DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Spinal Muscle Atrophy – Spinraza Drug Quantity Management Policy – Per Days
- Spinraza® (nusinersen injection – Biogen)

REVIEW DATE: 08/23/2022

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.

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

Automation: None.

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.

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, as a 90-day supply.

REFERENCES
1. Spinraza® intrathecal injection [prescribing information]. Cambridge, MA: Biogen; June 2020.