

## Nusinersen

### **Goal(s):**

- Approve nusinersen for funded OHP conditions supported by evidence of benefit (e.g. Spinal Muscular Atrophy)

### **Length of Authorization:**

- Up to 8 months for initial approval and up to 12 months for renewal.

### **Requires PA:**

- Nusinersen (billed as a pharmacy or physician administered claim)

### **Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD-10 code. Go to #2	
2. Is this a request for continuation of therapy?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to #3
3. Does the patient have type 1, 2 or 3 Spinal Muscular Atrophy documented by genetic testing and at least 2 copies of the SMN2 gene?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
4. Is a baseline motor assessment available such as one of the following functional assessment tools: <ul style="list-style-type: none"> <li>• Hammersmith Infant Neurological Examination (HINE-2)</li> <li>• Hammersmith Functional Motor Scale (HFSME)</li> <li>• Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)</li> <li>• Upper Limb Module (ULM)</li> <li>• 6-Minute Walk Test</li> </ul>	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness.

## Approval Criteria

<p>5. Is the patient ventilator dependent (using at least 16 hours per day on at least 21 of the last 30 days)?</p> <p>Note: This assessment does not apply to patients who require ventilator assistance</p>	<p><b>Yes:</b> Pass to RPh. Deny; medical appropriateness.</p>	<p><b>No:</b> Go to #6.</p>
<p>6. Is the drug being prescribed by a pediatric neurologist or a provider with experience treating spinal muscular atrophy?</p>	<p><b>Yes:</b> For initial approval, approve 5 doses over 8 months.</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness.</p>

## Renewal Criteria

<p>1. Has the patient's motor function improved as demonstrated by:</p> <ul style="list-style-type: none"><li>• Improvement from baseline motor function score documented within one month of renewal request AND</li><li>• More areas of motor function improved than worsened</li></ul>	<p><b>Yes:</b> Approve for 12 months</p>	<p><b>No:</b> Pass to RPh; Deny; medical appropriateness.</p>
---	--	---

P&T Review: 7/17 (DM); 3/17  
Implementation: 9/1/17; 5/17