



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services
Prior Authorization Criteria
Amondys 45[®] (Casimersen)

Effective 05/26/2021

AMONDYS 45 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. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. **A clinical benefit of AMONDYS 45 has not been established.** Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Amondys 45 is currently billable only as a Pharmacy Point-of-Sale (POS) claim:

- Pharmacy POS - Contact RDTP, tel: (800) 847-3859/ fax (800) 531-7787

All requests require review by the Medical Director and may be approvable once the following criteria are met:

1. Patient must have a confirmed mutation of a DMD gene that is amenable to exon 45 skipping (chart notes required); **AND**
2. The patient must meet all label requirements as recommended by the FDA and the manufacturer; **AND**
3. Baseline renal function must be evaluated, and documentation provided with the request for Amondys 45; **AND**
4. Request must either be from a neurologist or from a physician who has provided documentation of a formal consultation with a neurologist; **AND**

Patient must be stabilized on corticosteroid therapy for at least 6 months prior to the request for coverage of Amondys 45. Documentation must be supplied detailing the prescribed steroid therapy and the patient must continue this therapy while receiving Amondys 45.

NOTE: If the patient cannot take steroid therapy, clinical justification must be provided by the physician, otherwise the prior authorization request shall be immediately denied; **AND**



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5. The results of appropriate and validated baseline functional tests must be submitted with the initial request for therapy. These results will be considered valid only if taken after the patient has received corticosteroid therapy for at least 6 months.

Acceptable tests may include, **but are not limited to**, any of the following:

- a. Ambulatory patients: Six-minute walk test (6MWDT) (patient must achieve > 180 meters for approval.
- b. Non-ambulatory patients: Brooke Upper Extremity Function Scale (of 5 or less) **AND** a Forced Vital Capacity of $\geq 30\%$ of predicted value are required for approval.

Other functional assessment tests may be accepted on a case-by-case basis at the discretion of the Medical Director. These tests must be quantitative in nature and accompanied with supporting documentation and references describing the test.

All prior authorization approvals are limited to 6 months at time and continuation of coverage requires the following conditions to be met:

- 1) Follow-up functional test results must show stabilization or improvement of patient function compared to baseline measures; **AND**
- 2) The results of regular renal function tests (as recommended by the manufacturer*) must be supplied with every request for Amondys 45; **AND**
- 3) Patient must maintain 100% compliance on all scheduled therapy – Amondys 45 must be dosed once per week and maintenance steroid therapy must continue as prescribed by the physician. Failure to maintain compliance with prescribed therapy shall result in immediate discontinuation of coverage unless the disruption can be medically justified by the prescribing physician.

*The following are recommended by the manufacturer: Measurement of glomerular filtration rate (GFR) by 24-hour urine collection prior to initiation of therapy, monitoring for proteinuria by dipstick urinalysis at baseline and monthly, monitoring of serum cystatin C and urine protein-to-creatinine ratio (UPCR) every three months. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

REFERENCES

- 1.) Amondys 45 Package Insert (Sarepta Therapeutics)
- 2.) Lexicomp Clinical application accessed 5/2021)
- 3.) Measures of Clinical Assessment in Patients with Duchenne Muscular Dystrophy (DMD)
<https://sarepta.appdataroom.com/download/v/bd16dff387135c4643386085c1bdc58fc508ef490459?ts=1582134595&sig=35e5f191eed1241b58063411fc49504f65bf63e7&trackingGuid=CD061BF-A492-4090-A22E-2FADB6F9B100&groupId=4411>



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- 4.) Birnrant et al. Lancet Neurol. 2018 March; 17(3): 251-267. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management.