

Montana Healthcare Programs Physician Administered Drug Coverage Criteria

Viltepso® (viltolarsen)

I. Medication Description

Viltepso® 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:

- Must have Duchenne muscular dystrophy (DMD) with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
 - The www.duchenneconnect.org website uses 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.
- 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 Viltepso®, unless corticosteroid use is contraindicated or was discontinued due to unfavorable side effects
- Corticosteroids (prednisone, prednisolone, etc.) must be used concurrently with Viltepso®, 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)
- Viltepso® is not used concomitantly with other exon skipping therapies for DMD.

IV. Renewal Coverage Criteria

Member must meet all the following criteria:

- Has been adherent to Viltepso®
- 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 six months using the same rating scale used at baseline and submitted with renewal request.
- Member is receiving a benefit from Viltepso® therapy, as demonstrated by one of the following:
 - Stabilization or improvement compared to baseline functional level assessment using the same rating scale submitted in initial approval.
 - Provider attests 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 80mg/kg IV once weekly

VI. Coverage Duration

- Initial approval duration: 6 months
- Renewal approval duration: 6 months