A Public Entity
Inland Empire Health Plan

Drug Prior Authorization Criteria
Spinraza (Nusinersen)
Medical Benefit

Line of Business: Medicaid
P & T Approval Date: August 21, 2019 **Effective Date:** October 1, 2019

This drug prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

CRITERIA:

SPINRAZA (NUSINERSEN)

Covered Uses:
*****Spinal Muscular Atrophy (SMA)
(*Subject to review by a Clinical Pharmacist)

Exclusion Criteria:
CCS eligible

Required Medical Information:
Must meet all of the following requirements:

a. Genetic testing results demonstrate homozygous SMN1 deletion or other mutations that result in the functional loss of all SMN1 genes
b. Must meet "1" of the following requirements:
    i. Member does not yet have SMA-associated symptoms (i.e. pre-symptomatic) and has documentation of the presence of one to three copies of SMN2 protein
    ii. Documentation of clinical signs of SMA (e.g. failure to meet motor milestones, level of function necessary to preserve communication, for instance finger or eye movements in response to prompt by examiner)
c. For older members with SMA and scoliosis, the drug may only be authorized if member meets "1" of the following requirements:
    i. Has scoliosis without spine surgery
    ii. Is post spine surgery with preserved window of accessibility for the intrathecal injection
    iii. Is post spine surgery but with surgical placement of an indwelling catheter or establishment of a new window for IT accessibility
d. Member does not have a coexisting terminal condition or a condition with which the risk of Spinraza treatment outweighs the potential benefit

e. Documentation of at least "1" of the following baseline neuromotor assessment:
    i. For non-sitters: CHOP Intend or Hammersmith Infant Neurological Exam-Part 2 (HINE-2)
    ii. For sitters: Hammersmith Functional Motor Scale (HFMS) or Revised Upper Limb Module (RULM)
    iii. For walkers: Timed Up and Go test (TUG), the 6-minute walk test or the 10-meter run/walk test
    iv. For non-ambulatory older members: Revised Upper Limb Module (RULM) or Standard muscle strength assessment
f. Requested dosage and administration are consistent with the FDA recommendations
g. Interdisciplinary comprehensive care, including physical therapy, respiratory care and nutritional support, is highly recommended. Please task to care management team for care coordination if deemed necessary

Age Restriction: N/A

Prescriber Restrictions: Neurologist

Other Criteria: Reauthorization Criteria:
Must meet all of the following requirements:
a. Documentation of "1" of the following (completed prior to each re-authorization):
    i. For non-sitters: CHOP Intend or Hammersmith Infant Neurological Exam-Part 2 (HINE-2)
    i. For sitters: Hammersmith Functional Motor Scale (HFMS) or Revised Upper Limb Module (RULM)
    ii. For walkers: Timed Up and Go test (TUG), the 6-minute walk test, the 10-meter run/walk test
    iii. For non-ambulatory older members: Revised upper limb module (RULM) or Standard muscle strength assessment
b. Documentation of meeting therapeutic goals including motor function improvement or stabilization of motor function loss compared to the predicted natural trajectory of disease
c. Requested dosage and administration are consistent with the FDA recommendations

Change Control		
Date	**Change**	**Author**
08/21/2019	• Renew	SV/ND
08/15/2018	• Reformatted document • Documentation of clinical signs of SMA (e.g. failure to meet motor milestones, level of function necessary to preserve communication, for instance finger or eye movements in response to prompt by examiner) • Additional neuromotor assessment: Revised Upper Limb Module (RULM) for sitters	HC