TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Casimersen (Amondys 45®)	**CRITERIA ID:** TX.CC.PHAR.11
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 6/1/21	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/22/21, 8/1/22, 7/12/23, 2/27/2024, 2/26/2025	
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 casimersen (Amondys 45®).

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 casimersen (Amondys 45®); procedure code: J1426.

Description/Mechanism of Action:
Casimersen (Amondys 45®) binds to exon 45 of dystrophin pre-messenger RNA (mRNA), resulting in exclusion of this exon during mRNA processing. Exon 45 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 45 skipping.

FDA Approved Indications:
Casimersen (Amondys 45®) 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 45 skipping.

Formulations:
Casimersen (Amondys 45®) injection is supplied in single-dose vials.
• 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 that confirms the client's DMD gene is amenable to exon 45 skipping.
3. Prescriber attestation that client's serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio will be measured prior to initiating therapy.
4. Prescriber attestation that client's baseline renal function (i.e. Glomerulus Filtration Rate) will be monitored with therapy initiation and continuation.
5. Documentation of the 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. Documentation of the client's baseline physical function. Testing tools used to measure the physical function must be age appropriate. Testing tools used can include but is not limited to: Brooke Upper Extremity Scale, Baseline 6-minute walk test (6MWT), or the North Star Ambulator Assessment.
7. Prescriber attestation that Amondys 45 will not be used concomitantly with other exon skipping therapies for DMD.
8. 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 managed care organization (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 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. 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. Amondys 45 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. Documentation that Amondys 45 will not be used concomitantly with other exon skipping therapies for DMD.
8. Prescriber attestation of continual renal function monitoring while on Amondys 45 therapy.
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:

Amondys 45® (casimersen) [prescribing information]. Cambridge, MA: Sarepta Therapeutics Inc; February 2021.

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS:

MCO Notice
Amondys 45 Become

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Removed blurb from Purpose Section that the drug is pass through. As of 6/9/21, the drug is not considered by HHSC/VDP as a non-risk based (NRB) payment drug.	6/9/21
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 Readded blurb to Purpose Section that the drug is pass through. As of 6/1/21, the drug is considered by HHSC/VDP as a non-risk based (NRB) payment drug. 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	Formatting Changes	7/12/23
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed of 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	2/27/24
Annual Review	Updated language in In I.A.4. to align with verbiage in TMHP CAD Manual	2/26/25