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 pediatric Health First Colorado Members who qualify under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit 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 receive a full approval, partial approval, a lack of information denial, or full medical denial as determined by the Health First Colorado Chief Medical Director 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 children ≤ 2 years old: Hammersmith Infant Neurological Examination Section 2 (HINE-2),
  - For children >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 Department's Spinraza Request Form and supporting clinical documentation, must be submitted to the following inbox: EPSDT@state.co.us
FAQ	https://www.colorado.gov/pacific/sites/default/files/PF_HCP_EPSDT-fact-sheet.pdf