TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Viltolarsen (Viltepso®)	**CRITERIA ID:** TX.CC.PHAR.10
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 3/8/21	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 3/26/21, 11/22/21, 8/1/22, 7/12/23, 2/27/2024, 2/20/2025	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Viltolarsen (Viltepso®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
NRB = non-risk based
PDAC = Precision Drug Action Committee
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Viltolarsen (Viltepso®); procedure code: J1427.

Description/Mechanism of Action:
Viltolarsen (Viltepso®) is antisense oligonucleotide. It is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping.

FDA Approved Indications:
Viltolarsen (Viltepso®) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping.

Formulations:
Viltolarsen (Viltepso®) is available as a single-dose vial, injection solution 250mg/5mL (50mg/mL)

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Duchenne Muscular Dystrophy (DMD)

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Documentation of genetic testing that confirms the client's DMD gene is amenable to exon 53 skipping (see Appendix A).
3. Documentation of client's current weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
4. Documentation of client's baseline physical function. Testing tools used to measure the physical function can include, but are not limited to: Brooke Upper Extremity Scale, Baseline 6MWT (6-minute walk test), or Pediatric Evaluation of Disability Inventory.
5. Documentation of client's baseline renal function test (i.e. glomerulus filtration rate) and urine protein-to-creatinine ratio before starting treatment.
6. Prescriber attestation that Viltepso will not be used concomitantly with other exon skipping therapies for DMD.
7. Documentation of the client's dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the request units per injection, and the dosage calculation must be submitted.

Approval duration: 6 months

I. Continued Therapy

A. Duchenne Muscular Dystrophy (DMD)

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
3. Request for continuation must be received no earlier than 30 days before the current authorization period expires. Requests for recertification/extension of prior authorization received after the current prior authorization expires will be denied for dates of service that occurred before the date the request is received
4. Documentation must include the client's continual renal function test while on therapy and current weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
5. The Medical Director will check for improvement in or maintenance of baseline physical function. Providers must use the same testing instrument as used in the initial evaluation. 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. Viltepso should not be continued on clients who experience decreasing physical function while on the medication.
6. Prescriber attestation that client has been compliant with the treatment
7. Prescriber attestation that Viltepso will not be used concomitantly with other exon skipping therapies for DMD.
8. Documentation of the client's dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the request units per injection, and the dosage calculation must be submitted.

Approval duration: 6 months

Appendix A:
Common mutations amenable to exon 53 skipping include: 3-52, 4-52, 5-52, 6-52, 9-52, 10-52, 11-52, 13-52, 14-52, 15-52, 16-52, 17-52, 19-52, 21-52, 23-52, 24-52, 25-52, 26- 52, 27-52, 28-52, 29-52, 30-52, 31-52, 32-52, 33-52, 34-52, 35-52, 36-52, 37-52, 38-52, 39-52, 40-52, 41-52, 42-52, 43-52, 45-52, 47-52, 48-52, 49-52, 50-52, 52, 54-58, 54-61, 54-64, 54-66, 54-76, 54-77.

REFERENCES:

Viltepso (vitolarsen) [prescribing information]. Paramus, NJ. NS Pharma, Inc.; August 2020

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	3/8/21
Ad Hoc Review	Removed age criteria 4-9 years old per VDP guidance (there is no age requirements for antisense oligonucleotides)	3/26/21
Ad Hoc Review	Remove PDAC designation effective 12/1/21 Reworded criteria #2 under Continued Therapy section to match TMPPM Manual Moved notes about dosage & administration schedule to criteria point under the Initial and Continued Therapy sections	11/21/21
Ad Hoc Review	Changed to new P&P template Removed specialist requirement	8/1/22
Annual Review	No changes	7/12/23
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed criteria step: The requested dosage is for no more than 80mg/kg once weekly as dose check is not listed in TMHP CAD Manual	2/27/2024
Ad Hoc Review	Annual review. No changes	2/20/2025