



GUIDE TO BENEFITS INVESTIGATIONS

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 page 8 and accompanying full Prescribing Information.

INVESTIGATING BENEFITS

A Benefits Investigation is an important step to complete to determine drug and ancillary procedure medical coverage for patients prescribed SPINRAZA. It will help define health plan requirements based on the patient's benefits and the individual care plan.

BEGINNING THE BENEFITS INVESTIGATION

A Benefits Investigation is a process that enables a provider to determine benefit design, coverage requirements, and coding guidance. There are many variables associated with each patient's benefits, and there may be differences by state and/or by site of care. There may be patients who travel to an out-of-state or out-of-network facility for administration of SPINRAZA. It is important to capture this information upfront during the Benefits Investigation process so that your practice or facility can submit the claim to be reimbursed for SPINRAZA and for its administration.

Step 1: GATHER PATIENT AND PROVIDER INFORMATION

✓ Contact information

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

✓ Insurance information

- Policy holder 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 health plan information (eg, commercial, Medicaid)

✓ 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

EPO=exclusive provider organization; HMO=health maintenance organization; NPI=National Provider Identifier; OOP=out of pocket; POS=point of service (plan); PPO=preferred provider organization.

SELECTED IMPORTANT SAFETY INFORMATION

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

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Step 2: CONTACT THE HEALTH PLAN TO DETERMINE BENEFITS

Gather the following information:

✓ Coverage

- Covered Prior authorization (PA) required Quantity

✓ Patient cost

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

Step 3: KEEP ACCURATE RECORDS OF THE BENEFITS INVESTIGATION

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

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

BENEFITS INVESTIGATION CONSIDERATIONS

Each individual health plan determines its own coverage policy. There is no specific timeline for policy development and some plans may never develop a policy. If a health plan has not conducted a formal coverage determination for a product, coverage may be granted on a case-by-case basis. During that time, providers will likely need to complete additional requirements, such as precertification/PA or medical exception, in order to gain coverage for the drug, its administration services, and, possibly, the site of care.

A **Benefits Investigation Worksheet** is available to help you gather information about a patient's coverage while engaging with his or her health plan. The worksheet is available at spinraza-hcp.com.



SMA360° PATIENT SUPPORT SERVICES AND BENEFITS INVESTIGATION

If your patient is enrolled, 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.

SELECTED IMPORTANT SAFETY INFORMATION

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

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EXAMPLES OF KEY BENEFITS INVESTIGATION CONSIDERATIONS

Your Biogen representative is also available to provide you with additional information about Benefits Investigations.



Preauthorization/precertification and required documentation

Health plans may require an authorization of coverage prior to treatment with SPINRAZA

- Determine if preauthorization/precertification is required for SPINRAZA, administration services (such as surgical procedures, imaging guidance, and hospital observation), and/or the site of care
- Determine if the patient is covered under the medical benefit or pharmacy benefit
- In addition, establish if specific documentation is required before the plan will approve the product, administration-related services, and/or site of care



Medical exception

When a patient does not meet SPINRAZA coverage requirements stated in health plan policy, or no policy is in place, coverage may be obtained through the medical exception process, which tends to vary among health plans

- Determine if there is a medical exception process and, if so, what type of documentation is required to demonstrate medical necessity



Health plan reimbursement methodology

Payer reimbursement methodology for facility and professional services may vary substantially across sites of care

- The facility and/or professional services may be subject to some form of global payment rules or prospectively set reimbursement rates (eg, global surgery payment, diagnosis-related group [DRG]-based payment)
- The payment for SPINRAZA may be separate or may be bundled within a prospectively set rate (eg, DRG-based rate, per diem rate)



Observation stay rules

For patients who may require additional monitoring after SPINRAZA administration, health plans may cover an outpatient observation stay for up to 48 hours

- Clarify the parameters that the health plan may cover for length of stay for an outpatient observation

SELECTED IMPORTANT SAFETY INFORMATION

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

Cases of rash were reported in patients treated with SPINRAZA.

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

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

- Verify the network and/or state participation status for the physician(s) and/or facility involved in the administration of SPINRAZA. Patients may be required or encouraged to seek care from in-network or in-state providers
- Investigate and record the patient OOP cost implications for out-of-network and/or out-of-state providers. OOP costs may be higher for patients seeking treatment through these providers
- Find out if there is an exception process for patients seeking care out of network and/or out of state



Coordination of benefits between multiple health plans

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

- In the case of multiple health plans, it is important to establish during the Benefits Investigation which payer is primary, which is secondary, and which is tertiary
- Once you have established the order of benefits, follow the instructions from each health plan regarding coordination of benefits



Patient financial responsibility

Patient OOP costs may vary based on the specific benefit design, site of care, 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

RESULTS OF A BENEFITS INVESTIGATION

If the Benefits Investigation determines that SPINRAZA is not covered by the health plan, you will need to submit a request for a medical exception. Please refer to the **Guide to Requesting Medical Exceptions and Appealing Denials** for more information about medical exceptions.

If SPINRAZA is covered, but a PA is required, refer to the **Guide to Prior Authorization Submissions** for more information about the PA process.

Both of these resources are available for download at spinraza-hcp.com.

SELECTED IMPORTANT SAFETY INFORMATION

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

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AN ADDITIONAL CONSIDERATION: MEDICAL BENEFIT AND PHARMACY BENEFIT INSURANCE CARDS

Another important consideration for your practice or facility is the determination of coverage based on the patient's insurance cards. For patients who have been prescribed SPINRAZA, it is important to gather as much information as possible.

DEPENDING ON THE HEALTH PLAN, SPINRAZA WILL MOST LIKELY BE COVERED UNDER THE MEDICAL BENEFIT, BUT MAY BE COVERED UNDER THE PHARMACY BENEFIT

- **Medical benefits** generally cover drugs, such as SPINRAZA, that are injected or infused by a healthcare professional in the doctor's office, infusion center, or hospital outpatient center¹
- **Pharmacy benefits** generally cover drugs that are self-administered orally, given by injection, or inhaled¹

PATIENTS WITH COMMERCIAL INSURANCE: 1 CARD OR 2 CARDS

Pharmacy benefits vs medical benefits can be determined based on the patient's insurance cards. Here's how:

1 CARD for both medical and pharmacy benefits. Health plans may combine the medical and pharmacy benefits into 1 program. The patient will have 1 card that includes member identification information (eg, group number and member number) for both the medical and pharmacy benefit. The card may also include copay or coinsurance costs for doctor's office, specialist, and emergency room visits. Insurance cards for both benefits typically note the pharmacy benefit with terms such as "prescription" or "Rx."

Health Star Insurance		<i>Comet Employer Group</i>	
Member Name John Doe	Dependent Name Jane Doe	Copays/Coinsurance Primary Care \$20 Specialist \$40 Urgent Care \$40 ER \$100	
Member ID EXP000099900	Group No. 32155-000 Effective Date 11/01/11	Plan STANDARD/OPTION	
Rx 			

→ Patient copays for office and emergency room visits indicate the medical benefit

→ The Rx symbol indicates that the pharmacy benefit is included on this card

For illustrative purposes only.



Remember to reverify your patient's benefits prior to each dose of SPINRAZA, as the health plan coverage may have changed since the patient's last procedure.

SELECTED IMPORTANT SAFETY INFORMATION

The most common adverse reactions ($\geq 20\%$ of SPINRAZA-treated patients and $\geq 5\%$ more frequently than in control patients) that occurred in the infantile-onset controlled study were lower respiratory infection and constipation. Serious adverse reactions of atelectasis were more frequent in SPINRAZA-treated patients (18%) than in control patients (10%). Because patients in this controlled study were infants, adverse reactions that are verbally reported could not be assessed. The most common adverse reactions that occurred in the later-onset controlled study were pyrexia, headache, vomiting, and back pain. Post-lumbar puncture syndrome has also been observed after the administration of SPINRAZA.

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 **SPINRAZA**[®]
(nusinersen) injection
12 mg/5 mL

2 CARDS: 1 for the medical benefit and 1 for the pharmacy benefit. Health plans may use a third-party provider for the pharmacy benefit, such as a pharmacy benefit manager. In this instance, the patient will have 1 card for the medical benefit that does not include pharmacy benefit information and another card with pharmacy benefit information.

ProVantage Health Insurance		<i>Preferred Provider Network</i>	
MEMBER NAME John Q Proof			
MEMBER ID ABC101202303			
GROUP Plan	PBMJ63 123456	Prevention Primary Care Specialist	\$0 \$25 \$45

Patient copays indicate the medical benefit

Lack of prescription information indicates that patient has a separate pharmacy benefit card

Benefit Rx	Prescription Card
JOHN Q PROOF ID 123456789	
RXBIN: 610029 RXPCN: CRK RXGRP: CMCDX Issuer: 80840	

"Prescription Card" indicates that this is a pharmacy benefit card

Rx identification numbers indicate the pharmacy benefit information

For illustrative purposes only.

Before a patient leaves the office, check the medical insurance card information to determine whether you need to obtain the pharmacy benefit information from a different card.

PATIENTS WITH MEDICAID: 1 CARD

These patients are likely to have a single card for all benefits. The appearance of Medicaid cards varies by state and may include the name of the health plan that administers the benefits.

Your Texas Benefits Health and Human Services Commission	Medicaid Program Name
Medicaid ID Card	
Member name: John Doe	Medical plan / plan médico Plan Name / nombre del plan 1-800-###-####
Member ID (Medicaid ID): 123456789	Dental plan / plan dental Plan Name / nombre del plan 1-800-###-####
Issuer ID: (09940) XXXXXXXXXX	Date Card Sent: 03/01/2012
RxBIN: 001111	
RxPCN: ADV	
RxGRP: RX1234	

Member ID is used for the medical benefit

Pharmacy information should be used for the pharmacy benefit

For illustrative purposes only.

KNOWING WHICH INSURANCE CARD TO USE ON THE SPINRAZA START FORM MAY HELP PATIENTS RECEIVE SMA360° SUPPORT SERVICES QUICKLY

If you are prescribing SPINRAZA, it may be necessary to fill out the SPINRAZA Start Form to enable patients to access SMA360°. Correctly completing the patient insurance information on the form can help to ensure that the request is processed in a timely manner. Also, a completed Start Form will enable your practice or facility to get assistance with your patient's Benefits Investigation from SMA360°.

If your patient has coverage under more than one health plan, please be sure to include all of the relevant patient insurance information on the SPINRAZA Start Form.

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Reference: 1. Midwest Business Group on Health. Managing the rising costs of specialty pharmacy [presentation]. January 29, 2014. http://ehcark.org/site/1747ehca/EHC_Arkansas_FINAL_012914.ppt. Accessed April 4, 2018.

