COMMUNITY HEALTH CHOICE

Amondys 45® (casimersen)

Effective Date: 7/1/24
Medical Care Management Committee Approval: 4/25/24

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Amondys 45® (casimersen) product:

HCPCS Code	Description	Maximum Dosage per Administration
J1426	Injection, casimersen, 10 mg	30 mg/kg

Diagnosis-Specific Criteria

Amondys 45® (casimersen) will be considered medically necessary for members meeting ALL of the following criteria:

1. Member has a documented diagnosis of Duchenne Muscular Dystrophy (DMD); AND
2. There is confirmed mutation of the DMD gene that is amenable to exon 45 skipping; AND
3. Member is less than 14 years of age at onset of therapy; AND
4. Member is able to walk a distance of at least 300 meters independently over 6 minutes; AND
5. Forced vital capacity is at least 50%; AND
6. Medication is prescribed by, or in consultation with, a neuromuscular specialist or neurologist; AND
7. Member is currently stable on oral corticosteroid regimen for at least 6 months; AND
8. Amondys 45® will not be used in combination with other exon skipping therapies for DMD

Continuation Criteria:

1. Member has documentation of beneficial response including the continued ability to walk

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J1426	Injection, casimersen, 10 mg

Diagnosis Code	Description
G71.01	Duchenne or Becker muscular dystrophy

Policy Revision History

Status	Effective Date	Description
Baseline	7/1/24	Initial version of casimersen diagnosis specific policy