

Duchenne Muscular Dystrophy: Amondys 45

Member Information

1. Last Name: _____ 2. First Name: _____
3. Trillium ID #: _____ 4. Date of Birth: _____ 5. Gender: _____

Prescriber Information

1. Prescriber Name: _____ 2. NPI #: _____
2. Requestor Name (Nurse/Office Staff): _____
3. Mailing Address: _____ City: _____ State: _____ Zip: _____
4. Phone #: _____ Ext. _____ Fax #: _____

Drug Information

1. Drug Name: **Amondys 45** 2. Strength: _____ 3. Quantity per 30 Days: _____
4. Length of Therapy (in Days): up to 30 days 60 days 90 days 120 days 180 days

Clinical Information

For initial authorization requests:

1. What is the member's weight? _____
2. Does the member have a diagnosis of Duchenne Muscular Dystrophy? Yes No
3. Are medical records attached to this request that confirm the mutation of the Duchenne Muscular Dystrophy gene is amenable to exon 45 skipping? Yes No
4. Is Amondys 45 being prescribed by or in consultation with a neurologist? Yes No
5. Does the member retain meaningful voluntary motor function (member is able to speak, manipulate objects using upper extremities, ambulate, etc.)? Yes No
6. Has the member been assessed for any physical therapy and/or occupational therapy needs? Yes No
7. Has the member's serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) been measured prior to starting therapy? Yes No
8. Does the prescriber attest that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio will be measured during treatment (monthly urine dipstick with serum cystatin C and urine protein-to-creatinine ratio every 3 months)? Yes No
9. Has baseline documentation of at least 1 of the following been performed: Dystrophin level, 6-minute walk test (6MWT) or other timed function tests, Upper limb function (ULM) test, North Star Ambulatory Assessment (NSAA), Forced Vital Capacity (FVC) % predicted, of Performance or Upper Limb (PUL)? Yes No
List: _____
10. Is the member taking any other RNA antisense agent or any other gene therapy? Yes No
11. Is the member receiving a dose that does not exceed 30mg/kg once per week? Yes No

For reauthorization: (answer 1-12)

12. Please attach documentation that shows the member has demonstrated a response to therapy compared to pretreatment baseline in at least 1 of the following:
 Increase in dystrophin level; OR
 Stability, improvement, or slowed rate of decline in 6MWT or other timed function tests; OR
 Stability, improvement, or slowed rate of decline in ULM test; OR
 Stability, improvement, or slowed rate of decline in NSAA; OR
 Stability, improvement, or slowed rate of decline in FVC% predicted; OR
 Improvement in quality of life; and that the member has not experienced any treatment-restricting adverse effects e.g., renal toxicities, proteinuria)

Signature of Prescriber: _____ Date: _____

(Prescriber Signature Mandatory)

I certify that the information provided is accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.