

Testosterone Replacement or Supplementation Therapy

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[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Applicable Codes	3
Background	4
Clinical Evidence	4
U.S. Food and Drug Administration	4
References	5
Policy History/Revision Information	5
Instructions for Use	6

Commercial Policy
<ul style="list-style-type: none"> Testosterone Replacement or Supplementation Therapy

Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Arizona	Refer to the state’s Medicaid clinical policy. Use drug-specific criteria, if available for the specific product, otherwise this Medical Benefit Drug Policy applies.
Florida	This Medical Benefit Drug Policy does not apply for Testopel (testosterone pellets); refer to the state’s Medicaid clinical policy. This Medical Benefit Drug Policy applies for all other drug products.
Indiana	Refer to the state’s Medicaid clinical policy
Kansas	Refer to the state’s Medicaid clinical policy
Kentucky	The gender-affirming hormonal therapy criteria in this policy are not applicable for the state of Kentucky. This Medical Benefit Drug Policy applies for all other indications.
Louisiana	Testosterone Replacement or Supplementation Therapy (for Louisiana Only)
North Carolina	None
Ohio	Testosterone Replacement or Supplementation Therapy (for Ohio Only)
Pennsylvania	Refer to the state’s Medicaid clinical policy
Texas	Refer to the state’s Medicaid clinical policy. Use drug specific criteria found within the <i>Texas Medicaid Provider Procedures Manual</i> if available for the specific product; otherwise, this Medical Benefit Drug Policy applies.

Coverage Rationale

This policy refers to the following testosterone products:

- Testosterone cypionate (Azmiro™, Depo-Testosterone®)
- Testosterone enanthate
- Testosterone pellets (Testopel®)
- Testosterone undecanoate (Aveed®)

Coverage for Azmiro will be provided contingent on the *Preferred Product Criteria* and the [Diagnosis-Specific Criteria](#). In order to continue coverage, members already on Azmiro will be required to change therapy to a generic testosterone cypionate product (i.e., generic Depo-Testosterone) unless they meet the criteria in this section.

Preferred Product Criteria

Treatment with Azmiro is medically necessary for the indications specified in the policy when one of the following criteria are met:

- **Both** of the following:
 - History of a trial to **one** other testosterone cypionate product resulting in minimal clinical response to therapy; **and**
 - Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Azmiro, than experienced with other testosterone cypionate products

or

- **Both** of the following:
 - History of intolerance, contraindication, or adverse event to **one** other testosterone cypionate product; **and**
 - Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Azmiro

Diagnosis-Specific Criteria

Injectable testosterone and Testopel (testosterone pellets) are medically necessary for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired), when the following criteria are met:

- **One** of the following:
 - Patient has history of **one** of the following:
 - Bilateral orchiectomy; **or**
 - Panhypopituitarism; **or**
 - A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

or

 - **All** of the following:
 - **One** of the following:
 - Two pre-treatment early morning serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab, taken at separate times; **or**
 - **Both** of the following:
 - Patient has condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **and**
 - **One** pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (< 5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab

or

 - **Both** of the following:
 - Patient is currently on testosterone therapy; **and**
 - **One** of the following:
 - Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is within or below the normal male limits of the reporting lab; **or**
 - Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy (i.e., on therapy for less than one year), or 12 months for patients continuing testosterone therapy (i.e., on therapy for one year or longer), is outside of upper male limits of normal for the reporting lab and the dose is adjusted

and

- Patient was male at birth; **and**
- Diagnosis of hypogonadism

and

- Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; **and**
- Authorization will be for no more than 12 months

Injectable testosterone and Testopel (testosterone pellets) may be covered for gender-affirming hormonal therapy for transgender adults when the following criteria are met:

- **All** of the following:

- Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5-TR) criteria, by a mental health professional; **and**
- Medication is prescribed by or in consultation with an endocrinologist or a medical provider knowledgeable in transgender hormone therapy; **and**
- Authorization will be for no more than 12 months

Compounded Hormone Products (e.g., Pellets)

Compounded drugs, including compounded testosterone, estrogen, or progesterone pellets are not FDA approved.³ Compounded hormone products (e.g., pellets), including but not limited to compounded testosterone, estrogen, and progesterone pellets, are considered experimental and investigational and not covered for any indication.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11980	Subcutaneous hormone pellet implantation

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HCPCS Code	Description
J1071	Injection, testosterone cypionate, 1 mg
J1072	Injection, testosterone cypionate (Azmiro), 1 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
S0189	Testosterone pellet, 75 mg

Diagnosis Code	Description
E23.0	Hypopituitarism
E23.3	Hypothalamic dysfunction, not elsewhere classified
E29.1	Testicular hypofunction
E30.0	Delayed puberty
E89.3	Postprocedural hypopituitarism
E89.5	Postprocedural testicular hypofunction
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
N44.00	Torsion of testis, unspecified
N45.2	Orchitis
Q53.00	Ectopic testis, unspecified
Q53.01	Ectopic testis, unilateral
Q53.02	Ectopic testes, bilateral
Q53.10	Unspecified undescended testicle, unilateral
Q53.111	Unilateral intraabdominal testis
Q53.112	Unilateral inguinal testis
Q53.12	Ectopic perineal testis, unilateral

Diagnosis Code	Description
Q53.20	Undescended testicle, unspecified, bilateral
Q53.211	Bilateral intraabdominal testes
Q53.212	Bilateral inguinal testes
Q53.22	Ectopic perineal testis, bilateral
Q53.9	Undescended testicle, unspecified
Q55.0	Absence and aplasia of testis
Z87.890	Personal history of sex reassignment
Z90.79	Acquired absence of other genital organ(s)

Background

Endogenous androgens are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of prostate, seminal vesicles, penis, and scrotum; the development of male hair distribution such as beard, pubic, chest and axillary hair, laryngeal enlargements, vocal cord thickening, alterations in body musculature, and fat distribution.¹

Clinical Evidence

In the 2018 update to the Testosterone Therapy in Men With Androgen Deficiency Syndromes guideline published in 2010, the authors recommend making a diagnosis of hypogonadism only in men with symptoms and signs consistent with testosterone (T) deficiency.⁹ The group recommends fasting morning total T concentrations along with confirmation be used for monitoring. Measurement of free T concentration should be completed when total T is near the lower limit of normal or when a condition that alters sex hormone-binding globulin is present. Upon confirmation of androgen deficiency, the committee recommends additional diagnostic evaluation to determine the cause. T therapy is recommended for symptomatic men with T deficiency to induce and maintain secondary sex characteristics and correct symptoms of hypogonadism. Potential benefits and risks and benefits of T replacement should be discussed with the patient prior to initiating therapy. Upon initiation of T therapy, T concentration goals should be in the mid-normal range during treatment with any of the approved formulations, taking into consideration patient preference, pharmacokinetics, formulation-specific adverse effects, treatment burden, and cost. Men receiving T therapy should be monitored to evaluate symptoms, adverse effects, and compliance; measuring serum T and hematocrit concentrations; and evaluate prostate cancer risk after initiating T therapy.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropic (luteinizing hormone-releasing hormone) LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation

Safety and efficacy of Testopel (testosterone pellets) in men with age-related hypogonadism, also referred to as late-onset hypogonadism, have not been established.^{1,13} The dosage guideline for the testosterone pellets for replacement therapy in androgen-deficient males is 150 mg to 450 mg subcutaneously every 3 to 6 months. The usual dosage is as follows: implant two 75 mg pellets for each 25 mg testosterone propionate required weekly. Thus, when a patient requires injections of 75 mg per week, it is usually necessary to implant 450 mg (6 pellets). With injections of 50 mg per week, implantation of 300 mg (4 pellets) may suffice for approximately three months.

Aveed (testosterone undecanoate injection) is administered 750 mg initially, at week 4, then every 10 weeks thereafter.

Testosterone cypionate and testosterone enanthate injections are administered 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per 14 days.

Compounded testosterone, estrogen, and progesterone pellets are not currently FDA approved and there has not been an FDA submission for approval of these products.

References

1. Testopel [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.
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3. FDA Compounding Laws and Policies. <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm606881.htm>. Accessed October 27, 2023.
4. Mulhall JP, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. American Urological Association Education and Research, Inc 2018.
5. U.S. Food and Drug Administration (FDA). Testosterone Products: Drug Safety Communication. <https://www.fda.gov/Drugs/DrugSafety/ucm436259.htm>. Accessed October 27, 2023.
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7. Bhasin, S, et al. Testosterone replacement and resistance exercise in HIV-infected men with weight loss and low testosterone levels. *JAMA.* 2000. 283.(6) 763-770.
8. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2017; 102:3869.
9. The Endocrine Society. Testosterone therapy in Adult Men with Androgen Deficiency Syndromes. *J Clin Endocrinol Metab*, May 2018, 103(5):1-30.
10. Depo-testosterone [prescribing information]. New York, NY: Pharmacia & Upjohn Co.; August 2018.
11. Aved [prescribing information]. Malvern, PA: Endo Pharmaceuticals; August 2021.
12. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health.* 2022;23(Suppl 1):S1-S259. Published 2022 Sep 6. doi:10.1080/26895269.2022.2100644.
13. Qaseem A, Horwitch CA, Vijan S, et al. Testosterone Treatment in Adult Men With Age-Related Low Testosterone: A Clinical Guideline From the American College of Physicians. *Ann Intern Med.* 2020;172(2):126-133. doi:10.7326/M19-0882.
14. Azmiro [prescribing information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; May 2024.

Policy History/Revision Information

Date	Summary of Changes
10/01/2025	<p>Application Kentucky</p> <ul style="list-style-type: none"> Added language to indicate the gender-affirming hormonal therapy criteria in this policy are not applicable for the state of Kentucky; this Medical Benefit Drug Policy applies for all other indications <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate: <ul style="list-style-type: none"> Coverage for Azmiro will be provided contingent on the <i>Preferred Product Criteria</i> and the <i>Diagnosis-Specific Criteria</i> [sections in the policy]; in order to continue coverage, members already on Azmiro will be required to change therapy to a generic testosterone cypionate product (i.e., generic Depo-Testosterone) unless they meet the criteria in the <i>Preferred Product Criteria</i> section [of the policy] Treatment with Azmiro is medically necessary for the indications specified in the policy when one of the following criteria are met: <ul style="list-style-type: none"> Both of the following: <ul style="list-style-type: none"> History of a trial to one other testosterone cypionate product resulting in minimal clinical response to therapy

Date	Summary of Changes
	<ul style="list-style-type: none"> – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Azmiro, than experienced with other testosterone cypionate products ▪ Both of the following: <ul style="list-style-type: none"> – History of intolerance, contraindication, or adverse event to one other testosterone cypionate product – Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Azmiro <p>Supporting Information</p> <ul style="list-style-type: none"> ● Archived previous policy version CS2025D0076M

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.