PBS criteria for testosterone prescribing: a few suggestions on implementation

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), 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 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.
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.