Reference number(s)
6033-A

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
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 the following exclusion:
A. Deletion in exon 8 and/or exon 9 in the *DMD* gene.

IV. CRITERIA FOR INITIAL APPROVAL

Duchenne muscular dystrophy (DMD)
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.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Elevidys.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Elevidys are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

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

