Mass General Brigham
Health Plan

Spinraza (nusinersen)
Effective 10/02/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

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 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. Members have a documented diagnosis of Type 1, 2 or 3 SMA or pre-symptomatic
2. ONE of the following:
    a. If pre-symptomatic, member has two copies of SMN2
    b. If SMA type 1, member has two copies of SMN2
    c. If SMA type 2 or 3, member is non-ambulatory
3. Copy of genetic test confirming diagnosis of SMA (e.g. SMN1 homozygous gene deletion or mutation or compound heterozygous mutation)
4. Prescriber is a neurologist or consult notes from a neurologist are provided
5. Baseline 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 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
7. Requested agent will NOT be used in combination with Evrysdi®
8. Appropriate dosing

Continuation of Therapy

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

1. ONE of the following:
    a. Current (within the past 3 months) 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