

Duchenne Muscular Dystrophy Agents
Amondys 45 (casimersen)
Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Amondys 45 is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Amondys 45 (casimersen) 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.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of Duchenne Muscular Dystrophy
2. Documentation of a confirmed out of frame deletion in the DMD that is amenable to exon 45 skipping
3. Prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided
4. Member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner)
5. Dosing is appropriate (30 mg/kg intravenously every week)
6. **ONE** of the following:
 - a. Member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent

- b. Contraindication to corticosteroids
- 7. Member has at least a baseline measurement for **ALL** of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
 - a. Timed ten-meter walk/run (time in seconds)
 - b. Timed floor (supine) to stand (time in seconds)
 - c. Timed four-step descend (time in seconds)
 - d. Timed four-step climb (time in seconds)
 - e. Timed sit to stand (time in seconds)

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition and the following:

- 1. Member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner)
- 2. Member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included)
- 3. Dosing remains appropriate
- 4. **ONE** of the following:
 - a. Member continues to utilize corticosteroids in combination with the requested agent
 - b. Contraindication to corticosteroids
- 5. Member has a stable or improving pattern of observed performance on at least **TWO** of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
 - a. Timed ten-meter walk/run (time in seconds)
 - b. Timed floor (supine) to stand (time in seconds)
 - c. Timed four-step descend (time in seconds)
 - d. Timed four-step climb (time in seconds)
 - e. Timed sit to stand (time in seconds)

Limitations

- 1. Initial approvals and reauthorizations will be granted for 3 months.

References

- 1. Amondys 45® [package insert]. Cambridge (MA): Sarepta Therapeutics, Inc.; 2024 Jul.
- 2. Birnkrant DJ, Bushby K, Bann CM, Apkon SD, Blackwell A, Brumbaugh D, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management. *Lancet Neurol*. 2018 Mar;17(3):251-267.
- 3. Darras BT. Duchenne and Becker muscular dystrophy: Clinical features and diagnosis. In: Dashe JF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2018 [cited 2020 Jan 1]. Available from: <http://www.utdol.com/utd/index.do>.



4. Center for Drug Evaluation and Research. Medical Review: Application number 206488Orig1s000. Food and Drug Administration. 2016 Sep [cited 2019 Mar 5]. Available from:
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000MedR.pdf.

Review History

09/22/2021 – Reviewed and Created for Sept P&T. Effective 11/01/2021

11/16/22 – Reviewed and updated for Nov P&T. Separated Comm/Exch vs MH and matched MH UPPL criteria.

Prior authorization was added to Amondys 45 on pharmacy benefit. Effective 2/1/23

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Effective 6/1/25

