Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Viltolarsen (Viltepso®)
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE:	**RETIRED:**
EFFECTIVE DATE: 3/8/21	**REVIEWED/REVISED:** 3/26/21, 11/22/21
PRODUCT TYPE: Star, Star Health, Star Kids, Star Plus, Chip, Chip Perinate	**REFERENCE NUMBER:** TX.PHAR.88

SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors

PURPOSE:

It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of viltolarsen (Viltepso®). This medication is a pass through 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 Superior 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.

BACKGROUND:

Description:
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 Indication(s)
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:
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.

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I. Initial Approval Criteria:

1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director, but will not make the final determination on any case.
3. Diagnosis of Duchenne Muscular Dystrophy (DMD) with exon 53 skipping.
4. Documentation of a neurologist's consultation dated no more than six months prior to the initially requested authorization start date. The consultation must include the neurologist's name, credentials, contact information, and a recommendation for treatment with Viltepso.
5. Documentation of genetic testing must confirm that the member is amenable to exon 53 skipping (see Appendix A).
6. Current member weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
7. Documentation of 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.
8. Baseline renal function test (i.e. glomerulus filtration rate) and urine protein-to-creatinine ratio should be measured before starting treatment.
9. Will not be used concomitantly with other exon skipping therapies
10. Documentation of the 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.
11. The requested dosage is for no more than 80mg/kg once weekly.
12. A maximum of 6 months may be approved by the Medical Director.

Approval duration: 6 months

II. Continued Therapy

1. Currently receiving medication via Centene benefit, or member has previously met initial approval criteria or was on the therapy by another managed care organization;
2. 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.
3. All approvals or denials for continued therapy will be reviewed by a Superior Medical Director to continue coverage.
4. The SHP pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the SHP Medical Director, but will not make the ultimate determination on any case. Should not be continued on member who experience decreasing physical function wile on the medication.
5. Diagnosis of Duchenne Muscular Dystrophy (DMD) with exon 53 skipping.
6. 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.
7. Neurologist's consultation must be dated no more than one rolling year of the recertification/extension date that includes the name, credentials, and contact information for the consulting neurologist recommending ongoing treatment.
8. 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.

9. Documentation includes a statement from prescribing clinician that the member has been compliant with treatment.
10. Will not be used concomitantly with other exon skipping therapies.
11. Documentation of the 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.
12. The requested dosage is for no more than 80mg/kg once weekly.

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:

DEFINITIONS/Abbreviations:

DMD: Duchenne Muscular Dystrophy

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REVISION LOG

REVISION	DATE
New Criteria Developed to mirror Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook criteria	3/8/21
Removed age criteria 4-9 years old per VDP guidance (there is no age requirements for antisense oligonucleotides)	3/26/21
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 a criteria point under the Initial and Continued Therapy sections	11/22/21

POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations

Dr. David Harmon, Sr. V.P., Chief Medical Officer

Pharmacy & Therapeutics Committee:

NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.