

Amondys 45® (casimersen) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1400 billable units every 28 days

III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

Universal Criteria ¹

- Member is not on concomitant therapy with other DMD-directed antisense oligonucleotides; **AND**
- Member is not on concomitant therapy with delandistrogene moxeparvovec-rokl; **AND**
- Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) are measured prior to starting therapy and periodically during treatment; **AND**

Duchenne Muscular Dystrophy (DMD) † Φ ¹⁻¹²

- Member has a confirmed mutation of the *DMD* gene that is amenable to exon 45 skipping; **AND**
- Member has been on a stable dose of corticosteroids, unless there is a contraindication or intolerance, for at least 6 months; **AND**
- Member retains meaningful voluntary motor function (e.g., member is able to speak, manipulate objects using upper extremities, ambulate, etc.); **AND**
- Member is receiving physical and/or occupational therapy; **AND**
- Baseline documentation of one or more of the following:
 - Dystrophin level
 - Timed function tests (e.g., 6-minute walk test [6MWT], time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB], etc.)
 - Upper limb function (ULM) test

- North Star Ambulatory Assessment (NSAA) score
- Forced Vital Capacity (FVC) percent predicted

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹⁻⁸

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: kidney toxicity (e.g., glomerulonephritis, persistent increase in serum cystatin C, proteinuria, etc.), hypersensitivity reactions (e.g., angioedema and anaphylaxis), etc.; **AND**
- Member has responded to therapy compared to pretreatment baseline in one or more of the following (not all-inclusive):
 - Increase in dystrophin level
 - Improvement in quality of life
 - Stability, improvement, or slowed rate of decline in one or more of the following:
 - Timed function tests (e.g., 6-minute walk test [6MWT], time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB], etc.)
 - Upper limb function (ULM) test
 - North Star Ambulatory Assessment (NSAA) score
 - Forced Vital Capacity FVC percent predicted

V. Dosage/Administration ¹

Indication	Dose
Duchenne Muscular Dystrophy	Administer 30 mg/kg intravenously once weekly

VI. Billing Code/Availability Information

HCPCS Code:

- J1426 – Injection, casimersen, 10 mg; 1 billable unit = 10 mg

NDC:

- Amondys 45 100 mg/2 mL single-dose vial: 60923-0227-xx

VII. References

1. Amondys 45 [package insert]. Cambridge, MA; Sarepta Therapeutics, Inc.; January 2026. Accessed March 2026.
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3. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. *Lancet Neurol*; 2010 Jan; 9(1):77-93.
4. Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. *Lancet Neurol*; 2010 Jan; 9(2):177-189.
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6. Darras BT, Urion DK, Ghosh PS. Dystrophinopathies. *GeneReviews*. www.ncbi.nlm.nih.gov/books/NBK11119/. Initial Posting: September 5, 2000; Last Revision: January 20, 2022. Accessed on March 20, 2026.
7. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. *Lancet Neurol* 2018; 17:251.
8. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: respiratory, cardiac, bone health, and orthopaedic management. *Lancet Neurol* 2018; 17:347.
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10. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 Feb 2;86(5):465-72. Doi: 10.1212/WNL.0000000000002337. Retired February 8, 2025.
11. Childs, AM, Turner, C, Astin, R, et al. (2023). Development of respiratory care guidelines for Duchenne muscular dystrophy in the UK: key recommendations for clinical practice. *Thorax*. 2024 Apr 15;79(5):476-485. doi: 10.1136/thorax-2023-220811. PMID: 38123347; PMCID: PMC11041593.

12. Landfeldt, Erik. Measuring health-related quality of life in Duchenne muscular dystrophy: Current perspectives and recommendations. Journal of the Neurological Sciences. 2023 Mar 15;446:120545. doi: 10.1016/j.jns.2023.120545. Epub 2023 Jan 20. PMID: 36706687.

Appendix A – Non-Quantitative Treatment Limitations (NQL) Factor Checklist

Non-quantitative treatment limitations (NQLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G71.01	Duchenne or Becker muscular dystrophy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC