

New Hampshire Medicaid Fee-for-Service Program Elevidys (delandistrogene moxeparvovec-rokl) Criteria

Approval Date: November 21, 2024

Medications

| Brand Names | Generic Name | Indication |
|-------------|--------------------------------------|---|
| Elevidys | delandistrogene moxeparvovec-rokl | <ul style="list-style-type: none">Indicated for the treatment of ambulatory patients aged 4 years and older with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene (traditional approval)Indicated for the treatment of non-ambulatory pediatric patients aged 4 years and older with DMD with a confirmed mutation in the DMD gene (accelerated approval) |

Criteria for Approval

1. Patient is at least 4 years of age or older; **AND**
2. Patient has been diagnosed with Duchenne muscular dystrophy (DMD); **AND**
3. Patient has a confirmed mutation of the DMD gene between exons 18 to 58; **AND**

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4. Patient must have a baseline anti-AArh74 total binding antibody titer of < 1:400 as measured by ELISA; **AND**
5. Patient is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g. golodirsen, casimersen, viltolarsen, eteplirsen); **AND**
6. Patient has not received a DMD-directed antisense oligonucleotides within the past 7 days; **AND**
7. Patient does not have an active infection, including clinically important localized infections; **AND**
8. Patient has been on a stable dose of a corticosteroid, unless contraindicated or intolerance, prior to the start of therapy and will be used concomitantly with a corticosteroid regimen pre- and post-infusion (refer to the package insert for recommended corticosteroid dosing during therapy); **AND**
9. Patient's troponin-1 levels will be monitored at baseline and subsequently as clinically indicated; **AND**
10. Patient will have liver function assessed prior to and following therapy for at least 3 months and as indicated.

Limitation

A single dose per lifetime. 1 kit based on patient weight.

Criteria for Denial

Above criteria are not met.

References

Available upon request.

Revision History

| Reviewed by | Reason for Review | Date Approved |
|-----------------------|-------------------|---------------|
| DUR Board | New | 12/08/2023 |
| Commissioner Designee | Approval | 01/22/2024 |
| DUR Board | Revision | 10/15/2024 |
| Commissioner Designee | Approval | 11/21/2024 |