TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Golodirsen (Vyondys 53®)	**CRITERIA ID:** TX.CC.PHAR.09
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, 7/12/2023, 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 golodirsen (Vyondys 53®).

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

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of golodirsen (Vyondys 53®); procedure code: J1429.

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.

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.

Formulations:
Golodirsen (Vyondys 53®) injection is supplied in single-dose vials containing 100 mg/2 mL (50 mg/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 must confirm that the client's DMD gene is amenable to exon 53 skipping.
3. Documentation of client's baseline renal function test (i.e., Glomerulus Filtration Rate, GFR).
4. 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.
5. Documentation of client's 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. Prescriber attestation that Vyondys 53 will not be used concomitantly with other exon skipping therapies for DMD.
7. Documentation of the client'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.

Approval duration: 6 months

II. 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 of continual renal function testing while on Vyondys 53.
5. 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.
6. 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.
7. Prescriber attestation that client has been compliant with the treatment.
8. Prescriber attestation that Vyondys 53 will not be used concomitantly with other exon skipping therapies for DMD.
9. Documentation of the client'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.

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

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 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	11/22/21
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
Annual Review	No changes	7/12/23
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed criteria step from initial and continuation: The requested dosage is for no more than 30mg/kg once weekly as dose check is not listed in TMHP CAD Manual	02/27/24
Ad Hoc Review	Annual review. No changes	2/20/2025