Amondys 45
(casimersen)

Date of Origin: 03/31/20 **Last Review Date: 05/19/23** **Effective Date: 04/01/2020**

Dates Reviewed: 03/31/20, 05/19/23

Developed By: Medical Criteria Committee

I. Length of Authorization

- Initial: 6 months
- Continuation: 12 months

II. Dosing Limits

- Duchenne muscular dystrophy
    - 350 billable units every week

III. Initial Approval Criteria

The use of casimersen (Amondys 45) for Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping does not meet the definition of medical necessity, defined as delivery of a service by a qualified healthcare provider, exercising prudent clinical judgement that meets all of the following:

a. Is for the purpose of preventing, evaluating, diagnosing or treating a medical condition or its symptoms
b. Is in accordance with generally accepted standards of medical practice
c. Is proven to be effective in producing intended effects on health outcomes (e.g., morbidity, mortality, quality of life, symptom control, function) associated with the member's medical condition or its symptoms
d. Has beneficial effects on health outcomes that outweigh the potential harmful effects
e. Is clinically appropriate in terms of type, frequency, extent, site and duration
f. Is not primarily for the convenience of the patient or healthcare provider
g. Is at least as likely to produce equivalent therapeutic or diagnostic results for the diagnosis or treatment of that patient's medical condition or its symptoms as an alternative service, including no intervention, and is not more costly than an alternative service or sequence of services.

For these purposes, "generally accepted standards of medical practice" are standards based on reliable scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas, and other relevant factors. For new treatments, effectiveness is determined by reliable scientific evidence that is published in peer-reviewed medical literature. For existing treatments, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion. The fact that services were furnished,

prescribed or approved by a physician or other qualified provider does not in itself mean that services are medically necessary. The fact that a service is FDA-approved does not in itself mean that the service is medically necessary.

IV. Renewal Criteria

- N/A

V. Dosage/Administration

Indication	Dose
Duchenne muscular dystrophy	Administer 30 mg/kg via intravenous infusion once weekly. - Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) should be measured before starting therapy. Consider measurement of glomerular filtration rate prior to initiation of Amondys 45.

VI. Billing Code/Availability Information

- 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; February 2021.