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UnitedHealthcare® Community Plan
Medical Benefit Drug Policy

TESTOSTERONE REPLACEMENT OR SUPPLEMENTATION THERAPY SUBCUTANEOUS IMPLANTABLE HORMONE PELLETS

Policy Number: CSLA2020D0076D

Effective Date: **TBD**

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APPLICATION

This Medical Benefit Drug Policy only applies to state of Louisiana.

COVERAGE RATIONALE

This policy refers to the following testosterone products:

- testosterone cypionate (Depo-Testosterone®)
- testosterone enanthate (Delatestryl®)
- testosterone pellets (Testopel®)
- testosterone undecanoate (Aveed®)
- Injectable testosterone and Testopel (testosterone pellets) ~~is~~ 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:
 - For **initial therapy**:
 - Patient has history of **one** of the following:
 - Bilateral orchiectomy; **or**
 - Panhypopituitarism (defined as two or more pituitary hormone insufficiencies prior to the diagnosis of hypogonadism); **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 fasting-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 (this may require treatment to be temporarily held) (document lab value and date for both levels); **or**
 - **Both** of the following:

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- 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 (this may require treatment to be temporarily held.)
- and**
- Patient is **not** taking any of the following:
 - Growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin; **and**
 - **Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])**
 - and**
 - Patient was male at birth; **and**
 - Diagnosis of hypogonadism; **and**
 - **One** of the following:
 - Significant reduction in weight (< 90% ideal body weight) (e.g., AIDS wasting syndrome); **or**
 - Osteopenia; **or**
 - Osteoporosis; **or**
 - Decreased bone density; **or**
 - Decreased libido; **or**
 - Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)
- and**
- Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
 - Initial authorization will be for no more than 6 months for new starts, 12 months for patients continuing therapy.
- For **continuation of therapy**, **all** of the following:
- **One** of the following:
 - Follow-up total serum 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 total serum 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; **or**
 - **Both** of the following
 - Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **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 is **not** taking any of the following:
 - Growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin; **and**
 - **Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])**
 - and**
 - Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
 - Initial authorization will be for no more than 12 months.

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- **Injectable testosterone and Testopel (testosterone pellets) is medically necessary** for gender-affirming hormonal therapy for transgender adults when the following criteria are met:
 - For **initial therapy**, **all** of the following:
 - Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) 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**
 - Patient is not taking any of the following any of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Tev-Tropin; **and**
 - Authorization will be for no more than 12 months.
 - For **continuation of therapy**, **all** of the following:
 - Diagnosis of gender dysphoria, according to the current DSM (i.e., DSM-5) 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**
 - **One** of the following:
 - Follow-up total serum 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 total serum 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; **or**
 - **Both** of the following
 - Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity); **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 is not taking any of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, or Tev-Tropin; **and**
 - Authorization will be for no more than 12 months.

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Compounded Hormone Products (e.g., Pellets/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 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 Coverage Determination Guidelines may apply.

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Subcutaneous Implantable Hormone Pellets Testosterone Replacement or Supplementation Therapy

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CPT Code	Description
11980	Subcutaneous hormone pellet implantation
<i>CPT® is a registered trademark of the American Medical Association</i>	

HCPCS Code	Description
<u>J1071</u>	<u>Injection, testosterone cypionate, 1 mg</u>
<u>J3121</u>	<u>Injection, testosterone enanthate, 1 mg</u>
<u>J3145</u>	<u>Injection, testosterone undecanoate, 1 mg</u>
S0189	Testopel 75 MG PLLT S0189-Testosterone pellet, 75 mg

ICD-10 Diagnosis Code	Description
E30.0	Delayed puberty
F64.0	Transsexualism
N44.00	Torsion of testis, unspecified
Q53.00	Ectopic testis, unspecified
Q53.111	Unilateral intraabdominal testis
Q53.112	Unilateral inguinal testis
Q53.20	Undescended testicle, unspecified, bilateral
Q53.211	Bilateral intraabdominal testes
Q53.212	Bilateral inguinal testes
Q53.22	Ectopic perineal testis, bilateral
Q55.0	Absence and aplasia of testis
Z87.890	Personal history of sex reassignment
Z90.79	Acquired absence of other genital organ(s)
N45.2	Orchitis
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
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
E89.3	Postprocedural hypopituitarism
E89.5	Postprocedural testicular hypofunction
E29.1	Testicular hypofunction
E23.0	Hypopituitarism
E23.3	Hypothalamic dysfunction, not elsewhere classified

Maximum Dosage Requirements

Maximum Allowed Quantities by HCPCS Units

This section provides information about the maximum dosage for testosterone administered by a medical professional.

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Medication Name		Diagnosis	Maximum Dosage per Administration	HCPCs Code	Maximum Allowed
Brand	Generic				
<u>Aveed</u>	<u>testosterone undecanoate</u>		<u>750mg</u>	<u>J3145</u>	<u>750 HCPCs units (1 mg per unit)</u>
<u>Delatestryl</u>	<u>testosterone enanthate</u>		<u>400 mg</u>	<u>J3121</u>	<u>400 HCPCs units (1 mg per unit)</u>
<u>Depo-Testosterone</u>	<u>testosterone cypionate</u>		<u>400 mg</u>	<u>J1071</u>	<u>400 HCPCs units (1 mg per unit)</u>
<u>Testopel</u>	<u>testosterone pellet</u>		<u>450 mg</u>	<u>S0189</u>	<u>6 HCPCs units (75 mg per unit)</u>

Maximum Allowed Quantities by National Drug Code (NDC) Units

The allowed quantities in this section are calculated based upon both the maximum dosage information supplied within this policy as well as the process by which NDC claims are billed. This list may not be inclusive of all available NDCs for each drug product and is subject to change. Absence of a specific NDC does not mean that it is not subject to the following maximum allowed.

Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
<u>Aveed</u>	<u>testosterone undecanoate</u>	<u>750 mg/3 mL</u>	<u>67979-0511-43</u>	<u>3 mL</u>
<u>Delatestryl</u>	<u>testosterone enanthate</u>	<u>200 mg/mL</u>	<u>00134-9750-01</u>	<u>2 mL</u>
<u>Depo-Testosterone</u>	<u>testosterone cypionate</u>	<u>200 mg/mL</u>	<u>00517-1830-01</u>	<u>2 mL</u>
			<u>52536-0625-10</u>	
			<u>52536-0625-01</u>	
			<u>64980-0467-99</u>	
			<u>69097-0802-32</u>	
			<u>69097-0802-37</u>	
			<u>00574-0827-01</u>	
			<u>76519-1210-00</u>	
			<u>00009-0086-01</u>	
			<u>00009-0417-01</u>	
			<u>00009-0520-01</u>	
			<u>69097-0536-37</u>	
			<u>69097-0537-31</u>	
			<u>69097-0537-37</u>	
			<u>50090-0330-00</u>	
			<u>00409-6562-02</u>	
			<u>00409-6562-22</u>	
			<u>00143-9659-01</u>	
			<u>62756-0017-40</u>	
			<u>62756-0016-40</u>	
			<u>00409-6557-01</u>	
			<u>00409-6562-01</u>	
			<u>00409-6562-20</u>	
			<u>76420-0650-01</u>	
			<u>00591-4128-79</u>	
			<u>00009-0085-10</u>	

Subcutaneous Implantable Hormone Pellets **Testosterone Replacement or Supplementation Therapy**

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Medication Name		How Supplied	National Drug Code	Maximum Allowed
Brand	Generic			
			00009-0086-10 00574-0827-10 00009-0520-10 00009-0347-02 62756-0015-40 00143-9726-01 00009-0417-02 63874-1061-01 00574-0820-01 00574-0820-10	
Testopel	testosterone pellet	75 mg pellet	66887-0004-01 66887-0004-10 66887-0004-20	6 pellets

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Maximum Allowed Frequencies:

The allowed frequencies in this section are based upon the FDA approved prescribing information for the applicable medications. For indications covered by UnitedHealthcare without FDA approved dosing, the frequencies are derived from available clinical evidence. This list may not be inclusive of all medications listed and is subject to change.

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Medication Name		Maximum Frequency
Brand	Generic	
Aveed	testosterone undecanoate	The recommended dose is 750mg initially, followed by 750mg after 4 weeks, then 750mg every 10 weeks thereafter.
Delatestryl	testosterone enanthate	For replacement therapy, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month
Depo-Testosterone	testosterone cypionate	For replacement in the hypogonadal male, 50 mg to 400 mg every 2 to 4 weeks, not to exceed 400 mg per month
Testopel	testosterone pellet	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.

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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

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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)

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 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. 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 month.

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 pellets (Testopel®), testosterone cypionate (Depo-Testosterone®), testosterone enanthate (Delatestryl®) and testosterone undecanoate (Aveed®). Local Coverage Determinations (LCDs) exist for testosterone replacement therapy: see the LCD for Treatment of Males with Low Testosterone. Local Coverage Article (LCA) specific to testosterone pellets (Testopel®) exists; see the LCA for Testopel Coverage. LCAs do not exist for testosterone cypionate (Depo-Testosterone®), testosterone enanthate (Delatestryl®) and testosterone undecanoate (Aveed®).

Medicare may cover 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. See the Medicare Benefit Policy Manual, Chapter 15, §50 Drugs and Biologicals.

(Accessed March 12, 2020)

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- 9-12. Aveed [prescribing information]. Malvern, PA: Endo Pharmaceuticals; October 2019

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
<u>TBD</u>	<u>Rename policy. Add injectable testosterone to the policy. Add maximum dosage criteria to applicable codes. Updated references.</u>

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