

# PBS criteria for testosterone prescribing: a few suggestions on implementation

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Andrology Australia has received numerous enquiries since the change in PBS criteria for testosterone prescribing (April 2015). In response, we offer some suggestions that may assist with understanding the changes and implementing the new PBS criteria.

## Why is there a difference between PBS criteria for supported testosterone prescribing and various clinical practice guidelines?

Clear-cut androgen deficiency due to established testicular disease or pituitary failure warrants testosterone treatment and has always been supported by the PBS and clinical practice guidelines. But there is a great deal of uncertainty about the significance of low testosterone levels in middle-aged and older men who do not have testicular disease or pituitary failure. The present lack of evidence can only be addressed by clinical studies such as the major Australian T4DM study ([www.t4dm.org.au](http://www.t4dm.org.au)), which is investigating whether testosterone treatment can prevent diabetes.

While clinical guidelines provide some flexibility about the use of testosterone in men without established testicular disease or pituitary failure, it is not known if testosterone treatment in this setting is safe or effective. In this situation the PBS criteria reflect a more conservative approach to using public money for health interventions.

## What about men who are about to start testosterone treatment for the first time?

If the patient is starting treatment for the first time, then the GP will need to identify the indication for treatment and the name and appointment time of a recognised specialist when gaining approval for prescribing testosterone with the PBS subsidy.

We recommend that the patient should see the specialist before treatment is started. Treatment can be started before the specialist appointment but if the specialist disagrees with the need for treatment, or there is not adequate documentation, then PBS-subsidised treatment cannot be continued. This may require stopping the testosterone treatment in order to allow a full re-evaluation. Note: the patient must see the specialist; for example, it is not enough for the GP to ring the specialist on behalf of the patient. It is possible for the doctor to prescribe testosterone treatment without the PBS subsidy

in which case the patient will have to pay the full cost of treatment.

## What about men who are already on testosterone treatment? What needs to happen for them to receive continued PBS support?

In consultation with their GP, men will need to be reviewed by an authorised specialist—for adult men this can be an endocrinologist, urologist, or a member of the Australasian

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Chapter of Sexual Health Medicine. Previous test results, if available, can be used for this review. If specialist opinion confirms established testicular disease or pituitary failure then treatment will be endorsed and continued PBS subsidy approved.

For those men, usually aged over 40 years, in whom the available documentation does not meet the new PBS criteria, such as serum testosterone levels above 6 nM, then options include the withdrawal of testosterone treatment to see if the very low serum testosterone levels return. If low testosterone levels are confirmed, the patient would qualify for treatment under the new PBS criteria.

Note that there is no 'grandfather clause': if a man previously had two serum testosterone levels  $<8$  nM, but both were over 6 nM, he does not qualify now. Similarly, some men have been on testosterone for years and their original serum testosterone results may no longer be available. To continue to be eligible for PBS-subsidised

testosterone treatment, these men will need to have testosterone treatment withdrawn for a sufficient time to allow the valid re-assessment of their baseline function. Such a withdrawal may lead to the reappearance of symptoms but would not be expected to have serious consequences.

Sometimes low serum testosterone levels will have spontaneously improved, especially if they were originally related to a chronic disease or obesity that has been addressed. Testosterone treatment is then no longer necessary.

#### **What about men who live in areas without the required specialist access?**

Some men will need to travel for their consultation with the specialist; however, this may only need to be on one occasion. Alternatively, they and their local doctor may be able to arrange a telemedicine consultation, which is available through Medicare. The GP needs to ensure that the test results are available to the specialist prior to the appointment.

#### **What happens when a patient has withdrawn from treatment under medical guidance but his serum testosterone level still does not fall within the new PBS criteria?**

If testosterone levels do not fall below 6 nM, the patient is not eligible for PBS-subsidised testosterone treatment. Testosterone treatment can still continue on a private prescription but without PBS subsidy. This decision is made by the patient in consultation with their doctor after discussing the risks and benefits of testosterone treatment.

#### **What happens when a patient's diagnosis of androgen deficiency has been verified and their serum testosterone levels are within the PBS criteria?**

After all criteria are met, the GP can manage the patient's future testosterone treatment, including changing the form of treatment, if necessary.

#### **Why might a doctor prescribe testosterone when levels fall outside of the PBS criteria?**

In consultation with a specialist, sometimes testosterone treatment is recommended when levels do not fall within the PBS criteria but remain within the broader scope of some clinical guidelines. In these circumstances the patient would not be eligible for PBS subsidy.

As mentioned, there are many controversies on the safety and efficacy of testosterone treatment in older men and these are recognised in clinical practice guidelines. Of recent concern is the possible risk of cardiovascular events in older men receiving testosterone treatment, particularly older men with underlying cardiovascular disease. Patients should thoroughly discuss the risks with the specialist who is aware of their overall health.

#### **Are clinical practice guidelines being reviewed in light of the change in PBS criteria?**

The Endocrine Society of Australia (ESA) is currently actively engaged in updating the original clinical practice guidelines for testosterone treatment (published in 2000) by looking at evidence that has accumulated in the 15 years since. The ESA will review new evidence and emerging research, and the positions taken by other leading international societies to develop a new position statement.

Testosterone treatment in older men is an area of active research and no doubt new research findings will lead to future reviews of the evidence and PBS criteria. In the meantime, Andrology Australia and the Endocrine Society of Australia strongly recommend that patients speak to their treating doctor before any decisions are made about treatment.

