

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.

Coverage Guidelines

Treatment of spinal muscular atrophy (SMA)

An individual must meet **ALL** of the following criteria for approval:

- Had a genetic test done confirming the diagnosis of SMA with bi-allelic mutations in the *survival motor neuron 1 (SMN1)* gene reported as at least one of the following: homozygous deletion, homozygous mutations, or compound heterozygous mutation
- Has 2 or 3 survival motor neuron 2 (SMN2) gene copies OR has 4 or more SMN2 gene copies with symptoms consistent with Types 1, 2, or 3 SMA
- Has not received Zolgensma in the past
- The following laboratory tests will be evaluated prior to the administration of Spinraza: prothrombin time and/or activated partial thromboplastin time, platelet count, and quantitative spot urine protein test
- Spinraza is prescribed by or in consultation with a physician who specializes in the management of spinal muscular atrophy and/or neuromuscular disorders
- For a re-authorization request, an individual is also responding to Spinraza therapy (e.g., improvement, achievement, and/or maintenance in motor milestones, reduced need for respiratory support, prevention of permanent assisted ventilation)

Approval duration (initial and renewal): 12 months

Dosing Recommendation

Spinraza is administered intrathecally.

The recommended dose is 12 mg (5mL) per administration. Initiate Spinraza treatment with 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.

References

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