Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 307.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Elevidys (delandistrogene moxeparvovec-rokl)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP			

I. Policy:
Elevidys (delandistrogene moxeparvovec-rokl)

II. Purpose/Objective:
To provide a policy of coverage regarding Elevidys (delandistrogene moxeparvovec-rokl)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Delandistrogene moxeparvovec is a nonreplicating, recombinant adeno-associated virus serotype rh74 vector-based gene therapy that delivers a normal copy of the gene encoding a micro-dystrophin protein expressed in normal muscle cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Elevidys (delandistrogene moxeparvovec-rokl) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene **AND**
- One of the following:
    - Medical record documentation that the member is a male based on assigned sex at birth

OR

    - Medical record documentation that the member is a female based on assigned sex at birth AND
    - Medical record documentation that the member has a confirmed X-inactivation of the unmutated X-chromosome OR confirmed biallelic variants in the *DMD* gene (cytogenetic or molecular) alteration involving the Xp21 locus
      AND
- Medical record documentation of patient age of at least 4 years of age **AND**
- Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene **AND**
- Medical record documentation that the patient has anti-adeno-associated virus serotype rh74 (anti-AAVrh74) antibody titers <1:400 **AND**
- Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) OR non-ambulatory **AND**
- Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that patient has been initiated on corticosteroids for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days* **AND**
- Medical record documentation that the patient is on the appropriate weight-based dose **AND**
- Medical record documentation that the patient has never received Elevidys treatment in their lifetime **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy **AND**
- Medical record documentation that the patient will not receive exon-skipping therapies for Duchenne Muscular Dystrophy [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

***** Deflazacort is not recommended for use as a peri-Elevidys infusion corticosteroid

AUTHORIZATION DURATION: One (1) time approval (auth duration: 2 months) per lifetime. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Note to Reviewer: Based on the Elevidys prescribing information, patients with deletions in the DMD gene in exons 1 to 17 and /or exons 59 to 71 may be at risk for severe immune-mediated myositis reaction.

Elevidys (delandistrogene moxeparvovec-rokl) will be considered medically necessary for the commercial, exchange and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene **AND**
- One of the following:
    - Medical record documentation that the member is a male based on assigned sex at birth

    OR

    - Medical record documentation that the member is a female based on assigned sex at birth AND
    - Medical record documentation that the member has a confirmed X-inactivation of the unmutated X-chromosome OR confirmed biallelic variants in the *DMD* gene (cytogenetic or molecular) alteration involving the Xp21 locus

    AND
- Medical record documentation of patient age of at least 4 years of age **AND**
- Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene **AND**
- Medical record documentation that the patient has anti-adeno-associated virus serotype rh74 (anti-AAVrh74) antibody titers <1:400 **AND**
- Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) **AND**
- Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that patient has been initiated on corticosteroids for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days* **AND**
- Medical record documentation that the patient is on the appropriate weight-based dose **AND**
- Medical record documentation that the patient has never received Elevidys treatment in their lifetime **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy **AND**
- Medical record documentation that the patient will not receive exon-skipping therapies for Duchenne Muscular Dystrophy [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

***** Deflazacort is <u>not</u> recommended for use as a peri-Elevidys infusion corticosteroid

AUTHORIZATION DURATION: One (1) time approval (auth duration: 2 months) per lifetime. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Elevidys (delandistrogene moxeparvovec-rokl) is considered unproven for:

- Use in non-ambulatory patients

<u>Note to Reviewer</u>: Based on the Elevidys prescribing information, patients with deletions in the DMD gene in exons 1 to 17 and /or exons 59 to 71 may be at risk for severe immune-mediated myositis reaction.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Elevidys [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc; 2024.
2. IPD Analytics. Elevidys for the Treatment of Pediatric Patients with Duchenne Muscular Dystrophy. July 25, 2023. Accessed October 5, 2023. https://www.ipdanalytics.com

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/22/23

Revised: 11/19/24 (age, antibody titers, non-ambulatory, auth duration, LOB table, taglines), 2/11/25 (reformatted policy)

Reviewed:

MA UM Committee approval: 5/22/24, 4/29/25

DHS PARP approval: 3/4/25