



Testosterones

Azmiro (testosterone cypionate) J1072

Prior Authorization Request

Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

50 to 400 mg IM every 2 to 4 weeks;
 Other Regimen _____

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Replacement Therapy for Hypogonadism

All of the following criteria must be met:

- Patient is a male.
- Patient is 18 years or older.
- Prior to starting therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided and Lab results confirm ONE of the following:
 - Patient is 70 years or younger with a serum testosterone level less than 300 ng/dL.
 - Patient is over 70 years of age with a serum testosterone level less than 200 ng/dL.
- Patient has a diagnosis of ONE of the following:
 - Primary Hypogonadism (Klinefelter Syndrome, orchitis, orchiectomy, age-related hypogonadism, etc).
 - Hypogonadotropic (Secondary) Hypogonadism (e.g., pituitary-hypothalamic injury, idiopathic deficiency).

- Patient presents with at least ONE of the following symptoms:
 - Reduced sexual desire (libido) and activity.
 - Decreased spontaneous erections.
 - Breast discomfort/gynecomastia.
 - Loss of body hair (axillary/public), reduced shaving.
 - Very small (<5 mL) or shrinking testes.
 - Infertility/low/zero sperm count.
 - Height loss, low trauma fracture, low bone mineral density.
 - Hot flushes, sweats.
 - Other signs (decreased energy, depressed mood, poor concentration, diminished performance).

Gender Dysphoria/Incongruence

- All of the following criteria must be met (per WPATH 2022):
 - Patient has a diagnosis of gender dysphoria/incongruence.
 - Patient has experienced puberty to at least Tanner Stage 2.
 - Patient fulfills the DSM V criteria for gender dysphoria.
 - Patient has (early) pubertal changes that have increased their gender dysphoria.
 - Patient does not have a comorbidity that interferes with diagnosis or treatment.
 - Patient has psychological and social support before and during treatment.
 - Patient has demonstrated knowledge of the expected risks and outcomes of hormone therapy.

Testosterone injections may NOT be approved for the following:

- **Untreated obstructive sleep apnea (OSA).**
- **Polycythemia (Hct >48% or >50% for high-altitude residents).**
- **Severe congestive heart failure (CHF).**
- **Uncontrolled hypertension.**
- **Known/suspected/history of prostate cancer (unless: post-radical prostatectomy/radiation, organ-confined, disease-free >2 years, PSA undetectable [e.g., <0.1 ng/dL]).**
- **Patient is trying to conceive.**

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Patient had an **adequate response** or **significant improvement** while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Testosterone Prior Authorization

Drug Name(s):

AZMIRO

TESTOSTERONE CYPIONATE

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.
 - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Azmiro

- Male hypogonadism

Off-Label Uses:

- Gender dysphoria - Transgender male

Age Restrictions:

N/A

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexolutions.com/micromedex2/librarian/CS/35139D/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B26D3F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=598190&contentSetId=100&title=Testosterone+Cypionate&servicesTitle=Testosterone+Cypionate&brandName=Azmiro&UserMdxSearchTerm=Azmiro#