COMMUNITY HEALTH CHOICE

Elevidys® (delandistrogene moxeparvovec-rokl)

Effective Date: 04/01/2024
Medical Care Management Committee Approval: 01/18/2024

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Elevidys® (delandistrogene moxeparvovec-rokl) product:

HCPCS Code	Description
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

Coverage Criteria

Elevidys® (delandistrogene moxeparvovec-rokl) will be considered medically necessary for members meeting ALL of the following criteria:

1. Diagnosis of Duchenne muscular dystrophy (DMD) by, or in consultation with, a pediatric neuromuscular specialist with expertise in the diagnosis; AND
2. Submission of laboratory documentation confirming BOTH:
    a) Mutation in the DMD gene; AND
    b) Mutation is NOT a deletion in exon 8 or exon 9; AND
3. Patient is 4 or 5 years of age; AND
4. Submission of medical records (chart notes) confirming that the patient is ambulatory without an assistive device (e.g., side-by-side assist, cane, walker, wheelchair, etc.); AND
5. Submission of medical records (laboratory values) showing patient does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400; AND

6. Patient is on a stable dose equivalent of oral corticosteroids and will continue prior to and following receipt of Elevidys; AND
7. Patient will receive an additional prophylactic corticosteroid regimen prior to and following receipt of Elevidys in accordance with the United States Food and Drug Administration (FDA) approved Elevidys labeling; AND
8. Elevidys is prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the treatment of DMD; AND
9. Elevidys dosing is in accordance with FDA approved labeling; AND
10. Patient will not receive exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly or following Elevidys treatment; AND
11. Patient has never received Elevidys treatment in their lifetime; AND
12. Authorization will be limited to no more than ONE treatment per lifetime and for no longer than 14 days from approval or until 6 years of age, whichever comes first

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose

Diagnosis Code	Description
G71.02	Duchenne or Becker muscular dystrophy

Policy Revision History

Status	Effective Date	Description
Baseline	04/01/2024	Initial version of Elevidys Review Guideline