 JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP106
		<i>Effective Date</i>	01/15/2025
		<i>Approval Date</i>	07/17/2024
	<i>Subject</i> Elevidys	<i>Supersedes Date</i>	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Elevidys

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I. POLICY

- A. Elevidys (delandistrogene moxeparvovec-rokl) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

- A. Elevidys may be approved for patients who meet the following:
1. Patient is 4 to 5 years of age
 2. Documentation has been submitted showing all of the following:
 - a. Definitive diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing
 - b. Patient is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)
 - c. Patient has anti-recombinant adeno-associated virus serotype rh74 (anti-AAVrh74) total binding antibody titers of < 1:400
 - d. Patient has not received treatment with Elevidys previously

III. AUTHORIZATION PERIOD/LIMITATIONS


- A. Approval will be for one month for a one-dose therapy.

IV. EXCLUSIONS

- A. Elevidys will not be covered for the following:
1. Patients with a deletion in exon 8 and/or exon 9 in the DMD gene
 2. Concurrent therapy with exon-skipping therapies (casimersen, eteplirsen, golodirsen, viltolarsen)
 3. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

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VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	J1413

VII. REFERENCES

1. Elevidys [prescribing information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2023.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation
01/15/2025	Removed prescriber specialty requirement

Review Date: 07/17/2024

Revision Date: 01/15/2025