

**Off-Label Transdermal Testosterone
for Hypoactive Sexual Desire Disorder (HSDD)
In Postmenopausal Females
March 2025**

VA Pharmacy Benefits Management Services and National Formulary Committee

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.

See the VA Clinical Summary document on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

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

- Patient is pregnant, lactating, or of childbearing potential
- Active breast cancer or other hormonally sensitive cancer
- Severe liver disease
- Baseline total testosterone level in the midrange or high range for premenopausal females (per local laboratory threshold)¹
- Uncontrolled severe cardiovascular or cerebrovascular disease²
- Uncontrolled hyperlipidemia²
- High risk of breast cancer²
- Known thrombophilia or unprovoked venous thromboembolism²

Inclusion Criteria

All of the following criteria must be met.

- Provider initiating treatment is a VA or VA Community Care women's health provider, urologist, or other locally designated provider experienced in the treatment of HSDD
- Patient is naturally or surgically postmenopausal³
- Documented diagnosis of hypoactive sexual desire disorder (HSDD)
- If present, any modifiable factors and comorbidities contributing to HSDD have been acknowledged and addressed (e.g., physical factors, psychosocial factors, relationship issues, medications, etc.)
- Any concurrent medical conditions and modifiable risk factors that can be exacerbated by hormone treatment have been considered and addressed⁴
- Baseline total testosterone, sex hormone binding globulin (SHBG), and liver function tests obtained and evaluated^{1,5}
- Patient informed of and expressed clear understanding of potential risks, benefits, side effects, and limitations of hormone treatment and that use is off-label. Discussion and patient understanding have been documented.
- Patient agrees on avoidance of additional testosterone hormonal treatments (including compounded products, pellets, etc.)
- Patient expresses understanding on proper use of the product (e.g., transdermal use, correct dose, how to avoid transfer to others)

1. Baseline mid-range to high total testosterone level indicates symptoms are likely unrelated to testosterone. Note testosterone levels are not used to diagnose HSDD and do not predict treatment efficacy.
2. Insufficient evidence exists to guide therapy. Recommend careful risk/benefit evaluation and shared decision-making approach and documentation in the Federal Electronic Health Record [EHR].
3. Perimenopausal patients who meet other criteria may be considered on an individual basis
4. E.g., sleep apnea, hypertension, diabetes, dyslipidemia, diseases worsened by fluid retention (heart failure, renal impairment, hepatic impairment), obesity, depression/mood disorders, etc.

5. Elevated SHBG is typically indicative of nonresponders to testosterone; however, SHBG may be elevated in patients on oral estrogens, thyroid replacement, and untreated hyperthyroidism. For patients with an elevated SHBG who have an unmodifiable risk factor (e.g., thyroid replacement therapy), a trial of testosterone therapy may still be considered.

Prepared: March 2025. Contact: Lisa Longo, Pharm.D., BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)
