Reference number(s)
6033-A

Standard Medicare Part B Management Elevidys

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Elevidys	delandistrogene moxeparvovec-rokl

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 Indications[1]

Elevidys is indicated in individuals at least 4 years of age:

- For the treatment of Duchenne muscular dystrophy (DMD) in patients who are ambulatory and have a confirmed mutation in the DMD gene.
- For the treatment of DMD in patients who are non-ambulatory and have a confirmed mutation in the DMD gene.

The DMD indication in non-ambulatory patients is approved under accelerated approval based on expression of Elevidys microdystrophin. 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 listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions:

- Genetic test results confirming the DMD diagnosis.

Exclusions

Coverage will not be provided for members with the following exclusion:

- Deletion in exon 8 and/or exon 9 in the DMD gene.

Coverage Criteria

Duchenne muscular dystrophy (DMD)[1]

Authorization of 3 months for one dose total may be granted for treatment of Duchenne muscular dystrophy when all of the following criteria are met:

- Member is at least 4 years of age.
- Member has a definitive diagnosis of DMD confirmed via genetic testing.
- Member has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of < 1:400.
- Member has not received treatment with Elevidys previously.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Elevidys.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

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

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Explanation of Rationale

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

References

1. Elevidys [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; August 2024.

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