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

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

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® (nusinersen injection)	12 mg/5 mL vial	1 vial	1 vial

*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 Revision	No criteria changes. Policy was updated to include the existing quantity limits when the product is obtained via home delivery.	08/23/2022
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 Revision	**Spinraza 12 mg/5 mL vials.** New overrides added: • 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.	04/12/2023