



Duchenne Muscular Dystrophy

Amondys (casimersen) J1426, Viltepsso (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.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	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

HCP 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)

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) \geq 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)

- 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**

**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:

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

Viltepsa 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:

N/A

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/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933252&contentSetId=100&title=Casimersen&serviceTitle=Casimersen&brandName=Amondys+45&UserMdxSearchTerm=Amondys+45&=null#



Part B Prior Authorization Guidelines

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Clinical / CMS
Only