MetroPlus Health

Policy and Procedure

Title: Spinraza (nusinersen)	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 4/20/2018	**LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP**
Effective Date: 4/20/2018	**Policy Number: UM-MP233**
Review Date: 5/30/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 5**

1. POLICY DESCRIPTION

Musculoskeletal Agent, Spinraza **(nusinersen)** (Rx)

2. RESPONSIBLE PARTIES

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

3. DEFINITIONS

SPINRAZA (nusinersen) is indicated for the treatment of spinal muscular atrophy (SMA) confirmed by SMN1 deletion. All other indications are considered experimental/investigational and are not a covered benefit.

4. POLICY

Spinraza used for the treatment of spinal muscular atrophy (SMA) will be covered with prior authorization when the following criteria are met:

INITIAL REQUEST

a. Patient has a confirmed diagnosis consistent with spinal muscular atrophy as defined by the following:
    i. SMN1 deletion or 5q SGM homozygous gene deletion, a homozygous mutation or a compound heterozygote*.
        1. No more than 2 copies of SMN2* **OR**
        2. The patient exhibited onset of clinical signs and symptoms consistent with SMA at 6 months of age or younger.* **AND**
b. 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 (HFSME)
    iii. Upper Limb Module (ULM) Test (Non-ambulatory)
    iv. Children's Hospital of Philidelephia Infant Test of Neuromuscular Disorders (CHOP INTEND) **AND**
c. Documentation of baseline platelet count, prothrombin time, activated partial thromboplastin time, and quantitative spot urine testing must be submitted for approval **AND**
d. Patient is not on permanent ventilation (≥16 hours of ventilation per day continuously for greater than 21 days in the absence of an acute reversible event or tracheostomy) **AND**

e. Patient does not have complete limb paralysis **AND**
f. Medication is prescribed or in consultation with a pediatric neuromuscular specialist or a neurologist specializing in SMA **AND**
g. Dose is within approved FDA dosing:
    i. 12 mg intrathecally at 14 day intervals for 3 doses, followed by a 4th dose 30 days after the 3rd dose

***Documentation, including chart notes and lab results, MUST be submitted for approval**

RENEWAL REQUEST

a) All initial conditions of coverage have been met **AND**
b) The patient's condition has **not** worsened while on therapy **AND**
c) The patient has **not** developed significant adverse drug effects including:
    a. Anaphylaxis or other hypersensitivity reactions
    b. Life-threatening or disabling infusion reactions
    c. Thrombocytopenia or coagulation abnormalities
    d. Renal toxicity

AND

d) ONE OF THE FOLLOWING:
    a. 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

    b. 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

e) Continued dosing is within approved FDA dosing:
    a. 12 mg intrathecally every 4 months

5. LIMITATIONS

Any non-FDA approved uses of Spinraza are not considered medically necessary, as there is not enough evidence to support its effectiveness.

6. APPLICABLE PROCEDURE CODES:

CPT Code	Description
J2326	Injections, nusinersen, 0.1 mg,

7. APPLICABLE DIAGNOSIS CODES

CODE	Description
G12.0	Infantile spinal muscular atrophy, type I
G12.1	Other inherited spinal muscular atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified

8. REFERENCES

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
4. New York State Medicaid Update - March 2023 Volume 39 - Number 6. www.health.ny.gov. Accessed May 11, 2023. https://www.health.ny.gov/health_care/medicaid/program/update/2023/no06_2023-03.htm#nusinersen

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REVISION LOG:

REVISIONS	DATE
Creation date	4/20/2018
Annual Review	6/8/2020
Annual Review	9/1/2021
Annual review	8/30/2022
Update	5/30/2023

Approved: **Date:**	**Approved:** **Date:**
Glendon Henry Digitally signed by Glendon Henry Date: 2023.06.02 07:36:24 -04'00'	Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.06.05 16:01:01 -04'00'
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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Medical Guideline Disclaimer:

 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 andor 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.