Reference number(s)
2133-A

STANDARD MEDICARE PART B MANAGEMENT

Spinraza (nusinersen)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist or neuromuscular specialist.

III. CRITERIA FOR INITIAL APPROVAL

Spinal muscular atrophy (SMA)
Authorization of 12 months may be granted for treatment of SMA when all of the following criteria are met:
A. Member has a diagnosis of SMA confirmed by genetic testing showing deletion or mutation at the SMN1 allele.
B. Member has Type 1, Type 2 or Type 3 SMA.
C. Member will not use Spinraza and Evrysdi concomitantly.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Spinraza.
B. Spinraza is being prescribed by a specialist listed in Section II.
C. Spinraza is being used to treat an indication enumerated in Section III.
D. The member is receiving benefit from therapy.
E. Member will not use Spinraza and Evrysdi concomitantly.

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V. REFERENCES

1. Spinraza [package insert]. Cambridge, MA: Biogen Inc.; June 2019.
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3. Burgunder JM, Schols L, Baets J, et al. EFNS guidelines for the molecular diagnosis of neurogenetic disorders: motoneuron, peripheral nerve and muscle disorders. *European J Neurol*. 2011;18:207-217.
4. Finkel RS, Chiriboga CA, Vajsar J, et al. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. *Lancet*. 2016;388:3017-26.
5. Ionis Pharmaceuticals, Inc. A Study to Assess the Efficacy and Safety of IONIS-SMN Rx in Infants with Spinal Muscular Atrophy. In: ClinicalTrials.gov [internet]. Bethesda (MD): National Library of Medicine (US). 2000- [2016 Feb 14]. Available from: https://clinicaltrials.gov/ct2/show/NCT02193074**.**
6. Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus sham control in later-onset spinal muscular atrophy. *N Engl J Med*. 2018; 378:625-635.
7. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard care in spinal muscular atrophy. *J Child Neurol*. 2007;22(8):1027-1049.