AMONDYS 45 (casimersen)

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:
- Patient must have the diagnosis of Duchenne muscular dystrophy (DMD).
- Submission of medical records (e.g., chart notes, laboratory values) as genetic test is required to confirm that a patient’s mutation of the DMD gene is amenable to exon 45 skipping.
- Medication is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD (i.e. pediatric neurologist, cardiologist or pulmonary specialist).
- Submission of cystatin C, urine dipstick, and urine protein-to-creatinine ratio prior to starting therapy.
- Patient has been on stable dose of oral corticosteroids for at least 24 weeks prior to starting therapy.
- Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, viltolarsen, or eteplirsen).
- If the patient is ambulatory, functional level determination of baseline assessment of ambulatory function (six-minute walk test (6MWT), time to run/walk 10-meter test (TTRW), time to climb 4-stair test (TTCLIMB), time to stand (TTSTAND) or North Star Ambulatory Assessment (NSAA)) is required.
- If not ambulatory, patient must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more.

CONTINUATION OF THERAPY:
- Patient met initial review criteria.
- Documentation of improvement of maintenance:
  - For ambulatory patients – submission of 6MWT, TTRW, TTCLIMB, TTSTAND or NSAA.
  - For non-ambulatory patients – submission of Brooke Upper Extremity Function Scale (five or less) documented OR a Forced Vital Capacity document (30% or more)
- Submission of cystatin C, urine dipstick, and urine protein-to-creatinine ratio.
- Patient is not concurrently treated with other DMD antisense oligonucleotides (e.g. golodirsen, viltolarsen, or eteplirsen).

DOSSING AND ADMINISTRATION:
- Administer 30 mg/kg once weekly intravenous (IV) infusion over 35 to 60 minutes via an in-line 0.2-micron filter.
- Available as 100 mg/2 mL single-dose vial (SDV).