

EASE D NOT "APLE THIS REA	Sample CMS-1500 Paper Claim Form for TESTOPEL®: MEDICARE							
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MEDICARE MEDICAID CHAMPUS CHAMPVA GROUM (Medicare #) (Medicaid #) (Sponsor's SSN) (VA File #) (SSN)	UP FECA LTH PLAN BLK LUNC N or ID) (SSN)	OTHER	1a. INSURED'	S I.D. NUN	IBER		(FOR F	PROGRAM IN ITEM 1)
PATIENT'S NAME (Last Name, First Name, Middle Initial)  3. PATIENT'S	C DIDTH DATE	SEX	4. INSURED'S	NAME (La	st Name,	, First Nan	ne, Middle	Initial)
PATIENT'S ADDRESS (No., Street) 6. PATIENT I	RELATIONSHIP TO INSU	F RED	7. INSURED'S	ADDRESS	S (No., Str	reet)		
Self STATE 8. PATIENT S	Spouse Child	Other	CITY					07475
Single		Other	OIIT					STATE
This sample represents how your Me require completion of claim forms form is not intended to replace or does not guarantee payment or take is part of the clinical decision, and e codes that most accurately describe guidance. Information is subject to any clinical or treatment recommendation or treatment recommendation.  The property of the property	or TESTOPE modify you e the place each provide the service change. This dation.  he following: (total milligrams imp	ninistra L® anc r MAC of prof r is res s provi s samp	CPT®  "s policites ponsible ded and le claim"	code cy, a al cod le for a form	nd uding sele adher doe	80. Tuse of adving ecting ering es no	this sof this ce. (g the to all the terminal the termina	sample s form Coding billing I payor
RESERVED FO [e.g., 6 TESTOPEL® x 75mg = 450mg]) NDC: 66887-004-10 and 66887-004-20		20. OUTSIDE LAB? \$ CHARGES  YES NO						
DIAGNOSIS OF  ICD-10 Dx Codes most commonly associated with  E29.1 Testicular hypofunction  E29.8 Other testicular dysfunction  E29.9 Testicular dysfunction, unspecified	TESTOPEL®:	<b>\</b>	22. MEDICAID CODE 23. PRIOR AU			ORIGINAL	. REF. NO	).
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Subcutaneous hormone pellet implantation (im testosterone pellets beneath the skin)	27. ACCEPT ASS (For govt. claim YES FACILITY WHERE SERV	NO	28. TOTAL CH	ARGE	\$		-	30. BALANCE DUE \$   PRESS, ZIP CODE

## **INDICATION**

#### **MALES**

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

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

Safety and efficacy of TESTOPEL® in men with "age-related hypogonadism" have not been established.

# IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL®

### **CONTRAINDICATIONS**

- Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate
- If administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. If the patient becomes pregnant while taking these drugs, she should be apprised of the potential hazard to the fetus

#### WARNINGS

- In patients with breast cancer, androgen therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued
- Prolonged use of high doses of androgens has been associated with the development of peliosis hepatis (which can be a life-threatening or fatal complication) and hepatic neoplasms including hepatocellular carcinoma
- Men treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma
- There have been postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as TESTOPEL®. Evaluate patients who report symptoms of DVT or PE. If a VTE is suspected, discontinue treatment with TESTOPEL® and initiate appropriate workup and management
- Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. Patients should be informed of this possible risk when deciding to use or to continue to use TESTOPEL®
- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If testosterone abuse is suspected, check serum testosterone concentrations to ensure that they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events
- Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease.
   In addition to discontinuation of the drug, diuretic therapy may be required

- Gynecomastia frequently develops in patients and occasionally persists in patients being treated for hypogonadism
- Postmarketing cases associate TESTOPEL® insertion with implant site infection (cellulitis and abscess) and/or pellet extrusion. Infection and/or extrusion can occur at any time and may require further treatment
- This drug has not been shown to be safe and effective for the enhancement
  of athletic performance. Because of the potential risk for serious adverse
  health effects, this drug should not be used for such purpose

## **PRECAUTIONS**

 There is less flexibility for dosage adjustment compared to oral, intramuscular, or aqueous suspension. Surgical removal may be required if testosterone therapy is discontinued

#### ADVERSE REACTIONS

- Side effects reported with the use of TESTOPEL® include: excessive frequency and duration of penile erections, hirsutism, oligospermia at high doses, nausea, cholestatic jaundice, rare hepatic neoplasms, increased serum cholesterol, acne, acceleration of bone maturation without compensatory gain in linear growth in children, male pattern baldness, alterations in liver function tests, suppression of clotting factors, bleeding in patients on concomitant anticoagulation therapy, polycythemia, fluid and electrolyte disturbances, increased or decreased libido, headache, anxiety, depression, generalized paresthesia, edema, and/or prostate enlargement accompanied by difficulty urinating
- TESTOPEL® insertion may cause pain at the site of subcutaneous implantation of pellets and is rarely associated with anaphylactoid reactions

## **DRUG ABUSE AND DEPENDENCE**

- Abuse and misuse of testosterone are seen in male and female adults and adolescents. Testosterone, often in combination with other anabolic androgenic steroids, may be abused by athletes and bodybuilders
- Serious adverse reactions have been reported in individuals who abuse anabolic androgenic steroids, and include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility, and aggression
- The following adverse reactions have been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemia, testicular atrophy, subfertility, and infertility
- The following adverse reactions have been reported in women: hirsutism, virilization, deepening of voice, clitoral enlargement, breast atrophy, male-pattern baldness, and menstrual irregularities
- The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth, and precocious puberty
- Withdrawal symptoms can be experienced upon abrupt discontinuation in patients with addiction. Withdrawal symptoms include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses for approved indications have not been documented.

Please click here for full Prescribing Information.



