SPINRAZA®
(nusinersen) injection
12 mg/5 mL

A GUIDE TO SPINRAZA REIMBURSEMENT

IMPORTANT INFORMATION TO HELP NAVIGATE THE ACCESS AND REIMBURSEMENT PROCESS

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 4 and accompanying full Prescribing Information.

Introduction

WELCOME

SPINRAZA is a US Food and Drug Administration (FDA)–approved treatment indicated for spinal muscular atrophy (SMA) in pediatric and adult patients.[1] Biogen is committed to providing detailed information to assist in obtaining reimbursement for SPINRAZA, drug administration, and related ancillary services.

We have developed this guide in conjunction with our support service, SMA360°*, to provide you with the information you need to help with the reimbursement process for SPINRAZA. SMA360° offers individualized support to help your patients and their families throughout the treatment process.

The information in this guide is intended for informational purposes only and does not represent legal or billing advice. For specific guidance in this area, consult your own legal/billing advisor and billing/coding specialist because it remains your responsibility to ensure the accuracy of the claims your office submits. The content herein is based on information current as of August 2020, which may have changed.

Any product, ancillary supplies, or services received free of charge cannot be billed to third-party payers because doing so could be a violation of federal and/or state laws and/or third-party–payer requirements.

SPINRAZA SUPPORT AND RESOURCES

SMA360° IS HERE FOR YOUR PATIENTS

Biogen's SMA360° program offers comprehensive and individualized support to help patients with SMA and their families navigate nonmedical barriers to access. Services include logistical assistance, product education, insurance benefits investigation, and financial assistance. A complete list of SMA360° offerings can be found at **https://www.spinrazahcp.com/en_us/home/support/sma360.html**.

SMA360™
Support services from Biogen

SMA is a highly variable disease and each patient will have his or her own unique set of needs. Your patients or their caregivers may feel like they could use a helping hand. Biogen has a team that will be there for them throughout the SPINRAZA journey.

Please remember that you should be the primary resource for any questions related to SMA and SPINRAZA. Additional information about the services provided by SMA360° is included in this guide.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. 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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SMA360°™* is available to assist you

SMA360° team members are available to assist your practice or site of care (SOC) by providing nonclinical education and support to help overcome access challenges.

RARE DISEASE REIMBURSEMENT MANAGER (RDRM)

The RDRM is responsible for helping you and your staff navigate the reimbursement and administrative processes for SPINRAZA.

The RDRM can

// Educate you and your staff on SPINRAZA procurement methods

// Provide enhanced education on claims forms and coding/billing

// Support your team's interactions with health plans

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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

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

Coagulation abnormalities and thrombocytopenia, including acute severe thrombocytopenia, have been observed after administration of some antisense oligonucleotides. Patients may be at increased risk of bleeding complications.

In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two SPINRAZA-treated patients developed platelet counts <50,000 cells per microliter, with the lowest level of 10,000 cells per microliter recorded on study day 28.

Renal toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. SPINRAZA is present in and excreted by the kidney. In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 71 of 123 SPINRAZA-treated patients (58%) had elevated urine protein, compared to 22 of 65 sham-controlled patients (34%).

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Cases of rash were reported in patients treated with SPINRAZA.

SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

The most common adverse reactions (≥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 accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Table of Contents

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

OVERVIEW OF THE REIMBURSEMENT PROCESS FOR SPINRAZA® (nusinersen)

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

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

The following pages highlight key phases of the reimbursement process for SPINRAZA, including steps for starting a patient on therapy, as well as the information needed to submit a claim for reimbursement. Biogen is here to support you in the administration of SPINRAZA and timely submission of claims for adjudication.

This overview also informs various stakeholders involved in the care of patients receiving SPINRAZA. Your Biogen representative is available to assist you with any questions you may have about the process.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

1. Benefits Investigation and authorization

A BENEFITS INVESTIGATION WILL HELP DETERMINE PAYER REQUIREMENTS BASED ON THE PATIENT'S SPECIFIC INSURANCE PLAN BENEFITS AND THE INDIVIDUALIZED CARE PLAN

A. Conduct a Benefits Investigation to help identify the following for SPINRAZA administration and related services:

// Coverage requirements, including precertification and/or medical documentation; referral restrictions; and observation stay rules

// Patient out-of-pocket (OOP) costs such as annual deductible vs amount met to date, coinsurance and/or copay, and annual OOP maximum vs amount met to date

// State and/or network considerations

- Participation status of the institution/practices and participating providers
- Coverage restrictions and related exceptions process
- OOP costs and related exceptions process
- Secondary coverage coordination of benefits and reimbursement/payment methodology from payers

// Billing guidelines

- All documentation required to be submitted with the claim
- National Drug Code (NDC) number reporting requirements

APPROVAL OF APPROPRIATE AUTHORIZATION(S) WILL PROVIDE PAYER COVERAGE DOCUMENTATION BEFORE TREATMENT INITIATION

B. Contact the patient's payer(s) directly to submit necessary documentation in order to obtain authorization for SPINRAZA administration and related services, such as

// Prior Authorization (PA)/precertification form(s) and/or Letter of Medical Necessity

// Out-of-state and/or out-of-network exception request and related documentation

C. If your authorization or exception request has been denied, locate the appeal process and timeline in the denial letter. Contact the payer for instructions if they are not documented for you.

Your RDRM and Family Access Manager (FAM) are available to assist you with any questions you may have about this process.

For additional details, please refer to pages 18-34 of this guide.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

2. Financial assistance and insurance counseling

THE SMA360°* TEAM WILL HELP CONNECT THE ENROLLED PATIENT WITH APPROPRIATE FINANCIAL ASSISTANCE PROGRAMS AND PROVIDE INSURANCE COUNSELING, IF NEEDED

A. The SMA360° team identifies appropriate financial assistance options for eligible patients and assists with program enrollment and any related additional documentation†:

// Biogen SPINRAZA Copay Assistance Program

// Biogen SPINRAZA Procedure Copay Assistance Program

// Third-Party Funding Assistance

B. The SMA360° team offers insurance counseling to the patient's family (if applicable), including

// Summary of current insurance status

// Review of potential alternative or supplemental sources of insurance coverage (eg, Medicaid)

THE SMA360° TEAM CAN COORDINATE SPINRAZA ADMINISTRATION LOGISTICS

C. The SMA360° team coordinates logistics with the patient's family and the SOC in preparation for the SPINRAZA administration visit

For additional details, please refer to pages 36-38 of this guide.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.
†Other programs may also be available for your patients.

SMA360™ Support services from Biogen

COMPREHENSIVE SUPPORT FOR YOUR PATIENT IS AVAILABLE

The SMA360° team will contact the enrolled patient's family to help set expectations.

We understand that for a caregiver or an individual living with SMA, life can be challenging. SMA360° is a support service from Biogen created to help families navigate the following areas of the treatment process with SPINRAZA:

// Treatment logistics

// Insurance and financial assistance

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

3. Patient treatment scheduling

SCHEDULE PATIENT VISIT FOR SPINRAZA ADMINISTRATION AND MAKE APPROPRIATE PATIENT COORDINATION ARRANGEMENTS

A. Considerations

// Clinic visit for preprocedure exam, if needed

// Intrathecal injection procedure scheduled with appropriate department

// Notify hospital outpatient admission department of PA approval and treatment date

// Notify correct pharmacy department of PA approval and treatment date

// Assist family with local overnight accommodations, if needed

CURASCRIPT SPECIALTY DISTRIBUTOR (SD) AND ACCREDO SPECIALTY PHARMACY (SP) ARE THE EXCLUSIVE AUTHORIZED PROVIDERS OF SPINRAZA

B. Order SPINRAZA from CuraScript SD or Accredo SP for delivery before the scheduled patient visit:

// The ordering process for SPINRAZA is through your facility's pharmacy or procurement department, as it would be for any other treatment

For additional details, please refer to page 41 of this guide.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

4. SPINRAZA administration and claim submission

ADMINISTER SPINRAZA ACCORDING TO THE PRESCRIBING INFORMATION AND INDIVIDUALIZED CARE PLAN

// SPINRAZA is administered intrathecally by, or under the direction of, healthcare professionals (HCPs) with experience performing lumbar punctures[1]

FOLLOWING PAYER BILLING GUIDELINES CAN FACILITATE CLAIM PROCESSING AND PROMPT PAYMENT

A. Submit claim(s) to the patient's payer(s) for SPINRAZA and related services according to the billing guidelines identified through the Benefits Investigation

For additional details, please refer to pages 43-58 of this guide.

B. Schedule the next patient visit for SPINRAZA administration

PAYER REMITTANCE MONITORING WILL BE CRITICAL FOR ENSURING APPROPRIATE PAYMENT

C. Monitor payer remittance for the submitted claim(s)

D. Submit appeal with required documentation within filing timelines if the claim is denied

E. Submit eligible OOP expenses to copay assistance or charitable funding programs, if applicable

For additional details, please refer to pages 59-60 of this guide.

SMA360™ Support services from Biogen

If you have any questions throughout this process, call SMA360°* at **1-844-4SPINRAZA (1-844-477-4672),** Monday through Friday, from 8:30 AM to 8:00 PM ET, or contact your Biogen representative.

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

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SITE-OF-CARE CONSIDERATIONS

Site-of-Care Considerations

Several factors can influence the decision to administer SPINRAZA in a particular SOC. In order to ensure that the selected SOC can appropriately address patient needs, it is important that these factors are considered by the key stakeholders involved in patient care, including clinicians, administrators, and the patient's family.

Outpatient hospital-based facility*

Freestanding ambulatory surgical center (ASC)

Physician office

Inpatient hospital facility

ADMINISTRATION PROCEDURE AND ANCILLARY SERVICES

// Remember, SPINRAZA is administered intrathecally by, or under the direction of, HCPs with experience performing lumbar punctures

// Ensure the availability of clinical specialists who may need to be involved with SPINRAZA administration (eg, neurologist, anesthesiologist, radiologist)

// Prepare facility or doctor's office with the necessary equipment (eg, sedation, lumbar puncture, ultrasound, fluoroscopy)

// If needed, ensure that logistical support is in place for the patient's travel needs, depending on the distance between the SOC and the patient's home

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

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Site-of-Care Considerations (cont'd)

Outpatient hospital-based facility*

Freestanding ASC

Physician office

COORDINATION OF CARE

// Some patients may require additional monitoring and/or management in a hospital facility

// Ensure that the facility or doctor's office can accommodate postinjection monitoring or admit or transfer patient for an inpatient stay

Inpatient hospital facility

// Some patients may require an inpatient hospital stay for additional monitoring and/or management

// Inpatient administration of SPINRAZA may require a "carve-out" reimbursement agreement with the patient's payer

// For insight about outpatient observation stays, see page 15

PAYER REIMBURSEMENT METHODOLOGY

Your practice or facility should check directly with the patient's payer(s) to verify specific coding and billing requirements.

Outpatient hospital-based facility*

Claim form
CMS-1450/UB-04

See page 51 for unique billing considerations and codes

Freestanding ASC

Claim form
CMS-1500

See page 55 for unique billing considerations and codes

Physician office

Claim form
CMS-1500

See page 55 for unique billing considerations and codes

Inpatient hospital facility

Claim form
CMS-1450/UB-04

See page 58 for unique billing considerations and codes

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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ADDITIONAL CONSIDERATIONS FOR PAYER REIMBURSEMENT

// The facility services may be subject to some form of global payment rule or prospectively set reimbursement rates (eg, global surgery payment, diagnosis-related group [DRG]–based payment, Enhanced Ambulatory Patient Groups [EAPG] payment)

// The payment for SPINRAZA may be separate or may be bundled within a prospectively set rate (eg, DRG-based rate, EAPG rate per diem rate)

OUTPATIENT OBSERVATION STAY INSIGHTS

An observation stay is a hospital outpatient service that can be ordered by physicians to allow for medical evaluation and/or testing in order to determine whether a patient may require an inpatient stay. For example, if a patient experiences a complication after an outpatient surgery, his or her physician may order outpatient observation services to allow for additional monitoring after the postoperative recovery period.

The following are some features of an observation stay that could affect billing:

// A patient may occupy any bed in the hospital, but with outpatient status

// Outpatient status has important implications for hospital reimbursement and patient OOP costs

// The stay is typically completed within 24 to 48 hours, after which time the patient can be admitted as an inpatient or discharged

// Payers may cover different lengths of outpatient observation stays

– Medicaid may allow up to 48 hours; other private payers may cover only 23 hours

It is important to verify the requirements for an outpatient observation stay with each insurance carrier.

SOC IMPLICATIONS FOR RELEVANT FINANCIAL ASSISTANCE PROGRAMS

There are several financial assistance programs available to eligible patients to support the administration of SPINRAZA. It is important to note to families that the SOC does not limit the patient's eligibility for Biogen financial assistance programs.

Biogen has several assistance programs for the SPINRAZA and its administration procedure. See page 37 for more information. For more information on third-party funding assistance, contact 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. SMA360° is intended for US residents only.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Patient Care Checklist

Below is a sample checklist for your consideration.

DETERMINE IF ANY ANCILLARY SERVICES MAY BE NEEDED TO SUPPORT SPINRAZA ADMINISTRATION VIA INTRATHECAL INJECTION

- ☐ Anesthesia
- ☐ Lumbar puncture
- ☐ Ultrasound
- ☐ Fluoroscopy
- ☐ Other

EVALUATE THE NEED FOR AND THE FEASIBILITY OF AN OUTPATIENT OBSERVATION STAY POST INJECTION

- ☐ Observation stay as a possibility in lieu of inpatient admission

DOCUMENT THE ADMINISTRATION PLAN FOR THE DOSING SCHEDULE

- ☐ Dates of loading doses
- ☐ Dates of maintenance doses (if applicable)

SELECT THE SETTING AND THE SOC FOR SPINRAZA ADMINISTRATION

Outpatient Setting

- ☐ Hospital outpatient off-campus clinic
- ☐ Hospital outpatient on-campus facility
- ☐ Hospital-based ASC
- ☐ Freestanding ASC
- ☐ Physician office

Inpatient Setting

- ☐ Inpatient hospital facility

Other Setting

- ☐ Other facility

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Patient Care Checklist (cont'd)

Below is a sample checklist for your consideration.

IDENTIFY WHICH PROVIDERS/PROVIDER PRACTICE GROUPS WILL OFFER PROFESSIONAL SERVICES RELATED TO SPINRAZA ADMINISTRATION

- ☐ Neurology
- ☐ Radiology
- ☐ Anesthesiology
- ☐ Other

COORDINATE WITH THE PATIENT AND HIS OR HER CAREGIVER TO CONFIRM SITE SELECTION AND LOGISTICS AND TO HELP SET APPROPRIATE EXPECTATIONS

- ☐ Treatment process and related timelines
- ☐ Current payer coverage situation and any anticipated changes
- ☐ Potential financial assistance needs
- ☐ SMA360°™* support services available for patients and their families

SUGGEST SMA360° SUPPORT SERVICES, WHICH MAY BE AVAILABLE TO HELP THE PATIENT'S FAMILY UNDERSTAND AND NAVIGATE THE TREATMENT PROCESS

- ☐ Provide the patient's family with the SPINRAZA Start Form, assist in completing the patient portion, and review caregiver consent (see page 71 for a sample Start Form)

  // Your practice or facility should complete the HCP portion of the SPINRAZA Start Form. Be sure to include the provider's signature in the Prescriber Authorization section. Fax the completed Start Form to **1-888-538-9781** or email it to **StartForm@Biogen.com**

- ☐ If signed consent is provided, advise the patient's family that a FAM from Biogen will assist in coordinating the logistics of treatment, such as insurance and financial considerations, if needed

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

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INVESTIGATING BENEFITS AND OBTAINING AUTHORIZATION

Investigating Benefits and Obtaining Authorization

A Benefits Investigation is an important step to complete for patients prescribed SPINRAZA to determine drug and ancillary procedure medical coverage. It will help define payer requirements based on the patient's specific insurance plan benefits and his or her individual needs.

BEGINNING THE BENEFITS INVESTIGATION

A Benefits Investigation is a process that enables a provider to determine benefit design, coverage requirements, and coding guidance. It is important to note that there are many variables associated with each patient's benefits, and there may be differences by payer, state, general benefit design, and SOC. For SPINRAZA treatment, there may be patients who travel to an SOC that is out of state and/or out of network for his or her payer. It is important to capture this information up front during the Benefits Investigation process so that your practice or facility can submit the claim to be reimbursed for acquiring SPINRAZA, as well as for its administration.

The following is basic patient and provider information that your practice or facility will need to gather to initiate the Benefits Investigation process.

BASIC PATIENT INFORMATION

✓ CONTACT INFORMATION

- ☐ Patient name
- ☐ Date of birth
- ☐ Phone number
- ☐ Address

✓ INSURANCE INFORMATION

- ☐ Policyholder name
- ☐ Policy start and end dates
- ☐ Member number
- ☐ Group number
- ☐ Type(s) of plan(s) (eg, HMO, PPO, POS, EPO, Medicaid)
- ☐ Primary, secondary, and tertiary insurance information (eg, commercial, Medicaid)

EPO=exclusive provider organization; HMO=health maintenance organization; POS=point of service; PPO=preferred provider organization.

SMA360™
Support services from Biogen

COMPREHENSIVE SUPPORT IS AVAILABLE THROUGHOUT THE BENEFITS INVESTIGATION

SMA360°* is a support service from Biogen created to help navigate the complexities of treatment logistics, insurance, and financial assistance. We understand that your patients' needs are unique, and the SMA360° team is here to help.

We can answer any questions you may have about obtaining preauthorization or precertification, and advise you on how to best navigate the complexities of Benefits Investigation or any unforeseen bumps in the road to approval.

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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BASIC PROVIDER INFORMATION

PHYSICIAN PRESCRIBING SPINRAZA

- ☐ Physician name
- ☐ NPI #
- ☐ Tax ID #

PHYSICIAN(S) ADMINISTERING SPINRAZA (IF DIFFERENT FROM THE PRESCRIBER)

- ☐ Physician name
- ☐ NPI #
- ☐ Tax ID #

SITE OF CARE ADMINISTERING SPINRAZA

- ☐ Practice/facility name
- ☐ NPI #
- ☐ Site of care/place of service

BASIC COVERAGE INFORMATION

Contact the payer to gather the following information:

COVERAGE

- ☐ Covered
- ☐ PA required
- ☐ Quantity

PATIENT COST

- ☐ Office visit copay or coinsurance
- ☐ Drug cost copay or coinsurance
- ☐ Deductible
- ☐ OOP maximum
- ☐ Pharmacy capitation

KEEPING ACCURATE RECORDS OF A BENEFITS INVESTIGATION

It is important to document each communication exchange that your practice or facility has with insurance companies. You may be communicating with them several times during the Benefits Investigation. When you do, be sure to record the following:

- ☐ Date of communication
- ☐ Time of communication
- ☐ Person(s) you spoke with
- ☐ Contact information (direct phone line, email)
- ☐ Communication preference (fax, email)
- ☐ Reference number for the call

NPI=National Provider Identifier.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

KEY CONSIDERATIONS FOR A BENEFITS INVESTIGATION

Preauthorization/ precertification and required documentation

Payers may require an authorization of coverage prior to treatment with SPINRAZA

// Determine if preauthorization/precertification is required for SPINRAZA, administration services, and/or the SOC

// Establish whether or not specific documentation is required before the plan will approve the product, administration services, and/or SOC

Medical exception/appeal

When a patient does not meet SPINRAZA coverage requirements stated in payer policy or no policy is in place, coverage may be obtained through the medical exception (ME) process and/or appeal, which tends to vary among payers

// Determine if there is an ME/appeal process and what documentation is required to demonstrate medical necessity

Referral restrictions

Depending on the patient benefits, a payer may require a referral from the primary care physician for the SOC and/or the specialists involved in the administration of SPINRAZA

// If it is determined that the patient will require a referral for the administration of SPINRAZA, find out who should provide the referral and what specifications may be needed

Observation stay rules

For patients who may require additional monitoring after SPINRAZA administration, payers may allow an outpatient observation stay of up to 48 hours

// Clarify the parameters that the payer may cover for length of stay for outpatient observation

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

Some patients who receive SPINRAZA may face restrictions from their commercial and/or Medicaid payers because the provider and/or the service facility is out of network or out of state. In these instances, waivers or exceptions can be granted on the basis of medical necessity

// Verify the state and/or network participation status for the physician(s) and/or facility involved in the administration of SPINRAZA

// Investigate and record the patient OOP cost implications for out-of-state and/or out-of-network providers

// Find out if there is an exception process for patients seeking care out of state and/or out of network

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

KEY CONSIDERATIONS FOR A BENEFITS INVESTIGATION (cont'd)

Coordination of benefits for multiple payers

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

// In the case of multiple payers, your Benefits Investigation must establish which payer is primary, which is secondary, and if needed, which is tertiary

// Once you have established the order of benefits, follow the instructions from each payer regarding coordination of benefits for reimbursement/payment

POTENTIAL PROVIDER NETWORK RESTRICTIONS

Each payer may have a network of participating providers who have contracted to provide healthcare services under specific terms. As a result, patients may be restricted or incentivized to seek care from in-network, or preferred, providers, or else OOP costs could be higher or might not be covered at all.[2,3]

For Medicaid beneficiaries, coverage is generally limited to participating providers in the specific state, and individuals enrolled in Medicaid managed care may also be restricted to care from in-network providers within their state.[4] However, coverage exceptions can be granted as long as medical necessity can be established, especially if there are no in-network providers with the required expertise.[5]

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

KEY CONSIDERATIONS FOR A BENEFITS INVESTIGATION (cont'd)

Coding and claims submission details

Specific coding and billing requirements may vary by payer

// Clarify the requirements for reporting an NDC number in a medical claim

// Check if any specific documentation is required to be submitted with the claim (eg, clinical records, drug invoice)

Patient financial responsibility

Patient OOP costs may vary based on the specific benefit design, SOC, and out-of-state/out-of-network restrictions

// Determine the patient's annual deductible and how much has been met to date

// Record the coinsurance and/or copay that will apply for SPINRAZA and related services

// Determine the patient's annual OOP maximum and how much has been met to date

SMA360°* PATIENT SUPPORT SERVICES AND BENEFITS INVESTIGATION

SMA360™ Support services from Biogen

SMA360° will also investigate the insurance benefits in order to help the patient and/or his or her family understand their current coverage and OOP costs, educate them about the financial assistance options, and offer counseling regarding the possibility of changing or adding insurance benefits, if needed. These services help supplement the Benefits Investigation conducted by your practice or facility. If you have any questions throughout this process, call SMA360° at **1-844-4SPINRAZA (1-844-477-4672)**, Monday through Friday, from 8:30 AM to 8:00 PM ET, or contact your Biogen representative.

Remember to reverify your patient's benefits prior to each dose of SPINRAZA, as the insurance coverage may have changed since the patient's last procedure. Remind your patients of the importance of immediately informing you and SMA360° of any insurance changes or updates to avoid unanticipated delays in therapy.

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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

KEY CONSIDERATIONS WHEN MEDICAL NECESSITY IS REQUIRED

The following are situations in which your practice or facility may need to demonstrate medical necessity for SPINRAZA during an appeal. The level of information in the letter will vary based on key areas that the payer requires be addressed to demonstrate medical necessity. Your practice or facility can customize the Letter of Medical Necessity based on the specific needs of the payer and the situation (see page 73 for an example of a Letter of Medical Necessity).

Preauthorization/PA

The payer requires that a preauthorization/PA be obtained before the treatment will be approved

// Based on the payer's requirements for authorization, demonstrate that the treatment is medically necessary based on the patient's diagnosis, clinical presentation, baseline motor functional testing, duration of symptoms, and current supportive care management

The initial preauthorization/PA was denied

The payer reviewed your request for a preauthorization/PA and denied it, determining that the treatment was not medically necessary

// Determine if the reason for the denial was clerical, clinical, or benefit-driven

- If the denial was for clerical reasons, immediately resubmit the request with the proper information
- If the denial was for clinical reasons, determine what additional information may be required to demonstrate medical necessity
- If the denial was for benefit reasons, call the payer to determine if an exception to the benefit is allowed and the process for such an exception (eg, no out-of-network benefits but only experienced provider is out of network)

// Emphasize in your resubmission that your practice or facility believes the treatment to be medically necessary for your patient

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

KEY CONSIDERATIONS WHEN MEDICAL NECESSITY IS REQUIRED (cont'd)

Exception based on policy

The payer has a policy for treatment and administration services for SPINRAZA, but your patient does not meet the requirements. However, the prescribing physician feels that the treatment is medically necessary

// Point out that the patient requires an exception to the plan's policy and provide the clinical rationale demonstrating that treatment with SPINRAZA is clinically appropriate

// Provide documentation or information to demonstrate medical necessity, such as

- Diagnostic evidence of SMA, including genetic testing
- Clinical presentation and duration of symptoms
- Current supportive care management
- Expectations of therapy and how efficacy will be measured by the clinician
- Other relevant aspects of patient history

Exception based on SOC restrictions

The payer will not cover the treatment and administration services because it will be administered at an out-of-network or out-of-state facility

// Emphasize your opinion that the facility is the most appropriate center to deliver the highly specialized services that may be provided when administering SPINRAZA

// Point out that the patient's plan does not, in your opinion, currently have an appropriate specialized center to treat SMA in the network and/or state, and that the patient has no other choice but to go out of his or her current network and/or state

// Point out continuity-of-care concerns for switching the patient to a new provider unfamiliar with the patient's history

// Indicate that it may be important for the plan to know whether a delay in treatment will impact a patient's function or disability

// Provide documentation or information to demonstrate medical necessity, such as

- Name and specialty area of your practice or facility to demonstrate its level of expertise
- Distance the patient needs to travel to your practice or facility because there are no specialized facilities in his or her network and/or state
- Areas of medical specialization and years of experience treating patients with SMA

When an ME/appeal is denied due to clinical reasons and the submission of an exception to benefit request has been disallowed or denied, the prescribing physician may contact the insurance carrier directly to speak with a clinical representative, who is typically a medical director or someone with a medical background. This is called a peer-to-peer discussion.

// A peer-to-peer discussion can be an effective way to help the health plan understand the patient's unique medical history, relevant clinical factors, and how those factors support treatment with SPINRAZA

// If the HCP is able to obtain the direct contact information for the clinical representative, consider tracking that information to use for future peer-to-peer discussions

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

OBTAINING APPROPRIATE AUTHORIZATIONS

When requesting a preauthorization or PA it is important to understand that each payer has different requirements with which your practice or facility must be familiar.

When obtaining details on the preauthorization or PA process, your practice or facility will need to

- ☐ Determine if the information can be phoned in, faxed, emailed, or submitted through the insurer's website
- ☐ Find out how long it will take for a decision to be made
- ☐ Identify the SOC for SPINRAZA administration, especially if it is in a different state than the patient lives
- ☐ Keep a copy of everything that is submitted relevant to the authorization
- ☐ Log any calls your office makes about the request
- ☐ Follow up with the payer if your practice or facility does not receive notification of the decision in a timely manner

A PREAUTHORIZATION VS PRECERTIFICATION

A preauthorization, or PA, is a request for the insurance company's approval for coverage of a drug and/or treatment before the treatment is administered, prescribing it as **medically necessary**.[3]

A precertification is similar to a preauthorization/PA in that the insurance company is requiring approval of the drug and/or treatment before it is provided. A payer may also refer to a precertification as a predetermination. In the case of a precertification, the insurer may require documentation that the treatment is medically necessary[6]; in most cases, this would be included in the form of a **Letter of Medical Necessity** (see page 73 for an example of this letter).

The important thing to remember about preauthorization and precertification is that approval is required prior to treatment to indicate there is medical necessity for treatment.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

EXAMPLES OF AUTHORIZATION DOCUMENTATION AND COVERAGE PARAMETERS

Identify specific documentation that must be submitted with the request	// Letter of Medical Necessity
	// Chart notes
	// Specific payer preauthorization/PA form
	// SPINRAZA Prescribing Information
	// Relevant literature, including previously published standards of care
	// Clinical documentation related to the disease, including
	– Diagnostic evidence of SMA, such as genetic testing
	– Clinical presentation and duration of symptoms
	– Current supportive care management
	– Baseline motor function measurement
	– Other relevant aspects of patient history

Determine the preauthorization/PA coverage parameters	// Number of doses
	// Time limits of authorization
	// Diagnosis limitations
	// Submission requirements

REAUTHORIZATION FOR SPINRAZA

For many drugs that treat rare diseases, insurance carriers may require an authorization renewal after a certain period (typically 1 year, but it may be less). This is true regardless of whether the patient is remaining on the same treatment or transitioning to another treatment.

// For patients continuing on therapy, medical plans have different intervals for reauthorization
- It is important to become familiar with the medical policy for SPINRAZA at the patient's health plan
- Be mindful of the duration of coverage at the health plan and the patient's start date

// Health plans vary widely in their requirements for reauthorization, but generally include diagnostic criteria and documentation of efficacy
- A diagnosis of SMA Type 1, 2, 3, or 4, which would include genetic testing confirming the diagnosis
- Efficacy of SPINRAZA is typically documented in terms of maintenance of or improvements in motor milestones as documented in functional exam testing

// Providing documentation of efficacy to health plans in a timely fashion may help enable the patient to continue treatment uninterrupted
- Clinical evaluations, such as evidence of progress in meeting motor milestones, should be conducted continually, in line with the patient's health plan
- Evidence of efficacy, such as maintenance of or improvement in motor function, can provide critical support for reauthorization

// The dosing schedule for SPINRAZA has implications for reauthorization
- Patients treated with SPINRAZA are given a loading dose on approximately days 0, 14, 28, and 58, and a maintenance dose every 4 months thereafter[1]
- If reauthorization is not achieved in time, the patient's coverage may end
- 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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

MOTOR MILESTONE ASSESSMENT TESTS FOR SMA

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.[7,8] These tests evaluate a range of motor functions and are appropriate for different populations with SMA.[8]

SUMMARY OF MOTOR FUNCTIONAL TESTS FOR SMA

The Hammersmith Infant Neurological Examination Section 2 (HINE-2) Age 2 months to 24 months		Measures neuromuscular development in infants, including voluntary grasp, sitting, ability to kick, crawling, head control, standing, rolling, and walking.[9] A 1-point increase in HINE score represents increased level of ability.[10]
The Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) Infants and children		The first SMA-specific test to assess patients with limited motor function; can measure response to gains and losses in motor function over time.[8] Includes 16 items that may be graded between 0 and 4, contributing to a total score of 64 points.[8]
World Health Organization (WHO) Motor Milestones Age 4 months to 24 months		Compares the actual windows of childhood development with those used in assessments of motor skills.[11] The 6 WHO motor milestones are measured and compared across similar populations in different countries.[11]

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SUMMARY OF MOTOR FUNCTIONAL TESTS FOR SMA (cont'd)

The Revised Upper Limb Module (RULM) Age >36 months		Assesses upper limb function in ambulatory and nonambulatory patients with SMA.[12] Nineteen items are graded on a 3-point scale, with a score of 0 (unable), 1 (able with modification), or 2 (able, no difficulty). The maximum total score is 37, which includes a can/cannot score of 1 or 0 for the first item in the assessment.[12]
The Hammersmith Functional Motor Scale–Expanded (HFMSE) Ambulatory patients with SMA Type 2 or Type 3		Assesses gross motor function of ambulatory patients.[7] A 2-point change is clinically relevant.[13]
6-Minute Walk Test (6MWT) Ambulatory patients		Measures the distance in meters a patient can walk unassisted.[14] Participants walk unaided for 25 meters; distance walked over 6 minutes, distance covered each minute, (patients can rest without sitting), and time to complete the 25-meter course are recorded. Falls are recorded.[14]

HOW OFTEN DOES FUNCTIONAL TESTING NEED TO BE DONE?

Functional testing information is extremely important to include with all requests for authorizations and reauthorizations. It is recommended that testing be performed within 60 days of the intended dose, so it is important to remember not to send in authorization requests too early. In the case of a delay that affects the date of treatment, be sure to obtain new baseline functional exam scores prior to starting therapy because the patient's motor skills may have further declined during that period of no treatment. 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.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CLAIM RECONSIDERATION AND APPEALS CHECKLIST

If a claim has been denied, you can request an appeal. There are several common reasons that claims are denied, such as an incorrect patient identification number or omission of a Letter of Medical Necessity. Another reason that a claim for SPINRAZA may be denied is that the product is not yet being covered under the insurer's coverage benefit. In each of these cases, it is important to consider an appeal.

The following are some considerations for understanding and filing an appeal.

Review the EOB/RA to understand the reason for the denial

SOME TOP REASONS THAT CLAIMS ARE DENIED:

- ☐ Incorrect codes
- ☐ Missing information
- ☐ Incorrect product information
- ☐ Lack of a Letter of Medical Necessity

If additional information is requested, submit the necessary documentation immediately.

Verify the appeals process for the payer

CONSIDER THE FOLLOWING TO UNDERSTAND THE APPEALS PROCESS OF EACH PAYER:

- ☐ Is there a need for a particular form?
- ☐ How should the form be sent to the payer?
- ☐ Can the appeal take place over the phone via a physician-to-physician call with the payer?
- ☐ Who should receive the appeal (name, title, and contact information)?
- ☐ What must accompany the appeal (eg, supporting documentation)?
- ☐ How long does the appeals process usually take?
- ☐ How will I learn about the appeal decision?

RECORD THE CORRESPONDENCE WITH THE PAYER AT EVERY POINT OF THE APPEALS PROCESS

IF YOUR CLAIM IS DENIED A SECOND TIME, DETERMINE IF A NEXT-LEVEL APPEAL IS ALLOWED AND CAREFULLY SUBMIT IT WITHIN YOUR PAYER'S TIMELINES. REQUEST ASSISTANCE FROM YOUR BIOGEN REPRESENTATIVE IF NEEDED

EOB=explanation of benefits; RA=remittance advice.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ME/APPEAL CONSIDERATIONS FOR PEDIATRIC PATIENTS WITH SMA

FOR INITIAL AUTHORIZATION FOR SPINRAZA

Include the following to help support medical necessity when an initial authorization request has been denied:

- Test scores establishing baseline measurements, eg, HINE-2, CHOP INTEND, and WHO
- HCP observations
- The HCP's opinion of the anticipated course of SMA for the patient with and without treatment

FOR CONTINUED APPROVAL OF MAINTENANCE THERAPY WITH SPINRAZA

When translating test scores into support for an ME or appeal, highlight all improvements in functional measurements compared with baseline. Because the criteria of the SMA functional tests vary, outline cumulative gain in function that the patient achieved according to earlier tests. For example, if a patient has gained the ability to hold up his/her head according to HINE-2, note this even if the patient most recently achieved hand grip according to CHOP INTEND.

Children with advanced SMA may not express improvements from baseline based on the traditional scales, but rather may show

// Subtle improvements or preservation of residual distal muscles

// Subtle changes that may impact activities of daily living that are relevant to the patient

Any improvement may be significant to the patient and contrary to the natural history of the disease. Therefore, it is important to document these changes for the health plan to support the medical necessity of treatment with SPINRAZA

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ME/APPEAL CONSIDERATIONS FOR TEENAGERS AND ADULTS WITH SMA

It is very important to help the payer understand that the available functional tests for SMA may not be robust enough to translate functional improvement or maintenance for teenagers or adults with SMA. Payers need to understand that when a patient achieves a high score on a functional test at baseline, there may not be enough incremental difference on the scale to demonstrate the improvement that may be required by the payer.

However, there are functions that could either be achieved and/or maintained in older patients that may not be demonstrated on a scale at all, but are extremely important and medically necessary to the patient.

The Letter of Medical Necessity/Appeal Template can be reviewed on page 73 of this guide and is available to download at **SPINRAZAhcp.com** or from your Biogen representative.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

IF AN INTERNAL APPEAL IS DENIED, CONSIDER AN EXTERNAL REVIEW

Appeals should follow the individual payer's requirement(s) and include additional information that continues to emphasize the medical necessity of SPINRAZA for your patient. At the end of the internal appeals process, the health plan must provide you and your patient with a written decision, but this does not mean that the appeals process is over. There may be other courses of action, such as an independent external review.

// In an external review process, an independent, accredited medical professional will review your patient's case. The reviewer does not receive any financial incentives to perform the review. The insurance carrier is required by law to accept the reviewer's decision[15]

// To request an external review, most plans require that the patient file a written request within 45 days following the insurance carrier's final determination. The letter sent to you and your patient should describe how to request an external review[15]

// External review decisions are made as soon as possible and should take no longer than 45 days from receipt of request

EXPEDITED REVIEWS

Expedited reviews can be requested in the case of an urgent situation in which a delay in treatment would cause the patient to lose motor function, cause further disability in the patient, or risk the life of the patient.

// Reviews can be expedited by requesting that an external review be done simultaneously with the internal review. An expedited appeal may be granted if your patient is currently receiving or waiting to start a prescribed treatment and you believe a delay would be life threatening, affect the patient's ability to regain maximum function, or subject him or her to severe pain. The request for an expedited appeal may be made verbally. The health plan must make a decision within 4 business days after your patient's request is received[16]

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

YOUR BIOGEN REPRESENTATIVE IS HERE TO HELP

SMA360™ Support services from Biogen

If you have any questions throughout this process, call SMA360°* at **1-844-4SPINRAZA (1-844-477-4672)** or contact your Biogen representative.

For more information about an external claim review, go to **healthcare.gov/appeal-insurance-company-decision/external-review/** or contact your Biogen RDRM for assistance.†

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

†The link above will take you to a website that is outside the control of Biogen. Links are provided as a courtesy for informational purposes only. We do not make or imply any endorsement of external websites.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

NAVIGATING FINANCIAL ASSISTANCE OPTIONS

Navigating Financial Assistance Options

The SMA360°* team can help your patients' families navigate the cost of treatment with SPINRAZA. Patients may have a copay or coinsurance for the drug and/or for the administration of SPINRAZA after they meet their annual deductible and until they reach the annual limit for their maximum OOP costs.

Biogen believes that cost should not be a barrier to treatment. SMA360° offers personalized insurance and financial assistance to help your patients' families 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

PATIENT COST-SHARING STRUCTURE CONSIDERATIONS

During the Benefits Investigation, it is important to determine 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 OOP costs, such as deductibles and coinsurance, and it varies by benefit 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 payer

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

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

In addition to the Benefits Investigation conducted by your practice or facility, SMA360° will investigate patient benefits in order to be able to inform the patient's family about potential cost-sharing responsibility and to discuss potential implications.

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

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SMA360°™* FINANCIAL ASSISTANCE AND INSURANCE COUNSELING SERVICES

Biogen provides several comprehensive financial support services to help reduce nonclinical barriers to patient access, which may allow commercially insured patients to lower their out-of-pocket costs to as little as $0.

Biogen SPINRAZA Copay Assistance Program: Generally, all individuals on nongovernment insurance are eligible, regardless of income, and there is no annual maximum on the amount Biogen will cover as part of the program. Insurance will be billed first and must pay before copay assistance will be applicable.

Patients who have primary prescription drug coverage through a commercial insurer (under either a pharmacy benefit or a medical benefit, as determined by the insurer) and secondary coverage through Medicaid or another government payer may be eligible as long as reimbursement for SPINRAZA is not provided in whole or in part by Medicaid or other government payer.

Biogen SPINRAZA Procedure Copay Assistance Program: In addition to the above criteria, individuals are eligible for this program if they meet the following requirements:

// They are not a resident of Massachusetts, Michigan, Minnesota, or Rhode Island

// The HCP submits a request for treatment using an approved procedure code for anesthesia, imaging procedures, and/or surgical procedure/drug administration

// The following procedure codes approved by Biogen are eligible for the program

// **Anesthesia**[17,18]
- Lumbar region–00635
- Extreme age–99100
- Revenue Code–370

// **Imaging Procedure/ Guidance**[17]
- Fluoroscopy–77003
- Ultrasound–76942
- CT guidance–77012

// **Surgical Procedure and Drug Administration**[1]
- Intrathecal drug administration–96450
- Lumbar puncture, diagnostic–62270†
- Lumbar puncture, therapeutic–62272†
- Injection(s), without imaging guidance–62322
- Injection(s), with imaging guidance–62323
- Spinal puncture, lumbar, with imaging guidance–62328‡
- Spinal puncture, therapeutic, with imaging guidance–62329§

Third-Party Funding Assistance: Financial assistance for patients may be available from a third party if it is determined that a family is not eligible for the **Biogen SPINRAZA Copay Assistance Program** and/or the **Biogen SPINRAZA Procedure Copay Assistance Program**.

Patients are required to enroll separately in each Biogen financial assistance program. Your Biogen representative is available to provide you with additional information about financial resources for your patients.

See page 72 for an example of the SPINRAZA Copay Reimbursement Form, which is used for both Biogen copay programs. A copy of the form is available from your Biogen representative.

CT=computed tomography.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.
†If imaging guidance is being used, use codes 62328 or 62329 as appropriate.
‡Do not report 62270 or 62328 in conjunction with 77003 or 77012. If ultrasound or magnetic resonance imaging (MRI) guidance is performed, see 76942 and 77021.
§Do not report 62272 or 62329 in conjunction with 77003 or 77012. If ultrasound or MRI guidance is performed, see 76942 and 77021.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INITIATING THE BIOGEN SPINRAZA COPAY ASSISTANCE PROGRAM

This program generally is available for patients with nongovernmental insurance benefits who have provided consent to Biogen. It covers the amount of cost sharing for SPINRAZA, but does not cover administration-related costs. After conducting a Benefits Investigation, the SMA360°* team will contact eligible patients to introduce the program and to complete enrollment.

WHAT YOUR PRACTICE OR FACILITY NEEDS TO DO

1 Confirm patient enrollment

Confirm that the patient is enrolled in the Biogen SPINRAZA Copay Assistance Program 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 **1-844-4SPINRAZA (1-844-477-4672)**

An EOB is a statement sent by a health plan to a member to describe what medical treatments 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 his or her EOB/RA regarding SPINRAZA treatment.

2 Obtain EOB/RA

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

3 Fill out the Copay Reimbursement Form

Fill out the Copay Reimbursement Form

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 SP manages the adjudication via the Rx BIN, PCN, and Group Number

BIN=bank identification number; PCN=processor control number.

SMA360° Support services from Biogen

If you have any questions throughout this process, call SMA360° at **1-844-4SPINRAZA (1-844-477-4672)** or contact your Biogen representative.

SMA360° offers insurance counseling services to help patients' families understand their current insurance benefits for SPINRAZA and to provide assistance with changing or adding supplemental insurance benefits, such as Medicaid.

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

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INITIATING THE BIOGEN SPINRAZA PROCEDURE COPAY PROGRAM

This program generally is available for patients with nongovernmental insurance benefits who have provided consent to Biogen. It covers the amount of cost sharing for the administration procedure that is associated with SPINRAZA, but it does not cover the cost of the drug. After conducting a Benefits Investigation, the SMA360°™* team will contact eligible patients to introduce the program and to complete enrollment.

WHAT YOUR PRACTICE OR FACILITY NEEDS TO DO

1 Confirm patient enrollment

Confirm that the patient is enrolled in the Biogen SPINRAZA Procedure Copay Program 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 also is available by calling **1-844-4SPINRAZA (1-844-477-4672)**

2 Obtain EOB

Locate the provider/facility RA and/or the patient's EOB demonstrating the patient's financial responsibility for SPINRAZA

3 Fill out the Copay Reimbursement Form

Fill out the Copay Reimbursement Form

4 Submit for reimbursement

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

The eligibility criteria differ for the Biogen SPINRAZA Copay Program and the Biogen SPINRAZA Procedure Copay Program. For more information, consult with your Biogen representative.

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

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ORDERING SPINRAZA® (nusinersen)

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

Ordering SPINRAZA

The SMA360°™* team will contact the enrolled patient's family to coordinate treatment logistics for each SPINRAZA administration visit. It is important for your office to coordinate with your Biogen representative when ordering SPINRAZA so that the patient's family can be prepared for the visit.

HOW TO ORDER SPINRAZA

CuraScript SD and Accredo SP are the exclusive authorized providers of SPINRAZA. Ordering SPINRAZA is done in the same way as any other product that is administered at your SOC, whether it is an outpatient hospital-based facility,† physician office, freestanding ASC, or inpatient hospital facility. SPINRAZA can be ordered directly through CuraScript SD or from Accredo SP. Once the order for SPINRAZA has been submitted to your pharmacy or procurement department, the order for SPINRAZA will be placed.

SPINRAZA ORDERING CHECKLIST

CONFIRM THAT YOUR PRACTICE OR FACILITY IS READY TO ORDER SPINRAZA

- ☐ Benefits Investigation has been conducted
- ☐ Payer approval of appropriate authorizations has been obtained
- ☐ (Optional) Patient has been enrolled in available financial assistance program(s)

ORDER SPINRAZA FROM CURASCRIPT SD OR ACCREDO SP

- ☐ Follow the standard process for placing a prescription drug order in your practice or facility
  - // The SPINRAZA Start Form includes a prescription for SPINRAZA. However, some states may require a separate prescription to be sent to Accredo SP
- ☐ Your pharmacy or procurement department will need to submit the order form to CuraScript SD
  - // **1-855-778-1510** (phone)
  - // **1-888-538-9781** (fax)

COORDINATE SPINRAZA SHIPMENT DELIVERY WITH THE SCHEDULED PATIENT TREATMENT VISIT

- ☐ CuraScript SD or Accredo SP will ship SPINRAZA in a temperature-controlled container directly to your practice or facility
- ☐ Make sure there is a staff member available to accept delivery of SPINRAZA and to transfer the product to a refrigerated space in the pharmacy immediately upon receipt of the drug
- ☐ Coordinate the treatment procedure for SPINRAZA with your site's care team, including the pharmacy

For assistance with any step in this process, contact your Biogen representative.

*SMA360° services from Biogen are available only to those who have been prescribed SPINRAZA. SMA360° is intended for US residents only.
†Including off-campus clinic, on-campus facility, hospital-based ASC, and other outpatient outlets operated by a hospital.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SUBMITTING CLAIMS FOR SPINRAZA® (nusinersen) AND RELATED SERVICES

Following Payer Billing Guidelines Can Facilitate Claim Processing and Prompt Payment

When a patient has been administered the SPINRAZA injection and/or a related service, your practice or facility may submit a claim to the patient's insurance plan. Items included on your claim may depend on the SOC and the billing entity.

Hospital facilities and hospital-based ASCs may submit a CMS-1450/UB-04 claim form[19,20]

Physician office practices may submit a CMS-1500 claim form either for professional services related to drug administration or for the drug and the services related to drug administration[19,20]

Freestanding ASCs may submit a CMS-1500 claim form for the medication and the services related to drug administration[19,20]

The information within this section reviews some of the billing codes relevant for SPINRAZA and the related administration services, as well as key billing considerations across SOCs. However, coding and billing recommendations may vary by payer. Your practice or facility should check directly with the patient's payer(s) to verify specific coding and billing requirements. Biogen field representatives are available to answer questions and further support the reimbursement process.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Summary of Relevant Codes for SPINRAZA

ICD-10-CM CODE EXAMPLES

ICD-10-CM Code[21]	Description[21]
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 (NEW) Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander] Progressive bulbar palsy of childhood [Fazio-Londe] Scapuloperoneal form spinal muscular atrophy

NOTE: Be sure to use the appropriate code for SMA diagnosis so it will be accepted on the claim form by the payer. Using codes G12.8 (other spinal muscular atrophies and related syndromes) or G12.9 (SMA, unspecified) may result in a claim denial because SMA type is not specified.

HCPCS CODE

HCPCS Code[22]	Description[22]
J2326	Injection, nusinersen, 0.1 mg

HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

NDC NUMBER

NDC Number[1]		Description[1]
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)

Although the FDA uses a 10-digit format when registering NDC numbers, payers often require an 11-digit NDC format on claim forms for billing purposes.[23] It is important to confirm with your payer which NDC format is required. In addition, Medicaid requires that all claims for provider-administered drugs include NDC numbers.

This reporting requirement may also be implemented by some commercial payers.[24] Guidelines for reporting the NDC number in the appropriate format, quantity, and unit of measure[25] vary by state and by payer and should be reviewed prior to submitting a claim.

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Relevant CPT® Codes for SPINRAZA

CPT® CODE EXAMPLES

Procedure Type[17]	CPT® Code[17]	Description[17]
Drug Administration & Surgical Procedure	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)
Imaging Procedure/ Guidance	76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
	77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid)
	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)

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Relevant CPT® Codes for SPINRAZA (cont'd)

CPT® CODE EXAMPLES (cont'd)

Procedure Type[17]	CPT® Code[17]	Description[17]
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 *CPT® 2020 Professional Edition*
Outpatient Hospital 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
	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)
	99234-99236	Observation or inpatient hospital care is used for the evaluation and management of a patient who is admitted and discharged 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

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.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CONSIDERATIONS FOR ADMINISTRATION

SPINRAZA is administered intrathecally by, or under the direction of, an HCP with experience performing lumbar punctures. In addition, providers can consider the following services for the administration of SPINRAZA, as needed[1]:

// Sedation as indicated by the clinical condition of the patient

// Ultrasound or other imaging techniques to guide intrathecal administration of SPINRAZA

Moderate sedation (MS) is a drug-induced semiconscious state that allows patients to be comfortable during certain surgical or medical procedures. MS requires no interventions to maintain cardiovascular function or a patent airway, and spontaneous ventilation is adequate.[17]

Coding for MS is based on total intraservice time and the HCP who performs the procedure.[17]

CODING GUIDE FOR MODERATE SEDATION OF LESS THAN 52 MINUTES[17]

Total intraservice time for MS*	Patient age	Code(s)	Code(s)
<10 minutes	Any age	Not reported separately	Not reported separately
10-22 minutes	<5 years	99151	99155
10-22 minutes	≥5 years	99152	99156
23-37 minutes	<5 years	99151 + 99153 x 1	99155 + 99157 x 1
23-37 minutes	≥5 years	99152 + 99153 x 1	99156 + 99157 x 1
38-52 minutes	<5 years	99151 + 99153 x 2	99155 + 99157 x 2
38-52 minutes	≥5 years	99152 + 99153 x 2	99156 + 99157 x 2

*For MS coding of 53 minutes or longer, or for descriptions of individual codes, please refer to page 751 of the *CPT® 2020 Professional Edition.*

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Unique Billing Considerations for Outpatient Hospital-Based Facilities

CPT® CODE MODIFIER EXAMPLES

Modifier[17]	Description[17]
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

Appropriate modifier(s) can help report additional circumstances under which a specific procedure and/or ancillary services were provided.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

REVENUE CODE EXAMPLES FOR OUTPATIENT HOSPITAL-BASED FACILITIES*

Service Type[18]	Revenue Code[18]	Description[18]
Drug Product	**0636**	Pharmacy (ie, drugs requiring detailed coding)
Drug Administration, Surgical Procedure, Recovery, and Observation	**0331**	Radiology/therapeutic (ie, chemotherapy injected)
	0361	Operating room services (ie, minor surgery)
	0499	Ambulatory surgical care (ie, other ambulatory surgical care)
	0710	Recovery room permits identification of particular services, if necessary
	0760	Specialty services (ie, general classification)
	0762	Specialty services (ie, observation hours)
Anesthesia Services	**0370**	Anesthesia (ie, general classification)
Imaging Services	**0402**	Other imaging services (ie, ultrasound)
	0409	Other imaging services (ie, other imaging services)

Revenue codes are required for hospital outpatient billing and will vary depending on the revenue center to which your hospital maps SPINRAZA. Typically, SPINRAZA and the procedure involved with its administration will be reported using all of the revenue codes listed above.

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

CPT® CODE EXAMPLES FOR OUTPATIENT OBSERVATION

Procedure Type[17]	CPT® Code[17]	Description[17]
Outpatient Hospital 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
	99217	Observation care discharge is to be utilized to report all services provided to a patient on outpatient hospital observation status if the discharge is on other than the initial date of observation status
	99234-99236	Observation or inpatient hospital care is used for the evaluation and management of a patient who is admitted and discharged 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

Following administration, an additional observational period may be required after treatment administration for patients who have complications or need extended observation (beyond typical recovery time) to determine if the patient can be discharged or if he or she will need in patient admission. Use the CPT® codes listed above for observational stay.

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CODING SUMMARY FOR ELECTRONIC CLAIM SUBMISSION BY OUTPATIENT HOSPITAL-BASED FACILITIES*

The table below provides examples of relevant codes, along with corresponding locations, for paper and electronic claims submitted by outpatient hospital-based facilities for SPINRAZA and related administration services.

Requirements and location of information will vary by payer.

Examples of Relevant Codes for SPINRAZA and Electronic Billing Locations for Outpatient Hospital-Based Facilities[26]

Information	Sample Code(s) or Information	CMS-1450/ UB-04 Locator[26]	Electronic Loop[26]	Equivalent Segment[26]
HCPCS Level II Code	J2326	Field 44	**2400**	SV202-2
HCPCS Level II Code Units	120	Field 46	**2400**	SV205
Additional Product Information	SPINRAZA 64406-0058-01 12 mg/5 mL, 5 mL intrathecal inj	Field 80	**2300**	NTE
CPT® Code(s)	96450 Other CPT® codes may apply, as appropriate	Field 44	**2400**	SV202-2
ICD-10-CM Code (primary)	G12.0	Field 67	**2300**	HI01-2
Bill Type Code	Provider specific†	Field 4	**2300**	CLM05-1
Revenue Code(s)	0361 0636 Other revenue codes may apply, as appropriate	Field 42	**2400**	SV201

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

†A 4-digit bill type code documents facility type (second digit after the leading zero), care type (third digit), and the bill sequence for the given episode of care (fourth digit). Relevant examples for outpatient facilities include 013X (hospital outpatient), 074X (clinic outpatient physical therapy [OPT]), and 083X (hospital outpatient ASC), where X represents the sequence of the billing in this particular episode of care (eg, "1" for admit through discharge claim).[27]

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Cases of rash were reported in patients treated with SPINRAZA.

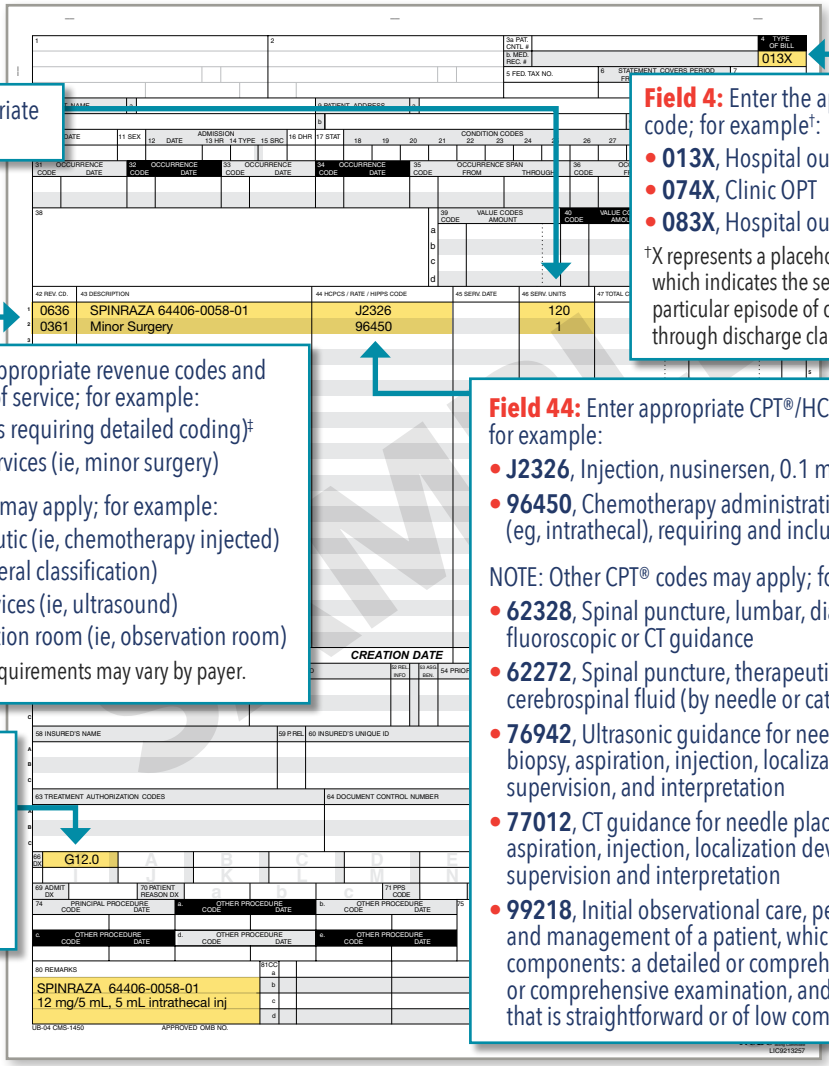
SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

Please see additional Important Safety Information on page 4 and accompanying 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 OPT
- **083X**, Hospital outpatient (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:

- **0636**, Pharmacy (ie, drugs requiring detailed coding)‡
- **0361**, Operating room services (ie, minor surgery)

NOTE: Other revenue codes may apply; for example:

- **0331**, Radiology/therapeutic (ie, chemotherapy injected)
- **0370**, Anesthesia (ie, general classification)
- **0402**, Other imaging services (ie, ultrasound)
- **0762**, Treatment/observation room (ie, observation room)

‡For Field 43, NDC reporting requirements may vary by payer.

Field 44: Enter appropriate CPT®/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:

- **62328**, Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance
- **62272**, Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
- **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
- **99218**, Initial observational 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 medical decision-making that is straightforward or of low complexity

Field 66: Enter the appropriate primary 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.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Unique Billing Considerations for Professional Services Only

CPT® CODE MODIFIER FOR THE PROFESSIONAL COMPONENT

Modifier[17]	Description[17]
26	Professional component

For procedure codes with professional and technical components, physician office practices may use the 26 modifier to bill for the professional services component of the procedure (eg, interpretation and report of a radiology service) performed in the hospital inpatient or outpatient setting.[17]

CODING SUMMARY FOR ELECTRONIC CLAIM SUBMISSION FOR PROFESSIONAL SERVICES

The table below provides examples of relevant codes, along with corresponding locations, for paper and electronic claims submitted by physician office practices for professional services associated with SPINRAZA administration.

Requirements and location of information will vary by payer.

Examples of Relevant Codes for SPINRAZA and Electronic Billing Locations for Professional Services[28]

Information	Sample Code(s) or Information	CMS-1500 Location[28]	Electronic Loop[28]	Equivalent Segment[28]
CPT® Code(s)	96450 76942 00635 Other CPT® codes may apply, as appropriate	Field 24D	**2400**	SV101
ICD-10-CM Code (primary)	G12.0	Field 21A	**2300**	HI01-2
Place of Service Code	Provider-specific*	Field 24B	**2300**	CLM05-1

*A 2-digit place of service code documents site of care. Relevant examples for professional services include 19 (off-campus outpatient hospital), 22 (on-campus outpatient hospital), and 21 (inpatient hospital).[29]

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.

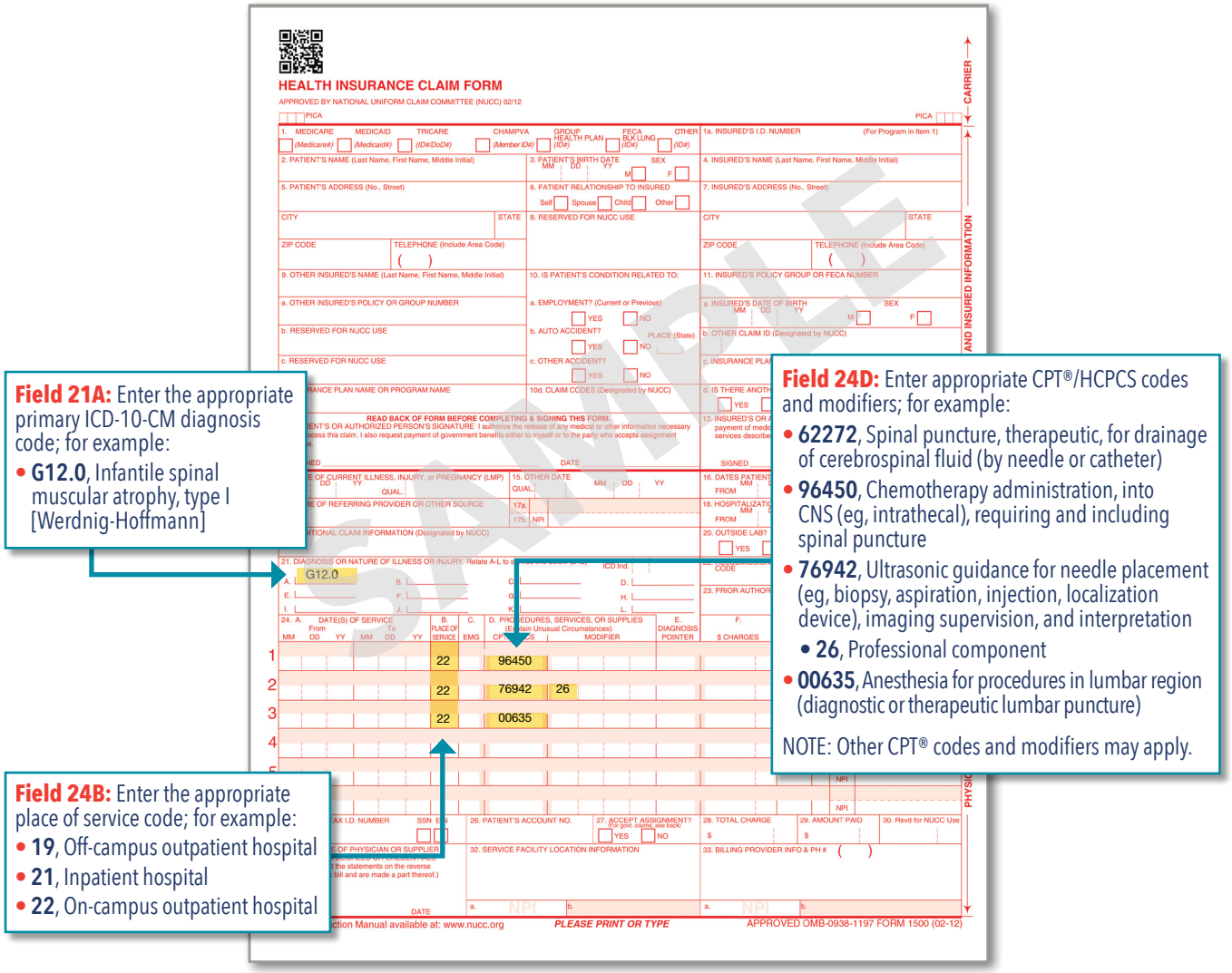
In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two 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 page 4 and accompanying 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 and modifiers; 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
- **76942**, Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision, and interpretation
  - **26**, Professional component
- **00635**, Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)

NOTE: Other CPT® codes and modifiers may apply.

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Unique Billing Considerations for Physician Offices and Freestanding ASCs

CODING SUMMARY FOR ELECTRONIC CLAIM SUBMISSION BY PHYSICIAN OFFICES AND FREESTANDING ASCs

The table below provides examples of relevant codes, along with corresponding locations, for paper and electronic claims submitted by physician office practices or freestanding ASCs for SPINRAZA and related administration services.

Requirements and location of information will vary by payer.

Examples of Relevant Codes for SPINRAZA and Electronic Billing Locations for Physician Offices and Freestanding ASCs[28]

Information	Sample Code(s) or Information	CMS-1500 Location[28]	Electronic Loop[28]	Equivalent Segment[28]
HCPCS Level II Code	J2326	Field 24D	**2400**	SV101
HCPCS Level II Code Units	120	Field 24G	**2400**	SV101
Additional Product Information	SPINRAZA 64406-0058-01 12 mg/5 mL, 5 mL intrathecal inj	Field 19	**2300**	NTE
CPT® Code(s)	96450 Other CPT® codes may apply, as appropriate	Field 24D	**2400**	SV101
ICD-10-CM Code (primary)	G12.0	Field 21A	**2300**	HI01-2
Place of Service Code	Provider-specific*	Field 24B	**2300**	CLM05-1

*A 2-digit place of service code documents site of care. Relevant examples for professional services include 19 (off-campus outpatient hospital), 22 (on-campus outpatient hospital), and 21 (inpatient hospital).[29]

For patients on Medicare being treated in an ASC, be sure to refer to Addendum AA and BB to ensure that the CPT® codes for the drug administration and for the drug itself are eligible for payment in the ASC setting.

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

Cases of rash were reported in patients treated with SPINRAZA.

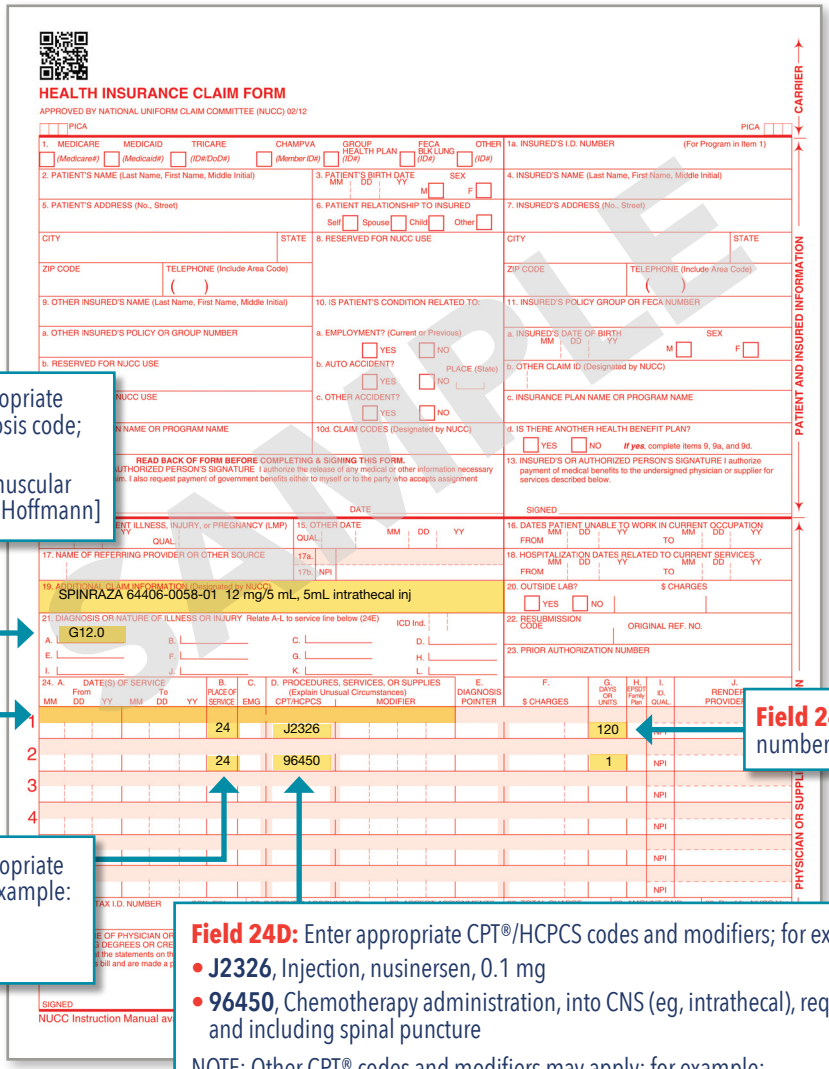
SPINRAZA may cause a reduction in growth as measured by height when administered to infants, as suggested by observations from the controlled study. It is unknown whether any effect of SPINRAZA on growth would be reversible with cessation of treatment.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Sample CMS-1500 Claim Form

FOR PHYSICIAN OFFICES AND FREESTANDING ASCs



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 payer.

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

- **11**, Office
- **24**, ASC

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

Field 24D: Enter appropriate CPT®/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 and modifiers may apply; for example:

- **00635**, Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)
- **76942**, Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision, and interpretation

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Unique Billing Considerations for Inpatient Hospital Facilities

REVENUE CODE EXAMPLES FOR INPATIENT HOSPITAL FACILITIES

Service Type[18]	Revenue Code[18]	Description[18]
Drug Product	**0636**	Pharmacy (ie, drugs requiring detailed coding)
Room and Board	**0101**	All-inclusive rate (ie, all-inclusive room and board)
Drug Administration, Surgical Procedure, Recovery, and Observation	**0272**	Medical/surgical supplies (ie, sterile supply)
	0331	Radiology/therapeutic
	0360	Operating room services (ie, general classification)
	0369	Operating room services (ie, other operating room services)
	0710	Recovery room permits identification of particular services, if necessary
Anesthesia Services	**0370**	Anesthesia (ie, general classification)
Imaging Services	**0402**	Other imaging services (ie, ultrasound)
	0409	Other imaging services (ie, other imaging services)

Revenue codes are required for hospital inpatient billing and will vary depending on the revenue center to which your hospital maps SPINRAZA. Typically, SPINRAZA will be reported using the revenue codes listed above.

ICD-10-PCS PROCEDURE CODE EXAMPLES

Procedure Type[30]	ICD-10-PCS Code[30]	Description[30]
Intrathecal Drug Administration	**3E0R3GC**	Introduction of other therapeutic substance into spinal canal, percutaneous approach
Imaging Procedure/ Guidance	**BR13YZZ**	Fluoroscopy of lumbar disc(s) using other contrast
	BR49ZZZ	Ultrasonography of lumbar spine
Inhalation Anesthesia	**3E0F7BZ**	Introduction of anesthetic agent into respiratory tract, via natural or artificial opening

When SPINRAZA is administered in the inpatient setting, appropriate inpatient procedure codes will need to be reported on the claim. Typically, SPINRAZA administration procedures will be reported using the ICD-10-PCS codes listed above.

ICD-10-PCS=*International Classification of Diseases, Tenth Revision, Procedure Classification System.*

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 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CODING SUMMARY FOR ELECTRONIC CLAIM SUBMISSION BY INPATIENT HOSPITAL FACILITIES

The table below provides examples of relevant codes, along with corresponding locations, for paper and electronic claims submitted by inpatient hospital facilities for SPINRAZA and related administration services (as part of a planned inpatient stay).

Requirements and location of information will vary by payer.

Examples of Relevant Codes for SPINRAZA and Electronic Billing Locations for Inpatient Hospital Facilities[26]

Information	Sample Code(s) or Information	CMS-1450/ UB-04 Locator[26]	Electronic Loop[26]	Equivalent Segment[26]
HCPCS Level II Code	J2326	Field 44	**2400**	SV202-2
HCPCS Level II Code Units	120	Field 46	**2400**	SV205
Additional Product Information	SPINRAZA 64406-0058-01 12 mg/5 mL, 5 mL intrathecal inj	Field 80	**2300**	NTE
ICD-10-PCS Code(s)	3E0R3GC BR13YZZ 3E0F7DZ Other ICD-10-PCS codes may apply, as appropriate	Fields 74-74E	**2300**	HI01-2 through HI05-4
ICD-10-CM Code (primary)	G12.0	Field 67	**2300**	HI01-2
Bill Type Code	Provider-specific*	Field 4	**2300**	CLM05-1
Revenue Code(s)	0101, 0272, 0360, 0370, 0409, 0636 Other revenue codes may apply, as appropriate	Field 42	**2400**	SV201

*A 4-digit bill type code documents facility type (second digit after the leading zero), care type (third digit), and the bill sequence for the given episode of care (fourth digit). Relevant examples for inpatient hospital facilities include 011X (hospital inpatient part A) and 014X (hospital other part B), where X represents the sequence of the bill in this particular episode of care (eg, "1" for admit through discharge claim).[27]

SELECTED IMPORTANT SAFETY INFORMATION

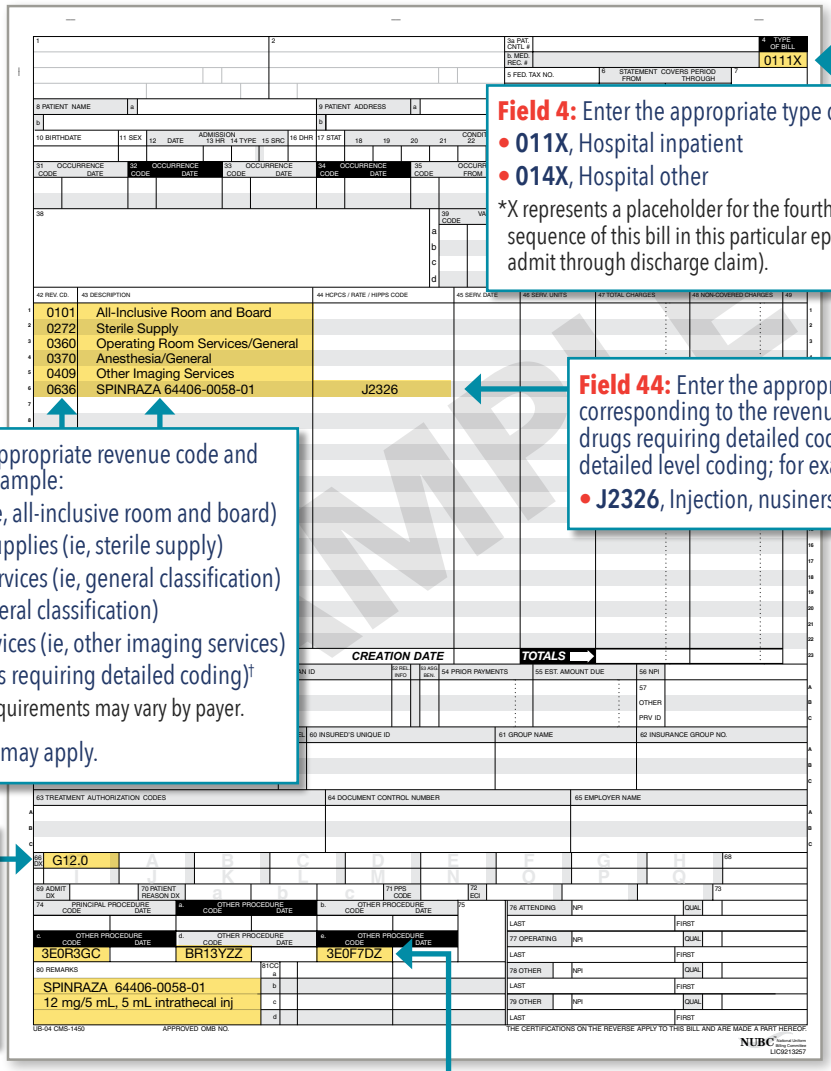
In the sham-controlled studies for patients with infantile-onset and later-onset SMA, 24 of 146 SPINRAZA-treated patients (16%) with high, normal, or unknown platelet count at baseline developed a platelet level below the lower limit of normal, compared to 10 of 72 sham-controlled patients (14%). Two 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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Sample CMS-1450/UB-04 Claim Form

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).

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

Fields 42 and 43: Enter appropriate revenue code and description of service; for example:
- **0101**, All-inclusive rate (ie, all-inclusive room and board)
- **0272**, Medical/surgical supplies (ie, sterile supply)
- **0360**, Operating room services (ie, general classification)
- **0370**, Anesthesia (ie, general classification)
- **0409**, Other imaging services (ie, other imaging services)
- **0636**, Pharmacy (ie, drugs requiring detailed coding)†

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

NOTE: Other revenue codes may apply.

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 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

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%).

Please see additional Important Safety Information on page 4 and accompanying 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 payer.

CLAIM SUBMISSION CONSIDERATIONS CHECKLIST

Confirm payer requirements

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

- ☐ Coverage and any 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, NPI number, name, address, place of service)
- ☐ Coding (eg, ICD-10, 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 payer (eg, PA, tax ID and/or drug NDC number)
- ☐ (If clinical documentation is required) Confirm with the payer 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

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CLAIM TRACKING CONSIDERATIONS

Tracking payer reimbursement for therapies and treatments is key for facilitating appropriate payment. It is important for offices to check payers' EOB/RA statements for accuracy in order to detect any claims processing errors or inappropriate adjustments and to monitor for denials.

THE FOLLOWING ARE CONSIDERATIONS FOR TRACKING CLAIMS:

- **ESTABLISH A ROUTINE PROCEDURE FOR MONITORING THE STATUS OF CLAIMS**
- **MAINTAIN A LOG OF ALL CORRESPONDENCE WITH EACH PAYER FOR EACH CLAIM. THIS WILL ENABLE YOUR OFFICE TO MONITOR PAYER CONTRACT COMPLIANCE**
- **MONITOR THE CLAIM FOR PAYERS WHO REQUEST ADDITIONAL INFORMATION (CLINICAL OR OTHER) AND SUBMIT PROMPTLY TO AVOID PROCESSING DELAYS**
- **REVIEW PAYER EOB/RA AGAINST CONTRACTED FEE SCHEDULES**
- **EVALUATE PAYER RESPONSIVENESS IN ADDRESSING REIMBURSEMENT ISSUES**
- **ESTABLISH A PROCEDURE FOR ADDRESSING CLAIMS DENIALS AND SUBMITTING APPEALS**

Consider using the Biogen Reimbursement Tracking Log, located at **SPINRAZAhcp.com**, to reconcile drug and procedure claims for SPINRAZA.

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

MEDICARE AND SMA

Medicare Eligibility for Patients With SMA*†

WHO IS ELIGIBLE?

People younger than 65 years who have received Social Security Disability Insurance (SSDI) benefits for at least 2 years (24 months)[31]

// For these patients, enrollment in Medicare is automatic[32]

People aged 65 years or older[31]

// Children who were receiving benefits as a minor child on a parent's Social Security record (via SSI) may be eligible to continue receiving benefits on that parent's record upon reaching age 18 if they are disabled[31]

– Marriage of the disabled "adult child" may affect eligibility for this benefit

// Medicare covers about 1 in 4 adults with SMA (aged 18 years and older)

A PERSON CAN QUALIFY FOR SSDI BENEFITS IF

He or she has a past work history[33]

He or she can no longer work due to his or her disability[33]

// SMA Types 0 and 1 qualify as compassionate allowances for Social Security disability (1 of more than 200 conditions); it is automatic in many states[34]

// State-based qualification parameters also apply

// To learn about disability benefits through Social Security, call **1-800-772-1213** or visit **https://www.ssa.gov/benefits/disability/**

HOW PATIENTS APPLY FOR MEDICARE

// Most people with SMA who are receiving SSDI benefits are automatically enrolled in Original Medicare (Parts A and B)[32]

– Patients who receive SSDI get Part A at no cost, but may have to pay a premium for Parts B and D. If patients do not want the Part B premium automatically deducted from their SSDI, they can call Medicare to opt out of Part B. However, please note that in certain situations, opting out of Medicare Part B may affect Medigap coverage and cause detrimental financial consequences for the patient. Be sure to discuss with your Medicare contact prior to opting out of Medicare Part B.

// Patients will be enrolled by the 25th month of receiving SSDI. They will get their Medicare card in the mail[32]

// Patients also get a notice in the mail about their Part D drug plan. It will tell them how to review or change it

If patients are not disabled, they will need to enroll in Medicare. They can sign up in 2 ways[32]:

// Call the Social Security office at **1-800-772-1213**

// Sign up online at **https://www.ssa.gov/benefits/medicare/**

*Please note that Maryland follows the terms of the Maryland All-Payer Model and some of the above information 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.[32]

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 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Medicare Basics

HOW DOES MEDICARE WORK?

Medicare has 4 parts to help cover services[32]:

A

Part A is hospital insurance. It covers inpatient care in a hospital, nursing home care, hospice care, and home healthcare. **Part A covers SPINRAZA** when patients receive it as an inpatient during a hospital stay.

B

Part B is medical insurance. Part B covers outpatient care (doctor's office visits and visits to treatment centers for injections, some home healthcare services, medical equipment, wellness services, lab tests, and select preventive screenings). **Part B covers SPINRAZA** when patients receive it as an outpatient, for instance, at an SMA hospital outpatient treatment center.

Parts A and B are known as "Original Medicare." Patients will have Original Medicare unless they choose a Medicare Advantage Plan or other type of Medicare health plan.

C

Part C is also called Medicare Advantage. Part C plans are sold by private insurance companies approved by Medicare. These plans include all benefits covered under Part A and Part B. Part C may offer additional benefits, as well. Medicare Advantage plans will often include Part D (prescription drug coverage). See the following page for more detailed information about Medicare Advantage plans.

D

Part D is prescription drug coverage. Part D covers drug costs (pills, self-administered injections, and inhaled treatments). Part D plans are sold by private insurance companies approved by Medicare. **These plans do not cover SPINRAZA**, but they may cover other drugs patients may need.

SMA360™ Support services from Biogen

SMA360°* can help patients navigate Medicare options. Patients can call **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. 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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

UNDERSTANDING THE DIFFERENT TYPES OF MEDICARE ADVANTAGE PLANS (PART C)

There are many types of Medicare Advantage plans. Each type of plan may keep certain copayments low (ie, office visits), provide varying levels of coverage, and operate in a unique way. Medicare Advantage plans offer the same benefits patients get under original Medicare (Part A and Part B), except hospice care. Medicare Advantage plans may also include other benefits such as prescription drug coverage, hearing, dental, and vision.[32]

Medicare Advantage plans may help keep copayments low. Each plan comes with a maximum OOP limit on how much patients will spend on health costs each year. Once patients reach the limit, they will pay nothing for the services covered. Each plan has different limits, and the OOP amount can change each year.[32]

The OOP maximum for Medicare Part C varies by plan. Patients paying higher monthly premiums may have lower maximum yearly OOP costs.[35]

The different types of Medicare Advantage plans include those outlined in the table below.

HOW EACH MEDICARE ADVANTAGE PLAN WORKS

More Common / Less Common

Types of commercial health plans	Has a network of providers?	Need a referral to see a specialist?	What happens if a patient needs out-of-network care?

HMO[36]	Yes	Yes	HMOs may cover out-of-network care if
			// The HMO's network of HCPs does not have the experience to treat a certain health problem
			// The patient has an emergency

PPO[37]	Yes	No	PPOs provide out-of-network care, but may not pay for the full cost of treatment. If the patient chooses to see an out-of-network HCP, he or she may have to pay for some of the treatment, even if it is an emergency
Private Fee-for-Service (PFFS)[38]	Depends on plan	No	These plans are also offered by private insurance companies. PFFS plans aren't the same as Original Medicare or Medigap. PFFS plans determine how much they will pay HCPs, other healthcare providers, and hospitals, and how much the patient will pay when receiving care
Special Needs Plan (SNP)[39]	Yes	Yes	These plans limit membership to people with certain characteristics or specific diseases such as SMA. SNPs tailor their benefits, provider choices, and drug formularies to best meet the specific needs of the groups they serve
HMO Point of Service (HMOPOS)[40]	Yes	No	HMOPOS plans provide out-of-network care, but patients may have higher costs for out-of-network providers
Medical Savings Account (MSA)[41]	No	No	These plans combine a high-deductible health plan with a bank account. Medicare deposits money into the account (usually less than the deductible). Patients can use the money to pay for healthcare services during the year, but only Medicare covered expenses count toward the deductible

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

A MEDIGAP POLICY MAY HELP PATIENTS PAY FOR TREATMENT COSTS NOT COVERED BY ORIGINAL MEDICARE

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.[32]

FACTS ABOUT MEDIGAP POLICIES

Medigap policies are not available to people covered by a Medicare Advantage Plan (Part C) or to patients with traditional Part D plans[32]

Patients must have Medicare Part A and Part B to have a Medigap Policy[32]

Patients cannot purchase a Medigap policy along with a Medicare MSA[42]

CONTINUING SPINRAZA 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

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

THE EXTENT OF WHAT MEDICARE COVERS DEPENDS ON WHETHER IT IS PAYING AS A PRIMARY OR SECONDARY PAYER

// Medicare as the primary payer pays up to the limits of its coverage[32]

- Hospital coverage (Part A)
- Physician visits, outpatient services, and physician-administered drugs like SPINRAZA (Part B)
- Self-administered prescription drugs, which do not include SPINRAZA (Part D)

// Coverage gaps may still exist with Medicare as the primary payer[32,35]

- Patients can cover gaps with secondary payer/supplemental insurance (eg, employer-sponsored health plan, Medigap policy)

// Medicare as the secondary payer

- Main role is to close the gap in OOP expenses[32]
- Pays only if there are costs not covered by the primary insurer[32]
- Medicare coinsurance will still apply[32]
- Sometimes covers claims when the primary payment is delayed or in dispute[43]

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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Hospital Reimbursement for SPINRAZA

SPINRAZA 340B REIMBURSEMENT UPDATE

As of January 1, 2018, Medicare pays an adjusted amount of the average sales price (ASP) minus 22.5% for certain separately payable drugs or biologics acquired through the 340B program. Furthermore, these products are furnished to a Medicare beneficiary by a hospital paid under the Outpatient Prospective Payment System (OPPS) that is not exempt from the payment adjustment policy.[44]

// As of July 1, 2020, SPINRAZA is reimbursed at ASP minus 22.5% (instead of ASP+6%) for 340B-purchased drugs only for Medicare patients treated at affected sites of care[44,45]

// On September 28, 2022, the United States Court of Appeals for the District of Columbia Circuit ruled against the previous reimbursement rate enacted in 2020, and CMS will be reimbursing at ASP plus 6% for 340B-purchased drugs only for Medicare patients treated at affected sites of care[46]

// For more information about billing 340B-acquired drugs (and use of modifiers), visit **https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf**

UNDERSTANDING APCs VS DRGs (BUNDLED PAYMENTS)

// Ambulatory Payment Classifications (APCs) are the government's way to pay facilities for outpatient services under the Medicare program[47]

- Hospital-only, OPPS
- SPINRAZA is allowed separate payment in the hospital outpatient department setting
- APC payments are made to the hospital when a Medicare outpatient is discharged or is transferred to another hospital or facility not affiliated with the initial hospital where the patient received outpatient services

// Inpatient stays are paid under DRG methodology rather than APC.[47] DRG payments do not allow separate payment for drugs administered during an inpatient stay[48]

- Medicare inpatient stays are subject to the 3-day rule. All outpatient services during the 3 days prior to an inpatient stay need to be incorporated into the inpatient DRG stay[48]

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Did you know

ORIGINAL MEDICARE PATIENTS' OOP COSTS ARE CAPPED IN THE HOSPITAL OUTPATIENT SETTING

// OOP costs for patients receiving SPINRAZA in this treatment setting may be limited to the Medicare Part A deductible

- Typically, outpatient facility claims process under Part B benefits, so beneficiaries who do not have supplemental insurance (eg, Medigap) are responsible for a 20% coinsurance (Medicare Part B covers 80%)[35]
- However, in the outpatient facility setting, if the patient's coinsurance under Medicare Part B exceeds the Medicare Part A deductible, then **the patient pays the Part A deductible and Medicare pays the difference**.[35,49] This may significantly reduce OOP costs

// Although hospital outpatient department claims for SPINRAZA are still covered under Medicare Part B, the claims are submitted to the Part A Medicare Administrative Contractor (MAC)

If your patient has Original Medicare and is being treated in the hospital outpatient setting, you can contact Medicare to find out the current Part A deductible amount he or she would pay. Call **1-800-MEDICARE** or **1-800-633-4227**.

Resources to determine the actual cost savings for patients treated in the outpatient setting are available from 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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Medicare Considerations Nationally and Locally

NATIONAL CONSIDERATIONS

// The Centers for Medicare & Medicaid Services (CMS) contracts with private companies known as MACs to process and pay claims[50]

// CMS issues National Coverage Determinations (NCDs)[50]

// An NCD describes the circumstances under which a particular item or service (eg, a drug) is covered nationally under Medicare[50]

// NCDs apply to all MACs nationwide[50]

// CMS has not issued an NCD for SPINRAZA

LOCAL MEDICARE CONSIDERATIONS

MACs process Medicare Part A and Part B (A/B) claims for a defined geographic area or "jurisdiction."[51]

// A/B MACs process Part A and Part B claims for a defined geographic area servicing institutional providers, physicians, practitioners, and suppliers[51]

// Durable Medical Equipment MACs process Medicare Durable Medical Equipment, Orthotics, and Prosthetics (DMEPOS) claims for a defined geographic area servicing suppliers of DMEPOS[51]

There are 7 A/B MACs covering a total of 12 jurisdictions[52]

// Claims for SPINRAZA are processed by A/B MACs. Each MAC may have its own rules for coverage, billing/coding, etc[50]

// Healthcare insurers can be awarded more than 1 jurisdiction to process claim[52]

MACs AND MEDICAL POLICY

CMS-ISSUED NCDs APPLY TO ALL MACs NATIONWIDE[50]

// If an NCD does not exist, MACs can issue a Local Coverage Determination (LCD)

// An LCD is a coverage policy detailing the MAC's coverage criteria for items of services within their jurisdiction(s). MACs may choose to cover items and services without developing an LCD

MACs CAN IMPACT COVERAGE POLICY[51]

// Establish LCDs

// Handle first-stage appeals process

// Review medical records for selected claims

// Regional MACs **may review SPINRAZA claims on a case-by-case basis** until they issue an LCD or until CMS issues an NCD with conditions for coverage

SELECTED IMPORTANT SAFETY INFORMATION

Laboratory testing and monitoring to assess safety should be conducted. Perform a platelet count, coagulation laboratory testing, and quantitative spot urine protein testing at baseline and prior to each dose of SPINRAZA and as clinically needed.

Severe hyponatremia was reported in an infant treated with SPINRAZA requiring salt supplementation for 14 months.

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 page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

APPENDIX

Sample SPINRAZA Start Form

START FORM Questions? Contact Biogen at: 1-844-4SPINRAZA (1-844-477-4672)

SPINRAZA® (nusinersen) injection 12 mg/5 mL

AUTHORIZATION TO SHARE HEALTH INFORMATION FOR PATIENT SUPPORT SERVICES AND MARKETING/OTHER COMMUNICATIONS

I have read and understand the Authorization to Share Health Information for Patient Support Services and Marketing/Other Communications and agree to the terms. A signature is required in order to receive Biogen services.

A
Signature of patient or parent/guardian (if under 18) Date

In addition, I authorize the disclosure of my health information to the following designated individual(s) (optional):

Name (print) Relationship

Name (print) Relationship

B OPT-IN FOR AUTOMATED MARKETING MESSAGES

☐ I have read and understand the Opt-In for Automated Marketing Calls and Text Messages and hereby agree to receive these types of communications from Biogen (optional).

PATIENT INFORMATION

First name Last name

☐ Male ☐ Female Date of birth

My preferred language

CONTACT INFORMATION

C
Email address

Home telephone Mobile phone

Address

City State ZIP code

☐ OK to leave message

ALL INFORMATION MUST BE COMPLETED BY A HEALTHCARE PROVIDER IN ORDER TO RECEIVE BIOGEN SERVICES.

PRESCRIBER INFORMATION

First name Last name

Address

City State ZIP code

Telephone Fax

Email

NPI # State license #

Tax ID # Clinic/hospital affiliation

ADMINISTERING PHYSICIAN INFORMATION

First name Last name

Specialty Care coordinator contact

Telephone Fax

NPI # Tax ID #

MEDICAL INSURANCE INFORMATION*

Disease type: ☐1 ☐2 ☐3 ☐4 ☐Genetic test on file

Primary insurance Policy #

Group # Insurance company telephone

Policyholder's first name Policyholder's last name

Secondary insurance Policy # /group #

Medicaid/governmental payer

*Please remember to include front and back copy of insurance card(s) along with this Start Form.

TREATMENT

☐ Prior/current treatment (medication) Next scheduled SPINRAZA dose

Name of treatment Date

SITE OF CARE

Facility name

Address

City State ZIP code

Telephone Fax

NPI # Tax ID #

PROCUREMENT

☐ Specialty pharmacy—optional prescription below ☐ Direct buy—order must be submitted

☐ Unknown

PLACE OF SERVICE (POS) CODE

☐ Physician office (11) ☐ Outpatient off-campus clinic (19)

☐ Inpatient (21) Observation a possibility in lieu of inpatient admission? Yes ☐ No ☐

☐ Outpatient on campus (ie, infusion, short stay, surgical suite) (22)

☐ Ambulatory surgical center (24) ☐ Other

PRESCRIPTION FOR SPECIALTY PHARMACY (OPTIONAL)†

Inject SPINRAZA treatment with 4 loading doses. The 1st 3 loading doses should be administered at 14-day intervals. The 4th should be administered 30 days after the 3rd dose. A maintenance dose should be administered every 4 months. For more information, please refer to the Prescribing Information.

SPINRAZA (nusinersen) injection 12 mg/5 mL (2.4 mg/mL) in a single-dose vial:

☐ Loading doses (4 doses) ☐ 1 year of SPINRAZA with maintenance doses (3 doses)

☐ 1 year of SPINRAZA with loading doses (6 doses) Refills _____

Prescriber signature (dispense as written) Prescriber signature (substitution allowed)

Name (print) Date

I authorize Biogen as my designated agent and on behalf of my patient to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient.

†In New York, please attach copies of all prescriptions on Official New York State Prescription Forms.

PRESCRIBER AUTHORIZATION (REQUIRED)

I authorize Biogen as my designated agent on behalf of my patient to furnish any information on this form to his/her insurer.
I will either administer treatment or supervise the treatment accordingly.

Prescriber signature Date

Written signature only; stamps not acceptable. 07/20 SPZ-US-0266V9

Once complete, submit by fax or email:
1-888-538-9781
StartForm@biogen.com

Page 4 of 6

SAMPLE

The SPINRAZA Start Form must always be accompanied by the consent information. Please contact your Biogen representative for a copy of this document or download it from **SPINRAZAhcp.com**.

SELECTED IMPORTANT SAFETY INFORMATION

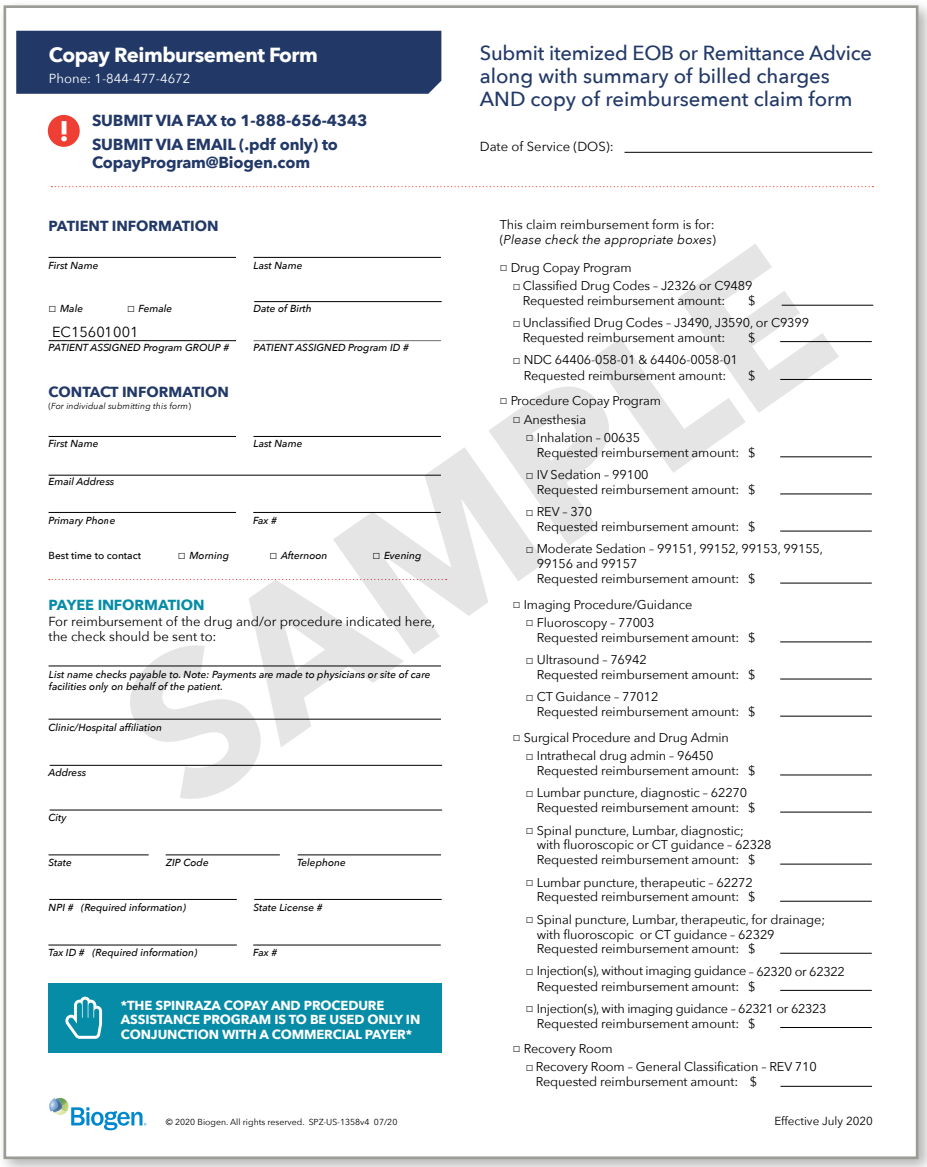
The most common adverse reactions (≥20% of SPINRAZA-treated patients and ≥5% more frequently than in control patients) that occurred in the infantile-onset controlled study were lower respiratory infection and constipation. Serious adverse reactions of atelectasis were more frequent in SPINRAZA-treated 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.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Sample SPINRAZA Copay Reimbursement Form

Please see your Biogen representative for a copy of the SPINRAZA Copay Reimbursement Form.



Copay Reimbursement Form
Phone: 1-844-477-4672

SUBMIT VIA FAX to 1-888-656-4343
SUBMIT VIA EMAIL (.pdf only) to CopayProgram@Biogen.com

Submit itemized EOB or Remittance Advice along with summary of billed charges AND copy of reimbursement claim form

Date of Service (DOS): _____

PATIENT INFORMATION

First Name _____ Last Name _____

□ Male □ Female Date of Birth _____

EC15601001
PATIENT ASSIGNED Program GROUP # _____ PATIENT ASSIGNED Program ID # _____

CONTACT INFORMATION
(For individual submitting this form)

First Name _____ Last Name _____

Email Address _____

Primary Phone _____ Fax # _____

Best time to contact □ Morning □ Afternoon □ Evening

PAYEE INFORMATION
For reimbursement of the drug and/or procedure indicated here, the check should be sent to:

List name checks payable to. Note: Payments are made to physicians or site of care facilities only on behalf of the patient. _____

Clinic/Hospital affiliation _____

Address _____

City _____

State _____ ZIP Code _____ Telephone _____

NPI # (Required information) _____ State License # _____

Tax ID # (Required information) _____ Fax # _____

THE SPINRAZA COPAY AND PROCEDURE ASSISTANCE PROGRAM IS TO BE USED ONLY IN CONJUNCTION WITH A COMMERCIAL PAYER

This claim reimbursement form is for:
(*Please check the appropriate boxes*)

□ Drug Copay Program
- □ Classified Drug Codes – J2326 or C9489 Requested reimbursement amount: $ _____
- □ Unclassified Drug Codes – J3490, J3590, or C9399 Requested reimbursement amount: $ _____
- □ NDC 64406-058-01 & 64406-0058-01 Requested reimbursement amount: $ _____

□ Procedure Copay Program
- □ Anesthesia
  - □ Inhalation – 00635 Requested reimbursement amount: $ _____
  - □ IV Sedation – 99100 Requested reimbursement amount: $ _____
  - □ REV – 370 Requested reimbursement amount: $ _____
  - □ Moderate Sedation – 99151, 99152, 99153, 99155, 99156 and 99157 Requested reimbursement amount: $ _____
- □ Imaging Procedure/Guidance
  - □ Fluoroscopy – 77003 Requested reimbursement amount: $ _____
  - □ Ultrasound – 76942 Requested reimbursement amount: $ _____
  - □ CT Guidance – 77012 Requested reimbursement amount: $ _____
- □ Surgical Procedure and Drug Admin
  - □ Intrathecal drug admin – 96450 Requested reimbursement amount: $ _____
  - □ Lumbar puncture, diagnostic – 62270 Requested reimbursement amount: $ _____
  - □ Spinal puncture, Lumbar, diagnostic; with fluoroscopic or CT guidance – 62328 Requested reimbursement amount: $ _____
  - □ Lumbar puncture, therapeutic – 62272 Requested reimbursement amount: $ _____
  - □ Spinal puncture, Lumbar, therapeutic, for drainage; with fluoroscopic or CT guidance – 62329 Requested reimbursement amount: $ _____
  - □ Injection(s), without imaging guidance – 62320 or 62322 Requested reimbursement amount: $ _____
  - □ Injection(s), with imaging guidance – 62321 or 62323 Requested reimbursement amount: $ _____
- □ Recovery Room
  - □ Recovery Room – General Classification – REV 710 Requested reimbursement amount: $ _____

Biogen © 2020 Biogen. All rights reserved. SPZ-US-1358v4 07/20

Effective July 2020

SAMPLE

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.

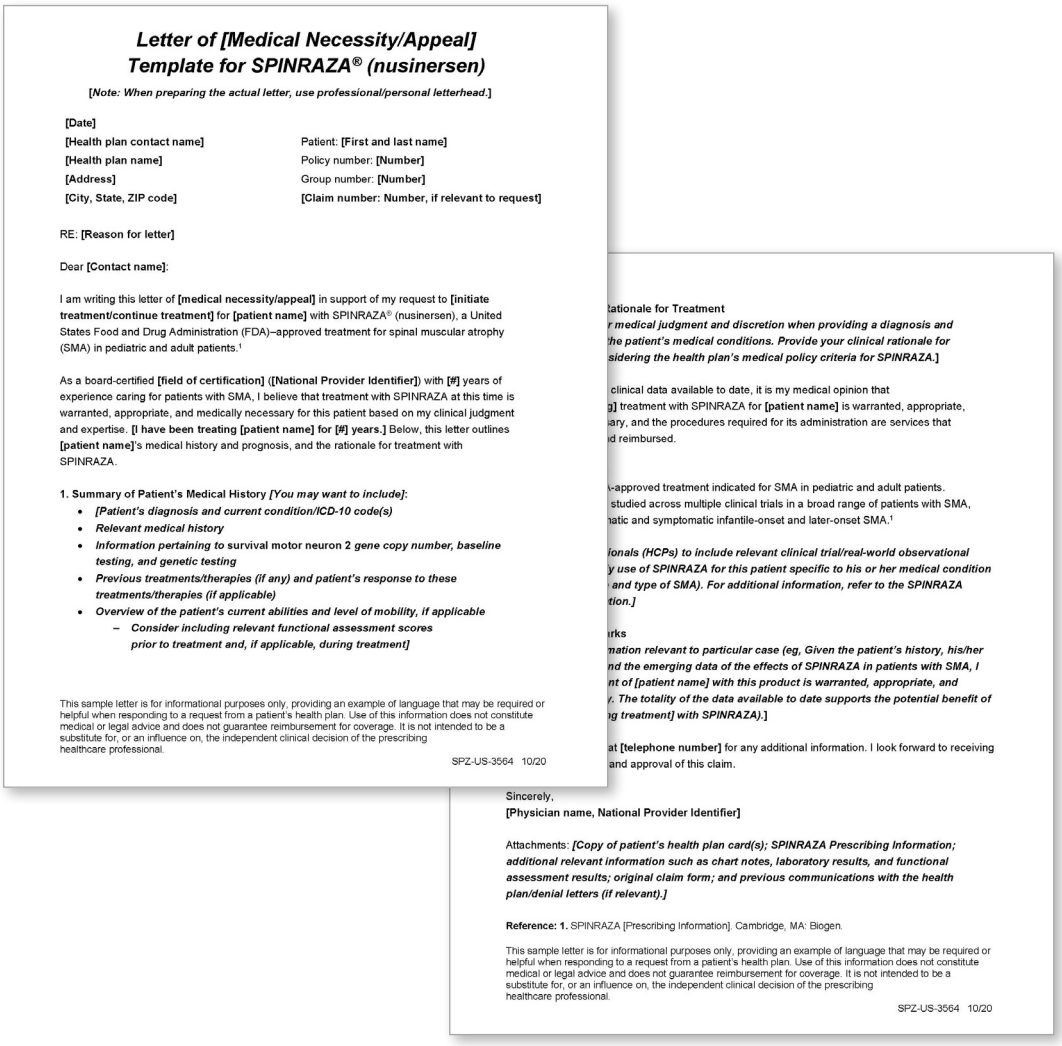
Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

Letter of Medical Necessity/Appeal Template

This Letter of Medical Necessity/Appeal Template is intended to be used as a guide to help you structure your letter. Remember to include the relevant health plan information and patient information (eg, policy number and/or claim number).

Remember to tailor each section of the Letter of Medical Necessity/Appeal template as appropriate to align with the letter's purpose and the patient about whom you are writing.



Letter of [Medical Necessity/Appeal] Template for SPINRAZA® (nusinersen)

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

[Date]

[Health plan contact name]
[Health plan name]
[Address]
[City, State, ZIP code]

Patient: **[First and last name]**
Policy number: **[Number]**
Group number: **[Number]**
[Claim number: Number, if relevant to request]

RE: **[Reason for letter]**

Dear **[Contact name]**:

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

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

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

- ***[Patient's diagnosis and current condition/ICD-10 code(s)***
- ***Relevant medical history***
- ***Information pertaining to* survival motor neuron 2 *gene copy number, baseline testing, and genetic testing***
- ***Previous treatments/therapies (if any) and patient's response to these treatments/therapies (if applicable)***
- ***Overview of the patient's current abilities and level of mobility, if applicable***
  - ***Consider including relevant functional assessment scores prior to treatment and, if applicable, during treatment]***

This sample letter is for informational purposes only, providing an example of language that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

SPZ-US-3564 10/20

tionale for Treatment
r medical judgment and discretion when providing a diagnosis and he patient's medical conditions. Provide your clinical rationale for sidering the health plan's medical policy criteria for SPINRAZA.]

clinical data available to date, it is my medical opinion that
g] treatment with SPINRAZA for **[patient name]** is warranted, appropriate, ary, and the procedures required for its administration are services that d reimbursed.

-approved treatment indicated for SMA in pediatric and adult patients. studied across multiple clinical trials in a broad range of patients with SMA, natic and symptomatic infantile-onset and later-onset SMA.[1]

ionals (HCPs) to include relevant clinical trial/real-world observational y use of SPINRAZA for this patient specific to his or her medical condition and type of SMA). For additional information, refer to the SPINRAZA tion.]

rks
nation relevant to particular case (eg, Given the patient's history, his/her nd the emerging data of the effects of SPINRAZA in patients with SMA, I nt of [patient name] with this product is warranted, appropriate, and . The totality of the data available to date supports the potential benefit of g treatment] with SPINRAZA).]

at [telephone number] for any additional information. I look forward to receiving and approval of this claim.

Sincerely,
[Physician name, National Provider Identifier]

Attachments: ***[Copy of patient's health plan card(s); SPINRAZA Prescribing Information; additional relevant information such as chart notes, laboratory results, and functional assessment results; original claim form; and previous communications with the health plan/denial letters (if relevant).]***

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

This sample letter is for informational purposes only, providing an example of language that may be required or helpful when responding to a request from a patient's health plan. Use of this information does not constitute medical or legal advice and does not guarantee reimbursement for coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescribing healthcare professional.

SPZ-US-3564 10/20

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%).

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

REFERENCES

1. SPINRAZA [Prescribing Information]. Cambridge, MA: Biogen.
2. Rapaport C. *An Introduction to Health Insurance: What Should a Consumer Know*? https://www.fas.org/sgp/crs/misc/R44014.pdf. Published April 30, 2015. Accessed November 16, 2022.
3. Glossary of health coverage and medical terms. Centers for Medicare & Medicaid Services website. https://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf. Accessed August 24, 2020.
4. The Lewin Group, Inc. *Medicaid Non-Emergency Out-of-Network Payment Study*. http://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/OutofNetworkStudyReport.pdf. Published July 13, 2009. Accessed November 16, 2022.
5. Biogen, Data on file. SMA payer and channel strategic issues. Published January 28, 2016.
6. Little T. Referral, predetermination, authorization, precertification: what's the difference? MGMA website. https://www.mgma.com/resources/operations-management/guide-to-closing-a-private-equity-transaction-pre. Published July 16, 2019. Accessed November 16, 2022.
7. O'Hagen JM, Glanzman AM, McDermott MP, et al. An expanded version of the Hammersmith Functional Motor Scale for SMA II and III patients. *Neuromuscul Disord*. 2007;17(9-10):693-697.
8. Glanzman AM, Mazzone E, Main M, et al. The Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND): test development and reliability. *Neuromuscul Disord*. 2010;20(3):155-161.
9. Haataja L, Mercuri E, Regev R, et al. Optimality score for the neurologic examination of the infant at 12 and 18 months of age. *J Pediatr*. 1999;135(2 pt 1):153-161.
10. Biogen, Data on file. Nusinersen brand book. Volume 1.
11. WHO Multicentre Growth Reference Study Group. WHO Motor Development Study: windows of achievement for six gross motor development milestones. *Acta Paediatr Suppl*. 2006;450:86-95.
12. Mazzone ES, Mayhew A, Montes J, et al. Revised Upper Limb Module for spinal muscular atrophy: development of a new module. *Muscle Nerve*. 2017;55(6):869-874.
13. B. Stolte, J.-M. Bois, S. Bolz, et al. Minimal clinically important differences in functional motor scores in adults with spinal muscular atrophy. *Eur. J. Neurol*. 2020;27:2586–2594.
14. Dunaway Young, S, Montes J, Kramer SS, et al. Six-minute walk test is reliable and valid in spinal muscular atrophy. *Muscle Nerve*. 2016;54(5):836-842.
15. Appealing a health plan decision: external review. Healthcare.gov website. https://www.healthcare.gov/appeal-insurance-company-decision/external-review/. Accessed November 16, 2022.
16. Patient Advocate Foundation. *A Patient's Guide to Navigating the Insurance Appeals Process*. https://www.patientadvocate.org/wp-content/uploads/Navigating-the-insurance-appeals-guide-pages.pdf. Accessed November 16, 2022.
17. American Medical Association. *CPT® 2020 Professional Edition*. Chicago, IL: American Medical Association; 2019.
18. Centers for Medicare & Medicaid Services. CMS Manual System: Uniform Billing (UB-04) Implementation. 1767. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1767CP.pdf. Published July 10, 2009. Accessed November 16, 2022.
19. Ambulatory surgical center. HMSA Provider Resource Center website. https://hmsa.com/portal/provider/zav_pel.fh.AMB.500.htm. Accessed November 16, 2022.
20. Centers for Medicare & Medicaid Services. Important guidance on the new CMS-1500 and UB-04 forms. *MLN Matters*. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se0659.pdf. Accessed November 16, 2022.
21. ICD-10-CM 2020 ICD-10-CM. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Accessed November 16, 2022.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

REFERENCES (cont'd)

22. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries for drugs, biologicals and radiopharmaceuticals. https://www.cms.gov/files/document/2019-hcpcs-application-summary-may-14-2019-drugs-and-biologicals.pdf. Published May 14, 2019. Accessed November 16, 2022.

23. Academy of Managed Care Pharmacy. *AMCP Guide to Pharmaceutical Payment Methods, 2013 Update*. Version 3.0. https://www.amcp.org/sites/default/files/2019-03/Full-Pharmaceutical-Guide-%283.0%29.pdf. Accessed November 16, 2022.

24. Butler K, Davis G, Loftis J, Spector N. A "how to" for reporting NDC in health care claims [presentation]. https://docplayer.net/30789407-A-how-to-for-reporting-ndc-in-health-care-claims.html. Published May 1, 2013. Accessed November 16, 2022.

25. National Drug Code requirements. UnitedHealthcare website. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf. Accessed November 16, 2022.

26. ASC 837I version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmetto GBA website. https://www.palmettogba.com/Palmetto/Providers.Nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf. Accessed November 16, 2022.

27. Centers for Medicare & Medicaid Services. CMS Manual System: Pub 100-04 Medicare claims processing. Transmittal 1775. https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r1775cp.pdf. Published July 24, 2009. Accessed November 16, 2022.

28. ASC 837 v5010 to CMS-1500 Crosswalk. Palmetto GBA website. https://www.palmettogba.com/Palmetto/Providers.Nsf/files/CMS1500_837v5010_Crosswalk.pdf/$File/CMS1500_837v5010_Crosswalk.pdf. Accessed November 16, 2022.

29. Place of service code set. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set. Updated September 2021. Accessed November 16, 2022.

30. 2020 ICD-10-PCS codes. ICD10Data.com website. http://www.icd10data.com/ICD10PCS/Codes. Accessed November 16, 2022.

31. Social Security Administration. *Benefits for Children With Disabilities*. https://www.ssa.gov/pubs/EN-05-10026.pdf. Accessed November 16, 2022.

32. Centers for Medicare & Medicaid Services. *Medicare & You – 2023.* https://www.medicare.gov/publications/10050-Medicare-and-You.pdf. Accessed November 16, 2022.

33. How you qualify. Social Security Administration website. https://www.ssa.gov/planners/disability/qualify.html. Accessed November 16, 2022.

34. Compassionate allowances conditions. Social Security Administration website. https://www.ssa.gov/compassionateallowances/conditions.htm. Accessed November 16, 2022.

35. Medicare costs. Medicare.gov website. https://www.medicare.gov/basics/costs/medicare-costs. Accessed November 16, 2022.

36. The ins and outs of seeking out-of-network care. Patient Advocate Foundation website. https://www.patientadvocate.org/wp-content/uploads/Migraine-Out-of-Network-Care.pdf. Accessed November 16, 2022.

37. Preferred provider organization (PPO). Medicare.gov website. https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/preferred-provider-organization-ppo. Accessed November 16, 2022.

38. Private fee-for-service (PFFS) plans. Medicare.gov website. https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/private-fee-for-service-pffs-plans. Accessed November 16, 2022.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

REFERENCES (cont'd)

39. Special needs plans (SNPs). Medicare.gov website. https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/special-needs-plans-snp. Accessed November 16, 2022.

40. What's the difference between Medicare HMO-POS and PPO plans? Priority Health website. https://www.priorityhealth.com/medicare/medicare-explained/extra-credit/difference-between-hmo-pos-ppo#. Accessed November 16, 2022.

41. Medicare Medical Savings Account (MSA) Plans. Medicare.gov website. https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/medicare-medical-savings-account-msa-plans. Accessed November 16, 2022.

42. How Medicare MSA plans work with other coverage. Medicare.gov website. https://www.medicare.gov/sign-upchange-plans/types-of-medicare-health-plans/how-medicare-msa-plans-work-with-other-coverage. Accessed November 16, 2022.

43. Congressional Research Service. *Medicare Secondary Payer: Coordination of Benefits*. Report No. RL33587. https://www.everycrsreport.com/files/20140508_RL33587_a4115c77876940c4301dbae3244c3100d0d926ff.pdf. Published May 8, 2014. Accessed November 16, 2022.

44. Centers for Medicare & Medicaid Services. *Medicare-FFS Program Billing 340B Modifiers Under the Hospital Outpatient Prospective Payment System (OPPS). Frequently Asked Questions.* https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf Published April 2, 2018. Accessed November 16, 2022.

45. Centers for Medicare & Medicaid Services. Medicare program: hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; organ procurement organization reporting and communication; transplant outcome measures and documentation requirements; electronic health record (EHR) Incentive programs; payment to nonexcepted off-campus provider-based department of a hospital; hospital value-based purchasing (VBP) program; establishment of payment rates Under the Medicare physician fee schedule for nonexcepted items and services furnished by an off-campus provider-based department of a hospital. Final rule with comment period and interim final rule with comment period. *Fed Regist*. 2016;81(219):79562-79892.

46. American Society of Health-System Pharmacists. *Federal Court Rules Against CMS Cuts to Reimbursement for 340B Drugs*. https://www.ashp.org/news/2022/09/29/federal-court-rules-against-cms-cuts-to-reimbursement-for-340b-drugs?loginreturnUrl=SSOCheckOnly. Published September 29, 2022. Accessed November 15, 2022.

47. APC (ambulatory payment classification) FAQ. American College of Emergency Physicians website. https://www.acep.org/administration/reimbursement/reimbursement-faqs/apc-ambulatory-payment-classifications-faq/. Accessed November 16, 2022.

48. Centers for Medicare & Medicaid Services. *Acute Care Hospital Inpatient Prospective Payment System*. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AcutePaymtSysfctsht.pdf. Published March 2020. Accessed November 16, 2022.

49. Centers for Medicare & Medicaid Services. Chapter 4 – Part B hospital (including inpatient hospital Part B and OPPS). In: *Medicare Claims Processing Manual*. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf. Revised September 8, 2022. Accessed November 16, 2022.

50. Department of Health and Human Services. *MACs Continue to Use Different Methods to Determine Drug Coverage*. OEI-03-13-00450. https://oig.hhs.gov/oei/reports/oei-03-13-00450.pdf. Published August 2016. Accessed November 16, 2022.

51. What is a MAC. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#:~:text=and%20Functional%20Contractors-,What's%20a%20MAC%20and%20what%20do%20they%20do%3F,%2DService%20(FFS)%20beneficiaries. Accessed November 16, 2022.

52. A/B MAC jurisdictions as of June 2019. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-Jurisdiction-Map-Jun-2019.pdf. Accessed November 16, 2022.

Please see additional Important Safety Information on page 4 and accompanying full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL