Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Viltepso® (Viltolarsen) PA Criteria

Viltepso® is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.

- Diagnosis of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. ICD-10 code: _____

For BOTH the initial and the reauthorization requests, the provider must submit the following:

- documentation of a recent clinical progress note including patient's current age and weight with the date the weight was obtained (the weight must be dated no more than 30 days before the request date)
- a copy of the prescription
- Viltepso® (Viltolarsen) prior authorization form.

INITIAL AUTHORIZATION requests shall also include documentation of*:*

- The genetic laboratory test result with specific mutation, and
- Physical function with age-appropriate testing tools used to measure physical function

REAUTHORIZATION requests shall also include documentation of either:

- An increase in the physical function from baseline, or
- That baseline physical function has been maintained.

Providers should use the same testing instrument as used in the baseline evaluation for physical function. If re-use of the initial testing instrument is not appropriate, for example, due to change in client status or restricted age range of the testing tool, the provider must explain the reason for the change.

Prior authorization requests for Viltepso® (Viltolarsen) may be approved if all the following criteria are met: (Yes should be checked for each statement):

☐ Yes ☐ No Male age ≤ 9 years at therapy initiation.

☐ Yes ☐ No Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 53 skipping confirmed by genetic testing (attach results of genetic testing)

☐ Yes ☐ No Viltepso® (Viltolarsen) is prescribed by or in consultation with a neurologist or a physician who specializes in treatment of DMD

☐ Yes ☐ No Patient is currently on a stable dose of a corticosteroid or has a documented reason not to be on this medication

☐ Yes ☐ No Comprehensive progress notes submitted document age appropriate and functional level determination of baseline assessment. Testing tools that can be used to demonstrate physical function include, but are not limited to:

- Baseline 6-Minute Walk Test (6MWT)]
  OR
- Brooke Upper Extremity Scale (some useful hand function present for use of adaptive technology),
  OR
- Forced Vital Capacity assessment.

☐ Yes ☐ No Patient is not in medically intractable congestive heart failure.

☐ Yes ☐ No Patient is not ventilator dependent.

☐ Yes ☐ No Viltepso® (Viltolarsen) is not prescribed concurrently with other exon-skipping therapies

☐ Yes ☐ No Dose does not exceed 80 mg/kg per week.

☐ Yes ☐ No Copy of prescription is provided.

☐ Yes ☐ No Patient's weight in kilograms and the date weight recorded.
Dates of Weight/Visit: _____ Weight (in kg) _____

Approval duration: Six (6) months

REATHORIZATION: (prior authorization will be issued for no more than a six-month duration):

☐ Yes ☐ No Patient initial authorization criteria for initial treatment are still met.

☐ Yes ☐ No Patient has not had significant decline in neuromotor function or forced vital capacity while on Viltepso® (Viltolarsen).

☐ Yes ☐ No Statement from prescribing physician that the patient has been compliant with treatment.

☐ Yes ☐ No Copy of prescription is provided.

☐ Yes ☐ No Patient's weight in kilograms and the date weight recorded.

Dates of Weight/Visit: _____ Weight (in kg) _____

Reauthorization: Six (6) months

Each prescription may be written for 6 months; however, the prescription must specify that medication is to be dispensed at no more than four (4) weeks supply at a time. Mississippi Division of Medicaid will only allow a 28-day supply to be dispensed at a time to ensure that the patient tolerates the medication prior to subsequent medication doses being dispensed to the physician clinic/hospital for administration.

NOTE: Mississippi Division of Medicaid's coverage of Viltepso® (Viltolarsen) is contingent upon continued FDA approval.