Clinical Policy Title:	casimersen
Policy Number:	RxA.677
Drug(s) Applied:	Amondys 45™
Original Policy Date:	06/10/2021
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

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™. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
casimersen (Amondys 45™)	Duchenne muscular dystrophy	30 milligrams per kilogram of body weight once weekly	30 mg/kg/dose IV once weekly

Dosage Forms

- Injection: 100 mg/2 mL in a single-dose vial

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Duchenne muscular dystrophy

1. Diagnosis of DMD gene amenable to exon 45 skipping as evidenced by documentation (e.g., chart notes, lab test results);
2. Prescribed by or in consultation with a neurologist, cardiologist or specialist in treating DMD;
3. Documentation of serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) before starting therapy with Amondys 45™;
4. Member meets one of the following, prior to starting Amondys 45 therapy, evidenced by documentation (a, b or c):
   a. Member is ambulatory with a 6-minute walk test (6MWT) ≥ 300 meters while walking independently (e.g., without assistive device like cane, walker, wheelchair, etc.);

b. Member has achieved North Star Ambulatory Assessment (NSAA) score greater than 17;
c. Member has achieved rise time (Gower's test) of less than 7 seconds;

5. Member has been stable on oral corticosteroid therapy for at least 24 weeks before starting therapy with Amondys 45™;
6. Amondys 45™ is not prescribed concurrently with other exon-skipping therapies (e.g., Vyondys 53™, Exondys 51™, etc.);
7. Maximum dosing of 30 mg/kg infused once weekly.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Duchenne muscular dystrophy

1. Member is currently receiving medication that has been authorized by RxAdvance, or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy evidenced by documentation;
3. Documentation confirming member is ambulatory without needing assisted device;
4. Amondys 45™ is prescribed concurrently with an oral corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
5. Amondys 45™ is not prescribed concurrently with other exon-skipping therapies (e.g., Vyondys 53, Exondys 51);
6. If request is for a dose increase, new dose does not exceed 30 mg/kg once weekly;

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DMD: Duchenne muscular dystrophy
FDA: Food and Drugs Administration
NSAA: North Star Ambulatory Assessment

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information

References

1. Amondys 45 (casimersen) [prescribing information]. Cambridge, MA: Sarepta Therapeutics Inc; February 2021. https://www.amondys45.com/. Accessed April 2,2021.

2. Amondys 45. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2020, March 17. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed April 26, 2021.
3. Amondys 45 (casimersen). New Drug Review. In: IPD Analytics. Aventure, FL; March 2021. Accessed with subscription at: https://secure.ipdanalytics.com/ Accessed April 26, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	04/05/2021	06/10/2021