HEALTH FIRST COLORADO (COLORADO MEDICAID'S PROGRAM) COVERAGE STANDARDS FOR NUSINERSEN (SPINRAZA)

INDICATIONS

Spinraza requests will be reviewed on a case by case basis for all Health First Colorado Members with a diagnosis of Spinal Muscular Atrophy (SMA).

SMA must be diagnosed and prescribed by a Neurologist experienced at treating SMA.

Copies of all clinical documentation must be attached and submitted at the time of the request.

Prior authorization requests for Spinraza may be approved, denied for lack of information, or receive a denial for a lack of medical necessity as determined by the Health First Colorado Chief Medical Officer or his/her designee.

GENETIC TESTING

Must have SMA documented by gene testing.

SMN1 mutation **AND** more than two SMN2 gene copies must be specified.

CLINICAL ASSESSMENT

Treatment *naïve* Members must meet all the requirements below to begin Spinraza treatment. Clinical documentation must include the following:

- Demonstrated SMA symptoms documented by a Neurologist using a motor exam. Acceptable motor exams include at least one of the following:
  - For Members ≤ 2 years old: Hammersmith Infant Neurological Examination Section 2 (HINE-2),
  - For Members ≥ 3 years old: Hammersmith Functional Motor Scale-Expanded (HFMSE) for ambulatory beneficiaries or Upper Limb Module (ULM) for non-ambulatory beneficiaries.
- Be free from permanent ventilation or requiring a maximum of 16 hours of assisted ventilation per 24 hours.
- Stable baseline labs including, but not limited to, a PT, PTT, platelets, and quantitative spot-urine protein testing prior to beginning treatment and prior to each subsequent Spinraza dose.

Members must meet all the requirements below to *continue* Spinraza treatment.

- Documentation of previous Spinraza doses including any doses received as part of an SMA clinical trial.
- Be assessed utilizing the same motor exam unless otherwise indicated.

- Has shown no adverse events to prior Spinraza treatment.
- Be free of permanent ventilation (16 hours or greater per 24 hours) or an increased number of hours of assisted ventilation.
- Stable laboratory values including, at a minimum, PT, PTT, platelets, and quantitative spot-urine protein testing prior to each dose.
- Demonstrated response to treatment by showing *significant clinical improvement* documented using quantitative scores using the same motor function test(s) used prior to initiating Spinraza treatment.
    - Improvement of SMA related symptoms must be compared to the baseline assessment and motor function must be measured against the degenerative effects of SMA.
    - An explanation must be submitted if a provider other than the one who initially performed the motor exam completes any follow-up exam(s).
- Documentation of clinical improvement must include, at a minimum, the following:
    - At least a two (2) point increase in ability to kick or a one (1) point increase in head control, rolling, sitting, crawling, standing, or walking in HINE-2;
    - At least a three (3) point increase in HFMSE;
    - At least a two (2) point increase in ULM.

REQUESTS	All Spinraza requests, including the Health First Colorado Spinraza Request Form and supporting clinical documentation, must be submitted to the following inbox: HCPF_Nusinersen@state.co.us

NUSINERSEN (SPINRAZA) REQUEST FORM
HEALTH FIRST COLORADO (COLORADO'S MEDICAID PROGRAM)

SPINRAZA REQUEST OVERVIEW

- ✓ Spinraza requests will be reviewed on a case by case basis for Health First Colorado Members with a diagnosis of Spinal Muscular Atrophy (SMA).
- ✓ Requests must be submitted to the following inbox: HCPF_Nusinersen@state.co.us
- ✓ **Copies of all clinical documentation supporting the information below, along with the Spinraza Request Form, must be attached and submitted at the time of the request.**
- ✓ Requests for Spinraza may be approved, denied for a lack of information, or denied for lack of medical necessity as determined by the Health First Colorado Chief Medical Officer or his/herdesignee.

PROVIDER INFORMATION

Provider Information

Was SMA *diagnosed* by a neurologist experienced in the treatment of SMA? Yes No

- ✓ If **Yes**, name of neurologist:_____.
- ✓ If **No**, name and specialty of diagnosing physician:_____.

Is Spinraza being *prescribed* by a neurologist experienced in the treatment of SMA? Yes No_

- ✓ If **Yes**, name of prescriber:_____.
- ✓ If **No**, name and specialty of prescribing physician:_____.

Will Spinraza be administered in a healthcare facility by a specialist experienced in performing lumbar punctures? Yes No Name of facility:_____.

Number of Spinraza doses requested:_____.

Contact name (print):_____. Phone:_____.

Email:_____.

Member Clinical Information

Member Name: _____

Health First Colorado Identification Number: _____

Date of Birth_____. Gender:_____. Ethnicity:_____.

SMA clinical subtype:_____.

Please indicate SMN1 mutation **AND** number of SMN2 gene copies:

_____.

Age at diagnosis of SMA:_____.

Age at onset of SMA symptoms, if different than time of diagnosis:_____.

Were the SMA symptoms documented by a neurologist using a motorexam? Yes No

CLINICAL INFORMATION

Which of the following motor exam(s) were used for the Member's ***baseline*** exam:

- ✓ Members ≤ 2 years old: Hammersmith Infant Neurological Examination Section 2 (HINE-2): Yes No N/A
- ✓ Members ≥ 3 years old and *ambulatory*: Hammersmith Functional Motor Scale- Expanded (HFMSE): Yes No N/A
- ✓ Members ≥ 3 years old and *non-ambulatory*: Revised Upper Limb Module Test (RULM]: Yes No N/A

Date of ***baseline*** motor exam(s):_____.

Summary of results of the ***baseline*** motor exam(s):

_____

_____.

Which of the following motor exam(s) were used for the Member's ***most recent*** exam:

- ✓ Members ≤ 2 years old: Hammersmith Infant Neurological Examination Section 2 (HINE-2): Yes No N/A
- ✓ Members ≥ 3 years old and *ambulatory*: Hammersmith Functional Motor Scale- Expanded (HFMSE): Yes No N/A
- ✓ Members ≥ 3 yearsold and *non-ambulatory*: Revised Upper Limb Module Test(RULM]: Yes No N/A

Date of ***most recent*** motor exam(s):_____.

Summary of results of the ***most recent*** motor exam(s):

_____

Does the Member require permanent ventilation? Yes No

- ✓ If **Yes**, describe type of ventilation required: _____.
- ✓ If **Yes,** number of hours of permanent ventilation support required every 24 hours including naps:_____.

Does the Member require respiratory support such as noninvasive or assisted ventilation? Yes No_

- ✓ If **Yes**, describe type of respiratory support required: _____.
- ✓ If **Yes,** number of hours of respiratory support required every 24 hours including naps:_____.

CLINICAL INFORMTION CONTINUED

Does the Member have stable *baseline* labs including, but not limited to, a PT, PTT, platelets, and quantitative urine protein testing? Yes No

Will the Member have labs drawn and monitored prior to each subsequent Spinraza dose? Yes No

Has the Member previously been treated with Spinraza: Yes No

If **Yes**, indicate the following:

- ✓ Number of Spinraza doses received:_____.
- ✓ Date(s) of previous Spinraza treatments: _____.
- ✓ Did Member receive any previous Spinraza doses as part of an SMA clinical trial? Yes No
- ✓ If **Yes,** how many Spinraza doses were received as part of an SMA clinical trial: _____.
- ✓ Please list all adverse events Member experienced following each dose: _____ _____.
- ✓ Has the Member shown a demonstrated response to Spinraza treatment by showing a *significant clinical improvement* documented using quantitative scores using the same motor function test(s) used prior to initiating Spinraza treatment? Yes No
- ✓ Was the improvement of SMA related symptoms compared to the baseline assessment and was motor function measured against the degenerative effects of SMA? Yes No

- ✓ Did a provider other than the one who initially performed the motor exam complete any follow-up exam(s)? Yes No

- ✓ Did the Member's clinical improvement include, at a minimum, the following?

- ➢ At least a two (2) point increase in ability to kick or a one (1) point increase in head control, rolling, sitting, crawling, standing, or walking in HINE-2?
  Yes No N/A

  - At least a three (3) point increase in HFMSE? Yes No N/A
  - A least a two (2) point increase in ULM? Yes No N/A

- ✓ Has the Member remained free of *permanent* ventilation (16 hours or greater per 24 hours) since onset of Spinraza treatment? Yes No

- ✓ Has the Member's required any additional respiratory support since the onset of Spinraza treatment? Yes No

- ✓ Describe *all* changes to the Member's respiratory status since the onset of Spinraza treatment:
  _____
  _____.

Has the Member previously been treated with Zolgensma: Yes No

If **Yes**, indicate the prior Zolgensma treatment date: _____

Please include additional pertinent clinical information below:

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