Reference number(s)
4564-A

Standard Medicare Part B Management Amondys 45

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Amondys 45	casimersen

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Amondys 45 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.

This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Amondys 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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- Initial requests: laboratory confirmation of Duchenne muscular dystrophy (DMD) diagnosis with a DMD gene mutation that is amenable to exon 45 skipping (refer to examples in Appendix).
- Continuation of therapy requests: documentation (e.g., chart notes) of response to therapy.

Coverage Criteria

Duchenne muscular dystrophy[1,2]

Authorization of 6 months may be granted for treatment of DMD when all of the following criteria are met:

- Genetic testing was conducted to confirm the diagnosis of DMD and to identify the specific type of DMD gene mutation.
- The DMD gene mutation is amenable to exon 45 skipping (refer to examples in Appendix).
- Treatment with Amondys 45 is initiated before the age of 14.
- The member is able to achieve an average distance of at least 300 meters while walking independently over 6 minutes.
- Dose will not exceed 30 mg/kg once weekly.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Amondys 45.
- Amondys 45 is being used to treat an indication in the coverage criteria section.
- The member has demonstrated a response to therapy as evidenced by remaining ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent).
- The member will not exceed a dose of 30 mg/kg once weekly.

Appendix[3,4]

Examples of DMD gene mutations (exon deletions) amenable to exon 45 skipping (not an all-inclusive list):

- Deletion of exon 44
- Deletion of exon 46-47
- Deletion of exon 46-48

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- Deletion of exon 46-49
- Deletion of exon 46-51
- Deletion of exon 46-53
- Deletion of exon 46-55

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Amondys 45.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Amondys 45 are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for requiring a minimum six minute walk time of greater than 300 meters can be found in the inclusion criteria for the ESSENCE trial.

References

1. Amondys 45 [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc; March 2023.
2. ClinicalTrials.gov. Study of SRP-4045 and SRP-4053 in DMD patients (ESSENCE). Available at: https://clinicaltrials.gov/ct2/show/NCT02500381. Accessed March 10, 2025.
3. Fletcher, S., et. al. Dystrophin Isoform Induction In Vivo by Antisense-mediated Alternative Splicing. The American Society of Gene & Cell Therapy. 2010;18(6):1218-1223.
4. Polavarapu K, Preethish-Kumar V, Sekar D, et al. Mutation pattern in 606 Duchenne muscular dystrophy children with a comparison between familial and non-familial forms: a study in an Indian large single-center cohort. J Neurol. 2019;266(9):2177-2185.

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