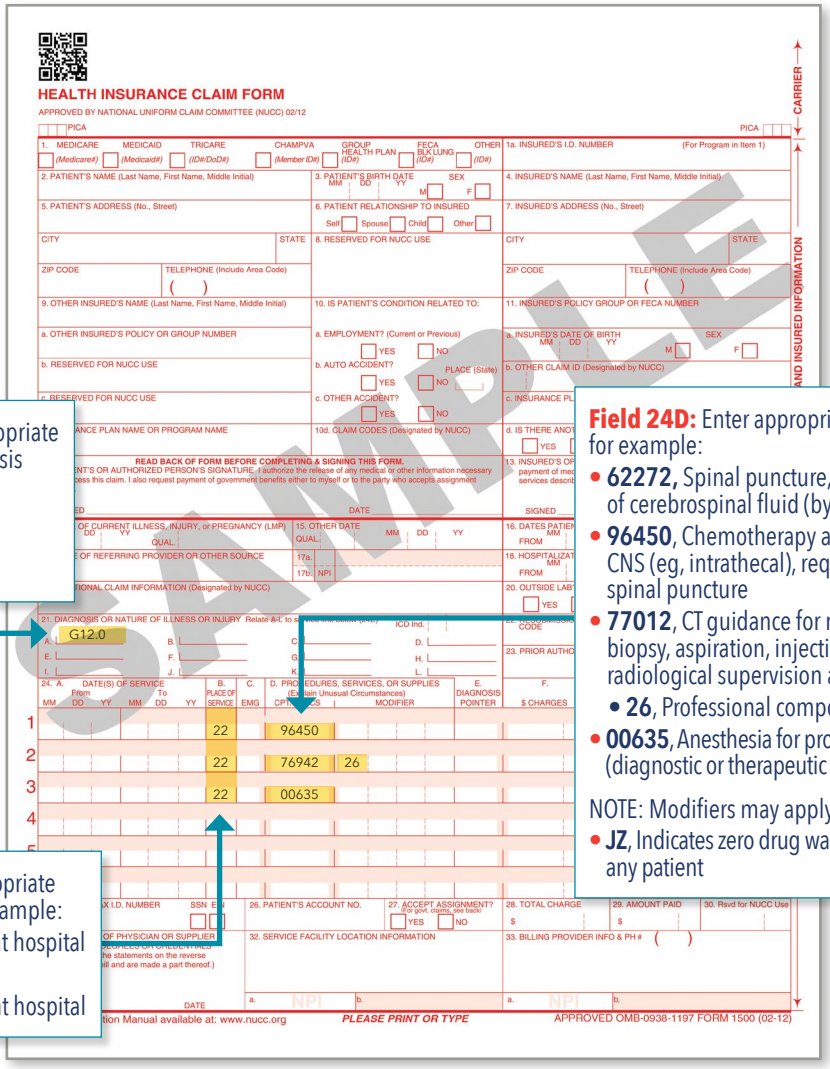
- **BR49ZZZ**, Ultrasonography of lumbar spine

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SAMPLE CMS-1500 CLAIM FORM

FOR PROFESSIONAL SERVICES



Field 21A: Enter the appropriate primary ICD-10-CM diagnosis code; for example:

- **G12.0**, Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]

Field 24B: Enter the appropriate place of service code; for example:

- **19**, Off-campus outpatient hospital
- **21**, Inpatient hospital
- **22**, On-campus outpatient hospital

Field 24D: Enter appropriate CPT®/HCPCS codes; for example:

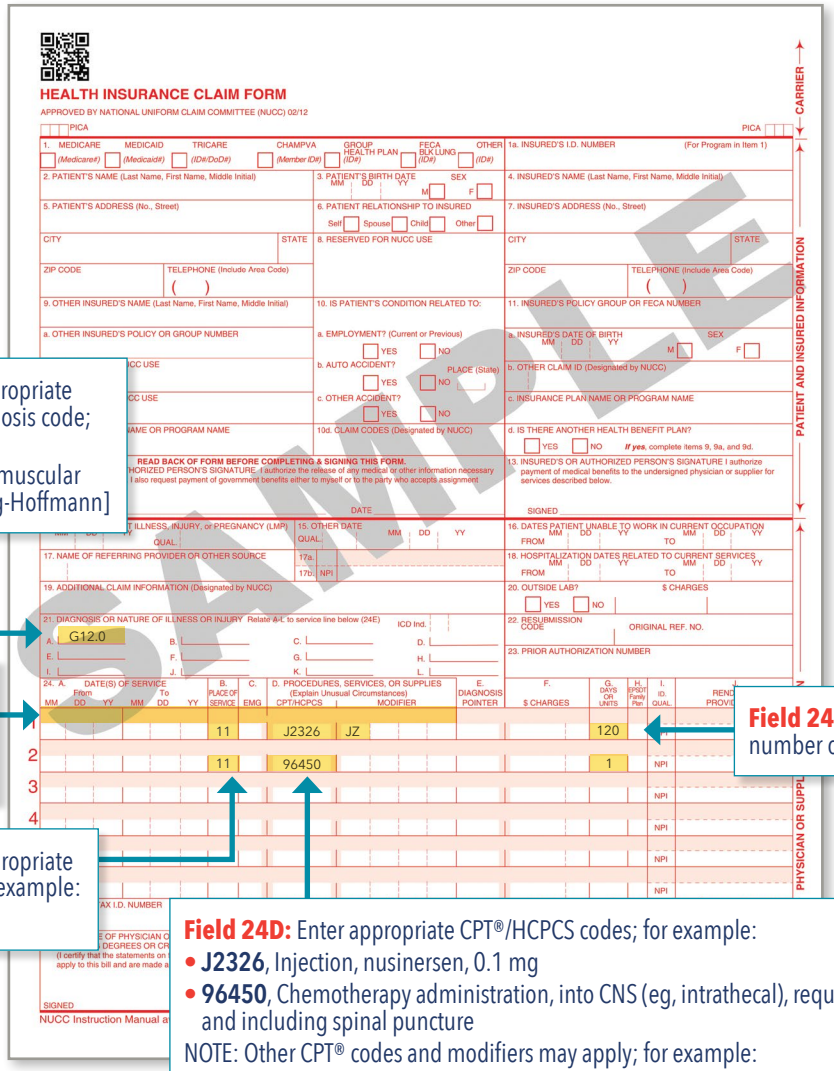
- **62272,** Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
- **96450**, Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture
- **77012**, CT guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
  - **26**, Professional component
- **00635**, Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)

NOTE: Modifiers may apply; for example:

- **JZ**, Indicates zero drug wasted/not administered to any patient

SAMPLE CMS-1500 CLAIM FORM (cont'd)

FOR PHYSICIAN OFFICES



Field 21A: Enter the appropriate primary ICD-10-CM diagnosis code; for example:

- **G12.0**, Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]

Shaded areas for fields 24A-D: NDC reporting requirements may vary by health plan.

Field 24B: Enter the appropriate place of service code; for example:

- **11**, Office

Field 24G: Enter the appropriate number of units of service.

Field 24D: Enter appropriate CPT®/HCPCS codes; for example:

- **J2326**, Injection, nusinersen, 0.1 mg
- **96450**, Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture

NOTE: Other CPT® codes and modifiers may apply; for example:

- **00635**, Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)
- **77003**, Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (eg, epidural or subarachnoid)

NOTE: Add modifiers, as applicable; for example:

- **JZ**, Indicates zero drug wasted/not administered to any patient

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CLAIM SUBMISSION AND TRACKING CHECKLISTS

Completing timely and accurate claims can help facilitate prompt payment. In order to help proactively prevent denials and underpayment, it is important to review claims before submitting them to a health plan.

CLAIM SUBMISSION CONSIDERATIONS CHECKLIST

Confirm health plan requirements

DURING THE BENEFITS INVESTIGATION PROCESS, CONFIRM THAT YOU HAVE IDENTIFIED THE FOLLOWING:

- ☐ Coverage and any prior authorization (PA) restrictions
- ☐ Coding and billing guidelines
- ☐ Required medical documentation

Check claim for accuracy and completeness

WHEN FILLING OUT THE CLAIM FORM, PLEASE DOUBLE-CHECK THE FOLLOWING:

- ☐ Patient information (eg, patient name, insurer, subscriber name, date of birth, member ID)
- ☐ Provider information (eg, National Provider Identifier (NPI) number, name, address, place of service)
- ☐ Coding (eg, ICD-10-CM, CPT®, revenue, and/or HCPCS codes along with appropriate modifiers)
- ☐ Billing units (consistent with the descriptors for the reported CPT® and/or HCPCS codes)
- ☐ Additional information required by the health plan (eg, PA, tax ID, and/or drug NDC number)
- ☐ (If clinical documentation is required:) Confirm with the health plan how documentation should be submitted with the initial claim submission

Confirm compliance with claim submission rules

WHEN SUBMITTING THE CLAIM, BE MINDFUL OF THE FOLLOWING:

- ☐ Required standards for electronic claims
- ☐ Punctuation and character limit requirements
- ☐ Time frame for submitting claims

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Procuring SPINRAZA® (nusinersen)

Ask your RDRM for more information about the procurement process for SPINRAZA

PROCURING SPINRAZA® (nusinersen)

TWO PATHWAYS to Obtain SPINRAZA

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Specialty Distributor (SD)

A wholesale pharmaceutical distributor that ensures supply chain integrity and an optimal patient experience. This form of distribution is common in the rare and/or chronic disease space.

Specialty Pharmacy (SP)

A licensed pharmacy that facilitates drug dispensing, reimbursement, and case management for products that require special handling or may not be widely available at traditional retail pharmacies.

CuraScript SD and Accredo SP are the exclusive providers of SPINRAZA. To obtain SPINRAZA through either CuraScript SD or Accredo SP, **call 1-855-778-1510**.

Please see Important Safety Information on page 2 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPECIALTY DISTRIBUTOR PROCESS

SD Key Steps

- **Refer to the patient's Benefits Investigation** to ensure health plan coverage for both SPINRAZA® (nusinersen) (drug and procedure) and any related services prior to ordering the product
- **Complete a prior authorization (PA) submission.** Refer to page 16 for guidance
- **Contact CuraScript SD** 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 faxing the order form to **1-888-454-8488** or calling **1-855-778-1510**. When calling, please stay on the line to listen for the menu options and press 2 if calling as an HCP and 6 to set up a shipment for SPINRAZA
- **Place orders** no later than 5 business days before the scheduled administration to ensure the product is on hand for the procedure
  - CuraScript SD accepts orders Monday through Friday
  - Orders received Monday through Thursday prior to 5 PM ET will ship within 24 hours
- Following the administration, **determine the appropriate claim form** (see page 22) for the patient's health plan and submit for reimbursement for both SPINRAZA and related services

It is important to coordinate with all key stakeholders to ensure that SPINRAZA will be delivered to your location in time for the patient's administration.

SPECIALTY PHARMACY PROCESS

SP Key Steps

Refer to the patient's Benefits Investigation to ensure health plan coverage for both SPINRAZA® (nusinersen) (drug and procedure) and any related services prior to ordering the product

- Accredo must conduct its own Benefits Investigation before it can dispense the product

Provide Accredo with a prescription or SPINRAZA referral form

- Fax to **1-888-454-8488**
- If faxing is not an option, a verbal prescription can be called in to **1-855-778-1510**; then select prompt #2, and finally prompt #2, again
- If submitting via electronic prior authorization (ePA), your Biogen FAM can assist you in deciding which ePA option is available based on the Benefits Investigation. Most health plan websites list and encourage utilization of ePAs

Accredo may contact your institution to obtain any additional information required for the PA

- If your site currently uses CoverMyMeds®, Accredo can use this system to expedite the PA process, depending on each specific payer guideline. All PA follow-up is coordinated by Accredo

Accredo will call to confirm shipment date and location with the administration site (shipment will not go out until verbal confirmation is made)

Please see Important Safety Information on page 2 and full Prescribing Information.

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Financial Assistance

Ask your RDRM for more information about financial assistance options for SPINRAZA® (nusinersen)

THE SPINRAZA® (nusinersen) COPAY AND ADMINISTRATION ASSISTANCE PROGRAMS

The Biogen Copay Program offers 2 ways in which your commercially insured patients may be eligible for financial assistance for SPINRAZA and for the treatment procedure. Patients must be enrolled in each program separately, and the patient's insurance must be billed first and paid before copay assistance will be applicable.

Copay Assistance Program*
Biogen will cover up to $15,800 per date of service towards your patient's SPINRAZA medication[1]

Administration Copay Assistance Program*,†,‡
Copay assistance for the administration of SPINRAZA

What your practice or facility needs to do

Step 1: Confirm patient enrollment

Confirm that the patient is enrolled in both the SPINRAZA Copay and Administration Assistance Programs for every treatment dose. At enrollment, the patient and HCP will receive a confirmation letter via fax from Biogen. This information also is available through your Biogen representative.

- Keep the confirmation of enrollment in the patient's file. If the patient withdraws, Biogen will send a withdrawal letter. This information is also available by calling **1-844-477-4672**

Step 2: Obtain explanation of benefits (EOB)/remittance advice (RA)

Locate the EOB/RA demonstrating the patient's financial responsibility for SPINRAZA.

- An EOB is a statement sent by a health plan to a member to describe what medical treatment and/or services were paid on his or her behalf. The EOB may also be called remittance advice and usually is used with Medicare and Medicaid payments. Ask your patient for their EOB/RA regarding SPINRAZA treatment

Step 3: Complete the form

Fill out the Copay Reimbursement Form or submit electronically via the Biogen Copay Portal.

Step 4: Submit for reimbursement

Fax the EOB/RA and the completed Copay Reimbursement Form to Biogen at **1-888-656-4343**.

Your practice or facility will receive a reimbursement check for plans that cover SPINRAZA under the medical benefit. For plans that cover SPINRAZA under the pharmacy benefit, Accredo Specialty Pharmacy (SP) manages the adjudication via the Bank Identification Number (BIN), Processor Control Number (PCN), and Group Number.

Your LCM is available to assist your patients with enrollment in the Biogen Copay Program

Please direct your patients to the Biogen Copay Program Portal and/or the Copay Reimbursement Form to begin enrollment.

*Generally, all individuals on nongovernment insurance are eligible, regardless of income. There is an annual cap on the amount of assistance that patients can receive over a 1-year period. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, the Veterans Affair/Department of Defense, TRICARE®, or any other federal plans are not eligible to enroll. Patients are eligible to enroll in the Biogen Copay Program for as long as it is offered and they are treated with SPINRAZA.

†The SPINRAZA Administration Copay Program is not offered to patients who are residents of Massachusetts, Minnesota, or Rhode Island.

‡HCPs must submit a request for treatment using a Biogen-approved procedure code for anesthesia, imaging procedures, and/or surgical procedure/drug administration.

Reference: Data on File. Biogen, Cambridge, MA.

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

FINANCIAL ASSISTANCE

THIRD-PARTY FUNDING ASSISTANCE

If it is determined that your patient is not eligible for the Biogen Copay Program, an LCM can help your patient find a charitable organization that may provide third-party assistance.

PATIENT COST-SHARING CONSIDERATIONS

During the Benefits Investigation, it is important to determine and communicate key elements of the cost-sharing structure under the patient's insurance benefits, including the following:

Patient cost-sharing considerations

Copay: Typically, a flat fee that patients pay each time they receive medical care. The copay may be in addition to other out-of-pocket (OOP) costs, such as deductibles and coinsurance, and it varies by benefits structure.

Coinsurance: A beneficiary cost-sharing amount that begins after the deductible is paid; coinsurance typically is based on a percentage of the cost of services and varies by health plan.

Deductible: A predetermined amount of money that the patient must spend before his or her health plan benefits take effect.

Maximum OOP cost: An annual limitation on all cost sharing that patients are responsible for under a health plan. This limit does not apply to premiums, balance-billed charges from out-of-network HCP, or services that are not covered by the plan.

The Biogen Copay Program applies to any patient OOP costs such as copay, coinsurance, and deductible.

The SMA360°™ team can help your patients and their caregivers navigate the cost of treatment with SPINRAZA® (nusinersen). Biogen believes that cost should not be a barrier to treatment. SMA360° offers personalized insurance and financial assistance counseling to help your patients and their caregivers understand their insurance benefits for SPINRAZA and to identify the most affordable way to start and stay on treatment as prescribed by their doctor.

SMA360™ Support services from Biogen

You can contact an LCM at 1-844-4SPINRAZA (1-844-477-4672), Monday through Friday, 8:30 AM to 8 PM ET, to get more information about these services.

SPINRAZA®
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Biogen®