

Amondys 45 (casimersen)

Override(s)	Approval Duration
Prior Authorization	6 months

Medications	Dosing Limit
Amondys 45 (casimersen)	30 mg/kg once weekly

APPROVAL CRITERIA

Initial requests for Amondys 45 (casimersen) may be approved if the following criteria are met:

- I. Individual has a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**
- II. Documentation is provided that individual has a genetic mutation that is amenable to exon 45 skipping; **AND**
- III. Individual is age 7-13 years (NCT02500381); **AND**
- IV. Individual has been on a stable dose of oral corticosteroids (NCT02500381); **AND**
- V. Documentation is provided that individual has a 6MWT (6 minute walk test) \geq 300 meters and less than 450 meters (NCT02500381); **AND**
- VI. Documentation is provided that individual has stable pulmonary function with forced vital capacity (FVC) equal to or greater than 50% predicted (NCT02500381); **AND**
- VII. Individual will not use with any other exon skipping agents for DMD (including but not limited to Exondys 51, Vyondys 53).

Continuation of therapy with Amondys 45 (casimersen) may be approved if the following criterion are met:

- I. Criteria above were met at initiation of therapy; **AND**
- II. Documentation is provided that individual remains ambulatory (with or without needing an assistive device, such as a cane or walker).

Requests for Amondys 45 (casimersen) may not be approved when the criteria above are not met and for all other indications.

Key References:

1. Kole R, Krieg AM. Exon skipping therapy for Duchenne muscular dystrophy. *Ad Drug Del Rev.* 2015; 87:140-107.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Available at: <https://clinicaltrials.gov/ct2/home> Accessed on January 28, 2021.
3. Amondys 45 [package insert]. Cambridge, MA: Sarepta Therapeutics, Inc.; 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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