MEDICAL REVIEW GUIDELINE

Viltepso Diagnosis Specific Policy



Viltepso® (viltolarsen)

Effective Date: 7/1/24

Medical Care Management Committee Approval: 4/25/24

Contents

Coverage Policy	1
Diagnosis-Specific Criteria	
Applicable Codes	2
Policy Revision History	2

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 Viltepso® (viltolarsen) product:

HCPCS Code	Description	Maximum Dosage per Administration
J1427	Injection, viltolarsen, 10 mg	80 mg/kg

Diagnosis-Specific Criteria

Viltepso® (viltolarsen) will be considered medically necessary for members meeting ALL of the following criteria:

- 1. Member has a documented diagnosis of Duchenne Muscular Dystrophy; AND
- 2. There is confirmed mutation of the DMD gene that is amenable to exon 53 skipping; AND
- 3. Member is less than 10 years of age at onset of therapy; AND
- 4. Member is able to walk; AND
- Baseline 6 minute walk test is submitted; AND
- 6. Medication is prescribed by, or in consultation with, a neuromuscular specialist or neurologist; AND
- 7. Member has been stable on an oral corticosteroid regimen for at least 3 months

Continuation Criteria:

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

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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
J1427	Injection, viltolarsen, 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 viltolarsen diagnosis specific policy