



Prior Authorization Criteria

AMONDYS 45[®] (casimersen) PA CRITERIA:

AMONDYS 45[®] (casimersen) is an antisense oligonucleotide 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.

Prior authorization is required for AMONDYS 45[®] (casimersen). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 6 Months

1. The patient is a male who is at least 7 years old; **AND**
2. The patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation of the DMD gene that is amenable to exon 45 skipping confirmed by genetic testing; **AND**
3. AMONDYS 45[®] is prescribed by or in consultation with a neurologist or a prescriber who specializes in treatment of DMD (i.e., pediatric neurologist, cardiologist, or pulmonary specialist); **AND**
4. The patient is on a stable dose of a corticosteroid, or there is documentation explaining why corticosteroid therapy is not appropriate; **AND**
5. The patient is not ventilator dependent; **AND**
6. The patient has completed recent renal function testing (including serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio) and results are within acceptable limits to safely initiate therapy; **AND**
7. Comprehensive progress notes are submitted documenting age-appropriate and functional level determination of baseline assessment; testing tools that can be used to demonstrate physical function include, but are not limited to:
 - a. Baseline 6-Minute Walk Test (6MWT); **OR**
 - b. Brooke Upper Extremity Scale (some useful hand function present for use of adaptive technology); **OR**
 - c. Forced Vital Capacity assessment; **AND**
8. The patient's weight is provided, and the prescribed dose does not exceed 30 mg/kg administered as an IV infusion once weekly.



Re-Authorization: 6 Months

1. The patient continues to meet initial authorization criteria;
AND
2. The patient's weight is provided, and the prescribed dose does not exceed 30 mg/kg administered as an IV infusion once weekly; **AND**
3. Documentation that the patient has been compliant with treatment is provided;
AND
4. Documentation of positive clinical response to therapy is provided.

AMONDYS 45[®] Dosing:

- The recommended dose is 30 mg/kg administered as an IV infusion once weekly.

Formulation:

- AMONDYS 45[®] is available as 100 mg/2 mL in a single-dose vial.