

Masculinizing Hormone Therapy (Testosterone) for Transgender and Gender Diverse Patients Criteria for Use

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VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information. **Note:** The use of hormone therapy for transgender and gender diverse patients is non-FDA approved or off-label.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive **testosterone therapy**.

- Uncontrolled or untreated erythrocytosis
- Unstable or severe cardiovascular or cerebrovascular disease (e.g., recent myocardial infarction or stroke within the past 6 months)
- Pregnancy (e.g., known or positive pregnancy test), desire for pregnancy, or breastfeeding
- Active breast cancer or other hormonally sensitive cancer*

*For patients with history of breast or other hormonally sensitive cancer, consider Hematology/Oncology consultation when evaluating risks and benefits of hormone therapy

Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria.

- Fulfills diagnostic criteria for gender dysphoria (GD)/gender incongruence (current version of DSM or ICD) that is persistent and well documented as determined by a trained mental health or other qualified provider with expertise in transgender-specific diagnoses
- Initial VA prescription restricted to VA or VA community care provider experienced in the use of gender affirming hormone therapy (or in consultation with an experienced provider)
- Any concurrent medical conditions and modifiable risk factors that can be exacerbated by hormone treatment have been considered and addressed*
- If present, concurrent mental health concerns are reasonably well controlled
- Patient informed of potentially irreversible infertility associated with gender affirming hormone therapy and provided information on options for fertility preservation prior to treatment
- Patient informed of potential risks, benefits, and limitations of hormone treatments and expresses clear understanding and that hormone therapy is off-label
- Patient accepts the expectations of ongoing monitoring plan and adherence to treatment regimen
- Patient agrees on avoidance of additional hormone treatments
- If patient is a tobacco user, tobacco cessation has been recommended

*e.g., sleep apnea, hypertension, diabetes, dyslipidemia, diseases worsened by fluid retention (heart failure, renal impairment, hepatic impairment), obesity, depression/mood disorders, etc.

For individuals of childbearing potential

- Pregnancy must be excluded prior to receiving testosterone and patient provided contraceptive counseling on potential risk vs. benefit of taking testosterone if patient were to become pregnant