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

SPINRAZA RESOURCE GUIDE FOR PRACTICES AND FACILITIES

For Coverage & Continued Treatment with SPINRAZA

INDICATION

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

SELECTED IMPORTANT SAFETY INFORMATION

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

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

Please see additional Important Safety Information on the next page and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INDICATION AND IMPORTANT SAFETY INFORMATION

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 full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

INTRODUCTION, PURPOSE, AND SUPPORT OVERVIEW

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

The SPINRAZA Resource Guide may be used to help navigate complex scenarios at your site such as:

- Navigating differences between various payer policies
- Managing appointment scheduling and capacity
- Coordinating prior authorizations, appeals, and medical exceptions
- Procurement processes
- Financial assistance options for patients

SMA360™ Support services from Biogen

Questions about support or treatment logistics?

Contact your Biogen Rare Disease Account Executive:
1-844-4SPINRAZA (1-844-477-4672)

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

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

TABLE OF CONTENTS

This guide provides resources to support your practice or facility in navigating the treatment access and procurement processes for patients who have been prescribed SPINRAZA.

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

BIOGEN CARE TEAM

NAVIGATING ACCESS

These SPINRAZA team members are available to provide clinical trial and nonclinical information to help navigate SPINRAZA access.

RARE DISEASE ACCOUNT EXECUTIVE (RDAE)

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

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

RARE DISEASE REIMBURSEMENT MANAGER (RDRM)

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

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

FAMILY ACCESS MANAGER (FAM)

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

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

PRODUCT FACT SHEET

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PRODUCT FACT SHEET

COMPANY: Biogen

PRODUCT TRADE NAME: SPINRAZA®

GENERIC NAME: nusinersen

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

How supplied	12-mg/5-mL injection
Packaging	Single-dose glass vial
Carton dimensions	2.28" x 3.15" x 2.56"
Shipping case dimensions	11.25" x 9.5" x 8" or 11.25" x 9.5" x 10.75"
NDC number	64406-058-01
J-code	J2326, Injection, nusinersen, 0.1 mg
Potential *ICD-10* Codes	**G12.0** - Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann] **G12.1** - Other inherited spinal muscular atrophy Adult form spinal muscular atrophy Childhood form, type II spinal muscular atrophy Distal spinal muscular atrophy Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander]

Not shown actual size

ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code.

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

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

Source: SPINRAZA [Prescribing Information]. Cambridge, MA: Biogen.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

CLINICAL OVERVIEW

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

SPINRAZA CLINICAL OVERVIEW

SPINRAZA has been studied in multiple controlled and uncontrolled open-label trials that included presymptomatic and symptomatic patients who had or were likely to develop SMA Type 1, 2, or 3.[1-5]

CONTROLLED STUDIES

STUDY	ENDPOINTS
ENDEAR **Patients with infantile-onset SMA, most likely SMA Type 1 (n=121)**[1,2] • Phase 3, multicenter, randomized, double-blind, sham-procedure–controlled study • Infants had symptom onset at age <6 months*	• **Primary endpoints:** proportion of patients meeting the criteria for a trial endpoint named "motor milestone response" using HINE-2, event-free survival[1,2,5] • **Secondary endpoints:** overall survival, CHOP INTEND, CMAP, percentage of infants not requiring mechanical ventilation, event-free survival in patients with disease duration of ≤12 weeks and >12 weeks[1,5,6] • **Additional assessment:** safety[1,2,5]

RESULTS

47% reduction in risk of death or permanent ventilation with SPINRAZA compared with untreated patients (HR=0.53; *P*=0.005).[2]

- **63% reduction in risk of death alone** (HR=0.37; *P*=0.004)

More patients treated with SPINRAZA achieved a HINE-2 response compared with untreated patients.[1,2,6]

- Interim analysis: 40% SPINRAZA (n=52) vs 0% untreated (n=30) (*P*<0.0001)†
- Final analysis: 51% SPINRAZA (n=73) vs 0% untreated (n=37) (*P*<0.0001)

More patients treated with SPINRAZA had a **≥4-point improvement from baseline in CHOP INTEND score** compared with untreated patients: 71% (52/73) vs 3% (1/37), respectively (*P*<0.001).[2]

- Fewer patients treated with SPINRAZA had a **≥4-point worsening:** 3% (2/73) vs 46% (17/37), respectively[6]

The most common ARs that occurred in at least 20% of patients treated with SPINRAZA and occurred at least 5% more frequently than in control patients were lower respiratory infection and constipation.[1]

AR=adverse reaction; CHOP INTEND=Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders; CMAP=Compound Muscle Action Potential; HINE-2=Hammersmith Infant Neurological Examination Section 2; HR=hazard ratio; SMA=spinal muscular atrophy

*Inclusion criteria

†The interim analysis in the Finkel et al publication indicates a motor milestone responder rate of 41%. This reflects 78 patients, excluding 4 patients who died and were not enrolled early enough to reach the day 183 cutoff

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 Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA CLINICAL OVERVIEW (cont'd)

CONTROLLED STUDIES

STUDY	ENDPOINTS
CHERISH **Patients with later-onset SMA Type 2 or Type 3 (n=126)**[3] • Phase 3, multicenter, randomized, double-blind, sham-procedure–controlled study • Patients (aged 2 years to 12 years) had symptom onset at age >6 months*	• **Primary endpoint:** change from baseline in HFMSE score at month 15[3,7] • **Secondary endpoints:** HFMSE (≥3-point change), WHO motor milestones, RULM, standing alone, walking with assistance[3,7] • **Additional assessment:** safety[3,7]

RESULTS

Patients treated with SPINRAZA demonstrated a **clinically meaningful change (≥3-point increase) in HFMSE total score** from baseline, improving in ≥2 motor skills compared with untreated patients.[3]

- Change from baseline at month 15 (least squares mean†): SPINRAZA 3.9 ±0.49 (n=84); untreated patients -1.0 +/-0.76 (n=42) (*P*=0.0000001)

Patients treated with SPINRAZA demonstrated a **clinically meaningful improvement in upper limb function** (change in RULM total score from baseline) compared with untreated patients.[3]

- Change from baseline at month 15 (least squares mean): SPINRAZA 4.2 ±0.40 (n=84); untreated patients 0.5 +/-0.56 (n=42)

The most common ARs that occurred in at least 20% of patients treated with SPINRAZA and occurred at least 5% more frequently than in control patients were pyrexia, headache, vomiting, and back pain.[1]

HFMSE=Hammersmith Functional Motor Scale–Expanded; RULM=Revised Upper Limb Module; WHO=World Health Organization

*Inclusion criteria

†Least squares mean: a mathematical analysis that accounts for the estimation of missing data values of children who had not completed the study at the time of the efficacy analysis

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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 Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA CLINICAL OVERVIEW (cont'd)

OPEN-LABEL STUDIES

STUDY	ENDPOINTS
NURTURE **Presymptomatic, genetically diagnosed infants (N=25)**[4] • Phase 2, ongoing, open-label, single-arm, multinational, long-term, supportive study	• **Primary endpoint:** median time to death or respiratory ventilation[4] • **Other endpoints:** WHO motor milestones, HINE-2, CHOP INTEND[4]

RESULTS

As of February 2020, **all 25 patients were alive and remained free of permanent ventilation.**[4,8]

All 25 patients treated with SPINRAZA could sit without support; 96% of patients (24/25) eventually achieved the ability to walk with assistance, and 88% (22/25) had achieved the ability to walk alone.[4,8]

HINE-2 motor milestones improved over time (>2 years); infants who had 3 *SMN2* copies saw an increase in mean total score to the maximum of 26 points, while infants with 2 *SMN2* copies saw a mean increase to 23.9 points.[4]

Treatment with SPINRAZA in the presymptomatic stage improved infant motor skills over time, with 100% (10/10) of infants with 3 *SMN2* copies and 73% (11/15) of infants with 2 *SMN2* copies achieving a maximum CHOP INTEND score of 64.[4,8]

All 25 infants experienced ARs, with 12 experiencing serious ARs and 5 experiencing severe ARs; the benefit-risk profile was consistent with data from ENDEAR and CHERISH, and no new safety concerns were identified.[4]

SMN2=survival motor neuron 2 gene

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA CLINICAL OVERVIEW (cont'd)

OPEN-LABEL STUDIES

STUDY	ENDPOINTS
CS2/CS12 **Patients with later-onset SMA Type 2 or Type 3 (N=28)**[9] • Phase 1b/2a, multiple-dose study (CS2=253 days) with an open-label extension (CS12=715 days) • Patients were aged 2 years to ≤15 years at time of first dose*	• **Primary endpoints:** efficacy and safety of SPINRAZA administered intrathecally[9] – Efficacy was assessed using HFMSE, ULM, 6MWT, CMAP, and motor unit number estimation

RESULTS

Results at day 1150 in patients receiving SPINRAZA[9]*:*

10.8-point increase in HFMSE score from baseline of 21.3 (patients with SMA Type 2; n=11).

1.8-point increase in HFMSE score from baseline of 48.9 (patients with SMA Type 3; n=17).

92.0-meter increase in 6MWT walking distance from baseline of 253.3 meters (patients with SMA Type 3; n=13).

Some nonambulant patients with later-onset SMA were able to walk independently[9]*:*

- At least **1 of 11 patients** with SMA Type 2 **gained the ability to walk for the first time**
- At least **2 of 4 patients** with SMA Type 3 **regained the ability to walk that they had lost previously**

The most common ARs that occurred in at least 20% of patients treated with SPINRAZA were post-lumbar puncture syndrome, headache, nasopharyngitis, upper respiratory tract infection, puncture site pain, back pain, scoliosis, pyrexia, joint contracture, rhinorrhea, and vomiting.[9]

6MWT=6-Minute Walk Test; ULM=Upper Limb Module.
*Inclusion criteria.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ADDITIONAL STUDIES

REAL-WORLD INDEPENDENT OBSERVATIONAL STUDY

STUDY	ENDPOINTS
INDEPENDENT OBSERVATIONAL STUDY (HAGENACKER T, ET AL) **Adult patients with later-onset SMA Type 2 or Type 3 (n=139, enrolled)[10]** • Prospective, multicenter, 14-month, observational study by an independent, third-party group • Adult patients aged 16 years to 65 years • **Study limitations:** no control group; observational design. Study powered on primary endpoint only. Statistics for other endpoints are descriptive only	• **Primary endpoint:** change from baseline in HFMSE score at 6, 10, and 14 months. Patients with missing baseline HFMSE scores were excluded from these analyses[10] • **Secondary endpoints:** change from baseline in RULM and 6MWT scores at 6, 10, and 14 months[10]

RESULTS

The majority of ARs were consistent with those in the SPINRAZA pivotal trials.

Other reported ARs were[10]

- Nausea
- Diffuse pain
- Constipation
- Vertigo
- Bladder disorder not otherwise specified
- Infection
- Meningitis, aseptic
- Tinnitus, aggravated

BIOGEN TEAM
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Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ADDITIONAL STUDIES (cont'd)

REAL-WORLD INDEPENDENT OBSERVATIONAL STUDY

RESULTS (cont'd)

Mean HFMSE scores with SPINRAZA were significantly increased from baseline (1.73 at 6 months [n=124], 2.58 at 10 months [n=92], and 3.12 at 14 months [n=57]). A clinically meaningful (≥3-point) increase in HFMSE score for motor function was seen in 28% of patients at 6 months, 35% of patients at 10 months, and 40% of patients at 14 months.[10]*

- 14 of 124 patients (11%) showed worsening motor function under treatment as measured by HFMSE
- 139 patients completed an assessment at 6 months, 105 at 10 months, and 61 at 14 months

Mean walking distances on the 6MWT improved from baseline to 22.1 meters at 6 months (n=47, 6.9% increase), 31.1 meters at 10 months (n=37, 8.8% increase), and 46.0 meters at 14 months (n=25, 12.4% increase).[10]

Arm motor function improved from baseline (RULM scores were 0.66 at 6 months [n=120], 0.59 at 10 months [n=90], and 1.09 at 14 months [n=58]).[10]

- At 6 months, 28 (23%) of 120 patients showed ≥2-point improvement in RULM from baseline (ie, a clinically meaningful improvement), whereas 74 (61%) showed no meaningful change,18 (15%) showed a decline of ≥1 point, and 10 (8%) showed a decline of ≥2 points
- Of the 28 patients who showed a clinically meaningful improvement in RULM score at 6 months, 75% (n=21) maintained these milestones at 14 months

*Exploratory endpoint.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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.

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SPINRAZA® (nusinersen) injection 12 mg/5 mL

ADDITIONAL STUDIES (cont'd)

REAL-WORLD INDEPENDENT OBSERVATIONAL STUDY

STUDY	ENDPOINTS
INDEPENDENT OBSERVATIONAL STUDY (MAGGI L, ET AL) **Adult patients with later-onset SMA Type 2 or Type 3 (N=116)[11]** • Retrospective, 14-month, observational cohort study by an independent, third-party group • Adult patients aged 18 to 72 years (SMA Type 2, n=13; SMA Type 3, n=103) • **Study limitations:** retrospective design, small SMA Type 2 sample size, missing data for some variables, and some results supported only by "nominal statistical significance"	• **Primary endpoints:** changes in overall motor function measured by HFMSE, changes in upper limb function measured by RULM, changes in walking ability measured by 6MWT[11]

RESULTS

The majority of ARs were consistent with those in the SPINRAZA clinical trials.[11]

- The most frequently reported ARs were postprocedural headache (37.1%) and lumbar pain (8.6%)
- 5 patients were hospitalized for headache
- Other reported ARs were transient worsening of existing hand tremor (2 patients) and renal colic (1 patient)

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

ADDITIONAL STUDIES (cont'd)

REAL-WORLD INDEPENDENT OBSERVATIONAL STUDY

RESULTS (cont'd)

Median RULM score for patients with SMA Type 3 increased by 0.5 points from baseline to 14 months.[11]

Median HFMSE scores for patients with SMA Type 3 increased by 1 point at 6 months (range -5 to 8; *P*<0.0001), 2 points at 10 months (range -3 to 9; *P*<0.0001), and 3 points at 14 months (range -3 to 11; *P*<0.0001), with independently significant changes in the sitter (median 3-point increase, *P*=0.0014) and walker (median 2-point increase, *P*=0.00016) subgroups.[11]

- SMA Type 2 subgroup showed positive trends in HFMSE, but results were not statistically significant, potentially due to the small number of patients

A significant increase in median 6MWT distance was seen at 6 months (11 meters) and 10 months (25 meters); additionally, there was a nominally significant 20-meter increase at 14 months.[11]

- Nominally significant changes were observed at 10 months (1 point) and 14 months (2 points) in nonambulant patients
- In ambulant patients with SMA Type 3 who showed a "ceiling" effect, RULM score did not change
- Median RULM score for patients with SMA Type 2 did not change, but a positive trend was observed by 14 months

Responders in at least 1 of 3 outcomes were defined as "overall responders": +3 points on HFMSE, +2 points on RULM, or +30 meters on 6MWT. Within the entire cohort study, clinically meaningful improvements were seen in 53% of patients at 6 months, 63% of patients at 10 months, and 69% at 14 months.[11]

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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.

References: 1. SPINRAZA. Prescribing Information. Cambridge, MA: Biogen. **2.** Finkel RS, Mercuri E, Darras BT, et al; for the ENDEAR Study Group. Nusinersen versus sham control in infantile-onset spinal muscular atrophy. *N Engl J Med*. 2017;377(18):1723-1732. **3.** Mercuri E, Darras BT, Chiriboga CA, et al; for the CHERISH Study Group. Nusinersen versus sham control in later-onset spinal muscular atrophy. *N Engl J Med*. 2018;378(7):625-635. **4.** De Vivo DC, Bertini E, Swoboda KJ, et al; on behalf of the NURTURE Study Group. Nusinersen initiated in infants during the presymptomatic stage of spinal muscular atrophy: interim efficacy and safety results from the phase 2 NURTURE study. *Neuromuscul Disord*. 2019;29(11):842-856. **5.** Biogen, Data on file. **6.** Finkel RS, Mercuri E, Darras BT, et al; for the ENDEAR Study Group. Nusinersen versus sham control in infantile-onset spinal muscular atrophy [supplemental appendix]. *N Engl J Med*. 2017;377(18):1723-1732. **7.** Mercuri E, Darras BT, Chiriboga CA, et al; for the ENDEAR Study Group. Nusinersen versus sham control in later-onset spinal muscular atrophy [supplemental appendix]. *N Engl J Med*. 2018;378(7):625-635. **8.** New results from landmark NURTURE study show that pre-symptomatic SMA patients treated with SPINRAZA® (nusinersen) continue to demonstrate sustained benefit from treatment [press release]. Biogen website. http://investors.biogen.com/news-releases/news-release-details/new-results-landmark-nurture-study-show-pre-symptomatic-sma. Accessed January 15, 2021. **9.** Darras BT, Chiriboga CA, Iannaccone ST, et al; ISIS-396443-CS2/ISIS-396443-CS12 Study Groups. Nusinersen in later-onset spinal muscular atrophy: long-term results from the phase 1/2 studies. *Neurology*. 2019;92(21):e2492-e2506. **10.** Hagenacker T, Wurster CD, Günther R, et al. Nusinersen in adults with 5q spinal muscular atrophy: a non-interventional, multicentre, observational cohort study. *Lancet Neurol*. 2020;19(4):317-325. **11.** Maggi L, Bello L, Bonanno S, et al. Nusinersen safety and effects on motor function in adult spinal muscular atrophy type 2 and 3. *J Neurol Neurosurg Psychiatry*. 2020;91(11):1166-1174.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BENEFITS INVESTIGATION GUIDE AND WORKSHEET

SPINRAZA® (nusinersen) BENEFITS INVESTIGATION GUIDE AND WORKSHEET

A Benefits Investigation is a process that enables a practice or facility to determine benefit design, coverage requirements, coding guidance, and drug acquisition options for a specific patient before administering treatment. For SPINRAZA, your practice or facility will need to know how the patient's health plan covers both the drug component and the administration component. Note that SPINRAZA will most often be covered under the health plan's medical benefit.

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

Best practices for conducting a benefit investigation/verification:

- Establish universal guidelines and identify common resources to help standardize the benefit investigation/verification process
- Prior to initiating a benefit verification, confirm that the patient's health plan information on file is accurate and up to date
- If the patient has coverage from more than 1 health plan, confirm coordination of benefits between primary and secondary payers
- Communicate patient's benefits or provide a summary of benefits to the appropriate members of the patient's care team
- Determine key elements of the health plan's cost-sharing structure
- Identify and record any payer-specific requirements for prior authorization and/or sites of care (eg, in-network, treatment in same state policy was issued)
- Establish a plan and frequency to verify the patient's benefits at regular intervals (eg, prior to ordering the next dose of SPINRAZA)
- Coordinate with Biogen's Family Access Managers (FAM), who advocate on behalf of patients to support access to treatment (including insurance coverage, reimbursement, financial limitations, site of care logistics, and procurement and distribution issues)

This form is available for download at **SPINRAZA-hcp.com.** One program that can help your patients and their caregivers with SPINRAZA treatment is SMA360°™. Biogen created this support service especially for patients with SMA who are prescribed SPINRAZA.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA® (nusinersen) BENEFITS INVESTIGATION GUIDE AND WORKSHEET (cont'd)

As you conduct the Benefits Investigation, this guide and worksheet can assist you in information gathering while engaging a patient's health plan. In this document, you will find:

- A sample Benefits Investigation Guide with instructions, which explains the type of information that needs to be captured in each field
- A second Benefits Investigation Worksheet that you may tear out of the binder to fill out and submit to your practice or facility

Step 1: OBTAIN BASIC PATIENT INFORMATION.

Patient Name: _____ Date of Birth: ____/____/_____

Policyholder Name: _____

Health Plan Name: _____

Phone Number: _____

Member #: _____ Group #: _____

Plan Type: ☐ HMO ☐ PPO ☐ POS ☐ Other _____

Health Plan: ☐ Primary ☐ Secondary ☐ Tertiary

Is There a Secondary Policy: ☐ Yes ☐ No In Network: ☐ Yes ☐ No

Physician Name/Practice or Facility: _____

Tax ID: _____ Provider #: _____

1 **Please fill out Step 1 with basic patient information before contacting the patient's health plan.**

Gather this information before calling the health plan.

Step 2: CONTACT PATIENT'S HEALTH PLAN.

Researched Date: ____/____/_____ Time: _____

Person(s) You Spoke With: _____

_____

Policy Year Is: ☐ Calendar ☐ Benefit

Effective Date: ____/____/_____ Termination Date: ____/____/_____

ICD Code[a]: _____ NDC Code[a]: _____

HCPCS Code[a]: _____ Procedure Code(s)[a]: _____

Billing Preference: _____

_____

2 **After contacting the patient's health plan, complete all the information in Step 2.**

Ask to speak to a case manager or neuromuscular specialist. Capture the details below for easier follow-up. Complete this information as early as possible before SPINRAZA administration.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SPINRAZA® (nusinersen) BENEFITS INVESTIGATION GUIDE AND WORKSHEET (cont'd)

Step 3: DETERMINE PROCUREMENT AND PATIENT COVERAGE.

	ADMINISTRATION	DRUG		
	Administration Through Major Medical Benefit (The practice or facility bills for the infusion/injection and receives reimbursement from the health plan)	**Practice or Facility Purchase Option Through Major Medical Benefit** (The practice or facility purchases treatment, bills for the drug, and receives reimbursement from the health plan)	**Specialty Pharmacy Option Through Major Medical Benefit** (Benefits are assigned to a network specialty pharmacy. The specialty pharmacy bills for the cost of treatment)	**Specialty Pharmacy Option Through Prescription Drug Benefit** (Treatment is covered under the pharmacy benefit. The specialty pharmacy bills for the cost of treatment)
Outcome:	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered
Drug covered:	–	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Deductible:	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **pharmacy benefit**: $
Deductible met:	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **pharmacy benefit**: $
Out-of-pocket maximum:	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **pharmacy benefit**: $
Out-of-pocket maximum met:	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **major medical benefit**: $	Enter amount that applies to **pharmacy benefit**: $
Accredo Specialty Pharmacy (SP)	–	–	Name: Phone #:	Name: Phone #:
Coinsurance or copay:	Enter % **or** $ amount that applies to **major medical benefit**	Enter % **or** $ amount that applies to **major medical benefit**	Enter % **or** $ amount that applies to **major medical benefit**	Enter % **or** $ amount that applies to **pharmacy benefit**
Additional benefit information:	Enter any important details here	Enter any important details here	Enter any important details here	Enter any important details here

*For detailed information about coding for SPINRAZA (including procedure codes), refer to the **Relevant Code and Sample Claim Form Guide**, available at **spinraza-hcp.com**.

3

In Step 3, fill out the administration column and 1 of the 3 drug columns depending on procurement needs and preferences.

SPINRAZA can be obtained either by placing an order through CuraScript Specialty Distributor (SD) or by submitting a prescription to Accredo Specialty Pharmacy (SP). It is up to your institution to determine the procurement option that works best for your practice or facility. The patient's health plan may also require a specific procurement option.

Step 4: DETERMINE IF THE PATIENT REQUIRES SPECIAL PRECLEARANCE BEFORE BEING COVERED FOR TREATMENT.

	ADMINISTRATION	DRUG		
	Administration Through Major Medical Benefit	**Practice or Facility Purchase Option Through Major Medical Benefit**	**Specialty Pharmacy Option Through Major Medical Benefit**	**Specialty Pharmacy Option Through Prescription Drug Benefit**
Prior authorization (PA)/ Predetermination (Pre-D) required?	N/A	Enter if there is a PA or other Pre-D requirement here	Enter if there is a PA or other Pre-D requirement here	Enter if there is a PA or other Pre-D requirement here
Required documentation:	–	Enter required PA or Pre-D documentation that must be submitted to the health plan here	Enter required PA or Pre-D documentation that must be submitted to the health plan here	Enter required PA or Pre-D documentation that must be submitted to the health plan here
Required criteria:	–	Enter required PA or Pre-D criteria here	Enter required PA or Pre-D criteria here	Enter required PA or Pre-D criteria here
Attention to:	–			
Phone:	–			
Fax:	–			
PA status:	–	Track the status of your PA here	Track the status of your PA here	Track the status of your PA here
PA expiration date:	–	Track the PA expiration here	Track the PA expiration here	Track the PA expiration here
PA instructions:	–	Record any special PA instructions here	Record any special PA instructions here	Record any special PA instructions here

4

In Step 4, determine if the patient requires special preclearance and record information in the boxes.

The following page contains a blank form that can be completed according to the instructions provided.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BENEFITS INVESTIGATION WORKSHEET

PATIENT INFORMATION

Patient Name: _____ Date of Birth: ____/____/_____ Policyholder Name: _____

Health Plan Name: _____ Phone Number: _____

Member #: _____ Group #: _____ Plan Type: ☐ HMO ☐ PPO ☐ POS ☐ Other _____

Health Plan: ☐ Primary ☐ Secondary ☐ Tertiary Is There a Secondary Policy: ☐ Yes ☐ No In Network: ☐ Yes ☐ No

Physician Name/Practice or Facility: _____ Tax ID: _____ Provider #: _____

CALL DETAILS

Researched Date: ____/____/____ Time: _____ Person(s) You Spoke With: _____

Policy Year Is: ☐ Calendar ☐ Benefit Effective Date: ____/____/_____ Termination Date: ____/____/_____

ICD Code[a]: _____ NDC Code[a]: _____ HCPCS Code[a]: _____ Procedure Code(s)[a]: _____

Billing Preference: _____

PATIENT BENEFIT OPTIONS

	ADMINISTRATION	DRUG		
	Administration Through Major Medical Benefit (The practice or facility bills for the infusion/injection and receives reimbursement from the health plan)	**Practice or Facility Purchase Option Through Major Medical Benefit** (The practice or facility purchases treatment, bills for the drug, and receives reimbursement from the health plan)	**Specialty Pharmacy Option Through Major Medical Benefit** (Benefits are assigned to a network specialty pharmacy. The specialty pharmacy bills for the cost of treatment)	**Specialty Pharmacy Option Through Prescription Drug Benefit** (Treatment is covered under the pharmacy benefit. The specialty pharmacy bills for the cost of treatment)
Outcome:	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered	☐ Covered ☐ Not Covered
Drug covered:	–	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Deductible:	$	$	$	$
Deductible met:	$	$	$	$
Out-of-pocket maximum:	$	$	$	$
Out-of-pocket maximum met:	$	$	$	$
Accredo Specialty Pharmacy (SP)	–	–	Name: Phone #:	Name: Phone #:
Coinsurance or copay:	% **or** $	% **or** $	% **or** $	% **or** $
Additional benefit information:				

[a]For detailed information about coding for SPINRAZA (including procedure codes), refer to the **Relevant Code and Sample Claim Form Guide**, available at **spinraza-hcp.com**.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

BENEFITS INVESTIGATION WORKSHEET (cont'd)

SPECIAL PRECLEARANCE

	ADMINISTRATION	DRUG		
	Administration Through Major Medical Benefit	Practice or Facility Purchase Option Through Major Medical Benefit	Specialty Pharmacy Option Through Major Medical Benefit	Specialty Pharmacy Option Through Prescription Drug Benefit
Prior authorization (PA)/ Predetermination (Pre-D) required?				
Required documentation:	–			
Required criteria:	–			
Attention to:	–			
Phone:	–			
Fax:	–			
PA status:	–			
PA expiration date:	–			
PA instructions:	–			

SPECIAL INSTRUCTIONS

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

PROCURING SPINRAZA® (nusinersen)

PROCUREMENT PROCESS: BUY-AND-BILL

SPINRAZA can be obtained either by placing an order through buy-and-bill (CuraScript Specialty Distributor), or by submitting a prescription to Accredo Specialty Pharmacy. It is up to your institution to determine the procurement option that works best for your practice or facility.

KEY STEPS

- Refer to the patient's Benefits Investigation to ensure coverage for both SPINRAZA (drug and procedure) and any related services
- Complete a prior authorization submission. Refer to the **Guide to Prior Authorization Submissions**, available at **SPINRAZA-hcp.com**, for guidance
- Contact CuraScript SD to confirm you have an active account and to obtain the SPINRAZA order form
  - Complete the SPINRAZA order form and place the order with CuraScript SD by faxing the order form to **1-888-538-9781** or calling **1-855-778-1510**
- Following the administration, determine the appropriate claim form for the patient's health plan and submit for reimbursement for both SPINRAZA and related services

BEST PRACTICES

- Place orders no later than 5 days before the scheduled administration to ensure the product is on hand for the procedure
  - CuraScript SD accepts orders Monday through Friday
  - Orders received Monday through Thursday prior to 5:00 pm EST will ship the same day for delivery the next day
- Refer to the **SPINRAZA Reimbursement Guide** for a summary of relevant codes and examples of populated claim forms

GUIDE

To receive a printed copy of the SPINRAZA Reimbursement Guide, please contact your Biogen representative. For an electronic copy, visit **SPINRAZA-hcp.com.**

SD=specialty distributor.

PROCUREMENT PROCESS: SPECIALTY PHARMACY

KEY STEPS

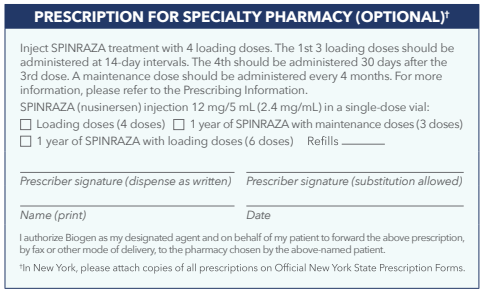
- Provide Accredo with a prescription or SPINRAZA referral form
  - The preferred and most efficient method is to fax to **1-888-538-9781**
  - If faxing is not an option, a verbal prescription can be called in to **1-855-778-1510**
- If a prior authorization (PA) is required for SPINRAZA, Accredo can begin the submission process. Include the following documentation when submitting a prescription to Accredo:
  - Diagnosis and genetic tests results
  - Most recent notes regarding age of onset and any baseline motor milestone assessments or physical therapy assessments
  - Letter of medical necessity for SPINRAZA
- Work with the patient to schedule treatment
- Following treatment, submit the appropriate reimbursement claim form. The SPINRAZA Reimbursement Guide provides a summary of relevant codes and examples of populated claim forms

BEST PRACTICES

- Refer to the patient's Benefits Investigation to ensure coverage for any service related to administering SPINRAZA
  - Accredo must conduct its own Benefits Investigation before it can dispense the product
- If a PA is required and your institution would like to manage the submission without Accredo's assistance, include Accredo's **tax ID number (11-3358535)** on the PA so it can be listed as the dispensing entity
  - In some cases, you also may need to include the National Provider Identifier (NPI) number of the Accredo service branch in your state
- Accredo may contact your institution to obtain any additional information required for the PA
  - Health plans generally require the prescriber to sign, complete, or finalize the PA and submit it for approval
  - If your site currently uses **CoverMyMeds®**, Accredo will use this system to expedite the PA process. All PA follow-up is coordinated by Accredo
- Accredo will check for status updates on the PA process until it receives a coverage decision
  - If a denial is received, Biogen and Accredo can help navigate the appeal process
- Accredo will call your practice or facility to receive verbal confirmation of the shipment date and location

GUIDE

For additional information, including the prescription for specialty pharmacy, please visit **SPINRAZA-hcp.com** and refer to the SPINRAZA Start Form.



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.

This prescription for specialty pharmacy box can be found on the Start Form on SPINRAZA-hcp.com

CoverMyMeds® is a registered trademark of CoverMyMeds, LLC.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

FINANCIAL ASSISTANCE OPTIONS

FINANCIAL ASSISTANCE OPTIONS FOR SPINRAZA® (nusinersen)

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

There are 2 ways in which your patients may be eligible for financial assistance from the Biogen Copay Program: for SPINRAZA itself and for the treatment procedure.

Please note that these are 2 different programs, and your patients must enroll separately as needed.

Drug Copay Program

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

Individuals receiving coverage from Medicare, Medicaid, Veterans Affairs/DoD, TRICARE®*, or any other governmental or pharmaceutical assistance may not be eligible. Contact a Lead Case Manager (LCM) for more information.

Procedure Copay Program

In addition to the above criteria, your patients are eligible for this program if they meet the following requirements:

- They are not a resident of Massachusetts, Minnesota, or Rhode Island
- Their healthcare provider submits a request for treatment using an approved procedure code for anesthesia, imaging procedures, and/or surgical procedure/drug administration. Only codes approved by Biogen shall be eligible under the program

Third-Party Funding Assistance

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

The Free Drug Program

This program can temporarily provide Biogen products free of charge for individuals who meet certain financial eligibility criteria such as residency requirements, therapy status, income, and insurance coverage.

Individuals approved and enrolled in the Free Drug Program are required to notify the program if their insurance or financial circumstances change during their enrollment, in order to be reassessed.

The Free Drug Program only covers the cost of the drug. It is not responsible for costs associated with administration of therapy, such as office visits, administration costs, or other professional services.

SMA360™ Support services from Biogen

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

*TRICARE is a registered trademark of the Department of Defense (DoD), Defense Health Agency. All rights reserved.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

FINANCIAL ASSISTANCE OPTIONS FOR SPINRAZA® (nusinersen) (cont'd)

Best practices for financial and insurance assistance options:

- Verify and document eligibility for financial assistance programs
- Counsel the patient and their family on the financial assistance options that they are eligible
- SMA360° can help inform the patient's family about potential cost-sharing responsibility, discuss potential implications, and review potential financial assistance options

Patient Cost-Sharing Considerations

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

Patient cost-sharing considerations

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

Coinsurance: A beneficiary cost-sharing amount that begins after the deductible is paid; coinsurance typically is based on a percentage of the cost of services and varies by 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 plan. This limit does not apply to premiums, balance-billed charges from out-of-network healthcare providers (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.

For additional information about Biogen financial and insurance assistance, please refer to the SPINRAZA Guide to Financial Assistance Options or contact SMA360°.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

RELEVANT CODES AND SAMPLE CLAIM FORMS

RELEVANT CODE AND SAMPLE CLAIM FORM GUIDE INTRODUCTION

This guide provides an overview of best practices to assist with coding for procedures related to SPINRAZA administration and ancillary services (if needed). It also provides examples of claim forms and guidance on how to complete them. For a more comprehensive presentation of applicable codes and claim forms, refer to the **Guide to SPINRAZA Reimbursement**, available at **SPINRAZA-hcp.com** or through your Biogen representative.

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

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

LINKS TO IMPORTANT RESOURCES

Medicare coverage for SPINRAZA is determined through individual MACs.

A map of MACs can be found at **www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs**.

For additional coverage information, visit the Medicare coverage database at

http://www.cms.gov/medicare-coverage-database/.

Note: CMS website links are subject to change. For the main CMS website, go to **www.cms.gov**.

CMS=Centers for Medicare & Medicaid Services; MAC=Medicare Administrative Contractor.

SUMMARY OF RELEVANT CODES FOR SPINRAZA

ICD-10-CM CODE EXAMPLES

ICD-10-CM Code[1]	Description[1]
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffmann]
G12.1	Other inherited spinal muscular atrophy Adult form spinal muscular atrophy Childhood form, type II spinal muscular atrophy Distal spinal muscular atrophy Juvenile form, type III spinal muscular atrophy [Kugelberg-Welander]

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

HCPCS CODE

HCPCS Code[2]	Description[2]
J2326	Injection, nusinersen, 0.1 mg

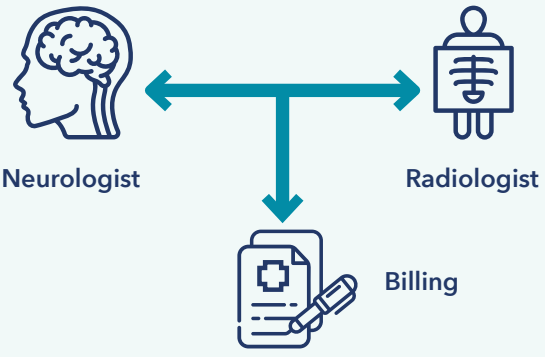
- **SPINRAZA has been assigned a permanent J-code, effective January 1, 2018. The C-code should no longer be used unless otherwise instructed by a health plan**

NDC NUMBER

NDC Number[3]		Description[3]
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)

COMMUNICATION IS KEY

CROSS-DEPARTMENT COMMUNICATION IS ESSENTIAL FOR PROPER CODING ALIGNMENT



HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

RELEVANT CPT® CODES FOR SPINRAZA

CPT® CODE EXAMPLES

Procedure Type[4]	CPT® Code[4]	Description[4]
Surgical Procedure WITHOUT Imaging Guidance	**62270***	Spinal puncture, lumbar, diagnostic
	62272*	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)
	62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
	96450	Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture
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) (list separately in addition to code for primary procedure)
	77012	CT guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
	77021	MRI guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
Surgical Procedure WITH Imaging Guidance	**62323**	Injection(s) of diagnostic or therapeutic substance(s) as described in code 62322; with imaging guidance (ie, fluoroscopy or CT)
	62328†	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance
	62329‡	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance
IMPORTANT: Note that 62270 (spinal puncture, lumbar, diagnostic) and 62272 (spinal puncture, therapeutic, for drainage of cerebrospinal fluid [by needle or catheter]) are still valid codes. These codes should now be used only if there is no imaging guidance (fluoroscopic or CT) used during the procedure.		

CNS=central nervous system.

*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 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.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

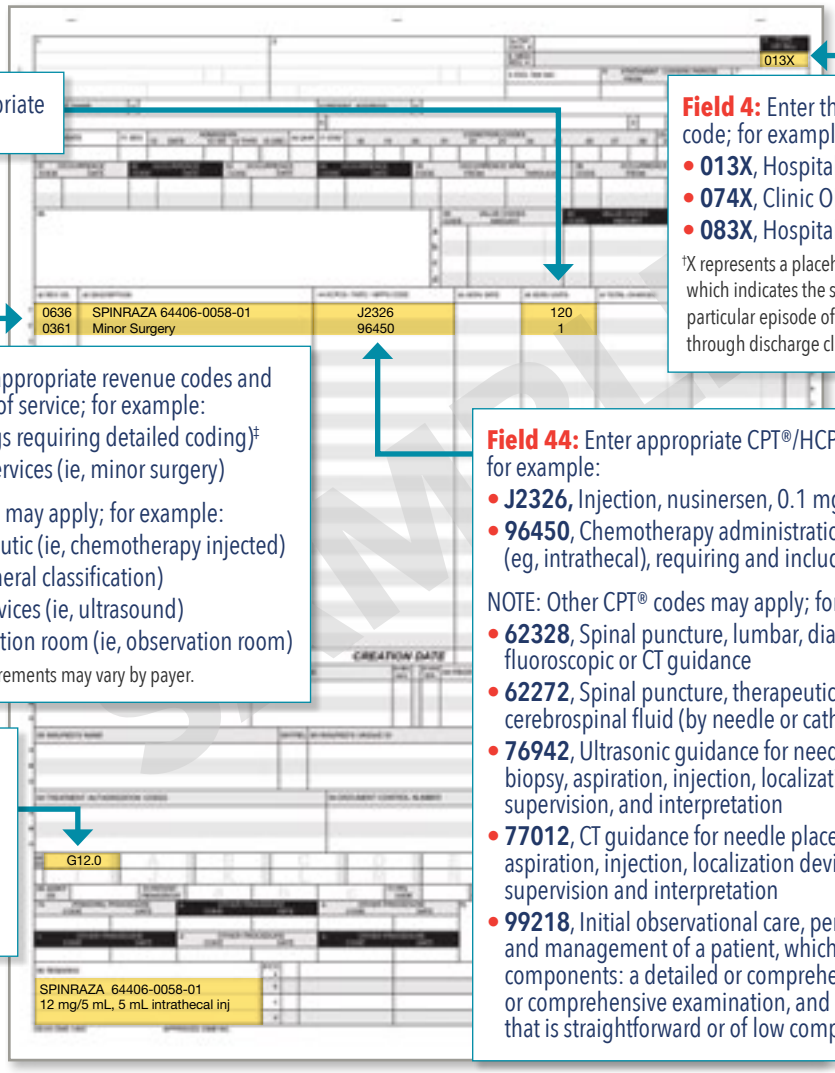
RELEVANT CPT® CODES FOR SPINRAZA (cont'd)

CPT® CODE EXAMPLES (CONT'D)

Procedure Type[4]	CPT® Code[4]	Description[4]
Anesthesia	00635	Anesthesia for procedures in lumbar region (diagnostic or therapeutic lumbar puncture)
	99100	Anesthesia for patient of extreme age, younger than 1 year and older than 70 years (list separately in addition to code for primary anesthesia procedure)
Moderate (Conscious) Sedation	99151-99153, 99155-99157	Drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Coding is based on total intra-service time and the healthcare professional who is performing the procedure. For descriptions of individual codes, refer to the current CPT® Professional Edition
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, for the evaluation and management of a patient, including admission and discharge on the same date, which requires these 3 key components: a detailed or comprehensive history; a detailed or comprehensive examination; and varying levels of medical decision-making complexity

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]

ASC=ambulatory surgical center; OPT=outpatient physical therapy.

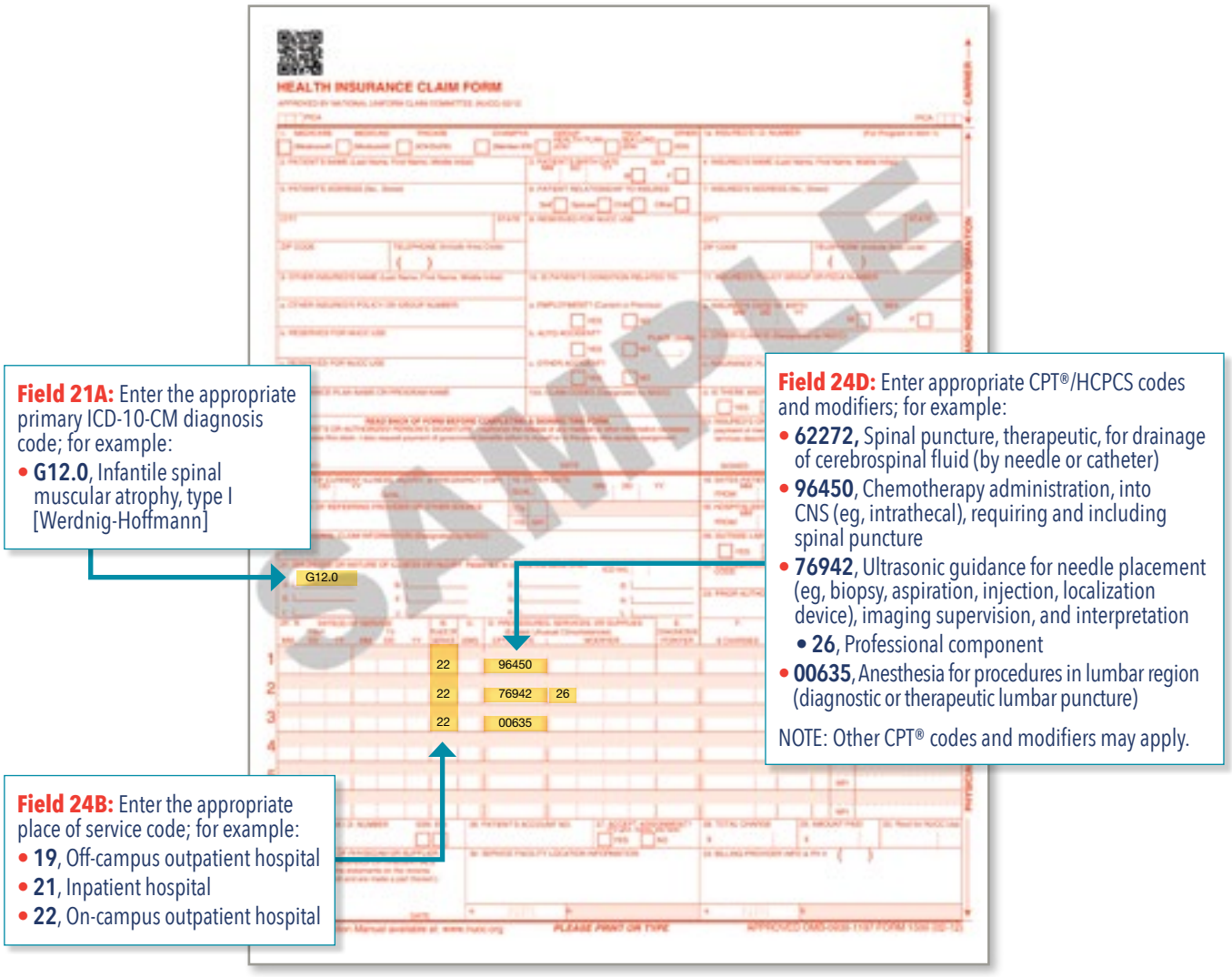
*Including off-campus clinic, on-campus facility, hospital-based ASC, and other outpatient outlets operated by a hospital.

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SAMPLE CMS-1500 CLAIM FORM

FOR PROFESSIONAL SERVICES



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

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

Field 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.

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

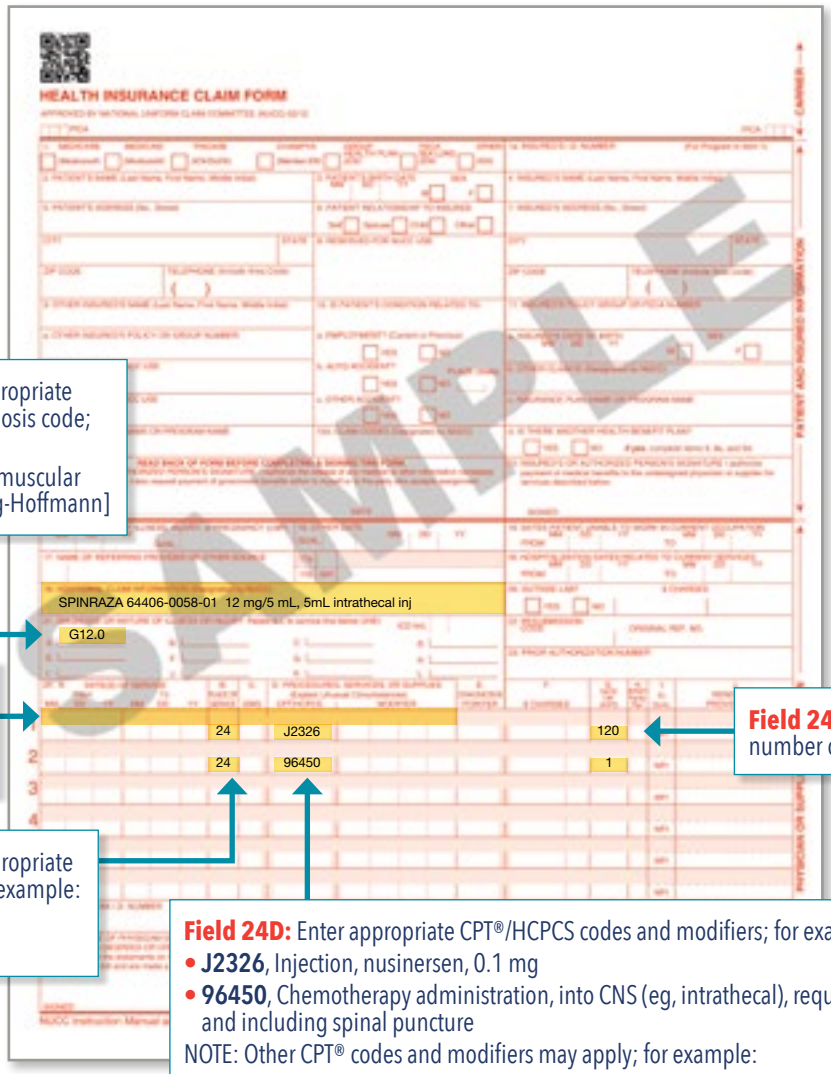
- **19**, Off-campus outpatient hospital
- **21**, Inpatient hospital
- **22**, On-campus outpatient hospital

Please see Important Safety Information on page 1 and full Prescribing Information.

SPINRAZA® (nusinersen) injection 12 mg/5 mL

SAMPLE CMS-1500 CLAIM FORM (cont'd)

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

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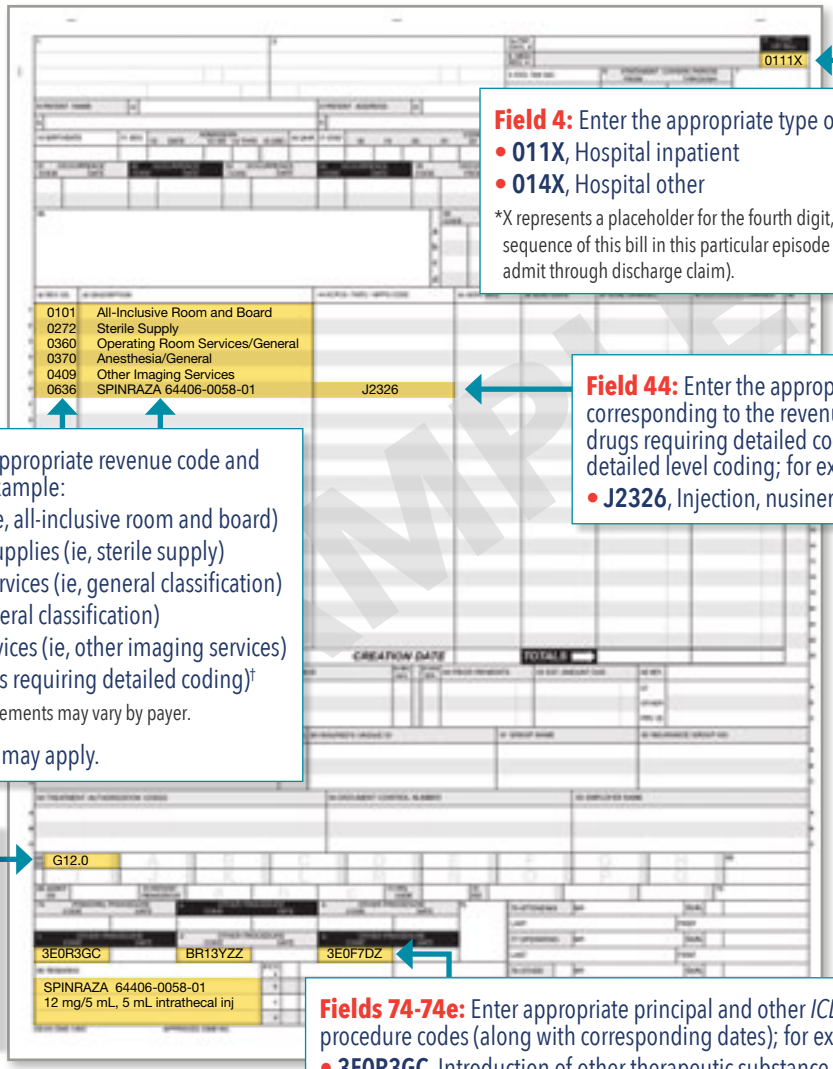
SPINRAZA® (nusinersen) injection 12 mg/5 mL

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

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

References: 1. ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Accessed August 10, 2021. **2.** HCPCS Code J2326. HCPCS. Codes website. https://hcpcs.codes/j-codes/J2326/. Accessed August 10, 2021. **3.** SPINRAZA [Prescribing Information] Cambridge, MA: Biogen. **4.** American Medical Association. *CPT® 2021 Professional Edition*. Chicago, IL: American Medical Association; 2020.

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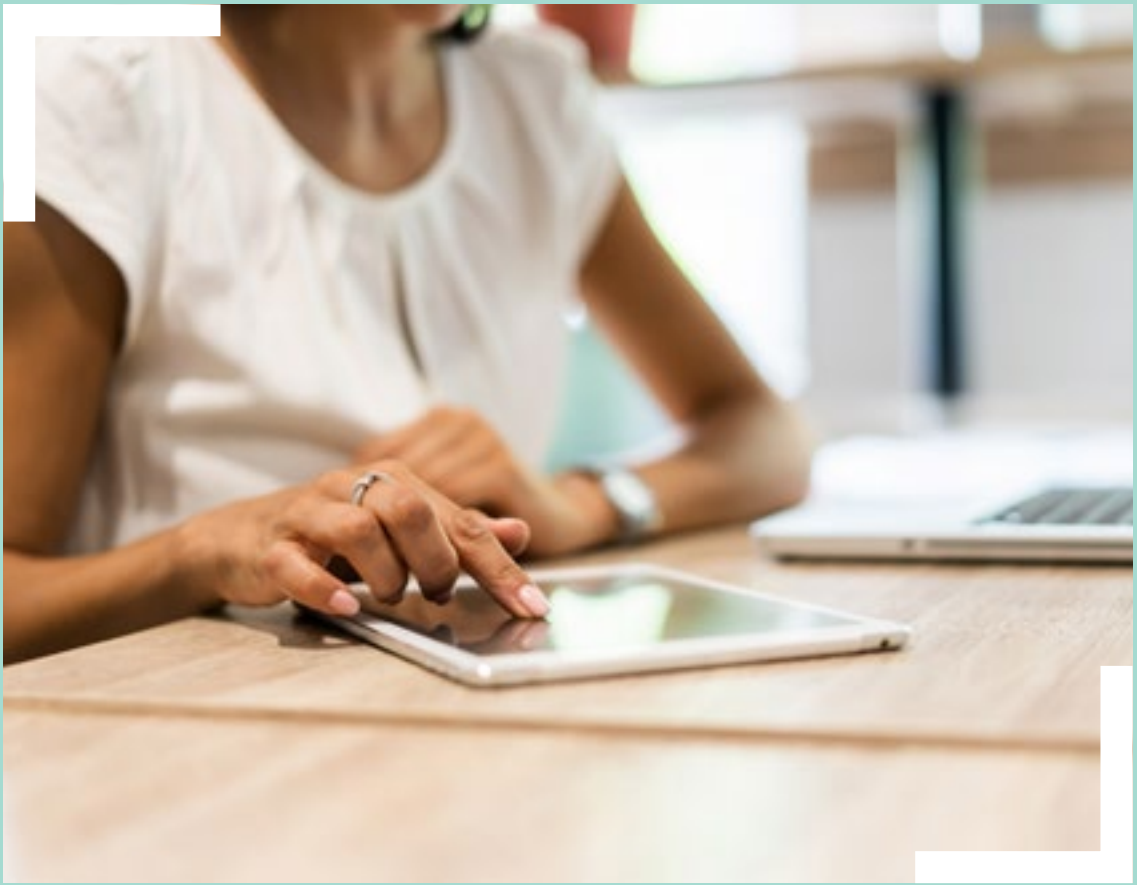
OFFICE RESOURCES



OFFICE RESOURCES TABLE OF CONTENTS

This section provides resources to support your practice or facility in navigating product access for patients who have been prescribed SPINRAZA® (nusinersen).

PRIOR AUTHORIZATION SUBMISSION GUIDE FOR SPINRAZA® (nusinersen)

STEPS AND BEST PRACTICES TO COMPLETING A PRIOR AUTHORIZATION (PA)

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

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

Step 1: Complete and submit the PA request

- Identify, review, and document any payer-specific requirements for authorization requests
- Fill out the appropriate PA form for that health plan and include supplemental documents to strengthen the request
  - Most prior authorizations for SPINRAZA include: a genetic test, baseline physical therapy evaluation, clinical notes, and a letter of medical necessity
- Be sure to communicate with a patient navigator who oversees the logistics of coordinating each patient treatment throughout the facility

Step 2: Track the status of the request

- Maintain a thorough log of the PA submissions and denials for each patient, as this information will be needed if the patient wishes to apply for financial support services from SMA360°

Step 3: Follow up as needed

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

One of the main reasons PA requests are denied is incomplete or inaccurate information on the PA form. Dedicating staff to manage/oversee the authorization process can reduce administrative denials.

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

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MEDICAL EXCEPTIONS GUIDE FOR SPINRAZA® (nusinersen)

STEPS AND BEST PRACTICES FOR REQUESTING A MEDICAL EXCEPTION

An ME communicates a physician's request to use a medication (citing the patient's individual circumstances) that is nonpreferred or not covered by the patient's health plan.

Step 1: Complete the ME request with a letter of medical necessity for SPINRAZA, as needed

- Find out if the health plan has its own ME request form or will accept a separate letter from your office
- Refer to the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA** for important information you may want to include with the ME request

Step 2: Submit and track your ME request

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

BEST PRACTICES

Provide background on your patient's condition:

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

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

- Provide a clinical justification supporting SPINRAZA treatment for your patient and cite any relevant literature
- State any patient-specific reasons for the treatment choice
- Review the health plan's medical policy criteria and point out the criteria that your patient meets. Explain why your patient should be excluded from any criteria that he or she does not meet

Providing additional documentation that supports your decision may strengthen your request:

- General medical history listing comorbidities and any medication history, if appropriate
- Letters from other healthcare professionals (such as physical therapists or nurses) that support your treatment choice
- Clinical information regarding your treatment choice

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

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APPEALS GUIDE FOR SPINRAZA® (nusinersen)

STEPS FOR APPEALING A DENIAL

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

Step 1: Understand the reason for the denial

- Identify the reason that treatment was denied and contact the health plan to find a way to resolve the matter

Step 2: Appeal the denial

- Complete the health plan's appeal request form and follow important guidelines and timeframes
- Refer to the **Guide to Developing Letters of Medical Necessity and Letters of Appeal for SPINRAZA** and the **Letter of Medical Necessity/Appeal Template for SPINRAZA**, available at **SPINRAZA-hcp.com**, for support and for information you may want to include with your appeal request

Step 3: Monitor the appeal

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

There are often multiple levels of appeal depending on the health plan. Please be sure to connect with the health plan directly to discuss all options for appeal.

Work with your SMA360° team to explore other options.

If the appeal is denied

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

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PATIENT SCHEDULING LOGISTICS

SITE OF CARE PATIENT NAVIGATOR

Patient coordination is a key component in managing the SPINRAZA patient experience. Designating a patient navigator at your site of care to provide centralized coordination can help ensure consistent communication between all stakeholders involved in SPINRAZA patient care.

Responsibilities of a patient navigator at your site of care can include:

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PATIENT SCHEDULING LOGISTICS (cont'd)

SCHEDULING AND CAPACITY

Inconsistent appointment scheduling practices or unexpected scheduling changes can affect access to treatment for SPINRAZA patients.

Best practices for scheduling SMA patients' appointments and ensuring predictable access to providers who administer SPINRAZA:

- Proactively **educate scheduling staff** about the logistical needs SPINRAZA patients may require and the importance of maintaining predictable appointment schedules
  - SPINRAZA patients may need to travel out of state for appointments
  - Travel time in or to metropolitan areas can be substantial

- Document patients' expected travel times or other logistical considerations and **communicate them directly to healthcare providers**

- Work with **administration site providers and staff** to ensure the administering physician will be available as scheduled or that another qualified provider can be available if needed

- When possible, increase efficiencies by scheduling specific days and procedure rooms to administer SPINRAZA

myBiogen™ TOOL


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Your patients. Our focus.
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Your patients are our focus

myBiogen is a treatment-tracking portal designed to help you start and continue patients on their Biogen therapy.

The tools at your fingertips are:

Alerts—notifications of tasks that need attention and next steps for your patients' therapy

Digital Start Forms—where you can enroll patients on a Biogen therapy

My Patients—a tracking system to monitor the progress of your Biogen-consented patients

Helpful Links—additional patient support, including CoverMyMeds, TOUCH On-Line, and no-charge genetic testing


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