TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Histrelin Acetate (Vantas, Supprelin LA)	**CRITERIA ID:** TX.CC.PHAR.37
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 7/9/2024	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 7/9/2024, 6/2/2025	**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 Histrelin acetate (Vantas, Supprelin LA).

PURPOSE:
To provide clinical criteria standards which align with FDA approved indication(s) and/or established practice guidelines for prior authorization review. Prior authorization is required to determine medical necessity of the requested drug(s), which ensures safety, clinical appropriateness and cost-effectiveness while maintaining optimal therapeutic outcomes.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
CPP: central precocious puberty
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
LH: luteinizing hormone
NCCN: National Comprehensive Cancer Network

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Histrelin acetate (Vantas® and Supprelin LA®).

Description/Mechanism of Action:
Histrelin acetate (Vantas® and Supprelin LA®) is a gonadotropin-releasing hormone (GnRH) agonist.

FDA Approved Indication(s)
Vantas is indicated for the palliative treatment of advanced prostate cancer.
Supprelin LA is indicated for the treatment of children with central precocious puberty (CPP).

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. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for Vantas;
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. Request is for palliative treatment;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 50 mg per 12 months (one implant per year);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Central Precocious Puberty (must meet all)**:**

1. Diagnosis of CPP confirmed by all of the following (a, b, and c):
   a. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/mL (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
   b. Difference between bone age and chronological age was > 1 year (bone age-chronological age);
   c. Age at onset of secondary sex characteristics (i or ii):
      i. Female: < 8 years;
      ii. Male: < 9 years;
2. Request is for Supprelin LA;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
   a. Female: 2 - 11 years;
   b. Male: 2 - 12 years;
5. Dose does not exceed 50 mg per 12 months (one implant per year).

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to: CP.PMN.255 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Vantas for prostate cancer and has received this medication for at least 30 days;
2. Request is for Vantas;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 50 mg per 12 months (one implant per year);
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Central Precocious Puberty (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request is for Supprelin LA;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in <u>any</u> of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirements (a or b):
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years;
5. If request is for a dose increase, new dose does not exceed 50 mg per 12 months (one implant per year).

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to: CP.PMN.255 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

B. The following are conditions for which treatment with Supprelin LA is considered NOT medically necessary:

1. Transsexualism (F64.0);
2. Dual role transvestism (F64.1);
3. Gender identity disorder of childhood (F64.2);

4. Other gender identity disorders (F64.8);
5. Gender identity disorder, unspecified (F64.9);

REFERENCES:

CP.PHAR.172 Histrelin Acetate (Vantas, Supprelin LA)
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	Created from Corporate criteria to align with TMHP guidance on Senate Bill 14 – Section III. B. added.	07/09/2024
Annual review	Font and formatting updated for 508 remediation	6/2/2025