Montana Healthcare Programs
Physician Administered Drug Coverage Criteria

VYONDYS 53® (golodirsen)

I. Medication Description

Vyondys 53® 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 53 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 DMD with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
  - The www.duchenneconnect.org website utilizes the following tool to find the genes amendable to exon 53 skipping: https://www.parentprojectmd.org/wp-content/exondeletiontool/
  - Genetic mutation test results must be submitted with request.
- Vyondys 53® 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 Vyondys 53®, unless corticosteroid use is contraindicated, or was discontinued due to unfavorable side effects.
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Vyondys 53®, 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).
- Vyondys 53® 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 Vyondys 53®.
- 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