# 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.

***Secretariat comments***

1. *TGA status: 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;*
   - *testosterone replacement in primary and secondary male hypogonadism;*

2. *The restriction is considered to be complex.*

3. *If the submission is rejected by the PBAC, it would meet the criteria for an Independent Review.*

4. *The Safety Net 20 Day Rule applies to the other PBS-listed testosterone products.*

5. *Testosterone preparations are currently out of scope for prescribing by nurse practitioners.*

***Suggested wording for the restriction:***

*A suggested restriction for testosterone has not been presented at this stage due to the potential complexity of the restriction. The revised restriction will require consultation with the Department of Human Services, the Restrictions Working Group, the LGBTI alliance, the sponsors of testosterone preparations and other stakeholders in the event of a positive recommendation.*



## 3 Background

3.1 In its August 2013 *special meeting* consideration of the DUSC analysis report, 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.

3.2 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)*.

3.3 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.

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.

## 5 Comparator

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

## 6 Consideration of the evidence

### *Clinical trials*

6.1 As a minor submission, no clinical trials were presented in the submission.

6.2 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.

6.3 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.

6.4 The sponsor presented an endorsement from a general practitioner in support of the submission.

***Economic analysis***

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

***Estimated PBS usage & financial implications***

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

## 6.14-MINOR OVR-5

***Further Information:***

a. The company's letter of application/submission is attached.

b. The following documentation from item 3 – testosterone – August 2013 Special meeting is attached.

c. The following documentation from item 4.1 – Review of proposed amendments to PBS restrictions for testosterone products – July 2014 PBAC meeting is attached.

d. The DUSC report on Testosterone: Utilisation analysis from October 2012 is attached.

# ATTACHMENT A

## CURRENT TESTOSTERONE RESTRICTIONS

At its July 2014 meeting, the PBAC recommended amendments to the restrictions for testosterone products. At its March 2015 meeting, the PBAC recommended two testosterone products (cream and gel). The revised restrictions came into effect for all PBS-listed testosterone products on 1 April 2015

| Name, Restriction, Manner of administration and form | Max. Qty | №.of Rpts | Proprietary Name and Manufacturer | |
|---|---|---|---|---|
| TESTOSTERONE<br>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<br>testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes | 1 | 3 | Primoteston Depot | BN |
| TESTOSTERONE UNDECANOATE<br>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<br>Cream 50mg/mL (w/v) 5%, 50mL | 1 | 6 | AndroForte 5 | |
| TESTOSTERONE<br>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: | ☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐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. |

## 6.14-MINOR OVR-7

| | |
|---|---|
| Restriction Level / Method: | ☐Restricted benefit<br>☒Authority Required - In Writing<br>☒Authority Required - Telephone<br>☒Authority Required – Emergency<br>☒Authority Required - Electronic<br>☐Streamlined |
| Clinical criteria: | Patient must have an established pituitary or testicular disorder |
| Population criteria: | Patient must be male |
| Administrative Advice | The name of the specialist must be included in the authority application |
| Restriction 2 | |
| Category / Program | GENERAL – General Schedule (Code GE) |
| Prescriber type: | ☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐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: | ☐Restricted benefit<br>☒Authority Required - In Writing<br>☒Authority Required - Telephone<br>☒Authority Required – Emergency<br>☒Authority Required - Electronic<br>☐Streamlined |
| Clinical criteria: | Patient must not have an established pituitary or testicular disorder<br>AND<br>The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs |
| Population criteria: | Patient must be male<br>AND<br>Patient must be aged 40 years or older |
| Prescriber Instructions | Androgen deficiency is defined as:<br>i) testosterone level of less than 6 nmol per litre; OR<br>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)<br>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.<br>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: | ☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐Midwives |
| Condition: | Micropenis |

## 6.14-MINOR OVR-8

| | |
|---|---|
| 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: | ☐Restricted benefit<br>☒Authority Required - In Writing<br>☒Authority Required - Telephone<br>☒Authority Required – Emergency<br>☒Authority Required - Electronic<br>☐Streamlined |
| Population criteria: | Patient must be male<br>AND<br>Patient must be under 18 years of age |
| Administrative Advice | The name of the specialist must be included in the authority application |

| Restriction 3b | |
|---|---|
| Category / Program | GENERAL – General Schedule (Code GE) |
| Prescriber type: | ☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists<br>☐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: | ☐Restricted benefit<br>☒Authority Required - In Writing<br>☒Authority Required - Telephone<br>☒Authority Required – Emergency<br>☒Authority Required - Electronic<br>☐Streamlined |
| Population criteria: | Patient must be male<br>AND<br>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)<br>. |
| Prescriber type: | ☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists<br>☐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. |

## 6.14-MINOR OVR-9

| | |
|---|---|
| Restriction Level / Method: | ☐Restricted benefit<br>☒Authority Required - In Writing<br>☒Authority Required - Telephone<br>☒Authority Required – Emergency<br>☒Authority Required - Electronic<br>☐Streamlined |
| Population criteria: | Patient must be male<br>AND<br>Patient must be under 18 years of age |
| Administrative Advice | The name of the specialist must be included in the authority application |

# TESTOSTERONE MEETING WITH LGBTI HEALTH ALLIANCE

## 18 SEPTEMBER 2015

## UNIVERISTY OF SYDNEY

**Attendees:**

Professor Andrew Wilson – Pharmaceutical Benefits Advisory Committee (PBAC) Chair
Jo Watson - PBAC Consumer Representative
s47F [redacted] - Executive Director, LGBTI Health Alliance
s47F [redacted] - Manager of Research and Policy, LGBTI Health Alliance
s47F [redacted] - Clinician invited by LGBTI Health Alliance
s47F [redacted] - PBAC Secretary
s22 [redacted] - PBAC Secretariat



**Purpose:**

The purpose of this meeting was to determine an appropriate restriction arrangement for testosterone for transgender (trans) and intersex populations.

**Background:**

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.

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.

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.

The revised restrictions recommended by the PBAC were implemented on 1 April 2015.

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.

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.

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.



**Discussion:**

LGBTI patient populations

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.

Current Practice

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.

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.

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.

Issues with current restrictions

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.

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.

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.

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.

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.

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.

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.



**PBAC Consideration**

The information presented by the Alliance about trans and intersex populations, how they utilise testosterone, their concerns about the current restrictions and potential ways forward will be taken to the November 2015 PBAC meeting for consideration by the committee.

**Note for File**

**Webex meeting with Lawley Pharmaceuticals**
**Topic: Discussion of the Androforte 5® PBS listing and barriers to patient access**
Date: 31 January 2024
Time: 10am to 11am

Department attendees

- s22 – Director, PBAC Assessment Section
- s22 – Director, PBS Analytics and Strategic Insight Section
- s22 – Assistant Director, PBAC Assessment Section

Lawley Pharmaceuticals attendees

- Michael Buckley – Chief Executive Officer
- s47F – Operations manager
- s47F – Financial Advisor
- s47F – Financial Advisor
- s47F – Consultant, Commercial Eyes



Discussion

The Department enquired whether Lawley Pharmaceuticals (Lawley) had received any correspondence concerning barriers to patient access to Androforte, that resulted from the 1 July 2021 PBS listing changes (specifying *the treatment must be applied to the scrotum area)*. Lawley indicated that they received a large number of phone calls shortly after the changes occurred. Enquires/complaints were from prescribers, patients with disabilities and groups representing trans and gender diverse patients. Lawley continues to receive enquires, but less frequently than in the first two months after the 1 July 2021 change.

Lawley stated that they felt blindsided by the enquires and, given that they are not experienced with dealing with the PBAC, acknowledged they may not have fully understood what they were agreeing to with respect to the restriction wording. Lawley raised that they contacted the Department regarding these enquiries, and was advised that a change to the Androforte listing would require another submission to the PBAC, with a costing analysis and revised estimates.

The Department explained that the changes to the Androforte PBS listing recommended by the PBAC in March 2021 were intended to link the requested equi-effective dose and price increase for scrotal use to the PBS restriction to ensure Androforte was used in a cost-effective way. It was not the PBAC's intention to create barriers to patient access.

The Department enquired whether Lawley was open to amending the PBS listing for Androforte to remove any potential or real barriers to patient access, noting the relationship between the PBS listing and the price. Though the Department cannot pre-

empt a PBAC decision, it was likely the PBAC would not agree to a change to the restriction without a commensurate change to the price.

Lawley stated that they were open to amending the listing, however strongly opposed any price reductions. Lawley discussed that if the predicted usage is correct (and they believe the current forecast is correct), then the revised Androforte listing will save the PBS/Government money. A tube of Androforte cream now lasts 100 days, instead of 25. The unit cost of Androforte (which is manufactured in Australia) is significantly less than competitor products. Lawley estimated that they now have four times as many patients being treated with Androforte since the changes were made. In particular Lawley noted that patients are moving from Testogel to Androforte.

The Department raised that a preliminary analysis of PBS supply data shows that the supply period is much shorter than 100 days, and does not show that that savings are being realised as predicted (with the majority of patients having medicine resupplied between 25-30 days). Lawley highlighted that they do not have access to PBS data and rely on information provided by their small sales force. Lawley's educational materials (and sales force) only promote scrotal application, and feedback from prescribers is that patients are being moved from torso application to scrotal application (as most prescribes feel scrotal application is beneficial). Lawley raised that the forecast uptake in its March 2021 submission was based on a gradual uptake of scrotal application to 90% of patients over 6 years, not reaching 90% until year 5.



Concerning estimates of trans and gender diverse patients, Lawley stated that the trans population is approximately 1-2% of the total population, with half of those transitioning from female to male and requiring testosterone (0.5-1% of the total population). Lawley also advised that some studies suggest that the optimal dose of testosterone for a trans-gender patient is half the dose in other indications. Lawley did not have data on hand for patients with disability (difficult to quantify), but stated it would only be a handful of patients. Cost is a factor for these patients.

It was discussed that the dose of testosterone provided by Reandron® was too high for some patients, therefore Androforte was more desirable. Lawley also has a female testosterone product that has been approved by the TGA, but is not listed on the PBS.

It was discussed that a component of the PBS data could reflect a quality use of medicines issues relating to the application of Androforte, though it is not known whether this could be due to patients not applying as directed, or how it is being prescribed. Lawley agreed with this. An outcome may be that education on usage may be required.

The Department agreed that a more detailed analysis of PBS data for Androforte will be undertaken, and shared with Lawley for comment prior to a proposal going to the PBAC for consideration. Lawley was interested in receiving data broken down by state/territory, due

to the limited reach of its sales force. The Department appreciated Lawley raising that geographic variation might be worth investigating. The Department explained that a caveat to providing any data to Lawley was that it would be limited by requirements to limit the possibility of patient reidentification. However, if data could not be provided to Lawley at state/territory level, the Department will inform Lawley generally of any variation in prescribing/patient number between states (if present).

Lawley stated that it can't afford to accept a price reduction for Androforte; the alternative would be to remove Androforte from the PBS.

It was discussed that the advice Lawley had initially received from the Department, that the onus was on Lawley to bring submission to the PBAC, would usually be the case. However, in this instance, the Department considered it would be appropriate for the Department to perform further analysis and bring it to the PBAC for consideration. This is subject to agreement by the PBAC Chair. The Department cannot commit to a PBAC meeting date at this time.

Lawley raised that the Endocrine Society of Australia and groups representing trans and gender diverse patients were aware that Lawley was meeting with the Department. It was agreed that Lawley would communicate that the Department is continuing to work on this issue. The Department will also communicate with the Endocrine Society of Australia in response to correspondence received on this matter.

The Department and Lawley remain committed to removing any barriers to patient access for Androforte.



Actions

1. Seek agreement from the PBAC Chair on proposed approach and timing for PBAC consideration (to be communicated to Lawley once agreed).
2. The Department to communicate with the Endocrine Society of Australia.

# 6.08 TESTOSTERONE, Transdermal cream 50 mg per mL, 50 mL, AndroForte® 5, LAWLEY PHARMACEUTICALS PTY LTD

## 1 Purpose of Item

1.1 To seek PBAC's advice on proposed changes to the restrictions for Androforte 5® (testosterone 5% cream, 50 mL) to facilitate access for trans and gender diverse people and patients with disability.

1.2 To seek the PBAC's advice on whether the proposed changes would affect the cost-effectiveness and utilisation of Androforte 5.

## 2 Background

2.1 In July 2015, the PBAC considered a submission from the National LGBTI Health Alliance (the Alliance) requesting changes to the restrictions applied to testosterone products for the treatment of androgen deficiency to enable access by transgender and intersex patients. 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 potentially 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 not be complex. (Para 7.1 Testosterone Public Summary Document (PSD) July 2015 PBAC meeting.

2.2 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 of preventing inappropriate utilisation of testosterone products, while also limiting or avoiding impacts on trans people and people with intersex variations (Para 7.3 Testosterone PSD July 2015 PBAC meeting).

2.3 In November 2015, the PBAC considered the outcomes of a stakeholder meeting with the Alliance held on 18 September 2015. 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 (Para 6.1 testosterone PSD November 2015 PBAC meeting)

2.4 In March 2021, the PBAC considered a submission from Lawley Pharmaceuticals Pty Ltd (Lawley) requesting reconsideration of the equi-effective dosing for testosterone transdermal cream 50 mg per mL, 50 mL (referred to as Androforte 5) following changes to approved application sites that reduced the recommended dose from 100 mg (2 mL) to 25 mg (0.5 mL) and increased the number of treatments per tube from 25 to 100 (Para 1.1, Androforte 5 Minutes March 2021 PBAC meeting).

2.5 The submission claimed that scrotal application reduced the risk of accidental exposure of the patient's partner and/or children via passive transfer. The submission added that *"…currently there are no other testosterone preparations registered in Australia that can be administered via transdermal scrotal application"* (Para 5.3 Androforte 5 Minutes March 2021 PBAC meeting).

2.6 In the sponsor's pre-PBAC response (p2), they advised direct feedback from prescribing physicians suggested a 25 mg scrotal dose would achieve mid-eugonadal range (the range in which the sponsor claimed the vast majority of patients experience resolution of symptoms) in 70% of hypogonadal men. The sponsor also submitted that *"…approximately 20% will require an increase to 50 mg and 10% will require a reduction to 12.5 mg"* (Para 5.5 Androforte 5 Minutes March 2021 PBAC meeting).

2.7 The estimates provided in the submission assumed gradual uptake of scrotal application to allow time for clinician education, with 70% Year 1 to 90% from Year 3 onwards (Para 5.13 Androforte 5 Minutes March 2021 PBAC meeting).

2.8 The PBAC considered that the evidence presented did not support a reconsideration of the equi-effective dose of testosterone. The PBAC considered that there was *"…considerable variation between the dose applied to upper body (100 mg) and scrotum (25 mg) and considered, based on the evidence provided, the proportion of patients that will achieve a clinical benefit with a 25 mg daily dose is uncertain"*. The PBAC therefore advised that *"…if a single restriction was maintained with one repeat for scrotal application, the premium amount requested above the current unit price (an increase in the DPMQ from $65.76 to $106.10) of Androforte 5 was appropriate"* (Para 6.2 Androforte 5 Minutes March 2021 PBAC meeting).

2.9 The PBAC noted the sponsor's claim that the requested price increase would be cost neutral to the PBS. The PBAC considered that it was appropriate that the requested price increase and change in the restriction to reduce the number of repeats to one and specify the application site as scrotal, should not result in any additional cost to the PBS (Para 6.3 Androforte 5 Minutes March 2021 PBAC meeting).

2.10 The PBS listing for Androforte 5 was amended on 1 July 2021.

# 3 Current situation

3.1 An unintended consequence of the change to PBS listing was to introduce a barrier to access for trans and gender diverse individuals and for some patients with disabilities

(for whom scrotal application is not appropriate). In August 2022 and January 2023, the PBAC Executive considered a request from the Endocrine Society of Australia to amend wording, *"must be applied to the scrotum"* to ensure trans and gender diverse individuals, and those with disabilities, were able to access Androforte 5 on the PBS (Attachments A to C). The PBAC Executive was supportive in principle of the proposed changes, noting that there may be pricing implications should an amendment proceed.

3.2 The Department met with the sponsor in January 2024. The sponsor is committed to removing barriers to patient access to Androforte 5, however indicated that it cannot accept a price reduction (Attachment D).

## *Analysis of PBS utilisation*

### Methods of data extraction

*Change of gender*

3.3 The Medicare system records patient gender (male/female) based on information provided by patients. Patients can change the gender recorded in the Medicare system. The currently recorded gender information from the Medicare system is recorded in prescriptions as they are processed by the PBS On-line claiming system. This information is available to the Department through the Line-by-line data (LBL). Using the LBL data, the number of transitions from one gender to another across the prescription history of Androforte was captured for all prevalent patients in a year[1].

*Prescription data*

3.4 Prescriptions were extracted from the LBL for PBS item 10378F (testosterone 5% (50 mg/mL) cream, 50 mL) from 1 August 2015 (the initial listing date). The extract included all prescriptions supplied and processed prior to 20 May 2024. From these data, the time between dispensing and unique patient counts were determined.

*Patient Counts*

3.5 Prevalent patients are the count of unique patient identifiers (IDs) recorded on prescriptions for the analysis period (e.g. quarters or years). In this report, initiating patients were defined as patients who had not had a prescription for the medicine since it was listed on the PBS.

3.6 As these analyses use date of supply prescription data, there may be small differences compared with publicly available Services Australia PBS date of processing data which only includes subsidised PBS and Repatriation PBS (R/PBS) prescriptions



[1] Date of extract 4 April 2024.

(i.e., prescriptions under the patient co-payment are not included). The Services Australia prescription database data used in this report includes under co-payment prescriptions from 1 January 2013.

### Affected population

3.7 While there are limitations on precisely determining the size of the affected population, based on PBS prescription data there are very small numbers of patients who have recorded a change in gender while accessing Androforte 5 on the PBS (see Table 1). It is not possible to calculate the size of a patient population with disability that would access Androforte 5, as this information is not explicitly recorded in the LBL data.

**Table 1: Androforte 5 patients with notified change of gender**

| Year | Notified Transitions |
|---|---|
| 2015 | <5 |
| 2016 | <5 |
| 2017 | <5 |
| 2018 | <20 |
| 2019 | <15 |
| 2020 | <15 |
| 2021 | <10 |
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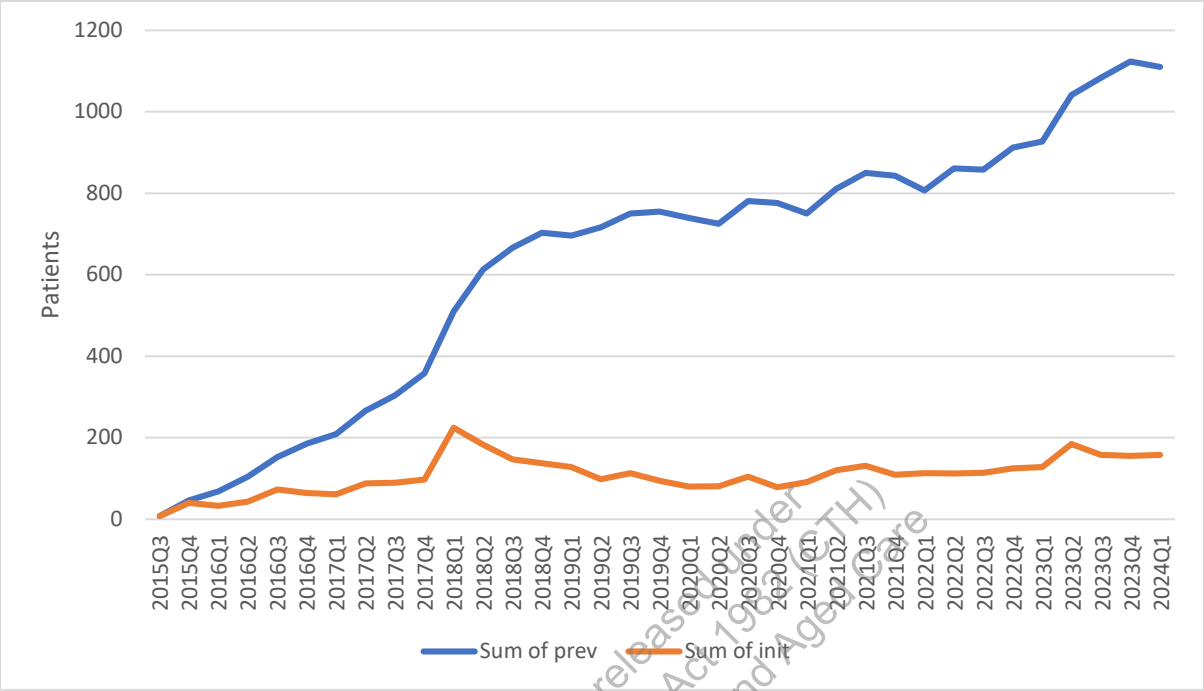
| 2023 | <5 |
| 2024* | <5 |

Source: PBS LBL data *Data is only for part year up to April 2024.



3.8 Based on this analysis, the quarterly PBS patient data (from Q1 2015 to Q1 2024) for Androforte 5 does not suggest that a large population has been excluded from treatment (Figure 1). However, the quarterly time period may not be sensitive enough to detect a very small patient group that has been excluded.

**Figure 1: Quarterly patient data – Initiating and prevalent patients – Androforte 5**

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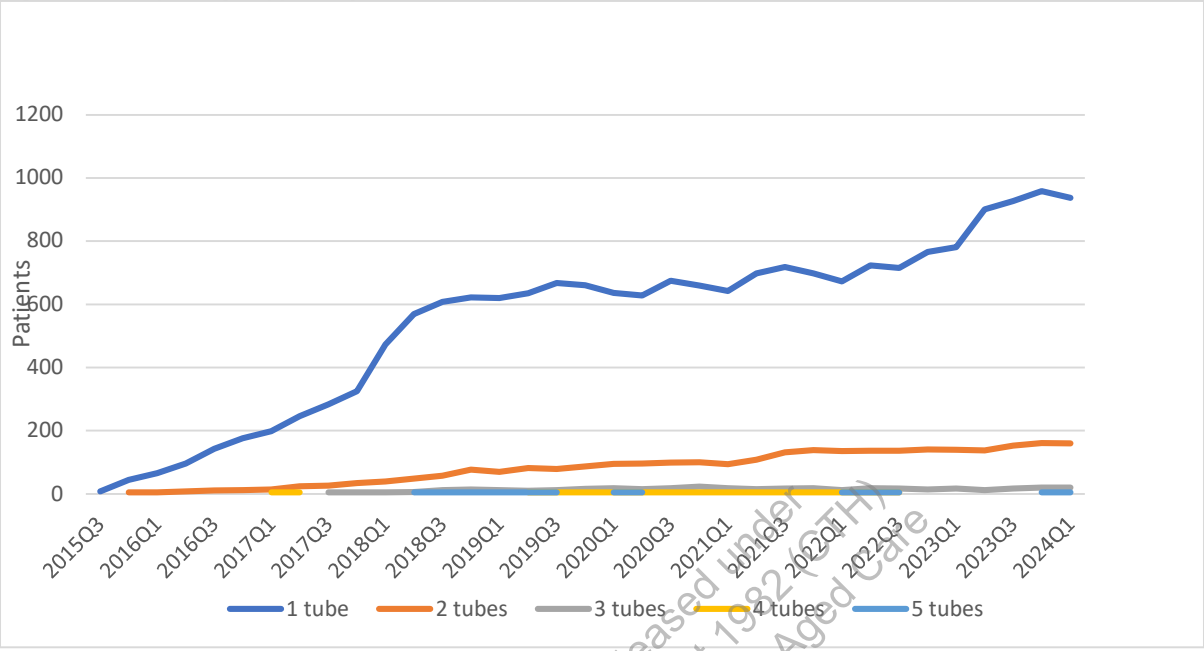
## Analysis of PBS supply data – utilisation

3.9 Based on the approved dose for scrotal application, (0.5 mL to 1 mL daily) a 50 mL tube of Androforte 5 cream should provide between 50 and 100 days of treatment, compared to the 12 to 25 days when applied to the upper torso (assuming a dose of between 2 mL and 4 mL daily). The current PBS listing for Androforte 5 allows for up to approximately 6.5 months' supply[2], depending on the dose.

3.10 Following the July 2021 changes to the PBS listing, there has been an increasing number of patients who receive a single tube of Androforte 5 (Figure 2) per prescription. However, the changes to the PBS listing have not affected the number of patients prescribed increased quantities of Androforte 5. The number of patients receiving supply of two tubes has continued to steadily increase.

[2] 200 days of treatment.

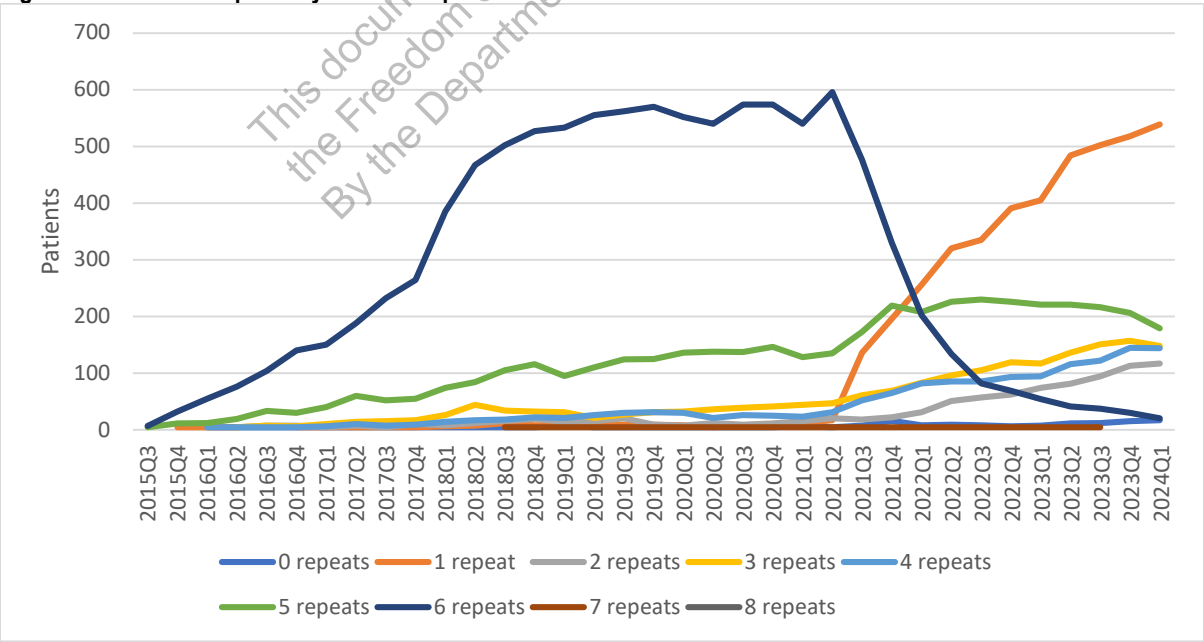
**Figure 2: PBS quantity supplied by number of patients**




Source: PBS LBL data. Note: any prevalent patient numbers less than five have been reported as five to reduce the risk of reidentification

3.11 Figure 3 shows the number repeats of Androforte 5 prescribed, by number of patients. The increase in patients with a prescription with a single repeat, and corresponding decrease in the number of patients receiving six repeats aligns with the July 2021 listing changes (See Figure 3).

**Figure 3: Number of repeats by number of patients - Androforte 5**




Source: PBS LBL data. Note: any prevalent patient numbers less than five have been reported as five to reduce the risk of reidentification

3.12 The mean time between supply for Androforte prescriptions with a quantity of one pack has slowly increased over the time (Table 2). The supply interval for prescriptions with a quantity of two packs has remained stable. This does not reflect the longer mean time to resupply that would be expected if the majority of patients were receiving 100 doses per tube (dose of 25 mg daily)

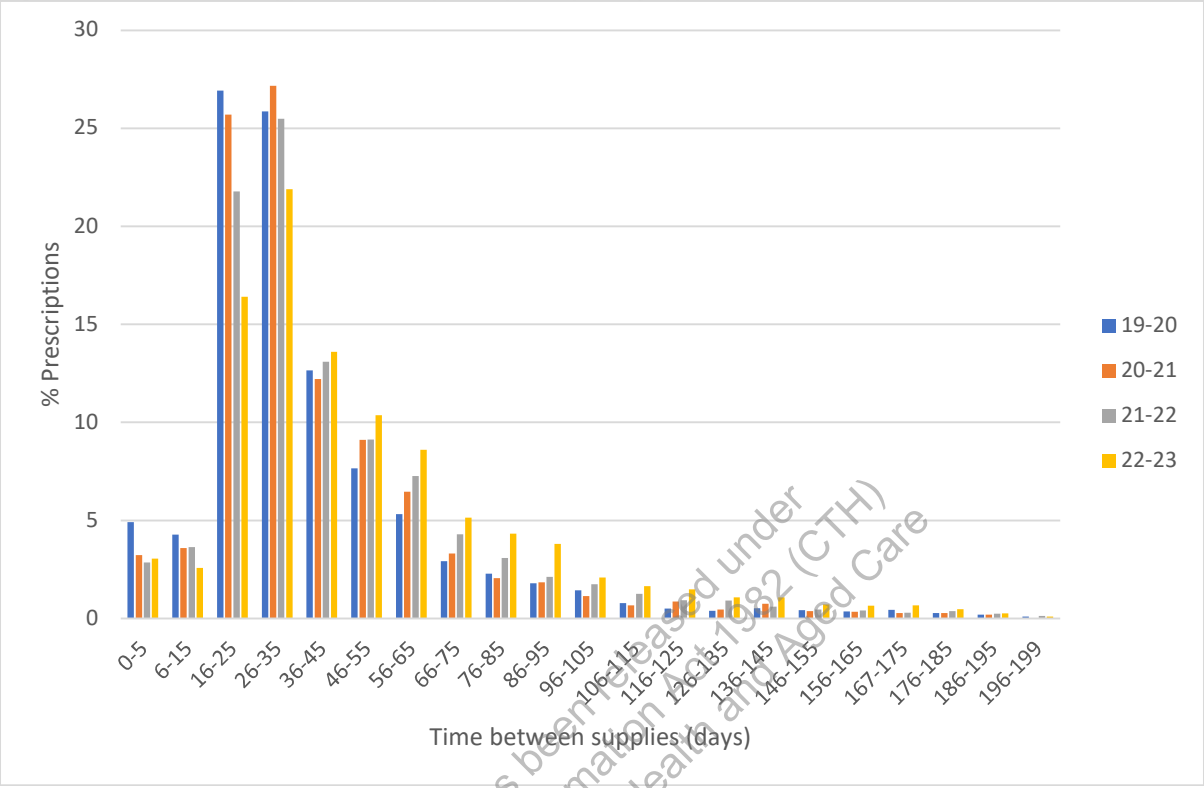
3.13 A detailed analysis of time between supply for prescriptions with a quantity of one pack shows that the percentage of prescription with a resupply time of 16 to 35 days has decreased to 38% (from 53% in 2020-2021) (Figure 4). In the 2022-2023 financial year approximate 10% of prescriptions had a resupply interval between 76 and 105 days. Whilst there is an overall increasing trend in resupply time, a high proportion of prescriptions are being resupplied at an interval that is not consistent with the supply interval that would be expected for the reduced dose associated with scrotal application.

**Table 2: Mean and median time between supplies for Androforte 5**

| List year | Dispensed quantity | Number of Scripts | Number of days between supply (Mean) | Number of days between supply (Median) |
|---|---|---|---|---|
| 2016 - 17 | 1 | 1344 | 35.0 | 28 |
| | 2 | 104 | 34.9 | 29 |
| 2017 - 18 | 1 | 2843 | 37.1 | 29 |
| | 2 | 257 | 40.8 | 34 |
| | 3 | 14 | 36.2 | 44 |
| 2018 - 19 | 1 | 4887 | 37.5 | 30 |
| | 2 | 594 | 36.7 | 29 |
| | 3 | 80 | 46.4 | 37 |
| 2019 - 20 | 1 | 5334 | 38.8 | 30 |
| | 2 | 720 | 39.7 | 32 |
| | 3 | 110 | 43.5 | 35 |
| | 4 | 10 | 55.5 | 33 |
| 2020 - 21 | 1 | 5204 | 40.1 | 31 |
| | 2 | 857 | 38.5 | 32 |
| | 3 | 142 | 43.8 | 37 |
| | 4 | 19 | 34.6 | 33 |
| 2021 - 22 | 1 | 4876 | 43.9 | 34 |
| | 2 | 1004 | 42.1 | 35 |
| | 3 | 128 | 47.9 | 36 |
| | 4 | 11 | 43.3 | 34 |
| 2022 - 23 | 1 | 4920 | 50.3 | 40 |
| | 2 | 1025 | 43.9 | 36 |
| | 3 | 128 | 41.9 | 35 |

Source: PBS LBL data

**Figure 4: Time between supplies – where prescription quantity equals 1 tube**




Source: PBS LBL data



# 4 Proposed restrictions

4.1 The Department proposes the following amendment to the PBS listings for Androforte 5 to address the August 2022 request from the ESA. The proposed changes promote scrotal application as the preferred administration method, however, allow for torso application where scrotal application is either not possible or appropriate.

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| TESTOSTERONE | | | | | |
| Testosterone 5% (50 mg/mL) cream, 50 mL | 10378F | 1 | 1 | 1 | Androforte |
| | | | | | |
| **Restriction Summary 11986** | | | | | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) | | | | |
| | **Prescriber type:** ☒Medical Practitioners | | | | |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* | | | | |
| 12269 | **Indication:** Androgen deficiency | | | | |
| 12273 | **Clinical criteria:** | | | | |
| 12272 | Patient must have an established pituitary or testicular disorder | | | | |
| 20677 | **Treatment criteria:** | | | | |

| | |
|---|---|
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11987** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12269 | **Indication:** Androgen deficiency |
| 12278 | **Clinical criteria:** |
| 12277 | Patient must not have an established pituitary or testicular disorder |
| | **AND** |
| 12280 | **Clinical criteria:** |
| 12279 | The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs |
| 12113 | **Population criteria:** |
| 12112 | Patient must be aged 40 years or older |
| 18986 | **Treatment criteria:** |
| 18985 | Must be treated by a specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 12282 | **Prescribing Instructions:**<br>Androgen deficiency is defined as:<br><br>(i) testosterone level of less than 6 nmol per litre; OR<br><br>(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 eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).<br><br>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. |
| 12283 | **Prescribing Instructions:**<br>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. |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |

| | |
|---|---|
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11984** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12284 | **Indication:** Micropenis |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
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| | |
| **Restriction Summary 11961** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12285 | **Indication:** Pubertal induction |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
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| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |

| | |
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| | |
| **Restriction Summary 11970** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12286 | **Indication:** Constitutional delay of growth or puberty |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
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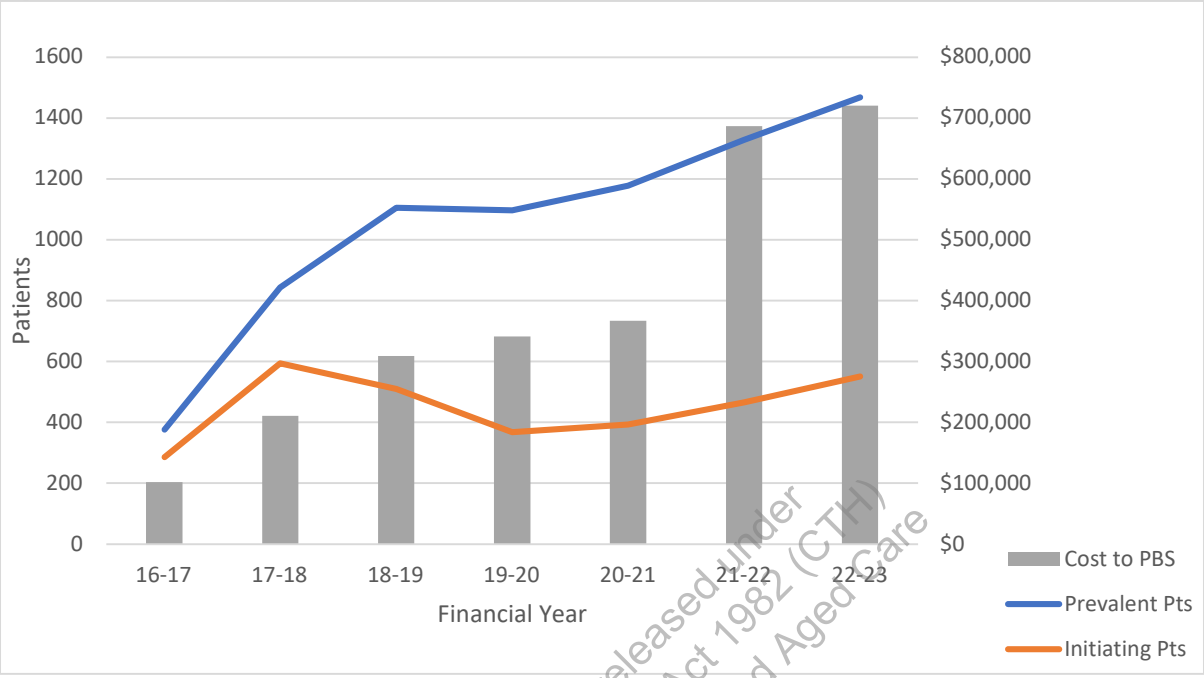
# 5 Financials

5.1 Given the utilisation analyses presented above, it is likely that there is a non-trivial, but difficult to quantify, level of use of Androforte 5 where the application site is the upper torso. On this basis, it is unlikely that the proposed change would have a significant impact on current utilisation and hence cost.

5.2 On the basis of the current utilisation patterns, the expected savings associated with the March 2021 restriction changes have not been realised. The price increase was to be offset by a 75% reduction in the prescription volume required to treat patients achieved through the dose reduction.

**Figure 5: Financial impact versus patient numbers**




Source: PBS LBL data



# 6 Requested PBAC Advice

6.1 The PBAC is asked to advise if the proposed changes to the PBS listing restriction criteria for Androforte 5 are appropriate.

6.2 Should the PBAC recommend change to the PBS listing, the PBAC is also asked to advise whether Androforte 5 remains cost-effective at the current price.

## Further information

A. Letter from the Endocrine Society of Australia to PBAC Chair – July 2022

B. Ratified minutes from PBAC Executive meeting August 2022

C. Ratified minutes from PBAC Executive meeting January 2023

D. Record of meeting between Lawley Pharmaceuticals and Department of Health and Aged Care – January 2024

*Ratified Minutes July 2024 PBAC Meeting*
*Commercial-In-Confidence*

**CHANGES TO PRESENT (OR RECOMMENDED) PBS AVAILABILITY**

When the PBAC makes a recommendation under section 101(3) of the *National Health Act 1953* ("the Act") in relation to a drug/medicinal preparation which it considers should be made available as a pharmaceutical benefit under Part VII of the Act, it is also required to consider whether the drug/medicinal preparation should be made available only in certain circumstances (see section 101(3C) of the Act). Where the PBAC considers that the drug/medicinal preparation should be made available only in certain circumstances, it specifies the circumstances in its recommendation under section 101(3).

At its meeting between **10 – 12 July 2024**, the PBAC in making its recommendation under section 101(3) of the Act, decided to recommend a change to the circumstances under which testosterone transdermal cream 50 mg per mL, 50 mL is made available as a pharmaceutical benefit under Part VII of the Act.

A note of the PBAC's decision follows.



# 6.08 TESTOSTERONE, Transdermal cream 50 mg per mL, 50 mL, AndroForte® 5

## 1 Purpose of Item

1.1 To seek PBAC's advice on proposed changes to the restrictions for AndroForte 5® (testosterone 5% cream, 50 mL) to remove barriers to access for trans and gender diverse people and people with disability.

1.2 To seek the PBAC's advice on whether the proposed changes would affect the cost-effectiveness and utilisation of AndroForte 5.

## 2 Background

2.1 In July 2015, the PBAC considered a submission from the National LGBTI Health Alliance (the Alliance) requesting changes to the restrictions applied to testosterone products for the treatment of androgen deficiency to enable access by transgender and intersex patients. 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 potentially 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 not be complex. (Para 7.1 Testosterone Public Summary Document (PSD) July 2015 PBAC meeting.

2.2 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 of Health and Aged Care undertake to identify, in consultation with affected stakeholders, an approach that would preserve the Committee's original intent of preventing inappropriate utilisation of testosterone products, while also limiting or avoiding impacts on trans people and people with intersex variations (Para 7.3 Testosterone PSD July 2015 PBAC meeting).

2.3 In November 2015, the PBAC considered the outcomes of a stakeholder meeting with the Alliance held on 18 September 2015. 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 (Para 6.1 testosterone PSD November 2015 PBAC meeting)

2.4 In March 2021, the PBAC considered a submission from Lawley Pharmaceuticals Pty Ltd (Lawley) requesting reconsideration of the equi-effective dosing for testosterone transdermal cream 50 mg per mL, 50 mL (referred to as AndroForte 5) following changes to approved application sites that reduced the recommended dose from 100 mg (2 mL) to 25 mg (0.5 mL) and increased the number of treatments per tube from 25 to 100 (Para 1.1, AndroForte 5 Minutes March 2021 PBAC meeting).

2.5 The submission claimed that scrotal application reduced the risk of accidental exposure of the patient's partner and/or children via passive transfer. The submission added that "…currently there are no other testosterone preparations registered in Australia that can be administered via transdermal scrotal application" (Para 5.3 AndroForte 5 Minutes March 2021 PBAC meeting).

2.6 In the sponsor's pre-PBAC response (p2), they advised direct feedback from prescribing physicians suggested a 25 mg scrotal dose would achieve mid-eugonadal range (the range in which the sponsor claimed the vast majority of patients experience resolution of symptoms) in 70% of hypogonadal men. The sponsor also submitted that "…approximately 20% will require an increase to 50 mg and 10% will require a reduction to 12.5 mg" (Para 5.5 AndroForte 5 Minutes March 2021 PBAC meeting).

2.7 The estimates provided in the submission assumed gradual uptake of scrotal application to allow time for clinician education, with 70% Year 1 to 90% from Year 3 onwards (Para 5.13 AndroForte 5 Minutes March 2021 PBAC meeting).

2.8 The PBAC considered that the evidence presented did not support a reconsideration of the equi-effective dose of testosterone. The PBAC considered that there was "…considerable variation between the dose applied to upper body (100 mg) and scrotum (25 mg) and considered, based on the evidence provided, the proportion of patients that will achieve a clinical benefit with a 25 mg daily dose is uncertain". The PBAC therefore advised that "…if a single restriction was maintained with one repeat for scrotal application, the premium amount requested above the current unit price

(an increase in the DPMQ from $65.76 to $106.10) of AndroForte 5 was appropriate" (Para 6.2 AndroForte 5 Minutes March 2021 PBAC meeting).

2.9 The PBAC noted the sponsor's claim that the requested price increase would be cost neutral to the PBS. The PBAC considered that it was appropriate that the requested price increase and change in the restriction to reduce the number of repeats to one and specify the application site as scrotal, should not result in any additional cost to the PBS (Para 6.3 AndroForte 5 Minutes March 2021 PBAC meeting).

2.10 The PBS listing for AndroForte 5 was amended on 1 July 2021.

# 3 Current situation

3.1 An unintended consequence of the change to PBS listing was to introduce a barrier to access for trans and gender diverse individuals and for some people with disabilities (for whom scrotal application is not appropriate). In August 2022 and January 2023, the PBAC Executive considered a request from the Endocrine Society of Australia to amend wording, "must be applied to the scrotum" to ensure trans and gender diverse individuals, and those with disabilities, were able to access AndroForte 5 on the PBS. The PBAC Executive was supportive in principle of the proposed changes, noting that there may be pricing implications should an amendment proceed.

3.2 The Department met with the sponsor in January 2024. The sponsor was committed to removing barriers to patient access to AndroForte 5, however indicated that it cannot accept a price reduction.



## *Analysis of PBS utilisation*

### Methods of data extraction

*Change of gender*

3.3 The Medicare system records patient gender (male/female) based on information provided by patients. Patients can change the gender recorded in the Medicare system. The currently recorded gender information from the Medicare system is recorded in prescriptions as they are processed by the PBS On-line claiming system. This information is available to the Department through the Line-by-line data (LBL). Using the LBL data, the number of transitions from one gender to another across the prescription history of AndroForte 5 was captured for all prevalent patients in a year[1].

*Prescription data*

[1] Date of extract 4 April 2024.

3.4 Prescriptions were extracted from the LBL for PBS item 10378F (testosterone 5% (50 mg/mL) cream, 50 mL) from 1 August 2015 (the initial listing date). The extract included all prescriptions supplied and processed prior to 20 May 2024. From these data, the time between dispensing and unique patient counts were determined.

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3.5 Prevalent patients are the count of unique patient identifiers (IDs) recorded on prescriptions for the analysis period (e.g. quarters or years). In this report, initiating patients were defined as patients who had not had a prescription for the medicine since it was listed on the PBS.

3.6 As these analyses use date of supply prescription data, there may be small differences compared with publicly available Services Australia PBS date of processing data which only includes subsidised PBS and Repatriation PBS (R/PBS) prescriptions (i.e., prescriptions under the patient co-payment are not included). The Services Australia prescription database data used in this report includes under co-payment prescriptions from 1 January 2013.



**Affected population**

3.7 While there are limitations on precisely determining the size of the affected population, based on PBS prescription data there are very small numbers of patients who have recorded a change in gender while accessing AndroForte 5 on the PBS (see Table 1). It is not possible to calculate the size of a patient population with disability that would access AndroForte 5, as this information is not explicitly recorded in the LBL data.

**Table 1: AndroForte 5 patients with notified change of gender**

| Year | Notified Transitions |
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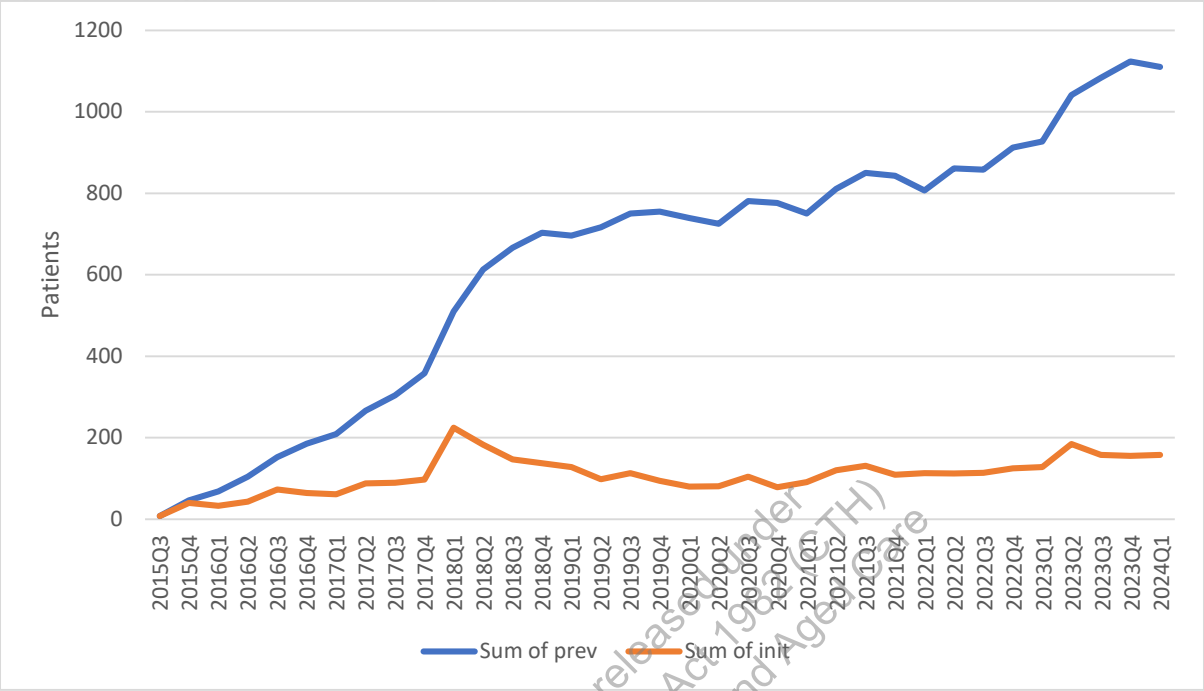
Source: PBS LBL data *Data is only for part year up to April 2024.

3.8 Based on this analysis, the quarterly PBS patient data (from Q1 2015 to Q1 2024) for AndroForte 5 does not suggest that a large population has been excluded from treatment (Figure 1). However, the quarterly time period may not be sensitive enough to detect a very small patient group that has been excluded.

**Figure 1: Quarterly patient data – Initiating and prevalent patients – AndroForte 5**

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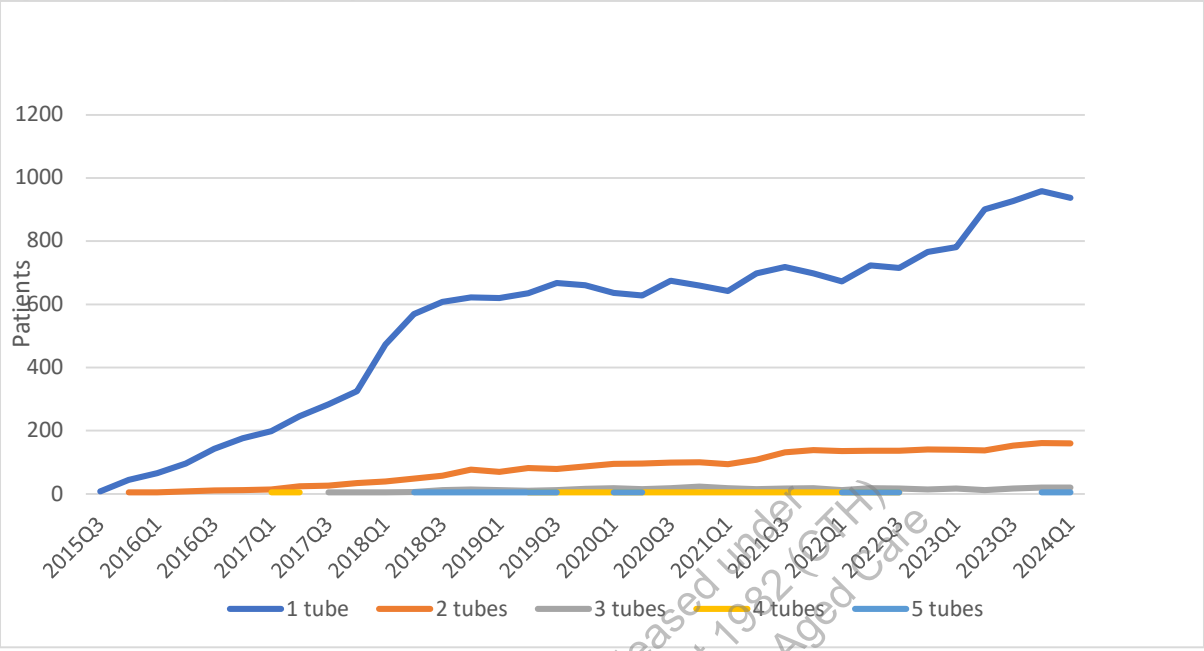
## Analysis of PBS supply data – utilisation

3.9 Based on the approved dose for scrotal application, (0.5 mL to 1 mL daily) a 50 mL tube of AndroForte 5 cream should provide between 50 and 100 days of treatment, compared to the 12 to 25 days when applied to the upper torso (assuming a dose of between 2 mL and 4 mL daily). The current PBS listing for AndroForte 5 allows for up to approximately 6.5 months' supply[2], depending on the dose.

3.10 Following the July 2021 changes to the PBS listing, there has been an increasing number of patients who receive a single tube of AndroForte 5 (Figure 2) per prescription. However, the changes to the PBS listing have not affected the number of patients prescribed increased quantities of AndroForte 5. The number of patients receiving supply of two tubes has continued to steadily increase.

[2] 200 days of treatment.

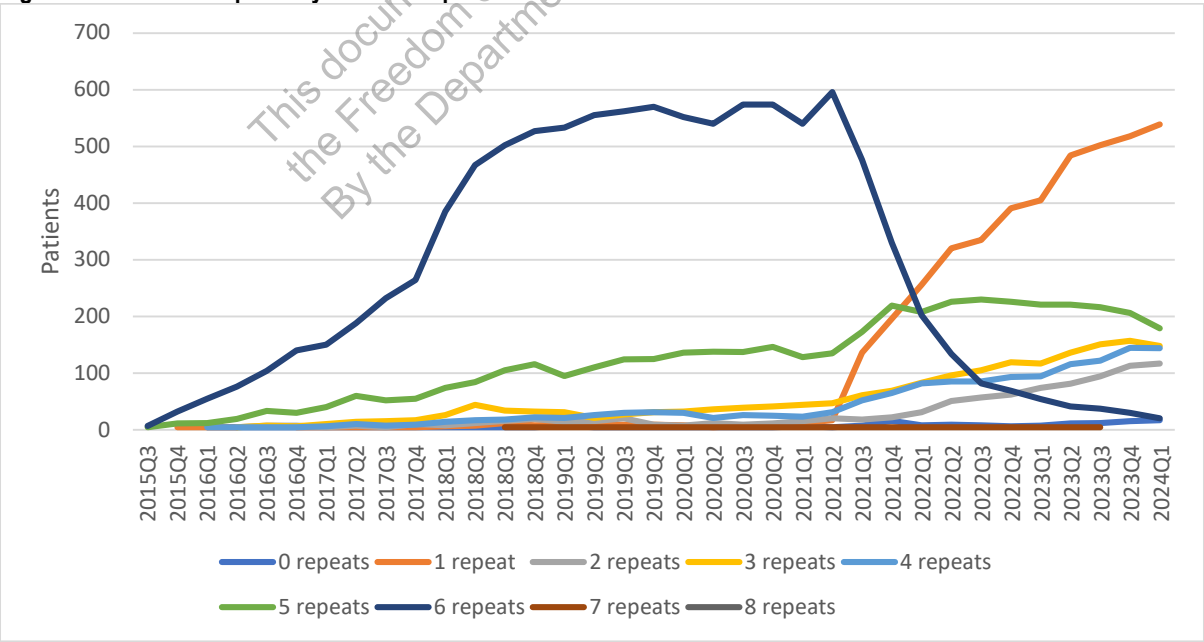
**Figure 2: PBS quantity supplied by number of patients**




Source: PBS LBL data. Note: any prevalent patient numbers less than five have been reported as five to reduce the risk of reidentification

3.11 Figure 3 shows the number repeats of AndroForte 5 prescribed, by number of patients. The increase in patients with a prescription with a single repeat, and corresponding decrease in the number of patients receiving six repeats aligns with the July 2021 listing changes (See Figure 3).

**Figure 3: Number of repeats by number of patients - AndroForte 5**




Source: PBS LBL data. Note: any prevalent patient numbers less than five have been reported as five to reduce the risk of reidentification

3.12 The mean time between supply for AndroForte 5 prescriptions with a quantity of one pack has slowly increased over the time (Table 2). The supply interval for prescriptions with a quantity of two packs has remained stable. This does not reflect the longer mean time to resupply that would be expected if the majority of patients were receiving 100 doses per tube (dose of 25 mg daily)

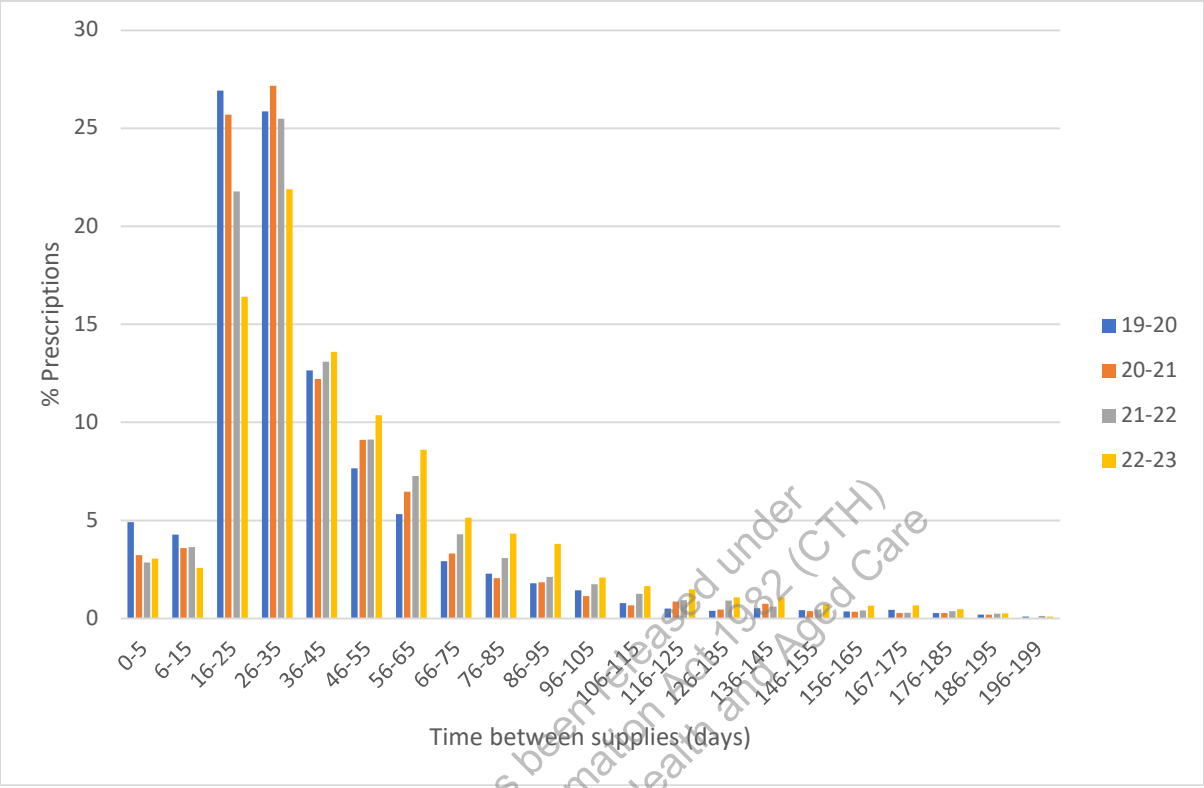
3.13 A detailed analysis of time between supply for prescriptions with a quantity of one pack shows that the percentage of prescription with a resupply time of 16 to 35 days has decreased to 38% (from 53% in 2020-2021) (Figure 4). In the 2022-2023 financial year approximate 10% of prescriptions had a resupply interval between 76 and 105 days. Whilst there is an overall increasing trend in resupply time, a high proportion of prescriptions are being resupplied at an interval that is not consistent with the supply interval that would be expected for the reduced dose associated with scrotal application.

**Table 2: Mean and median time between supplies for AndroForte 5**

| List year | Dispensed quantity | Number of Scripts | Number of days between supply (Mean) | Number of days between supply (Median) |
|---|---|---|---|---|
| 2016 - 17 | 1 | 1344 | 35.0 | 28 |
| | 2 | 104 | 34.9 | 29 |
| 2017 - 18 | 1 | 2843 | 37.1 | 29 |
| | 2 | 257 | 40.8 | 34 |
| | 3 | 14 | 36.2 | 44 |
| 2018 - 19 | 1 | 4887 | 37.5 | 30 |
| | 2 | 594 | 36.7 | 29 |
| | 3 | 80 | 46.4 | 37 |
| 2019 - 20 | 1 | 5334 | 38.8 | 30 |
| | 2 | 720 | 39.7 | 32 |
| | 3 | 110 | 43.5 | 35 |
| | 4 | 10 | 55.5 | 33 |
| 2020 - 21 | 1 | 5204 | 40.1 | 31 |
| | 2 | 857 | 38.5 | 32 |
| | 3 | 142 | 43.8 | 37 |
| | 4 | 19 | 34.6 | 33 |
| 2021 - 22 | 1 | 4876 | 43.9 | 34 |
| | 2 | 1004 | 42.1 | 35 |
| | 3 | 128 | 47.9 | 36 |
| | 4 | 11 | 43.3 | 34 |
| 2022 - 23 | 1 | 4920 | 50.3 | 40 |
| | 2 | 1025 | 43.9 | 36 |
| | 3 | 128 | 41.9 | 35 |

Source: PBS LBL data

**Figure 4: Time between supplies – where prescription quantity equals 1 tube**




Source: PBS LBL data Note: data for ≥ 200 days was excluded



# 4 Proposed restrictions

4.1 The Department proposed the following amendment to the PBS listings for AndroForte 5 to address the August 2022 request from the ESA. The proposed changes promote scrotal application as the preferred administration method, however, allow for torso application where scrotal application is either not possible or appropriate.

4.2 Suggestions and additions proposed are added in italics and suggested deletions are crossed out with strikethrough

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|
| TESTOSTERONE | | | | | |
| Testosterone 5% (50 mg/mL) cream, 50 mL | 10378F | 1 | 1 | 1 | Androforte |
| | | | | | |
| **Restriction Summary 11986** | | | | | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) | | | | |
| | **Prescriber type:** ☒Medical Practitioners | | | | |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* | | | | |
| 12269 | **Indication:** Androgen deficiency | | | | |
| 12273 | **Clinical criteria:** | | | | |

| | |
|---|---|
| 12272 | Patient must have an established pituitary or testicular disorder |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11987** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12269 | **Indication:** Androgen deficiency |
| 12278 | **Clinical criteria:** |
| 12277 | Patient must not have an established pituitary or testicular disorder |
| | **AND** |
| 12280 | **Clinical criteria:** |
| 12279 | The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs |
| 12113 | **Population criteria:** |
| 12112 | Patient must be aged 40 years or older |
| 18986 | **Treatment criteria:** |
| 18985 | Must be treated by a specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 12282 | **Prescribing Instructions:**<br>Androgen deficiency is defined as:<br><br>(i) testosterone level of less than 6 nmol per litre; OR<br><br>(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 eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).<br><br>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. |
| 12283 | **Prescribing Instructions:**<br>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. |

| | |
|---|---|
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11984** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12284 | **Indication:** Micropenis |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11961** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12285 | **Indication:** Pubertal induction |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |

| | |
|---|---|
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11970** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12286 | **Indication:** Constitutional delay of growth or puberty |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |

4.3 In the pre-PBAC response (p2 & 3 ), the sponsor agreed to amending the wording 'The treatment must be applied to scrotum area', but requested the wording be amended to 'The treatment should be applied to the scrotum, where possible'

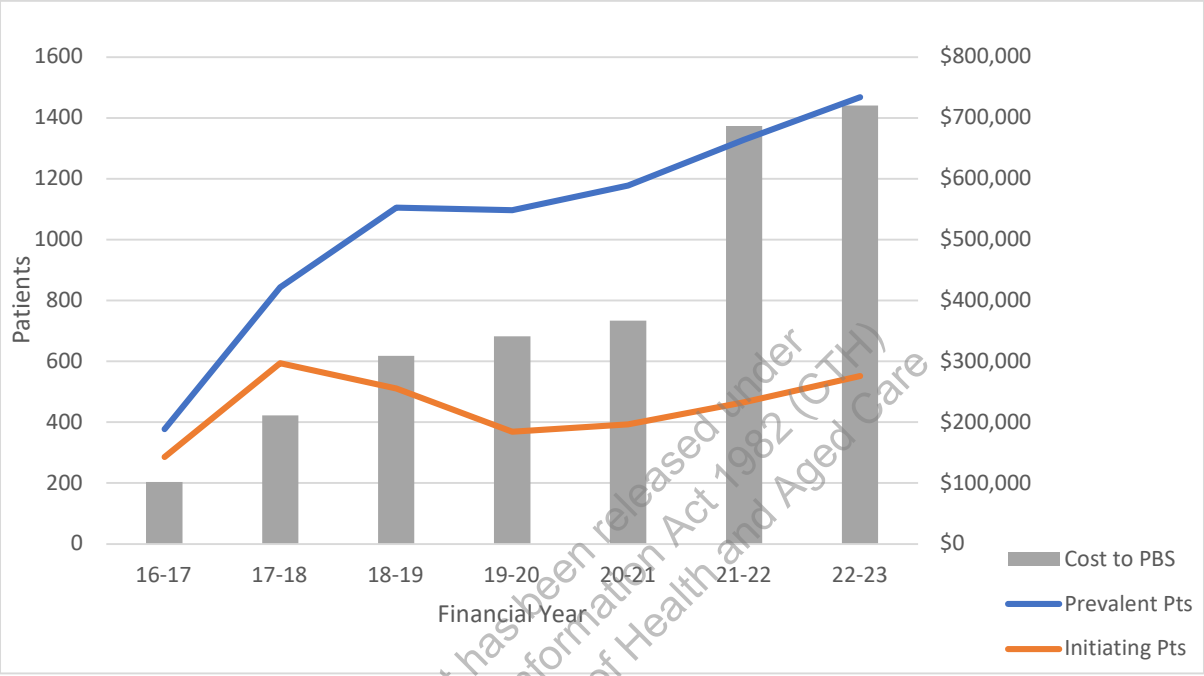


# 5 Financials

5.1 Given the utilisation analyses presented above, it is likely that there is a non-trivial, but difficult to quantify, level of use of AndroForte 5 where the application site is the upper torso. On this basis, it is unlikely that the proposed change would have a significant impact on current utilisation and hence cost.

5.2 On the basis of the current utilisation patterns, the expected savings associated with the March 2021 restriction changes have not been realised. The price increase was to be offset by a 75% reduction in the prescription volume required to treat patients achieved through the dose reduction.

**Figure 5: Financial impact versus patient numbers**




Source: PBS LBL data



# 6 PBAC Outcome

6.1 The PBAC recommended the proposed amendment to the current PBS listings for AndroForte 5 (testosterone 5% cream) to allow for torso application where scrotal application is not appropriate.

6.2 The PBAC noted that AndroForte 5 is the only topical form of testosterone listed on the PBS that is suitable for scrotal application. The PBAC recalled from its March 2021 consideration that scrotal application only requires about 25% of the testosterone dose that is required if applied to the torso, arms or legs. The PBAC recommendation for listing of AndroForte 5 was based on a price that reflected the dose requirement for scrotal application.

6.3 The PBAC expressed concern that the changes to the PBS listing for AndroForte 5 recommended in March 2021 led to unintended barriers to access for trans and gender diverse individuals and for some patients with disabilities.

6.4 The PBAC advised that the changes to the PBS restriction wording proposed by the sponsor were appropriate. However, the PBAC noted that the Department has set prefixes for clinical criteria to ensure consistency in the schedule which require the use of the word 'must'.

6.5 The PBAC considered that the change to allow non-scrotal application would lead to a higher amount of AndroForte 5 being applied (per dose). However, the PBAC noted that non-scrotal application was likely to occur in a small proportion of patients, and noted from the PBS data analysis that some non-scrotal application of AndroForte 5 may be currently occurring outside of the restriction criteria. Therefore, the PBAC anticipated minimal financial impact.

**Outcome**

Recommended.

# 7 Recommended listing

Amend existing listing as follows:

| **MEDICINAL PRODUCT**<br>**medicinal product pack** | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
|---|---|---|---|---|---|---|
| TESTOSTERONE | | | | | | |
| Testosterone 5% (50 mg/mL) cream, 50 mL | | 10378F | 1 | 1 | 1 | Androforte |
| | | | | | | |
| **Restriction Summary 11986** | | | | | | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) | | | | | |
| | **Prescriber type:** ☒Medical Practitioners | | | | | |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* | | | | | |
| 12269 | **Indication:** Androgen deficiency | | | | | |
| 12273 | **Clinical criteria:** | | | | | |
| 12272 | Patient must have an established pituitary or testicular disorder | | | | | |
| 20677 | **Treatment criteria:** | | | | | |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 | | | | | |
| | **Clinical criteria:** | | | | | |
| NEW CC1 | The treatment must be applied to the scrotum ~~area~~, *where possible* | | | | | |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. | | | | | |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* | | | | | |
| | | | | | | |
| **Restriction Summary 11987** | | | | | | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) | | | | | |
| | **Prescriber type:** ☒Medical Practitioners | | | | | |
| | **Restriction type:** | | | | | |

| | |
|---|---|
| | ☒ Authority Required - *Telephone Authority Required* |
| 12269 | **Indication:** Androgen deficiency |
| 12278 | **Clinical criteria:** |
| 12277 | Patient must not have an established pituitary or testicular disorder |
| | **AND** |
| 12280 | **Clinical criteria:** |
| 12279 | The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs |
| 12113 | **Population criteria:** |
| 12112 | Patient must be aged 40 years or older |
| 18986 | **Treatment criteria:** |
| 18985 | Must be treated by a specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum ~~area~~, *where possible* |
| 12282 | **Prescribing Instructions:**<br>Androgen deficiency is defined as:<br><br>(i) testosterone level of less than 6 nmol per litre; OR<br><br>(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 eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).<br><br>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. |
| 12283 | **Prescribing Instructions:**<br>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. |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11984** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12284 | **Indication:** Micropenis |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |

| | |
|---|---|
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum ~~area~~, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11961** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12285 | **Indication:** Pubertal induction |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |
| | **Clinical criteria:** |
| NEW CC1 | The treatment must be applied to the scrotum ~~area~~, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |
| | |
| **Restriction Summary 11970** | |
| **Concept ID** (for internal Dept. use) | **Category / Program:** GENERAL – General Schedule (Code GE) |
| | **Prescriber type:** ☒Medical Practitioners |
| | **Restriction type:**<br>☒ Authority Required - *Telephone Authority Required* |
| 12286 | **Indication:** Constitutional delay of growth or puberty |
| 8116 | **Population criteria:** |
| 8115 | Patient must be under 18 years of age |
| 20677 | **Treatment criteria:** |
| 20676 | Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 |

| | **Clinical criteria:** |
|---|---|
| NEW CC1 | The treatment must be applied to the scrotum ~~area~~, *where possible* |
| 10884 | **Prescribing Instructions:**<br>The name of the specialist must be included in the authority application. |
| *25796* | ***Administrative Advice:***<br>*Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.* |

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed***.

PBAC Secretariat
Office of Health Technology Assessment Branch
Australian Government Department of Health
PO Box 9848 Canberra ACT 2601

3rd July 2024

Dear PBAC

***Re: AndroForte 5 PBS listing amendment Overview document for Lawley comment***

Thank you for the opportunity to review and comment on the draft recommendation to the PBAC Committee July 2024 meeting.

Overall, Lawley welcomes the Department's acknowledgement that the 2022 funding decision restricting PBS supply of AndroForte 5 use to scrotal only had the unintended consequence of excluding patients with disabilities and the trans and gender diverse communities from access.

Lawley has the following comments on the draft recommendations.

**Comment 1. 2.4 as proposed states:**

> *In March 2021, the PBAC considered a submission from Lawley Pharmaceuticals Pty Ltd (Lawley) requesting reconsideration of the equi-effective dosing for testosterone transdermal cream 50 mg per mL, 50 mL (referred to as AndroForte 5) following changes to approved application sites that reduced the recommended dose from 100 mg (2 mL) to 25 mg (0.5 mL) and increased the number of treatments per tube from 25 to 100 (Para 1.1, AndroForte 5 Minutes March 2021 PBAC meeting).*



This omits important context of Lawley's March 2021 request.

The purpose of the request was to make the product financially viable in order to remain on the PBS. The TGA approval for a lower testosterone dose to be applied the scrotum was a cost-effective mechanism to justify a PBS price increase.

Lawley requests this paragraph be amended to:

> *In March 2021, the PBAC considered a submission from Lawley Pharmaceuticals Pty Ltd (Lawley) requesting a price increase to maintain financial viability by reconsideration of the equi-effective dosing for testosterone transdermal cream 50 mg per mL, 50 mL (referred to as AndroForte 5) following changes to approved application sites that reduced the recommended dose from 100 mg (2 mL) to 25 mg (0.5 mL) and increased the number of treatments per tube from 25 to 100 (Para 1.1, AndroForte 5 Minutes March 2021 PBAC meeting).*

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T. +61 8 9388 0096 F. +61 8 9388 0098 Toll Free Phone. 1800 627 506 Toll Free Fax. 1800 751 275
USA & Canada Toll Free Phone. 1-800-961-7813 Toll Free Fax. 1-800-961-7650
E. info@lawleypharm.com.au W. www.lawleypharm.com.au
Lawley Pharmaceuticals Pty Ltd, ABN: 12 095 973 523

**Comment 2. 2.9 as proposed states:**

> *The PBAC noted the sponsor's claim that the requested price increase would be cost neutral to the PBS. The PBAC considered that it was appropriate that the requested price increase and change in the restriction to reduce the number of repeats to one and specify the application site as scrotal, should not result in any additional cost to the PBS (Para 6.3 AndroForte 5 Minutes March 2021 PBAC meeting).*

The submission provided six-year cost projections that showed even with upper body use included the net benefit to the PBS was cost saving and therefore cost neutral.

Lawley requests this paragraph be amended to:

> *The PBAC noted the sponsor's claim that the requested price increase, including upper body use, would be cost neutral to the PBS. The PBAC considered that it was appropriate that the requested price increase and change in the restriction to reduce the number of repeats to one and specify the application site as scrotal, should not result in any additional cost to the PBS (Para 6.3 AndroForte 5 Minutes March 2021 PBAC meeting).*

**Comment 3. 3.1 as proposed states:**

> *An unintended consequence of the change to PBS listing was to introduce a barrier to access for trans and gender diverse individuals and for some patients with disabilities (for whom scrotal application is not appropriate). In August 2022 and January 2023, the PBAC Executive considered a request from the Endocrine Society of Australia to amend wording, "must be applied to the scrotum" to ensure trans and gender diverse individuals, and those with disabilities, were able to access AndroForte 5 on the PBS (Attachments A to C). The PBAC Executive was supportive in principle of the proposed changes, noting that there may be pricing implications should an amendment proceed.*



Lawley agrees with the removal of the wording *"must be applied to the scrotum"* as it was not our request to have this inclusion. This PBAC decision was made in isolation and excluded upper body application which Lawley had projected would remain at 30% use in the first year and reduce to 90% by year 3 for existing and future AndroForte 5 users.

**Comment 4. 3.2 as proposed states:**

> *The Department met with the sponsor in January 2024. The sponsor is committed to removing barriers to patient access to AndroForte 5, however indicated that it cannot accept a price reduction (Attachment D).*

Since the March 2021 PBAC initial request Lawley has experienced a 35% increase in production, compliance and operational costs. A price reduction cannot be accepted as this will again make the product a borderline. Lawley is a 100% Australian owned entity, and we are the only testosterone product manufactured in Australia.

**Comment 5. 3.9 to 3.13 including all comment, graphs and tables under the heading Analysis of PBS supply data – utilisation.**

The Department has not provided Lawley with any data (as was agreed in the Jan 2024 meeting) to substantiate or verify the graphs and tables provided in this section.

The most relevant time period for assessing the impact of scrotal vs upper body application usage is July 2023 to the present, because in the 12 months beyond the 1 July 2022 implementation date there would be valid 7 repeat upper body Authority prescriptions for AndroForte 5 in the community with an expiry period of up to 12 months.

Figure 13 clearly demonstrates since the move to scrotal the vast majority of users have transitioned from upper body (7 repeats) to scrotal (1 repeat) use.

If the data is accurate, Lawley can only assume beyond July 2023 the Department has been granting Authority approvals with up to 5-8 repeats. If so, this may explain the discrepancy in Figure 5 and the conclusion drawn in 5.2.

There are inconsistencies in Table 2 which cannot be explained by prescription numbers alone without knowing patient numbers.



**Comment 6 Financials**

Th 4.1 proposed wording is acceptable to Lawley.

For all Restriction Summary Tables Lawley requests the wording for:

| | |
|---|---|
| NEW CC1 | The treatment must be applied to the scrotum area, *where possible* |

be amended to 'The treatment should be applied to the scrotum, *where possible*.'

The deletion of the word 'area' is because the scrotum, not the surrounding scrotal area, is the TGA approved site of application.

**General comments:**

- Please be advised that throughout the document, AndroForte 5 should be spelt with a capital F and finished with a 5 - AndroForte 5
- If the PBAC Committee agrees to reinstate upper body application, please remove from the Authority online and telephone dialogue the question "Is the cream being applied to the scrotum".
- Lawley would like to suggest the introduction a Brand Premium for all PBS testosterone products. The elephant in the room is the pricing of Testogel and Testavan compared to AndroForte 5 scrotal. The cost per day of treatment with AndroForte 5 is more than half the cost per day of Testogel (59% less) and Testavan (64% less).

Table 1 (below) shows the cost per day of treatment to the PBS for each of the minimum and maximum recommended doses for each PBS transdermal testosterone.

Lawley has little doubt that if a Brand Premium was implemented by the Department, then the projections provided in our original submission, and savings to the PBS, will be more quickly realised with the shift to scrotal AndroForte 5.

**Table 1.**

| Product | DPMQ | Total # min. doses | Min dose | Min $/day | Max dose | Max $/day |
|---|---|---|---|---|---|---|
| **AndroForte 5 scrotal** | 107.54 | 100 | 0.5mL | 1.08 | 1.0 | 2.16 |
| **Testogel sachets** | 75.90 | 30 | 1 sachet | 2.63 | 2 sachets | 5.26 |
| **Testogel Pump** | 78.96 | 2 x 60 | 4 pumps | 2.63 | 8 pumps | 5.26 |
| **Testavan** | 84.41 | 56 | 2 pumps | 3.01 | 3 pumps | 4.52 |
| **Reandron Injection** | 94.43 | 12 weeks | 1 | 1.12 | n/a | n/a |

- The 1 April 2024 Testogel 1.62% pump pack was included on the Pharmac NZ schedule of benefits at NZ $52.00 (AUD $47.40) as opposed to the Testogel 1% sachets and pump-pack (Besins) and Testavan (Clinect) on the PBS at DPMQ AUD $78.96 and $84.41 respectively indicating that at a minimum Besins have room to move if a Brand Premium was to be introduced.



Yours sincerely

s47F [redacted]

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