

6.14 TESTOSTERONE

National LGBTI Health Alliance

1 Purpose of Application

- 1.1 The minor submission requested changes to the restrictions that are applied to testosterone for the treatment of androgen deficiency to enable access by transgender and intersex patients.

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 **TGA status at the time of PBAC consideration:** Testosterone in various forms has been approved by the TGA for the following indications:
- androgen replacement therapy for confirmed testosterone deficiency in males;
 - testosterone replacement therapy for confirmed testosterone deficiency in males;
 - testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests; and
 - testosterone replacement in primary and secondary male hypogonadism;
- 3.2 In its August 2013 Special meeting consideration of the DUSC analysis, the PBAC noted the following recent utilisation and expenditure trends regarding testosterone products:
- Increased expenditure in the last five years coincided with the PBS-listing of the transdermal gel and the long-acting intramuscular injection 1000mg.
 - The number of PBS/RPBS-prescriptions increased, while non-PBS prescriptions remained stable and low.
 - Though the proportion of GPs writing the first testosterone prescription for a patient has increased only slightly (62% in 2005 to 68% in 2011), almost all of the growth in new patients treated in the most recent year of analysis (2011) was due to initiations by GPs (84%), rather than by specialists.
 - Utilisation in the younger age groups remained constant, while initiations for patients aged 40-79 years had increased over time. The PBAC considered that the growth in initiations for patients in the 40-79 aged cohorts may be due to the increase in diagnosis and treatment of PBS listed indications, however may also include inappropriate use outside the PBS restrictions, such as patients without a pathologically-based androgen deficiency.
- 3.3 The PBAC made the following recommendations regarding the PBS restrictions for testosterone products:
- Amending the serum testosterone threshold for men aged 40 years or older who do not have established pituitary disorders to 6-15nmol/L in combination with a high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU/L, whichever is higher). Confirmation of androgen deficiency should include measurement of serum testosterone, LH and FSH to allow for the appropriate diagnosis of primary androgen deficiency.
 - Patients prescribed testosterone must be treated by a specialist paediatric endocrinologist, specialist paediatrician, specialist endocrinologist, specialist urologist, or a general practitioner in consultation with one of the above specialists listed or to have an appointment to be assessed by one of these specialists.
 - Excluding treatment for low serum testosterone due primarily to age, obesity, cardiovascular diseases, infertility or drugs. These indications have not been assessed for efficacy and cost-effectiveness by the PBAC (*See Public Summary Document on testosterone – August 2013 PBAC Meeting*).
- 3.4 At its July 2014 meeting, the PBAC recommended amendments to the restrictions for testosterone products. The revised restrictions which came into effect for all PBS-

listed testosterone products on 1 April 2015 are provided at attachment A (*See Public Summary Document on review of proposed amendments to PBS restrictions for testosterone products - July 2014*).

4 Clinical place for the proposed therapy

- 4.1 Androgen deficiency is treated with androgen replacement therapy most often in the form of testosterone therapy. Restoring testosterone levels to within the normal range can result in improvements over time in muscle mass, mood, sexual desire, libido and sexual function.
- 4.2 The changes requested by the National LGBTI Health 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.

5 Comparator

- 5.1 As a minor submission, there was no economic comparison presented.

6 Consideration of the evidence

Sponsor hearing

- 6.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 6.2 The PBAC noted and welcomed the input from individuals (7), health care professionals (6) and organisations (4) via the Consumer Comments facility on the PBS website. The comments described a range of concerns and difficulties with accessing testosterone arising from the changes to the prescribing rules that came into effect on 1 April 2015.
- 6.3 The PBAC noted the advice received from organisations including the Western Sydney Transgender Support Group; Australian and New Zealand Professional Association for Transgender Health; Public Health Association Australia; and A Gender Agenda. The advice highlighted concerns regarding the recent changes to testosterone prescribing rules and the implications for delays and barriers to accessing treatment and the disruption to continuity of care. The organisations requested that the PBAC reconsider the changes to the restrictions in light of the negative implications for trans people and people with intersex variations. The PBAC noted that this advice was supportive of the submission.

Clinical trials

- 6.4 As a minor submission, no clinical trials were presented in the submission.
- 6.5 The basis of the minor submission's request was that the recent changes to testosterone restrictions have resulted in restricted access for intersex and trans patients. The submission claimed that:
- lifelong testosterone administration is medically necessary for trans patients seeking this medication as part of medical gender affirmation;
 - restricted access to testosterone results in harmful mental health outcomes for trans patients;
 - people with intersex variations are often subjected to involuntary and coerced medical interventions intended to 'normalise' their bodies' by specialist endocrinologists, urologists, and sexual health physicians and that intersex patients often report lack of safety, discomfort, distrust and avoidance of care with these specialists;
 - trans patients who are on a long term testosterone therapy do not require the involvement of a specialist;
 - the specialist consultation requirement for GPs treating trans patients and patients with intersex characteristics when prescribing testosterone has limited access to testosterone due to workforce shortages, specialist appointment waiting times. This submission therefore claims that this requirement will further exacerbate existing health disparities and access shortages faced by trans people and people with intersex variations in Aboriginal and Torres Strait Islander communities and those living in rural, regional and remote communities.
- 6.6 Furthermore, the submission claims that the current gender-specific restrictions are contrary to the intent of amendments to the *Sex Discrimination Act 1984* that prohibit both direct and indirect discrimination on the basis of sexual orientation, relationship status gender identity, and intersex status in Commonwealth activities. In order to comply with this legislation, the Medicare Benefits Schedule (MBS) has been amended to remove gender specific MBS item codes.
- 6.7 The sponsor presented an endorsement from a general practitioner in support of the submission.

Economic analysis

- 6.8 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

- 6.9 The minor submission did not provide estimated utilisation and financial estimates.

7 PBAC Outcome

- 7.1 The PBAC recommended amending the restriction wording for testosterone to remove the population criterion 'patient must be male'. The PBAC considered this clinical criterion was an unintentional barrier to some trans people and people with

intersex variations receiving PBS-subsidised testosterone replacement therapy. The PBAC also considered that implementing this change would be relatively straightforward.

- 7.2 The PBAC considered that the remaining requested changes to the restrictions for testosterone products were complex in nature. The PBAC recalled that the DUSC analysis of trends in utilisation and expenditure of testosterone products showed that PBS/RPBS prescriptions had increased while non-PBS prescriptions remained stable and low and that there was a trend towards more GPs initiating therapy. The PBAC also recalled its safety concerns with testosterone, including possible increased cardiovascular risk in older men. The PBAC reaffirmed that the PBS restrictions for testosterone products should appropriately address these concerns.
- 7.3 The PBAC considered that the impacts on trans people and people with intersex variations described in the submission were unintended consequences of the restriction amendments which came into effect on 1 April 2015. The PBAC requested that the Department undertake to identify, in consultation with affected stakeholders, an approach that would preserve the Committee's original intent to prevent inappropriate utilisation of testosterone products, while at the same time limiting or avoiding impacts on trans people and people with intersex variations.
- 7.4 The PBAC recommended a stakeholder meeting be held between the Department, representatives of the National LGBTI Health Alliance and other consumer representatives, relevant clinicians, the Department of Human Services, the sponsors of testosterone preparations and PBAC members. The aim of this meeting would be to determine an appropriate restriction arrangement (including appropriate prescriber groups) for transgender and intersex populations. A revised restriction would need to reflect the need for these patients to maintain continuity of care with a primary care provider.
- 7.5 The PBAC noted the consumer comments and acknowledged the unintended consequences of the changes to the restrictions for the transgender and intersex patient populations.

Outcome:

Recommended

8 Recommended listing

- 8.1 Amend existing listing as follows:

Public Summary Document – July 2015 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
TESTOSTERONE testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations	1	5	Axiron	EL
testosterone 2.5 mg/24 hours patch, 60	1	5	Androderm	GN
testosterone 5 mg/24 hours patch, 30	1	5	Androderm	GN
testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets	1	5	Testogel	BN
TESTOSTERONE ENANTHATE testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes	1	3	Primoteston Depot	BN
TESTOSTERONE UNDECANOATE testosterone undecanoate 40 mg capsule, 60	1	5	Andriol Testocaps	MK
testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule	1	1	Reandron	BN
TESTOSTERONE Cream 50mg/mL (w/v) 5%, 50mL	1	6	AndroForte 5	
TESTOSTERONE Testosterone 1% (12.5 mg/1.25 g actuation) gel, 2 x 88 g pump bottle	1	4	Testogel	HB

Restriction 1	
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Androgen deficiency
Treatment criteria:	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must have an established pituitary or testicular disorder
Administrative Advice	The name of the specialist must be included in the authority application

Public Summary Document – July 2015 PBAC Meeting

Restriction 2	
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Androgen deficiency
Treatment criteria:	Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must not have an established pituitary or testicular disorder AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs
Population criteria:	Patient must be aged 40 years or older
Prescriber Instructions	Androgen deficiency is defined as: i) testosterone level of less than 6 nmol per litre; OR ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher) Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated
Administrative Advice	The name of the specialist must be included in the authority application

Restriction 3a	
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Micropenis
Treatment criteria:	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be under 18 years of age
Administrative Advice	The name of the specialist must be included in the authority application

Public Summary Document – July 2015 PBAC Meeting

Restriction 3b	
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Pubertal induction
Treatment criteria:	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be under 18 years of age
Administrative Advice	The name of the specialist must be included in the authority application

Restriction 3c	
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Constitutional delay of growth or puberty
Treatment criteria:	Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Population criteria:	Patient must be under 18 years of age
Administrative Advice	The name of the specialist must be included in the authority application

9 Context of Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

10 Sponsor's Comment

The sponsor had no comment.