

## DRUG QUANTITY MANAGEMENT POLICY - PER DAYS

**POLICY:** nusinersen injection (Spinraza® - Biogen) Duration Limit

**DATE REVIEWED:** 07/23/2020

### OVERVIEW

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

### Dosing

Spinraza is administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures. The recommended dosage is 12 mg (5 mL) per administration. Spinraza treatment is initiated with four (4) loading doses. The first three loading doses should be administered at 14-day intervals. The 4th loading dose should be administered 30 days after the 3rd dose. A maintenance dose should be administered once every 4 months thereafter. If a loading dose is delayed or missed, administer Spinraza as soon as possible, with at least 14-days between doses and continue dosing as prescribed. If a maintenance dose is delayed or missed, administer Spinraza as soon as possible and continue dosing every 4 months.

### Spinraza 12 mg/5 ml vial

Maximum quantity per 120 days = 1 vial

A quantity of one 12 mg/5 ml vial every 120 days will be allowed without coverage review. This is enough drug for a 120-day (4 months) supply of 12 mg every 4 months. Exceptions are allowed for patients initiating therapy.

The objective of this program is to manage potential premature dose escalation of Spinraza in the treatment of SMA. This Drug Quantity Management Policy has been developed to complement the coverage provided by *Spinraza Prior Authorization Policy*. Consult the *Spinraza Prior Authorization Policy* for detailed information about evidence-supported approved treatment regimens and durations.<sup>2</sup>

### CRITERIA

All approvals are provided for 1 year in duration unless otherwise noted below. Authorization for additional quantities of Spinraza vials is recommended in those who meet one of the following criteria:

### Spinraza 12 mg/5 ml vials

1. For patients initiating treatment, a one-time override of 4 x 12 mg/5 ml vials may be approved.

### REFERENCES

1. Spinraza® [prescribing information]. Cambridge, MA: Biogen; June 2020.
2. Spinraza Prior Authorization Policy. Updated 06/03/2020.