



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 9, 2016 February 24, 2016

Testosterone (non-injectable formulations)

LENGTH OF AUTHORIZATION: One year

INITIAL REVIEW CRITERIA:

- Patient is ≥ 18 years old; AND
- Patient is male; AND
- Patient has a diagnosis of primary or secondary hypogonadism;* AND
- Patient does not have a history of prostate carcinoma or male breast carcinoma; AND
- Prescriber has submitted the results of two separate serum testosterone levels, each drawn in the morning, which indicate a low serum testosterone (normal range: 300 to 1,000 ng/dL) within the last six months.

* Causes of hypogonadism are classified as primary which are due to failure of the testes, or secondary, which are due to failure of the hypothalamus or pituitary gland. Either type of hypogonadism, may be caused by an inherited (congenital) or acquired factor.

* Examples of primary male hypogonadism include but are not limited to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, chemotherapy, radiation therapy, toxic damage from alcohol or heavy metals, testicular infections (such as mumps) and chromosomal abnormalities such as Klinefelter's Syndrome

*Examples of secondary male hypogonadism include but are not limited idiopathic gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency and pituitary hypothalamic injury from tumors, trauma, or radiation.

***Safety and efficacy in men "age-related hypogonadism" has not been established.*

PATIENTS WHO MEET CRITERIA SHOULD BE APPROVED FOR THE PREFERRED AGENTS- ANDROGEL GEL PACKET OR ANDROGEL GEL PUMP

CONTINUATION OF THERAPY CRITERIA:

- Patient has been compliant with treatment based on refill history
- Prescriber submits labs within the last twelve months indicating patient has a normal serum testosterone level on therapy (normal range: 300-1,000 ng/dL)

DOSING & ADMINISTRATION:

AndroGel 1%: 5 grams once daily, preferably in the morning (delivers 5 mg systemically); Dosing may be increased to 10 mg (by 2.5 mg increments)

AndroGel 1.62%: 40.5 mg (1.25 g of gel) once daily. Dosing may be adjusted between 20.25 mg and 81 mg based on levels drawn at 14 and 28 days after start of therapy

Apply to clean, dry intact skin of the shoulders and upper arms; do not apply to the genitals



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AndroGel 1% is available as:

- 2.5, 5 g packets (30 per package)
- 75 g pump (2 per package); dispenses 60 metered 1.25 g doses

AndroGel 1.62% is available as:

- 1.25, 2.5 g packets (contains 20.25 mg or 40.5 mg testosterone, respectively; 30 packets)
- 75 g pump with 60 pump actuations delivering 20.25 mg of testosterone per actuation (1.25 g of gel)