ATRIO HEALTH PLANS

Duchenne Muscular Dystrophy

Elevidys (delandistrogene moxeparvovec-rokl) J1413, Amondys (casimersen) J1426, Viltepso (viltolarsen) J1427, Exondys (eteplirsen) J1428, Vyondys (golodirsen) J1429

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Elevidys**

- ☐ Has a diagnosis of Duchenne Muscular Dystrophy (DMD); AND
- ☐ Patient Is 4 or 5 years old; AND
- ☐ Is ambulatory as confirmed by the North Star Ambulatory Assessment (NSAA) (i.e., patient has a score of 1 or greater). A copy of most the recent NSAA results (past 6 months) must be submitted.
- ☐ Can take and tolerate corticosteroids (e.g., prednisone)
- ☐ Anti-AAVrh74 total binding antibody titers are less than 1:400
- ☐ Does not have evidence of significantly impaired cardiovascular function
- ☐ Has not received a DMD-directed antisense oligonucleotide (i.e., “exon-skipping therapies”: casimersen, eteplirsen, golodirsen, viltolarsen) within the past 7 days, and will not receive one of these therapies after administration of Elevidys (delandistrogene moxeparvovec)
- ☐ Has not previously received Elevidys (delandistrogene moxeparvovec) or any other gene therapy product

☐ **Amondys 45**

- ☐ Individual has a diagnosis of Duchenne muscular dystrophy (DMD); AND
- ☐ Documentation is provided that individual has a genetic mutation that is amenable to exon 45 skipping; AND
- ☐ Individual is age 7-13 years AND
- ☐ Individual has been on a stable dose of oral corticosteroids AND
- ☐ Documentation is provided that individual has a 6MWT (6 minute walk test) ≥ 300 meters and less than 450 meters AND
- ☐ Documentation is provided that individual has stable pulmonary function with forced vital capacity (FVC) equal to or greater than 50% predicted

☐ **Exondys 51**

- ☐ Individual has a diagnosis of Duchenne muscular dystrophy (DMD); AND
- ☐ Documentation is provided that individual has a genetic mutation that is amenable to exon 51 skipping; AND
- ☐ Individual is age 7-13 years of age AND
- ☐ Individual is using a corticosteroid; AND
- ☐ Documentation is provided that shows individual must be able to walk an average distance between 200 and 400 meters (+/- 10%) while walking independently during 6MWT

☐ **Viltepso 53**

- ☐ Individual has a confirmed diagnosis of Duchenne muscular dystrophy (DMD); AND
- ☐ Documentation is provided that individual has a genetic mutation that is amenable to exon 53 skipping; AND
- ☐ Individual is age 4-9 years (NCT02740972) (Clemens 2020); AND
- ☐ Individual is using a corticosteroid; AND
- ☐ Documentation is provided that individual is ambulatory; AND
- ☐ Individual is able to complete the following assessments:
  - ☐ Time to stand from supine; AND
  - ☐ Time to run/walk 10 meters; AND
  - ☐ Time to climb 4 stairs.

☐ **Vyondys 53**

- ☐ Individual has a diagnosis of Duchenne muscular dystrophy (DMD); AND
- ☐ Documentation is provided that individual has a genetic mutation that is amenable to exon 53 skipping; AND
- ☐ Individual is age 6-15 years (NCT02310906, Study 4053-101; Frank 2020); AND
- ☐ Individual is using a corticosteroid; AND
- ☐ Documentation is provided that individual has a 6MWT (6 minute walk test) ≥ 250m AND
- ☐ ONE of the following:
  - ☐ NorthStar Ambulatory Assessment (NSAA) total > 17 and documentation is provided; OR
  - ☐ Rise (Gowers) time of < 7 seconds

☐ Continuation Requests: (Clinical documentation required for all requests)

- **Elevidys is a one-time therapy. No continuation is available.**

☐ Documentation is provided that individual remains ambulatory (with or without needing an assistive device, including but not limited to a cane or walker)

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Duchenne Muscular Dystrophy Drugs PA

Drug Name(s):

AMONDYS
EXONDYS
ELVIDYS
VILTEPSO
VYONDYS

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Age Restrictions:

See above criteria

Prescriber Restrictions:

Neurology and other DMD specialists

FDA Indications:

Elvidys:

- Duchenne muscular dystrophy, Ambulatory patients with a confirmed DMD gene mutation

Amondys 45:

- Duchenne muscular dystrophy, In patients with confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 45 skipping

Exondys 51:

- Duchenne muscular dystrophy, In patients with confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 51 skipping

Viltepso 53:

- Duchenne muscular dystrophy, In patients with confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 53 skipping

Vyondys 53:

- Duchenne muscular dystrophy, In patients with confirmed mutation of the Duchenne muscular dystrophy gene that is amenable to exon 53 skipping

Off-Label Uses:

N/A

Coverage Duration:

Approval will be for 12 months

Other Clinical Consideration:

Elvidys: Contraindicated in patients with any deletion in exon 8 and/or exon 9 in the Duchenne muscular dystrophy gene

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/959E3A/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8556D1/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T

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