Reference number(s)
6032-A

SPECIALTY GUIDELINE MANAGEMENT

ELEVIDYS (delandistrogene moxeparvovec-rokl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Elevidys is 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).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Genetic test results confirming the DMD diagnosis.
B. Medical records (e.g., chart notes, lab reports) documenting the member's ambulation status.

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. Member has a deletion in exon 8 and/or exon 9 in the *DMD* gene.
B. Elevidys will not be used in combination with exon-skipping therapies (casimersen, eteplirsen, golodirsen, viltolarsen).

IV. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD).

V. CRITERIA FOR INITIAL APPROVAL

Duchenne muscular dystrophy
Authorization of 1 month for one dose total may be granted for treatment of Duchenne muscular dystrophy when all of the following criteria are met:

A. Member is 4 to 5 years of age (inclusive).
B. Member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent).
C. Member has a definitive diagnosis of DMD confirmed via genetic testing.
D. Member has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of < 1:400.
E. Member has not received treatment with Elevidys previously.

VI. REFERENCES

1. Elevidys [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023.