TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Hormonal therapy agents (Depo-estradiol cypionate, Testosterone cypionate, Estradiol valerate, Testosterone enanthate, Testosterone undecanoate)	**CRITERIA ID:** TX.CC.PHAR.39
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, 5/1/2025	**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 depo-estradiol cypionate, testosterone cypionate, estradiol valerate, testosterone enanthate, and testosterone undecanoate.

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 policy and prior authorization requirements.

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

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan(SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of depo-estradiol cypionate, testosterone cypionate, estradiol valerate, testosterone enanthate, and testosterone undecanoate.

Description/Mechanism of Action:
Depo-estradiol and estradiol is an estrogen steroid.
Testosterone is an androgen.

FDA Approved Indication(s):
Depo-estradiol cypionate and estradiol valerate is indicated for moderate to severe vasomotor symptoms of menopause

Tesosterone cypionate, Testosterone enanthate, and Testosterone undecanoate is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

Note: This criteria applies to the following hormonal therapy agents: J1000 depo-estradiol cypionate, J1071 testosterone cypionate, J1072 testosterone cypionate (Azmiro), J1380 estradiol valerate, J3121 testosterone enanthate, J3145 testosterone undecanoate

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

Note: This criteria applies to the following hormonal therapy agents: J1000 depo-estradiol cypionate, J1071 testosterone cypionate, J1072 testosterone cypionate (Azmiro), J1380 estradiol valerate, J3121 testosterone enanthate, J3145 testosterone undecanoate

1. The hormonal therapy agent is NOT being requested for any of the following diagnosis codes:
   a. Transsexualism (F64.0);
   b. Dual role transvestism (F64.1);
   c. Gender identity disorder of childhood (F64.2);
   d. Other gender identity disorders (F64.8);
   e. Gender identity disorder, unspecified (F64.9);

Note: Hormonal therapy agents are not a benefit when submitted with any of the diagnosis codes listed above.

Approval duration: 12 months

II. Continued Therapy

Note: This criteria applies to the following hormonal therapy agents: J1000 depo-estradiol cypionate, J1071 testosterone cypionate, J1072 testosterone cypionate (Azmiro), J1380 estradiol valerate, J3121 testosterone enanthate, J3145 testosterone undecanoate

1. The hormonal therapy agent is NOT being requested for any of the following diagnosis codes:
   a. Transsexualism (F64.0);
   b. Dual role transvestism (F64.1);
   c. Gender identity disorder of childhood (F64.2);

d. Other gender identity disorders (F64.8);
e. Gender identity disorder, unspecified (F64.9);

Note: Hormonal therapy agents are not a benefit when submitted with any of the diagnosis codes listed above.

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	Created to align with TMHP guidance on Senate Bill 14	07/09/2024
Ad Hoc Review	Added additional HCPCS code to align with TMHP CAD Manual update, effective 5/1/25 - J1072 testosterone cypionate (Azmiro) Formatting change including font and font size. Modified header structure	05/01/2025