

4.09 TESTOSTERONE

National LGBTI Health Alliance

1 Purpose of Application

- 1.1 The PBAC considered the outcomes of a stakeholder meeting with the National LGBTI Health Alliance (the Alliance) held on 18 September 2015. The Alliance had made a minor submission to the requested changes to the restrictions that are applied to testosterone for the treatment of androgen deficiency to enable access by transgender and intersex patients. The purpose of this meeting was to determine an appropriate restriction arrangement for testosterone for transgender (trans) and intersex populations.

2 Requested listing

- 2.1 The submission requested changes to the revised restrictions for testosterone which came into effect on 1 April 2015.
- 2.2 The submission requested restoring the ability of General Practitioners (GP) to prescribe testosterone without consultation with a specialist when treating androgen deficiency in patients:
- a) who cannot produce testosterone within the normal male range due to absent or non-functioning testes (including trans patients and patients with intersex characteristics with a current testosterone prescription who are thus unable to document low testosterone despite requiring ongoing, lifelong administration of testosterone ;
 - b) undergoing gender affirmation; and
 - c) with intersex characteristics who give informed consent on their own behalf (excluding involuntary and coerced treatment of patients with intersex variations).
- 2.3 The submission requested that GP consultation with a (non-GP) specialist for populations a, b, and c (above) should only be required where BOTH of the following two criteria are met:
- a) routine monitoring or indicated assessment identifies a medical need beyond the individual GPs scope of practice and experience, as determined on a case-by-case basis; and
 - b) the consultation is with a specialist endocrinologist with specific expertise in testosterone therapy for the specific patient population (e.g., an endocrinologist with specific expertise in testosterone therapy for trans men will be consulted in the case of a trans man patient).
- 2.4 In addition, the submission requested changes to the restriction to comply with federal anti-discrimination legislation:
- a) the removal of the requirement for patients prescribed testosterone to be “male”;
 - b) restrict testosterone prescribing on the PBS by endocrinologists, urologists, and sexual health physicians for patients with intersex characteristics to only those who have given informed consent on their own behalf, including paediatric puberty induction and micropenis; and

- c) permit testosterone prescribing on the PBS for puberty induction and micropenis for patients with intersex variations who are over 18 years of age and can give informed consent on their own behalf.

3 Background

- 3.1 At its October 2012 meeting, the Drug Utilisation Sub-Committee (DUSC) reviewed the utilisation of PBS listed testosterone. The analysis highlighted that utilisation of testosterone had doubled over the previous five years, that there was a trend towards more general practitioners (GPs) initiating therapy, and that there may have been some use of testosterone that was not within the PBS restriction.
- 3.2 In its August 2013 consideration of the DUSC analysis report, the PBAC noted that though the proportion of GPs writing the first testosterone prescription for a patient increased only slightly (62% in 2005 to 68% in 2011), almost all of the growth in new patients treated was due to initiations by GPs(84%), rather than by specialists.
- 3.3 In July 2014, the PBAC made recommendations regarding the PBS restrictions for testosterone products, including:
 - Patients prescribed testosterone must be treated by one of the following specialists;
 - paediatric endocrinologist, specialist paediatrician, specialist general paediatrician specialist endocrinologist, specialist urologist; or
 - Patients must be treated by a GP in consultation with one of the above specialists; or
 - Patients must have an appointment to be assessed by one of the aforementioned specialists.
- 3.4 The revised restrictions recommended by the PBAC were implemented on 1 April 2015.
- 3.5 In July 2015, the PBAC considered a minor submission from the National LGBTI Health Alliance (the Alliance) that requested changes to the newly revised PBS restrictions. The submission requested that the ability of GPs to prescribe testosterone without consultation with a specialist be restored when treating androgen deficiency in the following populations:
 - Patients who cannot produce testosterone within the normal male range due to absent or non-functioning testes;
 - Patients undergoing gender affirmation; and
 - Patients with intersex characteristics who give informed consent on their own behalf.
- 3.6 The submission also noted that the gender specific population criterion “the patient must be male” was contrary to the intent of amendments to the Sex Discrimination Act 1984, and requested that the criteria be removed.
- 3.7 Due to the complex nature of the submission, the PBAC recommended holding a stakeholder meeting with the Alliance to determine an appropriate restriction arrangement for testosterone for trans and intersex populations.

4 Stakeholder meeting

- 4.1 The changes requested by the LGBTI Alliance are intended to ensure initial and continuing access to testosterone on the PBS for consenting intersex and transgender patients within a primary care setting.
- 4.2 Regarding current practice, the Alliance explained that transgender and intersex populations utilise PBS listed testosterone to aid in either gender affirmation or gender reparation; this treatment is primarily initiated and maintained via GPs, and generally requires lifelong administration of testosterone. The alliance further outlined that non-binary patients (individuals who do not identify as male or female) use testosterone intermittently, where they move in and out of treatment as necessary to achieve a preferred muscular aesthetic. The Alliance posited that in clinical settings there is insufficient awareness around the appropriate treatment of non-binary population and, as a result, some patients are declined treatment.
- 4.3 The Alliance explained that GPs initiate testosterone treatment after the patient has undergone a psychiatric assessment with a psychiatrist or clinical psychologist; this assessment can range from 3-6 visits. In most instances there is no inclusion of specialists in the initiation of treatment; this is similar to international practice where GPs are the primary carers of trans and intersex patients, and guidelines for the appropriate clinical management of these patients are accessible online.
- 4.4 The Alliance highlighted that in Victoria there is a shared care arrangement between GPs and specialists particularly in Monash and Royal Children's Hospital which has shown to be effective.
- 4.5 With regard to the prevalence of GPs initiating testosterone treatment for trans and intersex patients, the Alliance noted that the 2012 DUSC analysis may not have captured an increase due to the assumption that care of trans and intersex patients was undertaken by specialists.
- 4.6 The Alliance outlined their main concern with the revised restrictions was that prescribing had to be initiated at a specialist level. Intersex and transgender patients are reluctant to consult specialists and are more comfortable in the care of general practitioners. The Alliance noted that restricting prescribing to specialists will reduce the accessibility of testosterone for these patients, particularly in rural and regional areas, and that restricted access to hormone treatment has the potential to result in adverse mental health outcomes for transgender and intersex patients.
- 4.7 The Alliance also explained that due to the increasing population of transgender and intersex individuals, there is an increasing demand for hormone treatment and waiting times for specialists can be significant. It was the Alliance's position that this impacts both patients and the hospital system, as gender clinics are currently overwhelmed with patient appointments and consultations. The Alliance considered that allowing trained GPs to prescribe testosterone would reduce this burden.
- 4.8 The Alliance also explained that in restriction wording they would not like gender dysphoria to be used as it does not represent the patient population correctly.

Gender affirmation and reparation more correctly explain the conditions under which the population utilise the hormone.

- 4.9 PBAC representatives noted the concerns of the Alliance, and explained that the restrictions were revised to reduce the safety issues associated with the misuse of testosterone. While the effect of impeded testosterone access for transgender and intersex populations was inadvertent, the PBAC retained its safety concerns that led to the recommendation to amend the restrictions.
- 4.10 The PBAC representatives also advised that the current restriction wording for testosterone will be revised, with the removal of the criterion that 'the patient must be male'. The PBAC considered this clinical criterion was an unintentional barrier to some transgender and intersex individuals.
- 4.11 Regarding potential ways forward, the Alliance noted that there is limited information about transgender and intersex patients available in Australia for treating clinicians, and advised that ANZPATH (Australian and New Zealand Professional Association for Transgender Health) are currently developing guidelines and an online training module that will provide Australian clinicians information about appropriate treatment of trans and intersex patients. These are being modelled on overseas programmes such as the UCSF guidelines in primary care. It was discussed that these online modules could be used to implement accreditation to designated GPs which would give them specialist prescribing rights, a notion currently in practice for GP's treating HIV patients. It was also noted by the Alliance that these training programmes would need to include information on non-binary patients and their appropriate treatment. The Alliance considered that if an accreditation programme is implemented, shared care between rural GPs and accredited GPs would allow easier access for those living in remote regions.
- 4.12 The grandfathering of transgender and intersex patients across to the restrictions currently in place for testosterone maintenance was also discussed as a potential way to allow for continuity of care, however it was highlighted that this was not conventional practice for other restriction changes, and could be perceived as biased in that grandfathering was not permitted in the 1 April 2015 amendments.

5 PBAC discussion

- 5.1 The PBAC noted the issues faced by intersex and transgender patients seeking to access testosterone on the PBS. The Committee considered that it is important to identify a means to balance facilitated access for this vulnerable patient group with the safety concerns that had driven the 1 April 2015 amendments.
- 5.2 The PBAC noted the ongoing development of guidelines for treatment of intersex and transgender patients, as well as training for clinicians in primary healthcare settings. The PBAC considered that these resources could be useful once deployed, and may help to identify GPs who have undertaken appropriate training for the purposes of PBS prescribing.
- 5.3 The PBAC recalled that grandfathering arrangements had intentionally not been included in the 1 April 2015 restriction changes, arising as they had from concerns of

inappropriate utilisation. The PBAC considered it important that further restrictions changes be equitable for all patients requiring appropriate treatment with PBS-subsidised testosterone. The PBAC therefore considered that a grandfather restriction for intersex and transgender patients was not a feasible approach.

6 PBAC outcome

- 6.1 The PBAC requested that the Department continue to work on amendments to PBS restrictions for testosterone products to facilitate access for intersex and transgender patients.