Delandistrogene moxeparvovec

Goal(s):
- Restrict use of this gene therapy to patients with the FDA-labeled indication.

Length of Authorization:
- 1 lifetime dose

Requires PA:
- Delandistrogene moxeparvovec (pharmacy and provider administered claims)

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		
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		
7. Has baseline testing been completed and is within normal limits? Recommended baseline testing includes testing for anti-AAVrh74 antibodies (by ELISA), troponin-I, platelets, and liver function tests.	**Yes:** Go to #8 For any testing that is not within normal limits, refer to medical director for review. Liver function tests should be <3x the upper limit of normal.	**No:** Pass to RPh. Deny; medical appropriateness.
8. Has the patient received, or have contraindications to, all routine immunizations recommended for their age? 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.	**Yes:** Go to #9 Document provider attestation of immunization history.	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the patient able to tolerate an elevated dose of prednisone for at least 60 days and complete necessary ongoing monitoring?	**Yes:** Go to #10 Document provider attestation.	**No:** Pass to RPh. Deny; medical appropriateness.
10. Is there documentation that the provider and member have discussed potential risks of treatment? 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.	**Yes**: Go to #11	**No:** Pass to RPh. Deny; medical appropriateness.
11. Has the patient received a prior dose of an adeno-based gene therapy?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve single infusion (max 1 dose per lifetime)