

# Initial Prior Authorization

## Azmiro, Depo-Testosterone

### Testosterone Products – Injectable

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Azmiro	testosterone cypionate	injection
Depo-Testosterone	testosterone cypionate	injection

## Indications

### FDA-approved Indications

#### Azmiro

Azmiro is indicated for testosterone replacement therapy in males in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy, Klinefelter's syndrome, or toxic damage from alcohol or heavy metals, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

#### Limitations of Use

- Safety and efficacy of Azmiro in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of Azmiro in pediatric patients below the age of 12 years have not been established.

Reference number(s)
976-A

## Depo-Testosterone Injection

Depo-Testosterone Injection is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy.
- Hypogonadotropic hypogonadism (congenital or acquired)-gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.

Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

## Compindial Uses

Gender dysphoria<sup>3-4,6-8</sup> (also known as transgender and gender diverse (TGD) persons)

## Coverage Criteria

### Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism).
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, the patient meets ALL of the following criteria:
  - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.
  - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

### Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism).
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

# Continuation of Therapy

## Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

## Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism).
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

## Duration of Approval (DOA)

- 976-A: DOA: 12 months

## References

1. Azmiro [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; May 2024.
2. Depo-Testosterone [package insert]. New York, NY: Pharmacia & Upjohn Co; September 2018.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed January 11, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/11/2024).
5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
6. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
8. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.