Division: Pharmacy Policy	**Subject: Prior Authorization Criteria**
Original Development Date: Original Effective Date: Revision Date:	February 9, 2016 February 24, 2016; January 21, 2022; June 16, 2022

Testosterone (non-injectable formulations)

TOPICAL:

- Clinical PA required (preferred): Androderm® patch, AndroGel® pump (brand and generic testosterone)
- Clinical PA required (non-Preferred): Fortesta® gel (pump), Natesto® nasal gel pump, Testim® gel tube, Testosterone gel packet/pump/tubes, Testosterone (topical solution), Vogelxo® gel packet/pump/tube

IMPLANT:

- Preferred: N/A
- Non-Preferred: Testopel®

ORAL:

- Preferred: N/A
- Non-Preferred: Jatenzo®, Tlando®

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 themorning, which indicate a low serum testosterone (normal range: 300 to 1,000 ng/dL) within thelast 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 damagefrom alcohol or heavy metals, testicular infections (such as mumps) and chromosomal abnormalities suchas Klinefelter's Syndrome
*****Examples of secondary male hypogonadism include but are not limited idiopathic gonadotropin orluteinizing hormone releasing hormone (LHRH) deficiency and pituitary hypothalamic injury fromtumors, 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

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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:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/