Amondys 45 (casimersen)  
Effective 11/01/2021

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**Specialty Limitations**

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**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.

**Coverage Guidelines**

Authorization may be granted for new members to AllWays Health Partners who are currently receiving treatment with Amondys 45 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. The member has a documented diagnosis of Duchenne muscular dystrophy with a mutation of the DMD gene that is amenable to exon 45 skipping
2. The prescribing physician is a neurologist or a provider who specializes in the treatment of Duchenne muscular dystrophy
3. 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)
4. Dosing is appropriate (30 mg/kg intravenously every week)
5. 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
6. 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 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)
2. Dosing remains appropriate
3. ONE of the following:
   a. Member continues to utilize corticosteroids in combination with the requested agent
   b. Contraindication to corticosteroids
4. 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 will be for 6 months.
2. Reauthorizations will be for 12 months

Appendix
Examples of DMD gene mutations (exon deletions) amenable to exon 45 skipping (not an all-inclusive list):
1. Deletion of exon 44
2. Deletion of exon 46-47
3. Deletion of exon 46-48
4. Deletion of exon 46-49
5. Deletion of exon 46-51
6. Deletion of exon 46-53
7. Deletion of exon 46-55

References


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

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.