



Spinraza® (nusinersen)

When requesting Spinraza® (nusinersen), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

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

Approved Off-label Compendial use(s)

None

Coverage Guidelines

For Spinal muscular atrophy (SMA), an individual must meet all of the following criteria:

- The diagnosis has been confirmed by genetic testing showing either homozygous mutation or deletion of the *SMN1* gene on chromosome 5q OR compound heterozygous mutation of the *SMN1* gene on chromosome 5q
- Has SMA type I or II
- For an initial authorization request, an individual has obtained baseline motor milestones using the appropriate exam(s) based on individual's age and motor ability
- For a re-authorization request, an individual is responding to Spinraza therapy (e.g., improvement in motor milestones, maintenance of motor milestones, achievement of new motor milestones)

Approval duration (initial and renewal): 12 months

References

1. Spinraza [prescribing information]. Cambridge, MA; Biogen Inc. May 2017. Available at: https://www.spinraza.com/content/dam/commercial/specialty/spinraza/caregiver/en_us/pdf/spinraza-prescribing-information.pdf. Accessed on October 2, 2017.
2. Arnold WD, Kassar D, Kissel JT. Spinal Muscular Atrophy: Diagnosis and Management in a New Therapeutic Era. *Muscle Nerve* 2015;51(2):157-167.
3. Finkel RS, Chiriboga CA, Vajsaar J, et al. Treatment of Infantile-onset spinal muscular atrophy with nusinersen: a phase2, open-label, dose-escalation study. *Lancet* 2016;388(10063):3017-3026.

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