

Spinraza (nusinersen)
Effective 07/01/2024

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

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. If the member has previously received Zolgensma[®], **ALL** of the following:
 - a. Attestation that the member has had an inadequate response to Zolgensma[®]
 - b. Pre-treatment baseline motor function test (prior to treatment with any SMA agent)
 - c. Pre-Zolgensma[®] baseline motor function test (if different than pre-treatment baseline) ||
 - d. Post-Zolgensma[®] motor function tests ||
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

|| *Pre- and post-Zolgensma testing should be within 1 year pre- and post-Zolgensma administration.*

Continuation of Therapy

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

1. **ONE** of the following:
 - a. Current (within the past 3 months or >3 months [up to 12 months] if member is being followed regularly) motor function test documenting positive response to therapy based on the same test previously provided
 - b. Medical necessity for continuing therapy (e.g., disease stabilization or a reduction in normal motor decline)
2. 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

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.; 2020Jun.

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

