Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

AMONDYS 45® (casimersen)

I. Medication Description

Amondys 45® is an antisense oligonucleotide indicated for:

Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping

II. Position Statement

Coverage is determined through a prior authorization process that must include supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping
  - The www.duchenneconnect.org website uses the following tool to find the genes amendable to Exon 45 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
  - Genetic mutation test results must be submitted with request.
- Must be prescribed by or in consult with a neurology specialist
- Must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Amondys 45®, unless corticosteroid use is contraindicated or was discontinued due to unfavorable side effects
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Amondys 45®, unless corticosteroid use is contraindicated or was discontinued due to unfavorable side effects.
- If ambulatory, baseline functional level assessment required by one of the following:
  - Six-minute walk test (6MWT)
  - NorthStar Ambulatory Assessment
- If non-ambulatory, baseline functional level assessment required by one of the following:
  - Revised Upper Limb Module (RULM)
  - Performance Upper Limb (PUL)
- Amondys 45® is not used concomitantly with other exon skipping therapies for DMD.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Member has been adherent to Amondys 45®.
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
• Functional level assessment must be completed every 6-months using the same rating scale utilized at baseline and submitted with renewal request.
• Member is receiving a benefit from Amondys 45® therapy, as demonstrated by one of the following:
  o Stabilization or improvement compared to baseline functional level assessment utilizing the same rating scale submitted in initial approval.
  o Provider attests that member requires continued use of medication, despite not meeting improved baseline functional level assessment criteria and the benefits of continued use of medication outweigh the risks.
• Annual specialist consult provided if prescriber not a specialist.

V. Quantity Limitations

Max 30mg/kg IV once weekly.

VI. Coverage Duration

• Initial approval duration: 6 months
• Renewal approval duration: 6 months