Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health	**Submission Date:** 8/1/2021
Policy Number:	**Effective Date:** 8/1/2021 **Revision Date:** 5/2021
Policy Name: Spinraza (Non-PDL)	
Type of Submission – Check all that apply: ☐ **New Policy** X **Revised Policy** ☐ **Annual Review – No Revisions**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:**	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** 

Last Review: 5/2021
Previous PARP Approval: 5/2021
Current PARP Approval: 9/2021

AETNA BETTER HEALTH®

Prior Authorization guideline for Spinraza (nusinersen) Non-PDL

Authorization guidelines

Initial Review: May be authorized when all the following criteria are met:

A. Member has a diagnosis of spinal muscular atrophy confirmed by genetic testing\

B. Prescribed by, or in consultation with a physician who specializes in the treatment of spinal muscular atrophy (SMA)

C. There is genetic documentation of 5q SMA homozygous gene mutation, homozygous gene deletion, or compound heterozygote

D. Submission of medical records (e.g., chart notes, laboratory values) of the baseline assessment for at least one of the following assessment tools (based on the member age and motor ability) to establish baseline motor ability prior to therapy initiation:
   a. Hammersmith Functional Motor Scale Expanded (HFMSE)
   b. Hammersmith Infant Neurologic Exam Part 2 (HINE-2)
   c. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
   d. Revised Upper Limb Module (RULM) test
   e. Six-minute walk test

E. Member meets one of the following criteria:
   a. Member has not previously received gene therapy for SMA

Last Review: 5/2021
Previous PARP Approval: 5/2021
Current PARP Approval: 9/2021

OR

b. Member has previously received gene therapy for SMA and has experienced a worsening in clinical status since receiving gene therapy as demonstrated by a decline of minimally clinical important difference from highest score achieved on one of the following exams (based on member age and motor ability):
    i. HINE-2: Decline of at least 2 points on kicking and 1 point on any other milestone (excluding voluntary grasp); OR
    ii. HFMSE: Decline of at least 3 points; OR
    iii. CHOP-INTEND: Decline of at least 4 points

F. Member will be monitored for coagulation abnormalities and thrombocytopenia

G. Member will be monitored for renal toxicity

H. If member has not received a loading dose, the loading dose will be dosed at 12mg (5mL) on Day 0, 14, 28, and 58.

I. Members who were previously established on nusinersen (Spinraza) and subsequently administered gene therapy must meet all initial nusinersen prior authorization criteria prior to re-starting therapy on nusinersen.

J. Medication is not concurrently prescribed with Evrysdi (risdiplam)

Renewals: May be authorized when all the following criteria are met:

A. Is prescribed Spinraza (nusinersen) by or in consultation with a neurologist with experience treating SMA; AND
B. Is prescribed a dose that is consistent with U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
C. Has documentation of an annual evaluation, including a standardized assessment of motor function, by a neurologist with experience treating SMA; AND
D. Is receiving comprehensive treatment based on standards of care for SMA; AND
E. Has a documented platelet count prior to each dose; AND
F. Based on the prescriber's assessment, continues to benefit from Spinraza (nusinersen); AND
G. Will not be using Spinraza (nusinersen) concomitantly with Evrysdi (risdiplam)

Note: Spinraza will not be approved for spinal muscular atrophy without confirmation of the chromosome 5q mutation or deletion testing.

Initial Approval: 4 months

Renewal Approval: 4 months

Renewals Require: Response to therapy based on the prescriber's assessment (submission of medical records required)

Quantity Level Limit:
Initial: 12 mg (5 mL) per administration

Last Review: 5/2021
Previous PARP Approval: 5/2021
Current PARP Approval: 9/2021

- Total of 4 loading doses. First 3 doses are given at 14-day intervals. The 4th dose is given 30 days after the 3rd dose.

Maintenance: Given once every 4 months

CPT Codes / HCPCS Codes / ICD-10 Codes

Code	Code Description
J2326	Injection, nusinersen, 0.1 mg
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified

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Last Review: 5/2021
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