

DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

POLICY: Spinal Muscle Atrophy – Spinraza Drug Quantity Management Policy –

Per Days

• Spinraza® (nusinersen intrathecal injection – Biogen)

REVIEW DATE: 04/12/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Spinraza, a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, is indicated for the treatment of **spinal muscular atrophy** in pediatric and adult patients.¹

Dosing

Spinraza is given intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.¹ The recommended dosage is 12 mg (5 mL) per administration. Initiate Spinraza treatment with four loading doses. The first three loading doses should be administered at 14-day intervals. The fourth loading dose should be given 30 days after the third dose. A maintenance dose should be given once every 4 months thereafter. The safety and effectiveness of Spinraza in pediatric patients from newborn to 17 years of age have been established. If a loading dose (or any of the four loading doses) is missed, administer the missing load dose as soon as possible. Then, adjust the date for subsequent doses to maintain the recommended interval between doses. Regarding missed maintenance doses, if it is less than 8 months from the last dose, give the missed maintenance dose as soon as possible; administer the next maintenance dose per the originally scheduled date as long as these two doses are given at least 14 days apart. For a

missed maintenance dose that is at least 8 months but less than 16 months from the last dose, give the missed maintenance dose as soon as possible, followed by one additional dose 14 days later; administer the next maintenance dose 4 months thereafter. For a missed maintenance dose at least 16 months but less than 40 months from the last dose, give the missed maintenance dose as soon as possible, followed by two additional doses 14 days apart; give the next maintenance dose 4 months thereafter. If it has been at least 40 months from the last missed maintenance dose, restart dosing.

Availability

Spinraza is available as a 12 mg/5 mL (2.4 mg/mL) solution in a single-dose glass vial.¹

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of Spinraza in the treatment of spinal muscular atrophy. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration outlined below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 120 Days*	Home Delivery Maximum Quantity per 120 Days*
Spinraza [®]	12 mg/5 mL vial	1 vial	1 vial
(nusinersen injection)			

^{*}This is a quantity sufficient for a 120-day supply at a dose of 12 mg every 4 months.

Spinal Muscle Atrophy – Spinraza Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Spinraza 12 mg/5 mL vials

- **1.** If the patient is initiating treatment, approve a one-time override of 4 vials at retail or home delivery.
- **2.** If the patient misses a maintenance dose at least 8 months but less than 16 months after their last dose, approve a one-time override for 2 vials at retail or home delivery.
- **3.** If the patient misses a maintenance dose at least 16 months but less than 40 months after their last dose, approve a one-time override for 3 vials at retail or home delivery.

4. If the patient misses a maintenance dose at least 40 months after their last dose, approve a one-time override for 4 vials at retail or home delivery.

REFERENCES

1. Spinraza® intrathecal injection [prescribing information]. Cambridge, MA: Biogen; February 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual	No criteria changes.	08/23/2022
Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	
Update	Policy statement was corrected to state that all approvals are for the duration outlined below. Criteria for Spinraza 12 mg/5 mL vials were clarified that the one time override is as a 90-day supply.	11/16/2022
Early Annual	Spinraza 12 mg/5 mL vials. New overrides added:	04/12/2023
Revision	 If the patient misses a maintenance dose at least 8 months but less than 16 months after their last dose, approve a one-time override for 2 vials at retail or home delivery. If the patient misses a maintenance dose at least 16 months but less than 40 months after their last dose, approve a one-time override for 3 vials at retail or home delivery. If the patient misses a maintenance dose at least 40 months after their last dose, approve a one-time override for 4 vials at retail or home delivery. 	

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