

Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

EXONDYS 51[®] (eteplirsen)

I. Medication Description

Exondys 51[®] 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 51 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:

- Member must have Duchenne Muscular Dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.
 - [The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to exon 51 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/](https://www.duchenneconnect.org)
 - Genetic mutation test results must be submitted with request.
- Exondys 51[®] must be prescribed by, or in consult with, a specialist familiar with DMD (usually a neurologist).
- Member must be on a stable dose of corticosteroids (prednisone, prednisolone, etc.) prior to starting Exondys 51[®], unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Exondys 51[®], unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Member must be ambulatory (able to walk with assistance, and not wheelchair dependent).
- Exondys 51[®] 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 Exondys 51[®].
- Corticosteroids must be used concurrently, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Member must be ambulatory (able to walk with assistance, and not wheelchair dependent).

V. Quantity Limitations

Max 30mg/kg IV once weekly.

VI. Coverage Duration

Initial approval duration: 6 months

Renewal approval duration: 6 months