ALASKA MEDICAID
Prior Authorization Criteria

Elevidys®

(delandistrogene moxeparvovec-rokl)

FDA INDICATIONS AND USAGE[1]

Elevidys is an adeno-associated virus vector-based gene therapy indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. This indication is approved under accelerated approval based on expression of ELEVIDYS micro-dystrophin in skeletal muscle observed in patients treated with ELEVIDYS. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

APPROVAL CRITERIA[1,2]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a neuromuscular specialist **AND**;
3. Patient has the diagnosis of Duchenne Muscular Dystrophy **AND**;
4. Patient has a confirmed mutation of the DMD gene **AND;**
5. If the patient has a mutation in exons 1-17 and/or 59-71 of the DMD gene, prescriber will monitor the patient for immune-mediated myositis and has a mitigation strategy in place **AND;**
6. Patient does not have a deletion in exon 8 and/or exon 9 of the DMD gene **AND;**
7. Patient is currently ambulatory **AND;**
8. Patient anti-AAVrh74 total binding antibody tier <1:400 **AND**;
9. Patient is not on concomitant therapy with DMD-directed antisense oligonucleotides and has not received a DMD-directed antisense oligonucleotide in the past 30 days) **AND**;
10. Patient is currently on a stable corticosteroid regimen as per FDA labeling guidance **AND;**
11. Patient has had the following laboratory assessments prior to administration:
    a. Liver function tests (ALT, AST, GGT, ALP, total bilirubin, and INR).
    b. Troponin-I

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient currently has a clinically significant active infection **OR**;
3. Patient currently has acute liver disease **OR**;
4. Patient has a deletion in exon 8 or exon 9 of the DMD gene **OR**;
5. Patient has been previously treated with gene therapy for DMD

CAUTIONS[1]

- LFTs should be monitored at baseline prior to therapy, weekly for the first three months following administration, and thereafter as clinically indicated

- Acute liver injury has been observed, frequently within 8 weeks of administration
- Cases of immune-mediated myositis have been observed
- Myocarditis has been observed following administration. Monitor Troponin-I prior to administration, weekly for one month following, and thereafter as clinically indicated.

DURATION OF APPROVAL

- Initial Approval: 3 months
  - No reauthorization will be approved.

QUANTITY LIMIT

- One infusion per lifetime.
- HCPCS: J3590

REFERENCES / FOOTNOTES:

1. Elevidys [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023 Accessed September 5 2023
2. A Phase 3 Multinational, Randomized, Double-Blind, Placebo-Controlled Systemic Gene Delivery Study to Evaluate the Safety and Efficacy of SRP-9001 in Subjects With Duchenne Muscular Dystrophy (EMBARK). ClinicalTrials.gov identifier: NCT05096221. Updated September 8 2023. Accessed September 21 2023.