Defense Health Agency (DHA) Clinical Communities Speaker Series

2026 NOV CCSS: Healthcare Innovations: Catalyzing the Future of Patient Care Delivery

2026 NOV CCSS S02: Testosterone: Physiology, Deficiency, and Screening in the Military

Resource List

Cardiovascular Safety of Testosterone-Replacement Therapy (2023) evaluates the cardiovascular safety of testosterone replacement therapy in men with confirmed hypogonadism who had existing cardiovascular disease or a high risk of developing it. Major cardiovascular events such as heart attack, stroke, or death from cardiovascular causes occurred at similar rates in the testosterone and placebo groups. These results suggest that testosterone therapy, when prescribed appropriately for men with confirmed hypogonadism, did not increase the overall risk of major cardiovascular events in the study population. However, some other health concerns, including atrial fibrillation, acute kidney injury, and pulmonary embolism, occurred more often in men receiving testosterone. The study supports careful patient selection, counseling, and monitoring when testosterone therapy is considered, particularly for men with cardiovascular risk factors.

The U.S. Food and Drug Administration (FDA) drug-safety communication FDA Issues Class-wide Labeling Changes for Testosterone Products (2025) describes class-wide labeling changes for prescription testosterone products. The changes follow the FDA's review of the Testosterone Replacement Therapy for Assessment of Long-term Vascular Events and Efficacy Response in Hypogonadal Men (TRAVERSE) clinical trial and postmarketing ambulatory blood-pressure monitoring studies. Based on the TRAVERSE findings, the FDA recommends removing the boxed warning that had described a possible increased risk of major adverse cardiovascular outcomes for testosterone products. However, the FDA also requires product labeling to include information about increased blood pressure, based on findings from the ambulatory blood-pressure studies. The communication retains the limitation-of-use language stating that testosterone products are intended for men with low testosterone associated with a medical condition and are not approved simply for age-related decreases in testosterone. The FDA notes that testosterone products are available in several formulations, including oral, injectable, topical gel, transdermal patch, and buccal forms. This drug-safety communication demonstrates that treatment decisions must consider both potential benefits and product-specific safety concerns, particularly blood-pressure monitoring and appropriate patient selection.

The Department of Veterans Affairs (VA) clinical guidance Evaluation for and Management of Males with Low Testosterone Recommendations for Use (2026) provides a practical framework for evaluating and managing low testosterone in male patients. It recommends testing only when patients have specific symptoms, physical signs, associated findings, or medical conditions that raise concern for hypogonadism, rather than screening based solely on nonspecific symptoms such as fatigue or reduced exercise tolerance. The guidance emphasizes that diagnosis requires consistently low testosterone measurements obtained in the early morning and confirmed on at least two separate occasions. It also explains that obesity, sleep apnea, depression, acute illness, caloric restriction, chronic opioid use, and other reversible factors can contribute to low testosterone measurements or similar symptoms. Clinicians are advised to measure luteinizing hormone and follicle-stimulating hormone after confirming low testosterone to help distinguish primary testicular dysfunction from secondary hypothalamic or pituitary causes. The resource discusses when specialty referral is appropriate, including concern for pituitary disease, significant prostate-specific antigen changes, or treatment complications. It outlines testosterone replacement therapy options, contraindications, fertility concerns, and monitoring requirements such as testosterone levels, hematocrit, hemoglobin, and prostate-specific antigen.

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References

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