Mass General Brigham
Health Plan

Amondys 45® (casimersen)
Effective 02/01/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

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®.

No PA	Drugs that require PA
	Amondys 45® (casimersen)

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, and documentation is provided:

1. Appropriate 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.; 2021 Feb.
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.