

Last review date: 6/20/2024

Applicable Products:
Elevidys (delandistrogene moxeparvovec)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must be prescribed by a neurologist or pediatric neuromuscular specialist who specializes in the treatment of muscular dystrophy; **AND**
- Must be 4 years of age or older; **AND**
- Must have a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing; **AND**
- Must have ALL of the following:
  - Confirmatory genetic testing demonstrating an out-of-frame mutation [e.g. frameshift (deletion or duplication) mutation or a premature stop codon mutation] of the DMD gene (a copy of the genetic testing must be provided); **AND**
  - Chart documentation of baseline motor dysfunction (e.g., North Star Ambulatory Assessment, Timed Functional Test, clinical assessment with physical exam); **AND**
  - Chart documentation that the member is ambulatory (able to independently ambulate 10 meters OR no requirement for permanent use of a wheelchair); **AND**
- Must have anti-adenovirus serotype rh74 (AAVrh74) total binding antibody titer < 1:400 when measured using a Total Binding Antibody enzyme-linked immunosorbent assay (ELISA) (a copy of the laboratory report must be provided); **AND**
- Must not have ANY of the following:
  - Any deletion in exon 8 and/or exon 9 in the DMD gene; **AND**
  - Prior treatment with gene therapy; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

N/A

Length of Authorization:

1 infusion per lifetime

*This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.*

*Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.*