POLICY AND PROCEDURE

POLICY NAME: Golodirsen (Vyondys 53)	**POLICY ID:** TX.PHAR.85
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 8/1/2020	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 3/30/21, 11/22/21, 8/1/22	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of golodirsen (Vyondys 53).

PURPOSE:
This medication is a pass through drug (non-risk based 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 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.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of golodirsen (Vyondys 53).

Description/Mechanism of Action:
Golodirsen (Vyondys 53) binds to exon 53 of dystrophin pre-messenger RNA (mRNA), resulting in exclusion of this exon during mRNA processing. Exon skipping allows for production of an internally truncated dystrophin protein.

Formulations:
Vyondys 53 injection is supplied in single-dose vials containing 100 mg/2 mL (50 mg/mL)

FDA Approved Indications:
Golodirsen (Vyondys 53) is approved 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.

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. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Documentation of genetic testing must confirm that the client's DMD gene is amenable to exon 53 skipping.
3. Documentation of baseline renal function test (i.e., Glomerulus Filtration Rate, GFR).
4. Current weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
5. Documentation of baseline physical function. The testing tool to be used includes but is not limited to: the Brooke Upper Extremity Scale, Baseline 6-minute walk test (6MWT), or the Pediatric Evaluation of Disability Inventory.
6. Documentation that golodirsen (Vyondys 53) will not be used concomitantly with other exon skipping therapies for DMD.
7. Documentation of the member's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted.
8. The requested dosage is for no more than 30mg/kg once weekly

Approval duration: 6 months

II. Continued Therapy

A. Duchenne Muscular Dystrophy (DMD)

1. 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).
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. Documentation of continual renal function testing while on golodirsen (Vyondys 53).
5. Current weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
6. Documentation that golodirsen (Vyondys 53) will not be used concomitantly with other exon skipping therapies for DMD.
7. 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. Vyondys 53 should not be continued on clients who experience decreasing physical function while on the medication.
8. Documentation of the member's dosage, administration schedule, number of injections to be administered during the prior authorization period, requested units per injection, and the dosage calculation must be submitted.
9. The requested dosage is for no more than 30mg/kg once weekly
10. Documentation includes a statement from prescribing clinician that the client has been compliant with the treatment.

Approval duration: 6 months

REFERENCES:

Vyondys 53 (golodirsen) [prescribing information]. Cambridge, MA: Sarepta Therapeutics Inc; February 2021.

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Added OUTPATIENT DRUG SERVICES HANDBOOK MARCH 2021to references Added criteria #10 to continuation of therapy: Documentation includes a statement from prescribing clinician that the client has been compliant with the treatment.	3/30/21
Ad Hoc Review	Remove PDAC designation effective 12/1/21 Added max dosing to Initial Therapy and Continued Therapy Sections	11/22/21

	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 Added DMD under Definitions/Abbreviations Updated References	
Ad Hoc Review	Removed specialist requirement Changed to new P&P template Removed step that states Medical Director may approve up to 6 months. Duplication of information since approval duration is only 6 months	8/1/22

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.