

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY:	Testosterone	P&T DATE:	03/10/2026
THERAPEUTIC CLASS:	Endocrine Disorders	REVIEW HISTORY: (MONTH/YEAR)	03/25, 03/24, 03/23, 07/22, 09/21, 09/20, 09/19, 05/18, 12/16, 05/14, 11/15
LOB AFFECTED:	MCL/Medicare		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) 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.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

Testosterone therapy can be used in multiple conditions such as in patients with hypogonadism and in transgender patients transitioning from female to male. This coverage policy will address both situations. The following are the most up-to-date guidelines/literature available for this coverage policy:

Testosterone Replacement Therapy for Hypogonadal Males

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). Due to the possible risk of increased cardiovascular events, only hypo-gonadal 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.¹ [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.^{1,9,10}

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.² Current options available for testosterone therapy do not

require prior authorization when administered and billed within standard dosing ranges, and may also be obtained on the pharmacy benefit.

⊞ MEDICAL 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 Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

⊞ 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: 8th 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.
4. Mulhall JP, Trost LW, Brannigan RE et al: Evaluation and management of testosterone deficiency: AUA guideline. *J Urol* 2018; 200: 423.
5. AVEED® (testosterone undecanoate) [prescribing information]. Malvern, PA: Endo USA; March 2024.
6. TESTOPEL ® (testosterone pellets) [prescribing information]. Malvern, PA: Endo USA; March 2024.
7. XYOSTED ® (testosterone enanthate) [prescribing information]. Ewing, NJ: Antares Pharma, Inc; August 2023.
8. Depo®-Testosterone (testosterone cypionate) [prescribing information]. New York, New York: Pfizer, Inc; August 2018.
9. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients--2002 update. *Endocr Pract.* 2002 Nov-Dec;8(6):440-56. Erratum in: *Endocr Pract.* 2008 Sep;14(6):802-3. Petak, Steven M [added]; Nankin, Howard R [added]; Spark, Richard F [added]; Swerdloff, Ronald S [added]; Rodriguez-Rigau, Luis J [added]. PMID: 15260010.
10. Corona G, Goulis DG, Huhtaniemi I, Zitzmann M, Toppari J, Forti G, Vanderschueren D, Wu FC. European Academy of Andrology (EAA) guidelines on investigation, treatment and monitoring of functional hypogonadism in males: Endorsing organization: European Society of Endocrinology. *Andrology.* 2020 Sep;8(5):970-987. doi: 10.1111/andr.12770. Epub 2020 Mar 20. PMID: 32026626.

⊞ 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
Review of Policy	Testosterone	3/2024	Matthew Garrett, PharmD
Update to Policy	Testosterone	3/2025	Matthew Garrett, PharmD
Update to Policy	Testosterone	3/2026	Matthew Garrett, PharmD

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