ALABAMA STATE BOARD OF MEDICAL EXAMINERS

Recommended Guidelines for Testosterone Replacement Therapy in Males

- Only symptomatic men with demonstrably abnormal serum testosterone levels below 300ng/dl confirmed on subsequent morning lab evaluations should be considered for testosterone replacement therapy (TRT) after exclusion of other related medical conditions.
    - Valid symptoms in the setting of testosterone less than 300ng/dl include:
        - Persistent fatigue after lifestyle and medical workup
        - Decline in muscle mass
        - Decline in libido
        - Erectile dysfunction
        - Depression
        - Sleep disturbance
        - Idiopathic anemia
        - Osteopenia / osteoporosis
        - Persistent sleep disturbance with ongoing treatment of sleep apnea
    - Subsequent / confirmatory lab evaluation should include fasting early morning serum total testosterone, LH, H/H, prolactin, FSH, and PSA.
        - Potential pituitary abnormalities, such as hyperprolactinemia or the combination of low LH and low testosterone, should be referred to a specialist for evaluation and management.
- All testosterone replacement therapy candidates should be screened for contraindications **prior** to initiating testosterone replacement therapy:
    - Desire to maintain sufficient quality and quantity of sperm production for future fertility
    - Active prostate cancer
    - Uncertain serum PSA status
    - Major cardiac or thromboembolic event within 6 months
    - Cardiac Arrythmia
    - Undiagnosed / Unmanaged Obstructive Sleep Apnea
    - Primary or secondary polycythemia
    - Active liver and/or gallbladder disease
- All testosterone replacement therapy candidates should undergo a physical exam including:
    - Penis

    - Scrotum
    - Testes
    - Prostate
    - Breasts
    - General body habitus
- All testosterone replacement therapy candidates should be counseled on the evidence-based risks of TRT; including, but not limited to:
    - Loss of testicular volume and function – impairment of fertility
    - Small increase in the risk of thrombotic events including cardiac and cerebral
    - Small increase in the risk of cardiac arrythmia
    - Significant risk of secondary polycythemia / erythrocytosis
    - Possible risk of a major cardiac event or thrombotic event if testosterone levels are allowed to elevate past a safe level or if the medicine is abused
    - Significant possibility for elevated estrogen levels and resulting gynecomastia and mood alteration
    - Potential for increase in prostate size and lower urinary tract symptoms
- All testosterone replacement therapy candidates should be counseled on the potential evidence-based benefits of testosterone replacement therapy including improvements in:
    - Libido
    - Erectile function
    - Body composition
    - Insulin sensitivity
    - Mood
    - Bone density, if deficient
- Initial lab evaluations should include two early morning serum testosterone levels.
    - Values below 300ng/dl should be considered “low”
- All men should be evaluated with serum LH, prolactin, Hemoglobin and Hematocrit (H/H), FSH, and PSA levels prior to initiating testosterone replacement therapy.
- Karyotype should be obtained on individuals with physical exam findings and lab findings concerning 47XXY / Klinefelter’s syndrome. Appropriate subspecialty referral(s) or consults should be made if 47XXY / Klinefelter’s syndrome is determined to be present.
- All men should be counseled on the importance of a high-quality diet, exercise, sleep quality, stress management, weight management, avoidance of marijuana and alcohol, and general medical evaluation. Optimizing these variables will often help patients normalize testosterone levels without testosterone replacement therapy.

- After initiation of testosterone replacement therapy, repeat serum testosterone, H/H, and PSA levels should be checked at 3 months by a physician to ensure safety and efficacy of therapy. At this time, the patient should be examined by the physician of record to ascertain benefits derived from therapy. If no benefits are confirmed, the physician should offer discontinuation of therapy at this time.
- When intramuscular testosterone replacement therapy is used, the following guidance should be followed:
    - Serum testosterone levels change daily for men on injectable TRT.
    - Physicians should standardize serum testosterone level testing by checking mid dose interval serum testosterone level. This testing allows the physician to ascertain the approximate peak and trough testosterone levels without overburdening the patient with multiple blood draws.
    - Self-injecting TRT patients should inject on a consistent day allowing lab testing to be accurately arranged and communicated to the patient.
    - Appropriate mid dose interval testosterone levels will vary from patient to patient. However, levels should never be above 700 ng/dl, which would suggest a peak testosterone level above 800ng/dl.

    - Serum estradiol may be checked for patients with breast complaints, paradoxically decreased libido and/or erectile dysfunction, or at the discretion of the physician and consider that referral to appropriate specialist may be indicated.
- Repeat safety labs (mid dose interval serum testosterone and H/H) every 6 months while on therapy.
    - Serum Total Testosterone above 800 ng/dl should be considered excessive.
    - Physicians should not refill testosterone prescriptions without safety screening labs on file within the past 6 months.
- Physicians should adhere to the philosophy of "lowest effective dose" when prescribing testosterone replacement therapy.
- After initial evaluation, patients should undergo a 3-month visit with lab studies (Serum testosterone, H/H, PSA) and must be seen <u>in person</u> annually by a physician.
    - Telehealth is <u>not</u> an acceptable visit to qualify as a managing physician visit.
    - PSA should be checked at least annually. Physicians should consider checking PSA every 6 months in men with a father or brother with a prostate cancer history or a personal history of prostate cancer in durable remission.
- Prescribers should consider checking the PDMP at initiation and thereafter to identify potential testosterone replacement therapy prescription abuse.
- Physicians should offer to refer the patient to a qualified urologist or endocrinologist for any challenging treatment situation.

The above guidelines were approved by the Alabama Board of Medical Examiners on February 20, 2025. More resources on testosterone replacement therapy can be found on the Board's website: www.albme.gov.