Amondys 45™ (casimersen intravenous infusion)

Effective Date: June 9, 2021    Number: MG.MM.PH.331

Medical Guideline Disclaimer

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Definitions:
Amondys 45 is an antisense oligonucleotide designed to bind to exon 45 of dystrophin pre-mRNA, resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 45 skipping. These patients represent up to 8% of all patients with DMD. This genetic manipulation intends to restore the reading frame of the resulting mRNA. The result would be production of a shortened, but partially functional dystrophin protein as seen in less severe forms of muscular dystrophy (e.g., Becker muscular dystrophy).

Length of Authorization
Coverage will be provided for six months and may be renewed.

Dosing Limits [Medical Benefit]:
The recommended dosage is 30mg/kg as an intravenous infusion over approximately 35 to 60 minutes once weekly.

Guideline
I. INITIAL APPROVAL CRITERIA
Coverage will be provided when the following criteria are met:

Duchenne muscular dystrophy (DMD)
- Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by genetic testing;  
  AND
- Specific type of DMD gene mutation which amenable to exon 45 skipping has been confirmed;  
  AND
- Patient must be ambulatory (e.g. 6-minute walk test (6MWT) greater than or equal to 300 meters while walking independently, North star Ambulatory Assessment (NSAA) score of greater than 17, or achieved rise time (Gower’s test) less than 7 seconds);  
  AND
- Patient has been on a stable dose of corticosteroids for at least 6 months (unless contraindicated or intolerance);  
  AND
- Prescribing provider is a neurologist or DMD specialist

II. RENEWAL APPROVAL CRITERIA
Coverage can be renewed for six months based on the following conditions:
- Stabilization of disease or absence of disease progression;  
  AND
- Absence of unacceptable toxicity from the drug.

Applicable Procedure Codes

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<tr>
<td>C9075</td>
<td>Injection, casimersen, 10 mg</td>
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<td>J3490</td>
<td>Unclassified drugs</td>
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Applicable NDCs

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<td>60923-0227-02</td>
<td>Injection, 100 mg/2 mL (50 mg/mL) solution in a single-dose vial</td>
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Applicable Diagnosis Codes

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Revision History

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<tr>
<td>6/9/2021</td>
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References: