

Delandistrogene moxeparvovec

Goal(s):

- Restrict use of this gene therapy to patients with the FDA-labeled indication.
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

Length of Authorization:

- 1 lifetime dose

Requires PA:

- Delandistrogene moxeparvovec (pharmacy and provider administered claims)

Covered Populations:

- FFS and CCO enrolled populations beginning 1/1/26

Covered Alternatives:

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

| Approval Criteria | | |
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| 1. What diagnosis is being treated? | Record ICD10 code. | |
| 2. Is the request for treatment of genetically-confirmed Duchenne Muscular Dystrophy? | Yes: Go to #3 Results of genetic testing are required for approval. | No: Pass to RPh. Deny; medical appropriateness. Note: Therapies are not indicated for other forms of muscular dystrophy or other diagnoses. |
| 3. Is the medication prescribed by a neuromuscular specialist? | Yes: Go to #4 | No: Pass to RPh. Deny; medical appropriateness. |
| 4. Is the request for an FDA approved age (i.e., 4 years or older)? | Yes: Go to #5 | No: Pass to RPh. Deny; medical appropriateness. |
| 5. Does the patient have deletions of exon 8 or 9? | Yes: Pass to RPh. Deny; medical appropriateness. | No: Go to #6 |
| 6. For patients with deletions of exons 1 to 17 or exons 59 to 71, is there documentation that the provider and patient have discussed potential risks of treatment? Note: these populations were excluded from clinical studies and may have increased risk for severe immune-mediated myositis reactions. | Yes: Go to #7 | No: Pass to RPh. Deny; medical appropriateness. |

Approval Criteria

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| <p>7. Has baseline testing been completed and is within normal limits?</p> <p>Recommended baseline testing includes testing for anti-AAVrh74 antibodies (by ELISA), troponin-I, platelets, and liver function tests.</p> | <p>Yes: Go to #8</p> <p>For any testing that is not within normal limits, refer to DMAP for secondary review. Liver function tests should be <3x the upper limit of normal.</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |
| <p>8. Has the patient received, or have contraindications to, all routine immunizations recommended for their age?</p> <p>Note: Routine vaccinations for patients at least 4 years of age typically include hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, COVID-19, and at least 2 doses of measles, mumps, rubella, and varicella.</p> | <p>Yes: Go to #9</p> <p>Document provider attestation of immunization history.</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |
| <p>9. Is the patient able to tolerate an elevated dose of prednisone for at least 60 days and complete necessary ongoing monitoring?</p> | <p>Yes: Go to #10</p> <p>Document provider attestation.</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |
| <p>10. Is there documentation that the provider and member have discussed potential risks of treatment?</p> <p>Note: Informed consent is recommended as this therapy has shown that it does not change global motor function in 2 clinical trials. It is associated with serious side effects including injury to the liver and heart and it may prevent use of any future adeno-based gene therapy.</p> | <p>Yes: Go to #11</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |

Approval Criteria

11. Has the patient received a prior dose of an adeno-based gene therapy?

Yes: Pass to RPh. Deny; medical appropriateness.

No: Pass to RPh. Pend; Refer to DMAP for secondary review.

Duration: Approvals cover one lifetime dose. Approval are valid for 12 months and will be extended if needed to cover treatment journey.

P&T/DUR Review: 10/24, 2/24 (SS)
Implementation: 12/1/2024; 4/1/24