Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Spinraza® (nusinersen)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Spinal muscular atrophy (SMA) is a rare, progressive neuromuscular disorder caused by a defect in the survival of the motor neuron 1 (SMN1) gene, which leads to a deficiency of SMN protein. The disease progressively destroys motor neurons—nerve cells in the brain stem and spinal cord that control essential skeletal muscle activity such as speaking, walking, breathing, and swallowing, leading to muscle weakness and atrophy. Motor neurons control movement in the arms, legs, chest, face, throat, and tongue.

Spinraza, an antisense oligonucleotide, was the first SMA drug approved by the Food and Drug Administration in 2016. At the time of approval, Spinraza was only studied in symptomatic, infantile-onset patients less than seven months of age at the time of first dose. Since then, clinical trial data in both later-onset SMA and presymptomatic infants showed positive outcomes and were subsequently incorporated into the Spinraza prescribing information. Additional clinical trials are in the pipeline.

Food and Drug Administration - Approved Indications

Spinraza (nusinersen) is a survival motor neuron-2 (SMN2)-directed antisense oligonucleotide indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Spinraza when **ALL** the following criteria are met:

1. The Member has a documented diagnosis of spinal muscular atrophy

Limitations

- Spinraza (nusinersen) may be authorized for 12 months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2326	Injection, nusinersen, 0.1 mg

References

1. Finkel RS, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. N Engl J Med 2017; 377:1723-1732.
2. Finkel RS, Mercuri E, Meyer OH, et al; SMA Care Group. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. Neuromuscul Disord. 2018;28(3):197-207.
3. Mercuri E, et al. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. N Engl J Med 2018; 378:625-635.

4. Mercuri E, Finkel RS, Muntoni F, et al; SMA Care Group. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. Neuromuscul Disord. 2018;28(2):103-115.
5. Spinraza (nusinersen) [prescribing information]. Cambridge, MA: Biogen Inc; April 2024.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).
- December 12, 2023: Removed the Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule (1/1/24).
- November 12, 2024: No change (eff 1/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.