Mass General Brigham
Health Plan

Spinal Muscular Atrophy (SMA) Agents
Spinraza (nusinersen)
Effective 07/01/2026

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions			

Overview
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.

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted for members when ALL the following criteria are met:

1. Diagnosis of Spinal Muscular Atrophy
2. Copy of genetic test confirming diagnosis of SMA (e.g. SMN1 homozygous gene deletion or mutation or compound heterozygous mutation)
3. **ONE** of the following:
    a. Copy of genetic test confirming member has 2 or 3 copies of SMN2
    b. Copy of genetic test confirming member has 4 copies of SMN2 and ONE of the following:
        i. Member is symptomatic
        ii. Member is a pre-symptomatic infant diagnosed via newborn screening
4. Prescriber is a neurologist or consult notes from a neurologist are provided
5. Current (within the last year) motor function test (e.g. Hammersmith Functional Motor Scale [HFMSE], Hammersmith Infant Neurological Examination [HINE], Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], World Health Organization [WHO] Motor Milestones, etc.)
6. Member has not previously received treatment with a gene therapy for spinal muscular atrophy
7. Member does not have evidence of permanent ventilator dependence defined as ANY of the following:
    a. Member has an endotracheal tube
    b. Member has a tracheotomy tube
    c. Member had at least 14 days of continuous respiratory assistance for at least 16 hours per day
8. Requested agent will NOT be used in combination with Evrysdi
9. Dosing is appropriate within the FDA labeling

Continuation of Therapy

Reauthorization may be granted when member meets **ALL** initial criteria and the following criteria:

1. Current motor function tests (defined as within the past 3 months or up to 12 months if the member is being followed regularly based on past test dates)
2. ONE of the following:
    a. Positive response to therapy as shown by improvement in motor function tests from baseline
    b. Medical necessity for continuing therapy (e.g., disease stabilization or a reduction in normal motor decline)
3. Member does not have evidence of permanent ventilator dependence defined as ANY of the following:
    a. Member has an endotracheal tube
    b. Member has a tracheotomy tube
    c. Member had at least 14 days of continuous respiratory assistance for at least 16 hours per day
4. Member has NOT previously received treatment with a gene therapy for spinal muscular atrophy

Limitations

1. Initial approvals will be granted for 7 months.
2. Reauthorizations will be granted for 12 months.

References

1. Bodamer OA. Spinal muscular atrophy. In Dashe JF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 Feb [cited 2020 Mar 4]. Available from: https://www.uptodate.com/contents/search.
2. U.S. National Library of Medicine. Spinal Muscular Atrophy [webpage on the Internet]. Bethesda (MD): Genetics Home Reference; 2017 [cited 2017 Jan 27]. Available from: https://ghr.nlm.nih.gov/condition/spinal-muscular-atrophy#definition.
3. Spinraza [package insert]. Cambridge (MA): Biogen, Inc.; 2024 Apr.

Review History

02/2017 – Reviewed by Clinical Experts
08/2017 – Revised (P&T approval)
11/2018 – Reviewed
03/18/2020 – Reviewed P&T Mtg
03/15/23 - Reviewed and updated for Mar P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Updated references. Updated approval durations to 7 months initial and 12 months reauth. Effective 4/1/23.
09/13/23 – Reviewed and updated for P&T. Removed documentation of baseline motor function skills, member being on established care with SMA care center, and member not having other factors. Effective 10/2/23
06/12/24 – Reviewed and updated for P&T. Updates included: 1) added standardize diagnosis verbiage and remove subtype restriction, 2) update restrictions for Spinraza to allow use in members with 2 or 3 copies of SMN2 or in certain patients with 4 copies of SMN2 (symptomatic, or pre-symptomatic infants), 3) recertification criteria adjusted to allow current functional tests to be >3 months (up to 12 months) old in situations where member is getting tested on a regular basis, 4) add criteria for Spinraza after utilization of Zolgensma. Effective 7/1/24
06/11/25 – Reviewed and updated for P&T. Part of annual UM review. Updated formatting and references. Effective 7/1/25
04/15/26 – Reviewed and updated for P&T. Removed criteria that allowed use after gene therapy and added restriction is previously utilized gene therapy. For recertification criteria, clarified functional tests are required for all requests regardless of response. Effective 5/11/26

6/10/26 – Reviewed and updated for P&T. Reauthorization criteria updated to limit use in patients who have previously received gene therapy. Further defined current motor function tests. Effective 7/1/26.