

Title: Spinraza (nusinersen)	Division: Medical Management Department: Utilization Management
Approval Date: 4/20/18	LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP
Effective Date: 4/20/18	Policy Number: UM-MP233
Review Date: 4/20/19	Cross Reference Number:
Retired Date:	Page 1 of 4

1. POLICY DESCRIPTION:

Spinraza (nusinersen) is indicated for the treatment of Spinal muscular Atrophy confirmed by SMN1 deletion.

All other indications are considered experimental/investigational and are not a covered benefit.

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

POLICY: Spinraza will be covered with prior authorization when the following criteria are met:

Initial Request:

1. The patient has a diagnosis of Spinal muscular atrophy confirmed by SMN1 deletion or 5q SGM homozygous gene deletion, a homozygous mutation or a compound heterozygote*.
 - a. The patient has no more than 2 copies of SMN2*

OR

 - b. The patient exhibited onset of clinical signs and symptoms consistent with SMA at 6 months of age or younger.*

AND

2. Baseline assessment of patient's motor function prior to therapy was provided including results. Written documentation must be submitted for approval. The following tests are acceptable*:

- i. Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
- ii. Hammersmith Functional Motor Scale Expanded (HFMSE)
- iii. Upper Limb Module (ULM) Test (Non ambulatory)
- iv. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

AND

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3. Patient is not on permanent ventilation (greater than or equal to 16 hours of ventilation per day continuously for greater than 21 days in the absence of an acute reversible event or tracheostomy)

AND

4. Dose is within FDA Labeled indications of 12 mg intrathecally at 14 day intervals for 3 doses, followed by a fourth dose 30 days after the third.

Renewal Request

1. The patient demonstrated a response to therapy as evidenced by **an improvement** in motor milestones on the Hammersmith Infant Neurological Examination (HINE) from the predicted natural disease progressions (e.g., head control, independent sitting, ability to kick in supine position). Documentation of results must be provided.

OR

2. The patient demonstrated a response to therapy as evidenced by prevention of permanent ventilation (greater than or equal to 16 hours of ventilation per day continuously for greater than 21 days in the absence of an acute reversible event or tracheostomy) and motor milestones that have not worsened from baseline assessment. Written documentation must be submitted for approval.

AND

3. Dose is within FDA Labeled indications of 12 mg intrathecally at 14 day intervals for 3 doses, followed by a fourth dose 30 days after the third.

3. APPLICABLE PROCEDURE CODES:

CPT Code	Description
J2326	Injections, nusinersen, 0.1 mg,

References

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1. Spinraza [package insert]. Cambridge, MA: Biogen Inc.; December 2017.
2. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. November 2016.
3. FDA News Release: FDA approves first drug for spinal muscular atrophy. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534611.htm>. Published December 23, 2016.

REVISION LOG:

REVISIONS	DATE
Creation date	

Approved:

Date:

Approved:

Date:

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Clinical Medical Director

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Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.