

# Clinical Oversight Review Board (CORB) Criteria for Prescribing Nusinersen (Spinraza)

## Notes:

- Quantity Limits: No
- \* Tracheostomy: surgically created hole in front of neck for placement of a tube into windpipe to help with breathing
- ^ Noninvasive ventilation refers to positive pressure ventilation delivered through a noninvasive interface (nasal mask, facemask, or nasal plugs)

Non-Formulary **nusinersen (Spinraza)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria:** Non-formulary **nusinersen (Spinraza)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by Neurologist
- Patient has a confirmed diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) with biallelic deletions or mutations in the SMN1 gene
- Patient has 2 to 4 copies of the SMN2 gene
- Patient is younger than 22 years old **OR** Patient is 22 to 65 years old and meets the following:
  - Baseline Hammersmith Functional Motor Scale-Expanded Exam (HFMSE) score of 35 or higher **AND**
  - Documented objective evidence of disease progression
- Patient is not using other treatments for SMA
- Patient has not had prior treatment and is not planning treatment with onasemnogene abeparvovec (Zolgensma) or other gene therapy for SMA
- Patient can breathe without permanent invasive ventilation or tracheostomy\*
- Patient can breathe without invasive or non-invasive^ ventilation during waking hours each day
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

**Continued use criteria:** Continued use will be contingent upon demonstrated response to therapy (to be reviewed every 12 months while on treatment). **Discontinuation is recommended in the following situations:**

- Patient is using other treatments for SMA
- Patient had prior treatment or is planning treatment with onasemnogene abeparvovec (Zolgensma) or other gene therapy for SMA

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- Patient requires permanent invasive ventilation or tracheostomy\*
- Patient is dependent on invasive or noninvasive ventilation^ support during waking hours each day
- Patient has experienced loss of function or progressive weakness (physical and/or pulmonary)

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