Testosterone Replacement or Supplementation Therapy

Policy Number: 2026D0076J
Effective Date: January 1, 2026

➲ Instructions for Use

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Community Plan Policy

- Testosterone Replacement or Supplementation Therapy

Coverage Rationale

➲ See Benefit Considerations

This policy refers to the following testosterone products:

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

Azmiro™ is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan. Refer to the Medical Benefit Drug Policy titled Medical Benefit Therapeutic Equivalent Medications - Excluded Drugs and the corresponding excluded drug list with preferred alternatives.

Note: For requests that require medical necessity review, also refer to the Diagnosis-Specific Requirements section below. (For Medicare reviews, refer to the CMS section.*)

Coverage for testosterone cypionate (Depo-Testosterone®), testosterone enanthate, testosterone pellets (Testopel®), and testosterone undecanoate (Aveed®) is contingent on criteria in the Diagnosis-Specific Requirements sections.

Diagnosis-Specific Requirements

The information below indicates the list of proven and medically necessary indications.

Injectable testosterone and Testopel (testosterone pellets) are proven 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).

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:

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- **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 United States Food and Drug Administration 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 all the following criteria are met:
- 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), including but not limited to compounded testosterone, estrogen, and progesterone pellets are not proven or medically necessary for any indication.
Compounded drugs, including compounded testosterone, estrogen, or progesterone pellets are not FDA approved.

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 the member specific benefit plan document 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
J1073	Testosterone pellet, implant, 75 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 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
Q53.9	Undescended testicle, unspecified
Q53.10	Unspecified undescended testicle, unilateral
Q53.12	Ectopic perineal testis, unilateral
Q53.111	Unilateral intraabdominal testis
Q53.112	Unilateral inguinal testis
Q53.20	Undescended testicle, unspecified, bilateral
Q53.22	Ectopic perineal testis, bilateral
Q53.211	Bilateral intraabdominal testes
Q53.212	Bilateral inguinal testes
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]

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some

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diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

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. 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 150mg to 450mg subcutaneously every 3 to 6 months. The usual dosage is as follows: implant two 75mg pellets for each 25mg testosterone propionate required weekly. Thus when a patient requires injections of 75mg per week, it is usually necessary to implant 450mg (6 pellets). With injections of 50mg per week, implantation of 300mg (4 pellets) may suffice for approximately three months.

Aveed (testosterone undecanoate injection) is administered 750mg 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.

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for Testosterone Replacement or Supplementation Therapy. Local Coverage Determinations (LCDs) exist; refer to the following LCDs:
For Testosterone replacement or supplementation therapy refer to the LCDs for Treatment of Males with Low Testosterone (L36569), Treatment of Males with Low Testosterone (L36538), and Treatment of Males with Low Testosterone (L39086).

In general, Medicare provides coverage for outpatient (Part B) drugs that are furnished “incident to” a physician’s service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals.
(Accessed October 10, 2025)

*Preferred therapy criteria for Medicare Advantage members, refer to Medicare Part B Step Therapy Programs.

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3. FDA Compounding Laws and Policies. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm606881.htm. Accessed October 27, 2023.
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10. Depo-testosterone [prescribing information]. New York, NY: Pharmacia & Upjohn Co.; August 2018.
11. Aveed [prescribing information]. Malvern, PA: Endo Pharmaceuticals; August 2021.
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14. Azmiro [prescribing information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; July 2025.

Policy History/Revision Information

<table>
<tr><th>Date</th><th>Summary of Changes</th></tr>
<tr><td>01/01/2026</td><td>
Coverage Rationale

Removed reference link to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for Azmiro™ (testosterone cypionate)
Added language to indicate:

Azmiro™ is typically excluded from coverage and coverage reviews may be in place if required by law or the benefit plan; refer to the Medical Benefit Drug Policy titled Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs and the corresponding excluded drug list with preferred alternatives
For requests that require medical necessity review, also refer to the Diagnosis-Specific Requirements section [of the policy]
Coverage for testosterone cypionate (Depo-Testosterone®), testosterone enanthate, testosterone pellets (Testopel®), and testosterone undecanoate (Aveed®) is contingent on criteria in the Diagnosis-Specific Requirements section [of the policy]

Applicable Codes

Updated list of applicable HCPCS codes to reflect annual edits:

Added J1073
Removed S0189

Supporting Information

Added CMS section
Updated References section to reflect the most current information

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Date	Summary of Changes
	• Archived previous policy version 2025D0076I

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.

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