Drug Coverage Policy

Effective Date.....4/15/2026
Coverage Policy Number.....IP0137
Policy Title.....Amondys 45

Muscular Dystrophy – Amondys 45

- Amondys 45™ (casimersen intravenous infusion – Sarepta)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Amondys 45, an antisense oligonucleotide, is indicated for the treatment of **Duchenne muscular dystrophy** (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.[1] This indication was granted accelerated approval based on an increase in dystrophin in skeletal muscle observed in patients treated with Amondys 45. The prescribing

information notes that continued FDA-approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Guidelines
Amondys 45 is not addressed in the guidelines for the diagnosis and management of DMD available from the DMD Care Considerations Working Group (2018).[2] Glucocorticoids slow decline in muscle strength and function in DMD and should be considered for all patients with DMD. Exondys 51 (eteplirsen intravenous infusion) is mentioned as an emerging product, approved by an accelerated pathway for those with a mutation in the dystrophin gene amenable to exon 51 skipping.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Amondys 45. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Amondys 45 as well as the monitoring required for adverse events and long-term efficacy, approval requires Amondys 45 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes, laboratory tests, medical test results, claims records, and/or other information.

Amondys 45 is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Duchenne Muscular Dystrophy.** Approve for the duration noted if the patient meets ONE of the following (A or B):
    - **A.** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
        - **i.** Less than 14 years of age at start of therapy; AND
        - **ii.** Documentation is provided that the patient has a diagnosis of Duchenne muscular dystrophy which is confirmed by a pathogenic or likely pathogenic variant in the *DMD* gene that is amenable to exon 45 skipping ; AND
        - **iii.** Able to walk a distance of at least 300 meters independently over 6 minutes; AND
        - **iv.** Forced vital capacity is at least 50%; AND;
        - **v.** Medication is prescribed by, or in consultation with, a neurologist, neuromuscular specialist, or by a Muscular Dystrophy Association clinic.
    - **B.** Patient is Currently Receiving Amondys 45. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
        - **i.** The above criteria were met prior to initiation of Amondys 45; AND
        - **ii.** Patient has experienced a beneficial clinical response, including the continued ability to walk; AND
        - **iii.** Medication continues to be prescribed by, or in consultation with, a neurologist, neuromuscular specialist, or by a Muscular Dystrophy Association clinic.

    Dosing. Approve 30 milligrams per kilogram administered once weekly as a 35 to 60-minute intravenous infusion

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Amondys 45 for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent use with other exon-skipping DMD agents**: Currently, there is no clinical evidence to support concurrent use of exon-skipping agents for the treatment of DMD.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1426	Injection, casimersen, 10 mg

References

1. Amondys 45 intravenous infusion [prescribing information]. Cambridge, MA: Sarepta; January 2026.
2. 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(3):251-267. Accessed February 24, 2026.
3. Shimizu-Motohashi Y, Murakami T, Kimura E, et al. Exon skipping for Duchenne muscular dystrophy: a systematic review and meta-analysis. *Orphanet J Rare Dis*. 2018;13(1):93.
4. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2026 Feb 24]. Available from: https://clinicaltrials.gov/ct2/show/NCT02500381. Search term: NCT02500381.

Revision Details

Summary of Changes	Review Date	Effective Date
Updated policy title; previously it was Casimersen. Added dosing to the policy.	6/6/2024	8/15/2024
Added "Documentation: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes,	3/20/2025	6/1/2025

laboratory tests, medical test results, claims records, and/or other information." **Duchenne Muscular Dystrophy** **Updated** criteria **from** "Documented diagnosis of Duchenne muscular dystrophy is confirmed by a pathogenic or likely pathogenic variant in the DMD gene that is amenable to exon 45 skipping" **to** "Documentation is provided that the patient has a diagnosis of Duchenne muscular dystrophy which is confirmed by a pathogenic or likely pathogenic variant in the DMD gene that is amenable to exon 45 skipping."		
No criteria changes.	3/26/2026	4/15/2026

The policy effective date is in force until updated or retired.