

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Testosterone	P&T DATE:	3/21/2023
THERAPEUTIC CLASS:	Endocrine Disorders	REVIEW HISTORY:	07/22, 09/21, 09/20, 09/19,
LOB AFFECTED:	MCL	(MONTH/YEAR)	05/18, 12/16, 05/14, 11/15

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Testosterone therapy can be used in multiple conditions, testosterone replacement therapy in patients with hypogonadism, and in Transgender patients transitioning from Female to Male. This coverage policy will address both situations. Testosterone therapy carries risks. Inappropriate use of testosterone can be potentially harmful, as it is not known what effects supplemental male hormones may have on cardiovascular outcomes and mortality. However, it has been noted that there is a possible link between testosterone therapy and heart attack risk.

Testosterone Replacement Therapy

Treatment of male hypogonadism involves testosterone replacement therapy (TRT). However, with the popularity of testosterone products increasing, there is a high probability that testosterone therapy is being used for normal age-associated symptoms (e.g. decreased energy and/or sexual interest). The Endocrine Society, American Association of Clinical Endocrinologists, and the European Academy of Andrology have developed recommendations to help with confirming male hypogonadism and addressing therapeutic risks.

Hormone Therapy for Gender Transition (Female to Male)

Masculinizing therapy is definitive treatment for gender nonconforming individuals wishing to transition. Though this is the case, serious adverse effects can occur, paralleling the risks in TRT. Additionally, masculinizing therapy should be performed only in patients who have undergone a comprehensive evaluation by a qualified provider. Medical necessity criteria for use are set by WPATH (World Professional Association for Transgender Health) guidelines and assess the mental and physical health of the patient.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1: Available Testosterone Agents

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
--	Testosterone (Androgel) <i>Gel, Gel Pump, Gel Packet</i>	1%, 1.62%, 2%	Yes	No
--	Testosterone (Androderm) <i>Patch 24 Hour</i>	2 mg, 4 mg	Yes	No
J1071	Testosterone Cypionate (Depo-Testosterone) <i>Oil</i>	100 mg/mL, 200 mg/mL	Yes	Yes (AL)
J3121	Testosterone Enanthate <i>Oil</i>	200 mg/5 mL	Yes	Yes (PA)
J3145	Testosterone Undecanoate (Aveed) <i>Oil</i>	750 mg/3 mL	Yes	Yes (PA)
S0189	Testosterone Pellet (Testopel) <i>Pellet</i>	75 mg	Yes	Yes (PA)

PA=prior authorization, AL=Age limit

Clinical Justification:

Hypogonadal Males: Due to the possible risk of increased cardiovascular events, only hypogonadal men who are properly assessed and documented with low testosterone levels should have access to testosterone administration. Peak testosterone values are seen in the morning as it follows a circadian rhythm. Per the Endocrine Society 2018 Guidelines, if a testosterone level is <300 ng/dL, a repeat testosterone level needs to be performed for confirmation.

Gender Transition: Hormone therapy carries the same cardiovascular risks in gender transition as in hypogonadal males. Providers should follow WPATH guidelines, which recommend: patients have persistent gender dysphoria, capacity to consent to treatment, and must be free of significant mental health and physical health conditions. As such, it is recommended that patients transitioning genders seek care from an experienced provider. Treatment of choice is injectable therapy.

Product Selection: Topical testosterone products provide more stable testosterone levels than injectable esters. However, both topical and injectable testosterone products are associated with risks. With topical products, there is the risk of unwanted secondary exposure to children and women. With injectable products, there is a higher risk of polycythemia. Hence, caution and continuous monitoring is needed for patients using testosterone therapy.

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

Androgenic Agents

Testosterone Cypionate (Depo-Testosterone)

- Coverage Criteria:** Limited to patients greater than or equal to 18 years of age.
- Limits:** None
- Required Information for Approval:** None

☒ REFERENCES

1. Bhasin S, Brito JP, Cunningham GR, et. al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism*, March 2018, Vol. 95(6):2536–2559.
2. *WPATH Guidelines; Standards of Care for Health of Transsexual, Transgender, and Gender Nonconforming People: 7th Version*
3. Testosterone. Lexi-Drugs. Lexicomp Online [database online]. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com>. Updated February 24, 2023. Accessed February 24, 2023.

☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Formulary Realignment PT 9-18-12.xlsx	09/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment 09-17-2013.xlsx	09/2013	Jonathan Szkotak, PharmD BCACP
Update to Policy	Androgenic Agents Class Review 2014-05-29.docx	05/2014	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Endocrine Disorders – Testosterone 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine Disorders – Testosterone 2018-5.docx	5/2018	Johnathan Yeh, PharmD
Update to Policy	Testosterone	9/2019	Matthew Garrett, PharmD
Update to Policy	Testosterone	9/2020	Matthew Garrett, PharmD
Review of Policy	Testosterone	9/2021	Matthew Garrett, PharmD
Review of Policy	Testosterone	7/2022	Matthew Garrett, PharmD
Review of Policy	Testosterone	3/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy