

Changes to PBS criteria for testosterone prescribing

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Recent changes to the criteria for PBS-subsidised testosterone prescriptions have caused some confusion. This article explains what these changes are and how they will affect your patients.

In April 2015, the Pharmaceutical Benefits Advisory Committee (PBAC) announced new criteria for patient eligibility for the prescription of testosterone subsidised by the Pharmaceutical Benefits Scheme (PBS).¹ Feedback to Andrology Australia from doctors and patients already taking or about to start taking testosterone has indicated a level of community concern over these new rules.

What are the changes?

There are two major changes to the PBS criteria for the prescription of testosterone.



The first is that GPs are no longer able to prescribe testosterone treatment without having their patient's diagnosis validated by a specialist (i.e. an endocrinologist, a urologist or a registered member of the Australasian Chapter of Sexual Health Medicine). At the time of authority being obtained, the GP must include the name of the specialist and the date of the appointment when the specialist will see the patient. After all criteria are met, the GP can manage the patient's future testosterone treatment, including changing the form of treatment, if necessary.

The second change relates to the prescription of androgens for men aged 40 years or over who do not have a defined pituitary or testicular disorder. For these men to receive PBS support, their threshold testosterone levels in the bloodstream must be less than 6 nmol/L, lowered from 8 nmol/L to effectively tighten the criteria. If their testosterone levels do not fall below 6 nmol/L, the patients are not eligible for PBS-subsidised testosterone treatment.

Occasionally, testosterone treatment is recommended to men when their testosterone levels do not fall within the PBS criteria but they remain suitable for treatment within the broader scope of some clinical guidelines.² In these circumstances, the patient would not be eligible for PBS subsidy.

What if the patient is starting 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 provide the name of a recognised specialist and appointment time for the patient when gaining approval for prescribing testosterone

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with the PBS subsidy. This could be problematic if the patient is to access a specialist through a public clinic where the name of the treating specialist may not be available at the time of booking the appointment.

Ideally, the patient should see the specialist before treatment is started. If treatment is started before the specialist appointment but 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 for a full re-evaluation.

What if the patient is already receiving treatment?

For men who are already receiving a PBS-subsidised prescription of testosterone, confirmation of their diagnosis must also now be provided. To continue to receive the PBS subsidy, these patients must be reviewed by an authorised specialist (i.e. an endocrinologist, a urologist or a registered 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 above 40 years, in whom the available documentation does not meet the new PBS criteria – for example, if their pretreatment serum testosterone levels are more than 6 nmol/L – options include the withdrawal of testosterone treatment to see if their low serum testosterone levels return. If testosterone levels below 6 nmol/L are confirmed and the patient has been seen by an authorised specialist, the patient will qualify for treatment under the new PBS criteria.

Is there a 'grandfather clause'?

There is no 'grandfather clause' to these changes to the PBS. If a man previously had two serum testosterone levels less than 8 nmol/L but both were more than 6 nmol/L, he does not qualify now for PBS subsidy. Similarly, some men have been taking 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 their testosterone treatment withdrawn for a sufficient period of time to allow for the valid reassessment 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 since been addressed. Testosterone treatment is then no longer necessary.

In all cases, GPs may prescribe testosterone treatment without the PBS subsidy if the patient is able to bear the full cost of treatment.

New clinical practice guidelines

The use of testosterone treatment in older men is controversial because of the safety and efficacy concerns 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.³ Patients should thoroughly discuss the risks with the specialist who is aware of their overall health.

The Endocrine Society of Australia is currently actively engaged in updating the original clinical practice guidelines for testosterone treatment (published in 2000)⁴ by looking at evidence that has accumulated in the 15 years since they were published. The Endocrine Society of Australia will review new evidence and emerging research, and the positions taken by other leading international societies to develop a new position statement.

Andrology Australia and The Endocrine Society of Australia have released an advisory note on the implementation of the new PBS criteria for the prescription of testosterone. The advisory note, which is targeted primarily at GPs, is available at the Andrology Australia website: www.andrologyaustralia.org/pbs-testosterone-2015.

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