Policy and Procedure

DEPARTMENT: Pharmacy, Medical Directors	**DOCUMENT NAME:** Casimersen (Amondys 45)
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE:	**RETIRED:**
EFFECTIVE DATE: 6/1/21	**REVIEWED/REVISED:** 11/22/21
PRODUCT TYPE: Star, Star Health, Star Kids, Star Plus, Chip, Chip Perinate	**REFERENCE NUMBER:** TX.PHAR.91

SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors

PURPOSE:

It is the policy of Superior HealthPlan (SHP) to follow state guidance for medical necessity review of casimersen (Amondys 45). All determinations will be performed by a Superior Medical Director. A SHP 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/Mechanism of Action:
Casimersen (Amondys) 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.

Formulations:
Amondys 45 injection is supplied in single-dose vials.
• Single-dose vials containing 100 mg/2 mL (50 mg/mL)

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.

PROCEDURE:

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. 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.
3. 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 Amondys 45.
4. Documentation of genetic testing must confirm that the client's DMD gene is amenable to exon 45 skipping.
5. Baseline renal function test (i.e. Glomerulus Filtration Rate) should be measured before starting treatment.
6. Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured prior to initiating therapy.
7. Current weight, including the date the weight was obtained; the weight must be dated no more than 30 days before the request date.
8. Documentation of baseline physical function. Testing tools used to measure the physical function must be age-appropriate. 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 North Star Ambulator Assessment.
9. Amondys 45 will not be used concomitantly with other exon skipping therapies for DMD.
10. 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.
11. The requested dosage is for no more than 30mg/kg once weekly
12. A maximum of 6 months may be approved by the Medical Director.

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 managed care organization (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. 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.
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. 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.
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. Amondys 45 should not be continued on clients who experience decreasing physical function while on the medication.
8. Documentation includes a statement from prescribing clinician that the client has been compliant with the treatment.
9. Documentation that Amondys 45 will not be used concomitantly with other exon skipping therapies for DMD.
10. Documentation of continual renal function monitoring while on Amondys 45 therapy.
11. 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.

12. The requested dosage is for no more than 30mg/kg once weekly

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

DEFINITIONS/ABBREVIATIONS:

DMD = Duchenne Muscular Dystrophy

REVISION LOG

REVISION	**DATE**
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

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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

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.