Spinraza (nusinersen) will be considered for coverage when the following criteria are met:

**Spinal Muscular Atrophy (SMA)**

**For initial authorization:**
1. Member’s gestational age is 37 to 42 weeks for singleton births or 34 to 42 weeks for twins;  
2. Medication must be prescribed by or in consultation with a neurologist; AND  
3. Member has a diagnosis of SMA confirmed by genetic/newborn testing showing any of the following:  
   a) Homozygous gene deletion of the survival motor neuron 1 (SMN1) gene (e.g., absence of SMN1 gene)  
   b) Homozygous mutation of the SMN1 gene (e.g., biallelic mutation of exon 7)  
   c) Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]); AND  
4. Member has 2 to 4 copies of SMN2; AND  
5. Member’s documented oxygen saturation is ≥ 92% (awake or asleep) without any supplemental oxygen or respiratory support; AND  
6. Member has documented ALL of the following:  
   a) Prothrombin time, Activated partial prothrombin time;  
   b) Platelet counts;  
   c) Quantitative spot protein urine testing; AND  
7. Member does not have shunt or central nervous system (CNS) catheter;  
8. Member has no history of bacterial meningitis or viral encephalitis;  
9. Member does not have prior treatment with Zolgensma (discontinuation of Spinraza prior to Zolgensma therapy is required and Spinraza will not be reauthorized after Zolgensma infusion).  
10. Member will not be using concomitantly with Evrysdi.  
11. **Dosage allowed/Quantity limit:** Initiate Spinraza treatment with 4 loading doses (12 mg (5 mL) per administration). The first three loading doses should be administered at 14-day intervals, the 4th loading dose should be administered 30 days after the 3rd dose. A maintenance dose should be administered once every 4 months thereafter. **Quantity limit:** 1 vial per 16 weeks  

*If all the above requirements are met, the medication will be approved for 6 months.*
For reauthorization:
1. Member has documentation of positive clinical improvement from pretreatment baseline status in spinal muscular atrophy-associated symptoms or maintenance (not worsening) of the disease state (e.g., decreased decline in motor function, increased ability to kick, increased in the motor milestones of head control, rolling, sitting, crawling, standing, or walking, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Spinraza (nusinersen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/05/2017</td>
<td>New policy for Spinraza created.</td>
</tr>
<tr>
<td>06/11/2019</td>
<td>Concomitant used of Spinraza with Zolgensma will not be authorized. Spinraza must be discontinued before Zolgensma infusion. Spinraza will not be reauthorized after Zolgensma infusion.</td>
</tr>
<tr>
<td>07/11/2022</td>
<td>Transferred to new format. Updated references. Removed baseline motor ability assessment scores.</td>
</tr>
</tbody>
</table>

References:

Effective date: 01/01/2023
Revised date: 07/11/2022