

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Testosterone	P&T DATE:	5/8/2018
THERAPEUTIC CLASS:	Endocrine Disorders	REVIEW HISTORY:	12/16, 5/14, 11/15
LOB AFFECTED:	MCL	(MONTH/YEAR)	

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.

OVERVIEW

Testosterone therapy can be used in multiple conditions. That of 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.

Table 1: Available Formulary Testosterone Agents (Current as of 2/2018)

Drug	Available Strengths	Route of Administration	Formulary Status	Restriction (Blank = No restriction)	Cost Per Rx
Androgel Gel Pump, Gel Packet	1%	Transdermal	PA	Testosterone Gel Packets, Gel Pump, and Gel therapy are reserved for patients who meet BOTH of the following criteria: [1] Treatment failure to or inability to administer intramuscular testosterone injections AND [2] undergoing Gender Transition OR having documentation of hypogonadism as evidenced by testosterone levels below 300ng/dL confirmed on two separate occasions with levels drawn before 10:00am. Note 1.62% Testosterone strengths are non-formulary.	\$637.52
Testim Gel	1%	Transdermal	PA		\$402.32
Testosterone Gel, Gel Pump, Gel Packet	1%	Transdermal	PA		\$316.42

Testosterone Cypionate (Depo-Testosterone) Oil	100 mg/mL, 200 mg/mL	Intramuscular	PA	Testosterone therapy is reserved for patients undergoing Gender Transition, or with documentation of hypogonadism as evidenced by testosterone levels below 300ng/dL confirmed on two separate occasions with levels drawn before 10:00am.	\$32.00
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ST = Step therapy, PA = Prior Authorization required.

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 2010 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. The preference for the AndroGel 1% formulations over the 1.62% formulations are due to decreased cost effectiveness with the higher concentration.

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Androgenic Agents

Testosterone (AndroGel 1%, Testim1%), Testosterone Cypionate (Depo-Testosterone)

☐ Coverage Criteria:

- Testosterone intramuscular therapy is reserved for patients undergoing Gender Transition, or with documentation of hypogonadism as evidenced by testosterone levels below 300ng/dL confirmed on two separate occasions with levels drawn before 10:00am.
- Testosterone topical therapy is reserved for patients who meet BOTH of the following criteria:
 - [1] Treatment failure to or inability to administer intramuscular testosterone injections AND
 - [2] undergoing Gender Transition OR having documentation of hypogonadism as evidenced by testosterone levels below 300ng/dL confirmed on two separate occasions with levels drawn before 10:00am.

☐ Limits: None

☐ Required Information for Approval:

- Documentation of hypogonadism with free testosterone levels below 300ng/dL confirmed on two separate occasions or of transsexualism.
- Both levels must be drawn before 10:00am.
- If for topical therapy, must have documentation of treatment failure or inability to administer intramuscular testosterone injections.

☒ **REFERENCES**

1. Bhasin S, Cunningham GR, Hayes FJ, et. al. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism*, June 2010, Vol. 95(6):2536–2559.
2. *WPATH Guidelines; Standards of Care for Health of Transsexual, Transgender, and Gender Nonconforming People: 7th Version*

☒ **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

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