Trillium Health Resources
Pharmacy Prior Approval Request for

Trillium HEALTH RESOURCES
Transforming Lives. Building Community Well-Being.

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.