

# The Hormone Foundation's Patient Guide to Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes

## 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. The clinical guidelines, first published in 2006, were updated in 2010. This patient guide incorporates the latest recommendations.

A clinical syndrome is a group of symptoms (health changes noted by the patient) and signs (abnormalities noticed by the physician). AD syndromes are due to a lack of the main male sex hormone, testosterone. This guide summarizes information about the best way to diagnose AD, how physicians will care for patients who have AD, and the potential benefits and risks of testosterone therapy. It also provides information for patients with AD to help them improve results 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 is not approved by the U.S. Food and Drug Administration and may be harmful to your health.

## How were the guidelines developed?

The clinical guidelines were developed after an extensive review of the best human research studies related to the diagnosis and treatment of AD. An expert group of doctors from The Endocrine Society reviewed the findings of studies published in quality medical journals and developed recommendations and suggestions based on these studies. The guidelines were then reviewed and approved by several committees and, finally, by general members of The Endocrine Society. No funding for the guidelines came from any drug company.

## What are the signs and symptoms of AD syndromes in adult men?

AD syndromes caused by low testosterone levels in the bloodstream are common in adult men. Signs and symptoms of AD include:

- Drop in sex drive (libido)
- Erectile dysfunction (ED—inability to get or keep an erection)
- Lowered sperm count and infertility (inability to have children)
- Breast enlargement or tenderness
- Reduced energy
- Increased irritability, inability to concentrate, and low mood
- Hot flashes (when testosterone levels are very low)

When a decrease in testosterone is prolonged and severe, men may have loss of body hair, reduced muscle size 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 and maintain muscle mass and strength
- Improve and maintain bone mineral density

## How is low testosterone diagnosed?

The expert group recommended that a diagnosis of AD in adult men should be made only when there are (1) symptoms and signs that could be caused by low testosterone and (2) consistently low levels of testosterone in the blood (measured on more than one occasion). Diagnosis involves the following:

### Medical history

- Puberty (sexual development)
- Past or present major illnesses and nutritional deficiency
- Treatment with medications that might affect testosterone levels, such as strong opiate pain medications (e.g., methadone) and strong steroid anti-inflammatory drugs (e.g., prednisone)
- Sexual problems
- Any major life events that have occurred
- Family history of similar problems
- Recent changes in body features and breasts
- Damage to or shrinkage of the testicles



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## Physical examination

- Amount of body hair (underarm and pubic hair)
- Presence of breast enlargement or tenderness
- Size and softness of the testicles
- Size of the penis

## Measurement of testosterone levels

- Generally, blood levels of testosterone of 300–1,000 ng/dL are considered normal, but these levels may be different in different laboratories.
- Morning measurement (when levels are highest) is recommended.



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

- Illness, malnutrition, and certain medications can reduce testosterone temporarily, so blood tests may need to wait until after you recover or stop taking such a medication.
- Levels should be measured more than once to make sure they really are low.

*Note:* Use of medications that cause very low testosterone levels has become an important way to treat some men with prostate cancer. These very low testosterone levels are linked to increased risk of sexual problems, fatigue, bone fractures, heart disease, and diabetes.

## Who should receive testosterone therapy?

The expert group recommended that treatment be given to men with low testosterone levels and symptoms or signs of AD. Certain groups of men should not receive testosterone therapy, however.

## Who should not receive testosterone therapy?

The expert group would not recommend testosterone therapy for certain patients because of possible negative effects of exposure to testosterone:

- Men with diagnosed breast or prostate cancer.
- Men who have not been evaluated for possible prostate cancer but have
  - a lump or hardness in the prostate detected during a rectal examination (in which a doctor feels the prostate gland with a gloved finger inserted into the rectum), or
  - a blood PSA (prostate specific antigen) level over 4 ng/mL (which suggests prostate cancer or other prostate problems), or
  - a PSA over 3 ng/mL in men at high risk for prostate cancer, such as African American men or men with close relatives who have had prostate cancer.
- Men with
  - a high number of red blood cells
  - untreated obstructive sleep apnea (long pauses in breathing followed by loud snoring or grunting)

- severe problems passing urine caused by untreated, non-cancerous enlargement of the prostate
- uncontrolled or poorly controlled heart failure
- Men who want to have children, since testosterone therapy can lead to reduced sperm counts.

## What are the goals of testosterone therapy?

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

## How will your doctor help you get to your testosterone therapy goals?

Your doctor can prescribe testosterone in one of several forms: injections (usually every 2 weeks), patches (put on skin every day), gels (put on skin every day), buccal tablets (applied to the gums two times a day), and in some countries outside the U.S., pills or pellets implanted under the skin.

In addition to the rectal exam and PSA test, a blood test for a hematocrit (amount of red blood cells in your blood) should be done at the start of testosterone treatment to check for abnormalities. A blood test for testosterone levels at various times during treatment is also recommended to see if levels are in the normal range. During treatment, you should see your doctor about three to six months after you start treatment to evaluate whether you are improving and if you are having any problems or side effects. A rectal examination, PSA, and hematocrit blood tests help spot problems. After that, check-ups every year are recommended.

For men with osteoporosis or a past bone fracture with little or no stress on the bone, a bone mineral density test of the spine and hip area should be done after one to two years of testosterone treatment.

## What can you do to 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. 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 may cause ups and downs in symptoms; patches may cause skin redness and rashes; gels may transfer testosterone to others if they contact skin where the gel has been applied; 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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June 2010  
2nd edition