

The Hormone Foundation's Patient Guide to Androgen Deficiency Syndromes in Adult Men

Why were the guidelines written?

This patient guide is based on clinical guidelines written to help physicians who are evaluating and treating men with androgen deficiency (AD) syndromes. A clinical syndrome is a group of symptoms (health changes noted by the patient) and signs (abnormalities observed by the physician). AD syndromes are due to a lack of the male sex hormone testosterone. This guide summarizes information about the best way to diagnose AD, how physicians will begin care and follow-up with patients who have this diagnosis, and the potential benefits and risks of testosterone therapy. It also provides information for patients with AD to help them improve the outcome of their treatment.

These guidelines do not apply to people who want to take testosterone to improve their strength, athletic performance, or physical appearance, or to prevent aging. Using testosterone for these purposes may be harmful to your health.

How were the guidelines developed?

The clinical guidelines were developed after an extensive review of the best clinical (human) research studies related to the diagnosis and treatment of AD. An expert panel of The Endocrine Society examined evidence from studies published in “peer-reviewed” medical journals (i.e., studies that were carefully evaluated by expert scientists and journal editors). The panel rated the studies and gave the highest quality rating to studies that were randomized and placebo controlled. This means that people in the study were assigned into groups at random (by chance). One group took testosterone and the other took a placebo (a similar preparation that did not contain testosterone). This approach allows physicians to learn whether testosterone is more effective than no treatment at all.

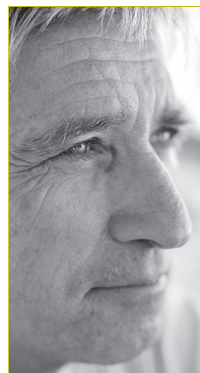
The panel developed “recommendations” based on high-quality studies or “suggestions” based on studies that were less carefully carried out. Once the panel agreed on their “recommendations” and “suggestions,” the guidelines were reviewed and approved by several committees and, finally, by the general membership of The Endocrine Society. No funding for the guidelines came from any pharmaceutical company.

What characterizes AD syndromes in adult men?

The panel determined that AD syndromes that are related to low testosterone levels in the bloodstream occur commonly in adult men. AD may be associated with:

- Decreased sex drive (libido)
- Erectile dysfunction (ED, inadequate erections)
- Lowered sperm count and fertility
- Increased breast size and tenderness
- Reduced energy
- Symptoms similar to menopause in women (e.g., hot flashes, increased irritability, inability to concentrate, depression)

With prolonged and severe decrease in testosterone, men may have loss of body hair, reduced muscle bulk and strength, brittle bones (osteoporosis), and smaller testicles.



Therapeutic goals of testosterone therapy

- Improve and maintain masculine characteristics
- Improve sex drive (libido) and erections
 - Increase energy and well-being
 - Improve muscle mass and strength
 - Improve bone mineral density

How is low testosterone diagnosed?

The panel recommended that a diagnosis of AD in adult men should be made only when there are (i) symptoms and signs that could be caused by low testosterone and (ii) consistently low levels of testosterone. Diagnosis involves the following:

Medical history

- Puberty (sexual development)
- Past or present major illnesses and nutritional deficiency



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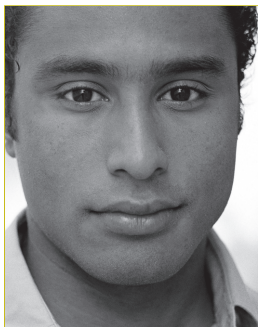
- All prescription and nonprescription drugs currently being taken
- Relationship problems, such as sexual problems
- Any major life events that have occurred
- Family history of similar problems
- Recent changes in body characteristics (e.g., breasts)
- Problems with your testicles

Physical examination

- Amount of body hair
- Presence of breast enlargement/tenderness
- Size and consistency of the testicles
- Size of the penis

Measurement of testosterone levels

- Generally, testosterone levels of 300–1,000 ng/dL are considered normal, but that can vary between laboratories.
- Morning measurement (when levels are highest) is recommended.
- Illness, malnutrition, and certain medications can reduce testosterone temporarily, and so measurement may need to wait until after you recover or stop taking such a medication.



To achieve your treatment goals, take your recommended medication as prescribed, keep regular appointments with your doctor, and adopt a healthy lifestyle that includes regular exercise and good nutrition.

Who should receive testosterone therapy?

- The panel recommended that treatment be given to men with low testosterone levels and symptoms or signs of AD.
- The panel suggested treatment be given to men with low testosterone levels and low libido, ED, HIV-infection, those receiving high doses of glucocorticoids (such as prednisone), and older men with consistently low testosterone levels on more than one occasion and significant symptoms and signs of AD.

Who should not receive testosterone therapy?

The panel recommended that men with one of the following should not be treated:

- Breast or prostate cancer.
- A lump or hardness in the prostate detected during the digital rectal examination (DRE), or a PSA (prostate specific antigen) level over 3 ng/mL, that has not been evaluated further for possible prostate cancer.
- A high number of red blood cells (erythrocytes), excessive blood thickness (hyperviscosity), untreated obstructive sleep apnea (long pauses in breathing followed by loud snoring), severe untreated

non-cancerous enlargement of the prostate (BPH), or severe heart failure.

What are the goals of testosterone therapy?

The panel suggested that the overall goal of testosterone therapy is to increase testosterone levels from the low to the middle of the normal range. Depending on the reason for treatment, goals may vary from case to case but should include improving and/or maintaining the signs of masculinity (e.g., deep voice, growth of beard, pubic hair), and improving sex drive (libido), erections, muscle bulk and strength, and bone strength.

How will your doctor help you get to your treatment goals?

There are several effective ways to achieve treatment goals. These include getting testosterone by injections (usually every 2 weeks), patches (put on skin every day), gel preparations (put on skin every day), or buccal tablets (applied to the gums two times a day).

The panel recommended that, in addition to the DRE and PSA test, a blood test for a hematocrit (percentage of red blood cells in your blood) should be done, as well as a blood test for testosterone levels at various times during treatment. You should see your doctor about three months after you start treatment to evaluate whether you are improving and if you are having any problems or side effects. A DRE, a PSA, and hematocrit blood tests should be also done at that time. After that, similar annual check-ups are recommended.

For men with osteoporosis or past bone fracture with little trauma, a bone mineral density test of the spine and hip area should be done one or two years after starting treatment.

How can you help your treatment process?

You and your doctor should be partners in your care. It is important that you provide a full description and history of your symptoms to your doctor. After a diagnosis has been made, it is important to use testosterone treatment as instructed and prescribed. Keep regular appointments with your doctor and ask questions.

You should tell your doctor how well treatment is helping your symptoms and any side effects you are having. For example, testosterone injections into the muscle may be uncomfortable and associated with ups and downs in symptoms; patches may cause skin redness and rashes; with skin contact where it is applied, gels may transfer testosterone to others; and buccal tablets may cause gum irritation.

You also will improve your health by following a healthy lifestyle that includes regular exercise, good nutrition, limited alcohol consumption, not smoking, and weight loss if you are overweight.

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