carolina complete health

Pharmacy Prior Approval Request for Amondys 45

Beneficiary Information

1. Beneficiary Last Name: _____ 2. First Name: _____
3. Beneficiary ID #: _____4. Beneficiary Date of Birth: _____ 5. Beneficiary Gender: _____

Prescriber Information

6. Prescribing Provider NPI #: _____
7. Requester Contact Information - Name: _____ Phone #: _____ Ext. _____

Drug Information

8. Drug Name: _____ 9. Strength: _____ 10. Quantity Per 30 Days: _____
11. 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 beneficiary's weight? _____
2. Does the beneficiary 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 beneficiary retain meaningful voluntary motor function (beneficiary is able to speak, manipulate objects using upper extremities, ambulate, etc? ☐ **Yes** ☐ **No**
6. Has the beneficiary has been assessed for any physical therapy and/or occupational therapy needs? ☐ **Yes** ☐ **No**
7. Has the beneficiary's serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) have 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 (6WMT) or other timed function tests, Upper limb function (ULM) test, North Star Ambulatory Assessment (NSAA), Forced Vital Capacity (FVC) % predicted, of Performance of Upper Limb (PUL)? ☐ **Yes** ☐ **No** List_____
10. Is the beneficiary taking any other RNA antisense agent or any other gene therapy? ☐ **Yes** ☐ **No**
11. Is the beneficiary 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 beneficiary 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 beneficiary 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.