

s22

From: s47E(d)
Sent: Tuesday, 15 November 2022 4:47 PM
To: s47E(d)
Subject: RE: MB22-003910 FW: Please launch a national review into current methods of care for gender dysphoric children [SEC=OFFICIAL]

Hey Team

Good news, you can NFA this brief 😊 we found some relevant info 😊

s22

Departmental Liaison Officer

s22

From: s47E(d)
Sent: Tuesday, 15 November 2022 4:05 PM
To: s47E(d)
Subject: RE: MB22-003910 FW: Please launch a national review into current methods of care for gender dysphoric children [SEC=OFFICIAL]

Good afternoon

The below MIR has been logged under MB22-003910 in PDMS.

Due to s47E(d) at 3 pm, 22 November 2022.

Kind regards

s22

Parliamentary Officer – Parliamentary Section

People, Communication and Parliamentary Division | Corporate Operations Group
 Ministerial and Parliamentary Services Branch
 Australian Government Department of Health
 T: s22 @health.gov.au
 Location: s22
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s47E(d) @Health.gov.au>
Sent: Tuesday, 15 November 2022 2:30 PM
To: s47E(d) @health.gov.au>
Subject: MB22-003910 FW: Please launch a national review into current methods of care for gender dysphoric children [SEC=OFFICIAL]

MIR – PHD – 22/11 please

s22

Departmental Liaison Officer

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE



Australian Government

Department of Health and Aged Care

Information Brief

MB23-002901

Version (1)

Date sent to MO: 20/09/2023

To: Minister Butler
cc: Assistant Minister Kearney

Subject: INFO BRIEF - The health of transgender and gender diverse young people – information on notice from LGBTIQ+ Health Australia (LHA)

Comments:			
Contact Officer:	§22	A/g Assistant Secretary, Health Equity Branch	Ph: §22 Mobile: §22
Clearance Officer:	Tiali Goodchild	A/g First Assistant Secretary, Population Health Division	Ph: §22 Mobile: §22

Key Issues:

- Following your meeting with Ms Nicky Bath, Chief Executive Officer of LGBTIQ+ Health Australia (LHA) on 9 August 2023, Ms Bath emailed your office (23 September 2023) to provide further information regarding questions you asked in relation to the health of trans and gender diverse young people (see **Attachment A**).
- In Australia, the provision of gender services is led by states and territories, who are responsible for the relevant services. Specialist gender services across a number of jurisdictions provide care to young people based on a multidisciplinary approach tailored to individual circumstances and needs. Decisions regarding clinical care are shared between the clinicians, the young person and their family.
- If there is a disagreement about the diagnosis, treatment or capacity of the minor to provide informed consent, the family court has ruled this requires an application to the court to resolve the dispute consistent with the child's best interests.

1. Numbers of young people in Australia accessing puberty blockers

- There is no complete data set available to provide the numbers of young people in Australia accessing puberty blockers. In July 2023 the International Journal of Transgender Health published a paper "The clinical profile of patients attending a large, Australian pediatric gender service: A 10-year review" that looked at the clinical profile of patients seen at the Royal Children's Hospital Gender Services over 10 years (2007-16)

- During the study period 359 patients were first seen. Although 81% of patients met eligibility for gender dysphoria, rates of hormonal treatment were much lower, with 29% of young people ≥ 10 years of age receiving puberty blocking treatment and 38% of adolescents ≥ 16 years of age receiving gender-affirming hormones (i.e. testosterone or estrogen).
- Each State and Territory has differing legislation on age and requirements for informed consent, including when to commence puberty blockers. It is the responsibility of all health care providers to practice according to their relevant legal obligations.

2. Pharmaceutical Benefits Scheme

- Gonadotropin releasing hormone (GnRH) analogues (or 'puberty blockers') are available on the PBS for the treatment of certain cancers and precocious puberty. When used for gender affirming hormone therapy these medicines are supplied on private prescriptions. The PBS listing of GnRH analogues reflects evidence considered by the Pharmaceutical Benefits Advisory Committee (PBAC) to date. The PBAC has not received a submission to consider listing GnRH analogues for gender affirming hormone therapy.
- Testosterone undecanoate is listed on the PBS for the treatment of androgen deficiency, micropenis, pubertal induction, and constitutional delay of growth or puberty under certain circumstances. Complete information on the PBS listings for testosterone undecanoate, including all patient eligibility criteria, is available at www.pbs.gov.au.
- For the indication of androgen deficiency, patients with an established pituitary or testicular disorder may access testosterone undecanoate provided they are treated by a specialist urologist, endocrinologist, a Fellow of the Australasian Chapter of Sexual Health Medicine or are provided or awaiting treatment in consultation with one of these specialists.
- In July 2014, the PBAC considered amendments to PBS restrictions for testosterone products to clarify the intent of the committee. The PBAC considered it was not necessary to identify specific pituitary and testicular disorders for patients to be eligible for PBS-subsidy under this restriction. Further details are available on the PBS website in the July 2014 PBAC public summary documents at **Attachment B**.
- At its July 2015 meeting, the National LGBTI Health Alliance provided a submission to the PBAC to consider further changes to the restrictions for testosterone. In November 2015, the PBAC and the then National LGBTI Health Alliance (now LHA) met to discuss concerns regarding the restriction changes to testosterone, particularly regarding prescribing having to be initiated at a specialist level. The PBAC noted unintended negative consequences on transgender people and people with innate variations of sex characteristics resulting from the restriction amendments. PBAC then recommended amending restriction wording for testosterone to remove the population criterion 'patient must be male'. Further details are available in the July 2015 PBAC Meeting public summary document for positive recommendations at **Attachment C**.

3. Medicare Benefits Schedule

- Gender affirmation is a complex medical process and there is no singular or overarching Medicare Benefits Schedule (MBS) item or group of items that captures all the consultations and surgical procedures that may be involved in gender affirmation. Rather there is a range of MBS items that could be used at various stages of the gender affirming process, including GP consultation items and plastic surgery items.

- Consumers accessing gender affirming care in the private setting can receive MBS rebates for some (but not all) of the surgical procedures involved in gender affirmation process if the treating practitioner deems these services to be clinically relevant to patient care.
- MBS items generally do not have age restrictions and are available for all eligible Australians if determined by the treating practitioner to be clinically relevant. Age restrictions to MBS items would primarily be applicable to common paediatric and neonatal procedures.
- The Medical Board of Australia recognises informed consent is an important part of good medical practice. This includes recognising the role of parents or guardians in a young person's treatment and when appropriate, encouraging the person to involve their parents or guardians in decisions about their care. Each State and Territory has differing legislation about the age and requirements for informed consent.
- MBS items reimburse some of the surgical procedures involved in gender affirmation. These include items for mastectomy and mammaplasty procedures which may be performed for gender affirming chest surgery, and penectomy and hysterectomy procedures, if the treating practitioner deems these procedures to be clinically relevant to patient care.
- All private health insurers are prevented from discriminating against policy holders based on the treatments they may require. Numerous Australian health insurers outline specific commitments to transgender members and provide specific advice on gender affirmation surgery coverage.
- For privately insured patients, when admitted to hospital as a private patient to receive treatment for which they are insured, Medicare will pay 75 per cent of the MBS fee for each MBS item and the private health insurance regulatory regime requires health insurers pay at a minimum the remaining 25 per cent of the MBS fee, and also make payments to the hospital for the theatre costs and other costs associated with a patient's stay in a hospital. The Government does not have authority to determine the fees charged by doctors or their billing practices.
- The MBS Taskforce reviews of plastic and reconstructive, gynaecology and urology items included items considered relevant by practitioners to be performed during gender affirmation surgery. Specific consideration of this patient group was not part of their review. Changes from the MBS Review supported by Government have not impacted access to the services for patients undergoing a gender affirmation process.

4. Medical Indemnity Insurance

- The Government understands the MDA National exclusion applies only to certain aspects of gender affirming treatment relating to the prescription of cross-sex hormones in the second phase of treatment. The Government will continue to monitor any further developments in this area noting MDA National are the only insurer who has included an exclusion in their policies which means cover remains available from other insurers.
- The Department is consulting with the Australian Society of Plastic Surgeons and other relevant clinical colleges, in relation to a proposal from the Australian Society of Plastic Surgeons to improve access to Medicare benefits for people who wish to receive gender affirmation treatment. This includes consideration of the listing of various procedures specifically performed as part of the gender affirmation process on the MBS by the Medical Services Advisory Committee.
- Your office has previously been briefed on Medical Indemnity Insurance pertaining to gender affirmation (**Attachment D - MB23-001628** refers).

Sensitivities

The Department receives a consistent number of enquiries regarding gender affirming care from stakeholders with diverse views. Some stakeholders express concern about the use of puberty blockers in young people, whilst others are concerned about the lack of access to gender affirming care and the out-of-pocket costs of procedures.

There is regular media expressing differing views on gender affirmation treatment. This media has often caused significant distress within the transgender community and has been raised at the LGBTIQ+ Expert Advisory Group for the development of the 10 year Action Plan, chaired by Assistant Minister Kearney.

Attachments

- A. LHA Briefing Note – The health of trans and gender diverse young people
- B. Public Summary Document – July 2014 PBAC Meeting
- C. Public Summary Document – July 2015 PBAC Meeting
- D. MB23-001628 – MDA National changed indemnity insurance policy conditions on gender affirming treatment for minors

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (Cth)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Minister	Minister Butler
PDR Number	MB23-002901
Subject	Info brief - The health of transgender and gender diverse young people – information on notice from LHA
Contact Officer	s22 [REDACTED]
Clearance Officer	Tiali Goodchild s22 [REDACTED]
Division/Branch	Primary and Community Care Population Health

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

From: s47E(d)
Sent: 13/09/2023 3:45:49 PM
To: s47E(d) @health.gov.au>
Cc: s22 @Health.gov.au>; "GOODCHILD, Tiali"
 <s22 @health.gov.au>; "STREET, Celia" <s22 @health.gov.au>; s47E(d)
 @Health.gov.au>
Subject: MB23-002901 - RE: Briefing Note for Minister Butler [SEC=OFFICIAL]
Attachments: 2023-08-09 Minister Butler briefing note.pdf

Hi all

A information brief has been logged under **MB23-002901** and assigned to **PHD** in PDMS.

Due to MO **20/09/2023**.

Thank you kindly

s22

Ministerial Coordination Officer

Ministerial and Parliamentary Services Branch (MPS)

People, Communication and Parliamentary Division | Corporate Operations Group

Australian Government, Department of Health and Aged Care

MPS Hotline: s22 | E: s47E(d) [@health.gov.au](mailto:s22@health.gov.au)

Location: s22

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community.

We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47E(d) @Health.gov.au>
Sent: Wednesday, 13 September 2023 2:32 PM
To: s47E(d) @health.gov.au>
Cc: s22 @Health.gov.au>; GOODCHILD, Tiali <s22 @health.gov.au>;
 STREET, Celia <s22 @health.gov.au>
Subject: MB23-002901 - RE: Briefing Note for Minister Butler [SEC=OFFICIAL]

Hi s47E(d),

Can you please initiate a PDR for an Info brief please – PHD

Please see below for detail - due Wed 20 Sept.

Title: The health of transgender and gender diverse young people – information on notice from LHA

Thanks,

s47F

s47F

Departmental Liaison Officer

Office of the Hon Mark Butler MP

Minister for Health and Aged Care

E: s47E(d) s47F @health.gov.au P: 02 6277 7220

M: s47F

Suite s47F | PO Box 6022

Parliament House, Canberra ACT 2600

From: FIRTH, Clare <s22 @Health.gov.au>

Sent: Wednesday, 13 September 2023 12:52 PM

To: GOODCHILD, Tiali <s22 @health.gov.au>; STREET, Celia <s22 @health.gov.au>; s47F @Health.gov.au>

Cc: s47F @Health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>

Subject: RE: Briefing Note for Minister Butler [SEC=OFFICIAL]

Wonderful. Thanks Tiali.

DLOs, can we please get this advice through a Min Info Brief please.

s47F – FYI, the dept is going to provide some additional info for Minister Butler to accompany the incoming letter from this morning from LGBTIQ+ Health.

Thanks all.

From: GOODCHILD, Tiali <s22 @health.gov.au>

Sent: Wednesday, 13 September 2023 12:46 PM

To: FIRTH, Clare <s22 @Health.gov.au>; STREET, Celia <s22 @health.gov.au>

Cc: s47F @Health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>

Subject: RE: Briefing Note for Minister Butler [SEC=OFFICIAL]

Many thanks Clare – we will provide some updates to go along side, there is relevant information for MBS, PBS and also MBD did a MIR on the Medical Indemnity Insurance issue for AMK which is relevant for you.

From: FIRTH, Clare <s22 @Health.gov.au>

Sent: Wednesday, 13 September 2023 12:38 PM

To: GOODCHILD, Tiali <^{s22} [REDACTED]@health.gov.au>; STREET, Celia <^{s22} [REDACTED]@health.gov.au>
Cc: ^{s47F} [REDACTED]@Health.gov.au; ^{s47E(d)} [REDACTED]@Health.gov.au>

Subject: FW: Briefing Note for Minister Butler [SEC=OFFICIAL]

Hi both – the Minister met with the CEO of LGBTIQ+ Health Australia recently to be briefed on the health or trans and gender diverse young people. LHA has provided some further information in writing (see attached) in response to questions from the Minister.

Before we provide this directly to the Minister, I wanted to check if there was any additional data or advice you wanted to provide the Minister to sit along side this? It's not essential. I just wanted to give you the opportunity to send up a related Ministerial Info Brief if you think more context would be helpful as the Minister reads thus.

Cheers
Clare

^{s22} [REDACTED]

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

BRIEFING NOTE

Meeting 9 August 2023

To Hon Mark Butler MP, Minister for Health and Ageing

Subject The health of trans and gender diverse young people

Introduction

Thank you for meeting with LHA and representatives from Transcend, Gender Centre and A Gender Agenda on 9 August 2023, to discuss the health and wellbeing of trans and gender diverse people in Australia and the provision of gender affirming care young people. During the meeting you asked several questions, and we agreed to provide more detail. Please find below information as requested that LHA has prepared in consultation with Transcend, Gender Centre and A Gender Agenda.

Information on Notice

1. Numbers of young people in Australia accessing puberty blockers

- The *Royal Children's Hospital Melbourne Gender Service (RCH)* received 634 referrals in 2022. In the 2022-23 financial year 154 Victorian patients were prescribed puberty blockers. This suggests 25% of young patients seeking gender affirming care may access puberty blockers. LHA is seeking data from other hospitals and will provide a further update.

2. Pharmaceutical Benefits Scheme

- Puberty blockers are not listed on the PBS for the purpose of gender affirmation and families seeking urgent medical access face out of pocket costs of up to \$6,000 per year for the medication.
- Testosterone medication is not listed on the PBS for the purpose of gender affirming healthcare and for a GP to get a PBS authority to prescribe, a patient must see an endocrinologist, urologist, or sexual health physician. Waitlists for appointments with an endocrinologist are around 12 months.

3. Medicare Benefits Schedule

- Most state and territory health systems have elective surgery policies that explicitly restrict access to gender affirming surgical interventions through the public health systems. Most surgical procedures need to occur in private hospitals.
- Private health insurance coverage of gender affirming care continues to be inconsistent in Australia and although many Australian trans people do have private health insurance the cost remains prohibitive.
- Even with the highest level of private insurance cover, there are still significant pay gaps and depending on the procedure, people can be out of pocket in a range of \$10,000 - \$80,000.

4. Medical Indemnity Insurance

- MDA National, a major medical defence organisation has withdrawn cover to medical practitioners working in private practice looking to initiate cross sex hormone therapy for adolescents under the age of 18. This will impact healthcare providers, patient experience and reduce access to care.

4.1 REVIEW OF PROPOSED AMENDMENTS TO PBS RESTRICTIONS FOR TESTOSTERONE PRODUCTS

1 Purpose of application

- 1.1 To advise the PBAC of responses from sponsors and stakeholders in relation to recommended amendments to the PBS restrictions for testosterone products from the August 2013 Special PBAC meeting.
- 1.2 To propose revised amended PBS restrictions for testosterone products that better clarify the intent of the Committee.

2 Requested listing

- 2.1 The PBAC noted that there are currently three separate PBS restrictions for testosterone products:

Restriction 1:

Authority required

Androgen deficiency in males with established pituitary or testicular disorders.

Restriction 2:

Authority required

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men).

Restriction 3:

Authority required

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

At its October 2012 meeting, DUSC reviewed the utilisation of PBS listed testosterone. The utilisation analysis highlighted the following key points:

- Utilisation of testosterone has doubled over the past 5 years.
- Expenditure has increased more than the growth in utilisation. This suggests that therapeutic relativities may require review.
- The listing of two products, testosterone gel and intramuscular injection 1000mg, have driven the growth in the market.
- There is a trend towards more GPs initiating therapy.
- There may be some use of testosterone that is not within the PBS restriction.
- There are some safety concerns with testosterone including possible increased cardiovascular risk in older men.

Public Summary Document – July 2014 PBAC Meeting

In its August 2013 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.

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 general 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.

Some of the issues raised in responses to stakeholder consultation on the recommended changes include:

- Concern that the proposal to lower the defined testosterone threshold level is not consistent with international and Australian consensus guidelines, which define androgen deficiency according to the thresholds in the current restriction (less than 8 nmol/L or 8-15 nmol/L with high LH);
- Concern that the proposal to lower the defined testosterone threshold level is based upon a single cohort study of men aged 70-89 years and may not be applicable to the wider PBS population;
- Inappropriate application of testosterone threshold levels to the indication for patients with established pituitary or testicular disorders;
- Concern for the requirement for testosterone to be prescribed by or in consultation with specialists;
- Confusion regarding the requirement for the condition not to be due to age, obesity, cardiovascular diseases, infertility or drugs;
- Suitability for sexual health physicians to be included among those specialists by or in consultation with whom testosterone may be prescribed.

4 Consideration of the evidence

Public Summary Document – July 2014 PBAC Meeting

4.1 Following stakeholder consultation, the Secretariat undertook a further review of the proposed amendments to the restrictions and considered that they did not accurately reflect the intent of the PBAC. The Secretariat noted the following in its review:

- it is unnecessary to have separate initial and continuing treatment restrictions for treatment of patients with established pituitary or testicular disorders (Restriction 1) if there is no measure of response in order to qualify for continuing treatment;
- reference to serum testosterone and LH thresholds should only be included in the restriction for men aged 40 years or older who do not have established pituitary or testicular disorders (Restriction 2);
- the thresholds intended by the PBAC were serum testosterone of less than 6 nmol per L or serum testosterone 6-15 nmol per L with high LH, where high LH is defined as 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;
- the requirement for prescribing by or in consultation with nominated specialists should be restriction-specific: e.g. it would not be appropriate for patients aged 40 years and over to be treated by paediatric specialists.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

- 5.1 The PBAC noted that the existing Restrictions 1 and 2 state that the condition (androgen deficiency) must not be due to age, obesity, cardiovascular diseases, infertility or drugs. The PBAC agreed with the Secretariat that this criterion is redundant for Restriction 1, where the condition for PBS eligibility is identified as being due to established pituitary or testicular disorders. The PBAC recommended the removal of this criterion from Restriction 1.
- 5.2 With regard to Restriction 1, the PBAC noted the Secretariat's request for advice on whether it is necessary to identify specific pituitary and testicular disorders for patients to be eligible for PBS-subsidy under this restriction. The PBAC considered that it was not necessary for specific disorders to be referred to in the restriction.
- 5.3 The PBAC noted the request from stakeholders to include specialist sexual health physicians among those specialists able to prescribe or be consulted on prescribing of PBS-listed testosterone products. The PBAC considered that a more appropriate definition would be "a registered member of the Australasian Chapter of Sexual Health Medicine". The PBAC recommended that this definition be included in all PBS restrictions for testosterone products.

Outcome:

Recommended

Following consideration of input from stakeholders and the Department, the PBAC recommended amending the restrictions for testosterone products to:

- For restrictions for androgen deficiency, remove redundant reference to the condition not being due to age, obesity, cardiovascular diseases, infertility or drugs;
- Include registered members of the Australasian Chapter of Sexual Health Medicine as prescribers that are able to prescribe testosterone products on the PBS.

6 Recommended listing

Public Summary Document – July 2014 PBAC Meeting

6.1 Amend existing listing as follows:

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

RESTRICTION 1

Condition:	Androgen deficiency
Restriction:	Authority required
Treatment criteria:	Must be treated by or in consultation with a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine or have an appointment to be assessed by one of these specialists.
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

Condition:	Androgen deficiency
Restriction:	Authority required

Public Summary Document – July 2014 PBAC Meeting

Treatment criteria:	Must be treated by or in consultation with a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine or have an appointment to be assessed by one of these specialists.
Clinical criteria:	Patient must not have an established pituitary or testicular disorder AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs
Population criteria:	Patient must be male AND Patient must be aged 40 years or older
Prescriber instructions	Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.
Prescriber instructions	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 3(a)

Condition:	Micropenis
Restriction:	Authority required
Treatment criteria:	Must be treated by or in consultation with a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine or have an appointment to be assessed by one of these specialists.
Population criteria:	Patient must be male AND Patient must be under 18 years of age.
Administrative Advice	The name of the specialist must be included in the authority application

Public Summary Document – July 2014 PBAC Meeting

RESTRICTION 3(b)	
Condition:	Pubertal induction
Restriction:	Authority required
Treatment criteria:	Must be treated by or in consultation with a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine or have an appointment to be assessed by one of these specialists.
Population criteria:	Patient must be male AND Patient must be under 18 years of age.
Administrative Advice	The name of the specialist must be included in the authority application

RESTRICTION 3(c)	
Condition:	Constitutional delay of growth or puberty
Restriction:	Authority required
Treatment criteria:	Must be treated by or in consultation with a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine or have an appointment to be assessed by one of these specialists.
Population criteria:	Patient must be male AND Patient must be under 18 years of age.
Administrative Advice	The name of the specialist must be included in the authority application

7 Context for Decision

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

8 Sponsors' Comments

Actavis Pty Ltd: The sponsor has no comment.

Bayer Australia Limited*: The sponsor has no comment.

Besins Healthcare Australia Pty Ltd: The sponsor notes the DUSC review and the subsequent considerations by the PBAC were instigated to ensure appropriate prescribing of

Public Summary Document – July 2014 PBAC Meeting

testosterone replacement therapies by GPs and specialists. The sponsor considers that the requirement that treatment must be by or in consultation with a specialist may add an additional cost and time burden for GPs and patients.

Eli Lilly Australia Pty Limited^{**}: Eli Lilly welcomes the removal of unnecessary initial and continuing treatment restrictions, and reference to serum and testosterone and LH thresholds for patients with established pituitary or testicular disorders.

We are concerned that patients accessing treatment could incur delays by linking prescribing to confirmation of a speciality consultation, it is therefore important that in implementing these new restrictions the guidance is clear to prescribers.

Hospira Pty Ltd^{***}: The sponsor has no comment.

Merck Sharp & Dohme (Australia) Pty Ltd: The sponsor has no comment.

* Bayer Australia Pty Ltd was the sponsor of Testogel® at the time the utilisation analysis was considered by the DUSC in October 2012. Besins Healthcare Australia Pty Ltd took over as sponsor of this product on 1 October 2014.

** Eli Lilly Australia Pty Ltd did not have a testosterone product listed on the PBS at the time the utilisation analysis was considered by the DUSC in October 2012, however Axiron® had received a positive recommendation from the PBAC in March 2012 and was listed in March 2013.

*** Hospira Pty Ltd was the sponsor of Androderm® products at the time the utilisation analysis was considered by the DUSC in October 2012. Ascent Pharma Pty Ltd took over as sponsor of these products on 1 February 2013, and then Actavis Pty Ltd on 1 October 2013.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH AND AGEING

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

JULY 2015 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
LEUPRORELIN 45 mg injection: modified release [1 x 45 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 LUCRIN® DEPOT 6 month PDS AbbVie Pty Ltd New listing (Minor Submission)	Prostate cancer	Authority Required (STREAMLINED) listing of an additional strength of leuporelin for the treatment of locally advanced or metastatic carcinoma of the prostate.	The PBAC recommended listing an additional strength (45 mg) of intramuscularly administered leuporelin for the treatment of locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate. The PBAC accepted that there was a clinical place for the additional strength and considered that it was acceptably similar to the 3- and 4-month formulations with regard to effectiveness and the adverse events profile. The PBAC noted that listing the 45 mg intramuscular formulation would result in savings to the PBS.
LEUPRORELIN 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 LUCRIN® DEPOT AbbVie Pty Ltd Change to listing (Minor Submission)	Central precocious puberty (CPP)	Amendment to the PBS restriction wording of Lucrin® Depot Paediatric to specify that the patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).	The PBAC recommended that the criterion pertaining to patient age in the initial treatment restriction for leuporelin for the treatment of CPP, be amended as follows: "Patient must be aged 10 years or younger (girls) or 11 years or younger (boys) AND Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys)". The PBAC noted that there may be a very small number of patients who may not have initiated treatment before 8 years (girls) or 9 years (boys) despite onset of symptoms before 8 years (girls) or 9 years (boys), and therefore considered it may be reasonable to extend the PBS age limit for initiating leuporelin therapy.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

JULY 2015 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>TESTOSTERONE</p> <p>testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets</p> <p>testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations</p> <p>testosterone 2.5 mg/24 hours patch, 60</p> <p>testosterone 5 mg/24 hours patch, 30</p> <p>Various sponsors</p> <p>National Lesbian, Gay, Bisexual, Transgender, and Intersex (LGBTi) Health Alliance</p> <p>Change to listing</p> <p>(Minor submission)</p>	Androgen deficiency	Amendment to the revised PBS restrictions to enable access by transgender and intersex patients.	<p>The PBAC recommended amending the restriction wording for testosterone to remove the population criterion 'patient must be male'. The PBAC considered that the remaining requested changes to the restrictions for testosterone products were complex in nature. The PBAC recommended a stakeholder meeting be held between the Department, representatives of the National LGBTI Health Alliance and other consumer representatives, relevant clinicians, the Department of Human Services, the sponsors of testosterone preparations and PBAC members. The aim of this meeting would be to determine an appropriate restriction arrangement (including appropriate prescriber groups) for transgender and intersex populations. A revised restriction would need to reflect the need for these patients to maintain continuity of care with a primary care provider.</p>

s22

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

OFFICIAL



Australian Government

Department of Health and Aged Care

Ministerial Information Request

MB23-002766

Version (1)

Date sent to MO: 8/09/2023

To: Assistant Minister Kearney

cc: Minister Butler

Subject/Issue: MIR - PBS & MBS gender affirming healthcare

Comments:			
Contact Officer:	Nigel Murray	Assistant Secretary, MBS Policy and Specialist Programs Branch, Medical Benefits and Digital Health Division	Ph: s22 Mobile: s22
Clearance Officer:	Daniel McCabe	First Assistant Secretary, Medicare Benefits and Digital Health Division	Ph: s22 Mobile: s22

Request:

Your office requested a briefing on the existing coverage of gender-affirming healthcare under both PBS and MBS across the continuum of care (from assessment, puberty blockers, hormones to surgical intervention). Briefing to include any stipulations on the provision of that care, including age restrictions, and any current or expected applications to Pharmaceutical Benefits Advisory Committee (PBAC) or Medical Services Advisory Committee (MSAC) in this area. Also information on the division of responsibility between commonwealth and state and territory jurisdictions.

Further information request:

Your office and Minister Butler's office have asked to be provided further information on the surgical intervention aspects of gender affirmation healthcare, particularly further detail

OFFICIAL

OFFICIAL

on the MSAC and MBS review processes as they relate to gender affirming surgery including former reviews. Further information is included below.

Response:

1. MBS access to gender-affirming healthcare

- The Australian Government supports Australians with access to Medicare benefits (rebates) for private services listed on the Medicare Benefits Schedule (MBS) and free hospital services for public patients in public hospitals.
- Gender affirmation is a complex medical process and there is no singular or overarching MBS item or group of items that captures all the consultations and surgical procedures that may be involved in gender affirmation. Rather there is currently a range of Medicare Benefits Schedule (MBS) items that could be used at various stages of the gender affirming process, including GP consultation items and plastic surgery items.
- For consumers accessing gender affirming care in the private setting, they are able to receive Medicare Benefits Schedule (MBS) rebates for some (but not all) of the surgical procedures that may be involved in gender affirmation process if the treating practitioner deems these services to be clinically relevant for the care of a patient.
- MBS items generally do not have age restrictions and are available for all eligible Australians, if the service is determined by the treating practitioner to be clinically relevant.
- Age restrictions to MBS items would primarily be applicable to common paediatric and neonatal procedures.
- The Government relies on medical practitioners to deliver the most clinically relevant services to a patient, and the bodies that regulate practitioners to ensure that appropriate services are delivered. As noted in the Medical Board of Australia's 'Good medical practice: a code of conduct for doctors in Australia', informed consent is an important part of good medical practice. This includes recognising the role of parents or guardians in a young person's treatment and when appropriate, encouraging the person to involve their parents or guardians in decisions about their care.
- Each State and Territory has differing legislation about the age and requirements for informed consent. It is the responsibility of all health care providers to practice according to their relevant legal obligations.

Consultation Items

- GP consultation items (time tiered items and equivalents) could be used to discuss gender affirmation issues with adults and children and provide appropriate referral to relevant allied and specialist health practitioners.

Commented 22/7/9 request from Minister Kearney office - 'The offices have asked for this MIR to please also focus on surgical intervention, particularly as it relates to MSAC/MBS process reviews.'

13/9 request from Minister Butler office - 'Minister Butler's Office has asked if further information can please be provided on the surgical intervention aspects, particularly with detail on the MSAC and MBS review processes on gender affirming surgery. The MO is keen for further detail on the history in this space, including any former reviews.'

OFFICIAL

OFFICIAL

- Similarly chronic disease management items, for example 721 and 723, could be used where a GP feels that a person has a complex condition, requiring care co-ordination.
- Children and adults with any chronic condition may be managed under a GP Management Plan. GPs may assess and refer children and adults with gender incongruence under these items.
- Where a person, including a child, has significant mental health impacts due to their condition, often in the form of gender dysphoria or major depression, they may be eligible for a GP Mental health care plan and subsequent focused psychological strategies. Mental health care item numbers which may be used by GPs in this context include 2713, 2715 and 2717 and equivalents.
- In addition, there are MBS items for specialist consultations including with plastic and reconstructive surgeons and psychiatrists, which are available for patients undergoing gender affirmation surgery.

Surgical Items

- The current Medicare Benefits Schedule (MBS) items reimburse some of the surgical procedures that may be involved in gender affirmation. These include items for mastectomy and mammoplasty procedures which may be performed for gender affirming chest surgery, and penectomy and hysterectomy procedures, if the treating practitioner deems these procedures to be clinically relevant for the care of the patient.

Further information on the surgical intervention aspects of gender affirmation healthcare

- The current MSAC application by Australian Society of Plastic Surgeons (ASPS) lists all surgical procedures that are required for gender affirming care and identifies the limitations of current MBS items as well as service gaps. The list of MBS items as identified by ASPS can be found at **Attachment A**.

Relevant MSAC applications

- You have recently been provided a copy of MB23-002667 which provided Minister Butler with an update on the Medical Services Advisory Committee (MSAC) application from Australian Society of Plastic Surgeons (ASPS). The applicant is seeking changes to MBS items to more specifically cover gender affirmation consultation and surgeries.
- The applicant will shortly be notified that the application is suitable to progress through the MSAC process and the application will be published on the MSAC website no later than 22 September 2023.

Further detail on the MSAC process for gender affirming surgery including former reviews

- This is the first application received by MSAC seeking public funding under the MBS for gender affirming care.

OFFICIAL

OFFICIAL

- On 8 September 2023, the ASPS were advised by the Department that their application has been deemed suitable for consideration by the MSAC.
- The application will be published on the MSAC website no later than 22 September 2023 together with a bulletin advising the public of the MSAC applications scheduled for consideration by MSAC's PICO Advisory Sub Committee (PASC) at its December 2023 meeting, this will include ASPS's application.
- The Department will provide further information as the application progresses through the MSAC process.
- Between 2015 and 2020, the MBS Review Taskforce looked at more than 5,700 MBS items to see if they needed to be amended, updated or removed. It identified services that were obsolete, outdated or potentially unsafe.
- The MBS Taskforce reviews of plastic and reconstructive, gynaecology and urology items did include consideration of items that may be considered relevant by practitioners to be performed during gender affirmation surgery, however, specific consideration of this patient group was not part of their review.
- The changes from the MBS Review that were supported by Government have not impacted current access to the services for patients undergoing a gender affirmation process.

2. PBS access to gender affirming care

- As noted above each State and Territory has differing legislation about the age and requirements for informed consent, including when to commence puberty blockers. It is the responsibility of all health care providers to practice according to their relevant legal obligations.
- *Puberty blockers and hormones*
 - Gonadotropin releasing hormone (GnRH) analogues (sometimes referred to as 'puberty blockers') are only available on the PBS for the treatment of certain cancers and precocious puberty (early puberty) under certain circumstances.
 - These medicines include goserelin 3.6 mg, 10.8 mg implant (Zoladex Implant®), leuprorelin acetate 7.5 mg, 22.5 mg, 30 mg, 45 mg modified release injection (Lucrin Depot® and Eligard®), triptorelin 3.75, 11.25 mg, 22.5 mg injection (Diphereline®) and triptorelin acetate 100 microgram/mL injection (Decapeptyl®).
 - GnRH analogues (puberty blockers) could be used "off label" for patients undergoing gender affirmation.
 - The only product indicated for children is LUCRIN Depot Paediatric 30 mg PDS, its product information states: "LUCRIN Depot Paediatric 30 mg PDS Injection must only be prescribed after initial assessment by a paediatric endocrinologist, who is experienced in the diagnosis and management of CPP and with the ongoing

OFFICIAL

OFFICIAL

supervision of such a specialist.” This is indicated for suppression of precocious puberty.

- Doctors may use medications off label where they are satisfied that the benefits outweigh the risks for the patient.
<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-PI-01299-3&d=20230601172310101>
- A range of medicines used in gender-affirming hormone therapy are available on the PBS and can be accessed by transgender patients. Estrogen containing products are available in many cases as unrestricted benefits while testosterone containing products are mainly available as Authority Required listings.

Relevant PBAC applications

- In their MSAC application the ASPS notes that there is no restriction on clinicians being able to prescribe feminising hormones (estradiol) and anti-androgens through current PBS listings.
- The PBS listings for masculinising hormones (testosterone) are ‘Authority Required’ listings and clinicians must contact Services Australia or the Department of Veterans Affairs and obtain approval before a prescription for PBS listed testosterone treatment can be written.
- The ASPS notes that it intends to submit an application to the PBAC for an amendment to the clinical criteria for existing PBS restrictions for testosterone for treatment of androgen deficiency to establish its use in people with gender incongruence. As yet, a PBAC application has not been received from ASPS in relation to this matter.
- At its March 2021 meeting, the pharmaceutical company (sponsor) of Androforte 5 (a testosterone cream formulation) requested a change in the number of repeats for the currently listed testosterone cream.
- The PBAC recommended amending the listing of AndroForte 5 to reduce the number of repeats from six to one and recommended an increase to the unit price which should not result in additional cost to the PBS.
- The PBAC’s recommendation was based on the TGA approval for scrotal application that reduces the dose from 100 mg to 25 mg daily and increases the number of treatments per tube from 25 to 100. The sponsor of AndroForte 5 accepted the PBAC recommendations with the addition of the PBS restriction criteria ‘The treatment must be applied to the scrotum area’. This has been the subject of several correspondences from transgender and LGBTI organisations, claiming it creates a barrier to transgender patients receiving therapy. The Department, following advice from the PBAC Executive on the matter, is working with the sponsor on a proposed amendment to the restriction to address this.

OFFICIAL

OFFICIAL

Division of responsibility between Commonwealth and State and Territory Governments

- State and territory Governments receive funding from the Government through the National Health Reform Agreements for the provision of public hospital services.
- As a general principle, medical treatment provided in the private sector can also be provided in a public hospital, including gender affirmation surgery. However, decisions about which procedures are provided in public hospitals and waiting times are matters for each state government and its hospital network. Some jurisdictions offer a range of services, which can support patients who are trans and gender diverse.

Further information on the impact on State and Territory gender affirmation treatments

- The assessment and potential listing of MBS services to encompass all surgery required for surgical gender affirming services is envisaged to also benefit patients receiving services in the public setting given MBS services for private services are generally also made available in public hospitals.
- The ACON (previously known as the AIDS Council of NSW) reports the variation in providing gender affirming care between States and Territories is based on the determination that gender affirming care is either elective or cosmetic. An information sheet from ACON can be found at **Attachment B**.

Sensitivities

- The Department receives a consistent number of enquiries expressing concern about the out-of-pocket costs of gender affirmation procedures, and there is regular media in relation to patient difficulties in accessing gender affirmation treatment.
- A number of petitions have also been lodged with the House of Representatives to request Medicare funding for gender affirmation surgery, most notably *Petition EN3307 - Gender affirming surgery should be covered by Medicare* in June 2021 which received 148,182 signatures, further information about this petition can be found at: www.aph.gov.au/e-petitions/petition/EN3307. The former government's position to these petitions was that a health technology assessment by MSAC would be required for any new gender affirmation treatment services.
- The department notes recent *Petition EN5135 Gender Affirming care should NOT be covered by Medicare* which closed on 28 June 2023 and received 63,060 signatures. Further information about this petition can be found at: www.aph.gov.au/e-petitions/petition/EN5135 (MC23-014763 refers).
- The ASPS MSAC application anticipates Medicare funding would be provided to adults between 18 and 50 years of age. Following a recent Four Corners investigation into gender-affirmation care of young patients at Westmead Children's Hospital in Sydney, the NSW government advised that it will commission a review by the Sax

OFFICIAL

OFFICIAL

Institute into the way gender-affirming care is delivered across the state to assist in the establishment of a new care framework for clinicians

(www.abc.net.au/news/2023-07-11/nsw-gender-affirmation-care-investigation-review/102585936.)

Further information on Sensitivities

- On 14 September 2023 the Guardian reported that the Victorian Coroner will be undertaking an inquest into the apparent suicides of five people who were undergoing a gender-affirmation process before their deaths ([Inquest to examine apparent suicides of five trans and gender-diverse Victorians in bid to stop further deaths | Victoria | The Guardian](#))

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

OFFICIAL

OFFICIAL

Minister	Assistant Minister Kearney
PDR Number	MB23-002766
Subject	MIR - PBS & MBS gender affirming healthcare - due 8 September 2023
Contact Officer	Nigel Murray §22 §22
Clearance Officer	Louise Riley §22 §22
Division/Branch	Health Resourcing Medicare Benefits & Digital Health
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

OFFICIAL



Australian Government

Department of Health and Aged Care

Information Brief

MB23-002667

Version (1)

Date sent to MO: 31/08/2023

To: Minister Butler

Subject: DEPARTMENT INITIATED BRIEF - MSAC APPLICATION 1754 - GENDER
AFFIRMATION IN ADULTS WITH GENDER INCONGRUENCE

Comments:			
Contact Officer:	Nigel Murray	Assistant Secretary, MBS Policy and Specialist Programs Branch, Medical Benefits and Digital Health Division	Ph: §22 Mobile: §22
Clearance Officer:	Daniel McCabe	First Assistant Secretary, Medicare Benefits and Digital Health Division	Ph: §22 Mobile: §22

Key Issues:

1. On 23 March 2023 the Australian Society of Plastic Surgeons (ASPS) submitted an application to the Medical Services Advisory Committee (MSAC) seeking the introduction of comprehensive Medicare Benefit Schedule (MBS) services specific to adult patients undergoing a gender affirmation process, including services for surgical procedures and consultations. The application will be published on the MSAC website no later than 22 September 2023 though it will be some time before a final decision is taken by MSAC, likely in 2025, as significant analysis and consultation is required. The publication of the application on 22 September is likely to generate additional queries and media coverage and Government may be asked for its position. The MSAC application from the ASPS can be found at [Attachment A](#).

2. Due to the size and complexity of the application the Department of Health and Aged Care sought advice from the MSAC Executive Committee on the appropriate Health Technology Assessment (HTA) pathway for the application at its meeting on 26 May 2023. The MSAC Executive Committee considered the application was suitable for MSAC consideration and noted their key concerns were the limited evidentiary basis to support the assessment of the application, and the importance for the proposed services to be provided within a multidisciplinary best practice model of care framework. The MSAC Executive Committee outcome for the ASPS application can be found at Attachment B.
3. It is anticipated that the next major step in consideration of the ASPS application will be consideration by MSAC's PICO Advisory Sub Committee (PASC) at its December 2023 meeting. The PICO process establishes the appropriate Population(s), Interventions, Comparators and Outcomes for the proposed intervention (health technology). It is informed by the application, and by any extra searches and input from stakeholders and the applicant. PASC reviews the PICO confirmation before further analysis and a final assessment report is developed for MSAC consideration.
4. In line with normal MSAC processes, this will mean the applicant will be notified that the application is suitable to progress through the MSAC process, and the application will be published on the MSAC website no later than 22 September 2023. An MSAC Email Bulletin notifying the public of the MSAC applications scheduled for consideration by PASC in December 2023 will be distributed to subscribers on Friday 22 September 2023. The application will then become available for public feedback following the publication of the application.
5. There are polarising views on the public funding of gender affirming services, evident in two opposing Parliamentary petitions – one supporting gender affirmation surgery under the MBS and one opposing.

Talking points (if required):

- My department has received a Medical Services Advisory Committee (MSAC) application for the assessment of public funding of patient consultations and surgical procedures for gender affirmation in adults with gender incongruence.
- MSAC is an independent, expert advisory group which provides advice to the Government on whether a new medical service or technology should be publicly funded, based on an assessment of the comparative safety, clinical effectiveness, cost effectiveness and total costs of services and/or procedures, using the best available evidence.
- Any person or organisation can submit an application to MSAC for the consideration of public funding of a medical service.
- I will await advice from MSAC following its assessment of the application.

Background:

- “Gender incongruence” is characterised by a marked and persistent incongruence between an individual’s experienced gender and the assigned sex, and if not managed may lead to significant psychological distress (dysphoria).
- Gender affirmation medical treatment is a complex medical process, and the current Medicare Benefits Schedule (MBS) items reimburse some, but not all of the surgical procedures involved in the gender affirmation process.
- Whilst there are some language inconsistencies in the ASPS application form in relation to the proposed eligible age group for the services, from discussions with the ASPS it considered that the services are proposed for adults, i.e. 18 years of age and older. It is expected this matter will be confirmed by PASC at its December meeting.

MSAC consideration of the application

- The MSAC Executive Committee considered that the appropriate HTA pathway to progress the application would be a focussed HTA via the full MSAC pathway (i.e., consideration by PASC, the Evaluation Sub-Committee (ESC) and MSAC) that would collectively evaluate the suite of MBS items for gender affirming surgery. The MSAC Executive Committee considered the assessment should be progressed as a two stage Assessment Report pathway where the first stage would assess the comparative clinical evidence to ensure there is adequate evidence to support an economic evaluation. The second stage would look at the economic evaluation and financial analysis. This is the most comprehensive MSAC pathway.
- As noted above, the PASC confirms the PICO of the proposed medical service which will provide the framework for the clinical and economic assessment of the medical service. The ESC reviews the evidence, expert opinion and assumptions integrated in the clinical comparisons, economic evaluations and financial analyses in each assessment for an application to be considered by the MSAC. The MSAC then appraises the application after reviewing all of the evidence made available through the assessment, public and targeted consultations and the ESC and provides advice to the Minister for Health and Aged Care on whether it considers the medical service should be publicly funded based on an assessment of the comparative safety, clinical effectiveness, cost effectiveness and total cost using the best available evidence.
- Once the applicant is informed of the suitability of the application for MSAC consideration, a HTA organisation will be contracted by the department to develop the PICO/PICCO confirmation. HTA organisations are usually university groups who specialise in preparing health technology assessment reports. They are selected from a panel of suitable organisations the Department has established.
- It is anticipated the application will be considered by the PASC at its December 2023 meeting. Following the December 2023 PASC meeting, the assessment of the comparative clinical evidence is anticipated to be considered by the ESC at its October 2024 ESC meeting and the MSAC at its November 2024 meeting. Should the MSAC consider there is adequate evidence to support an economic evaluation, the second stage of the MSAC assessment would be expected to occur in 2025.

Sensitivities

- The department receives a consistent number of enquiries expressing concern about the out-of-pocket costs of gender affirmation procedures, and there is regular media in relation to patient difficulties in accessing gender affirmation treatment.
- A number of petitions have also been lodged with the House of Representatives to request Medicare funding for gender affirmation surgery, most notably *Petition EN3307 - Gender affirming surgery should be covered by Medicare* in June 2021 which received 148,182 signatures, further information about this petition can be found at: www.aph.gov.au/e-petitions/petition/EN3307. The former government's position to these petitions was that a health technology assessment by MSAC would be required for any new gender affirmation treatment services.
- The department notes recent *Petition EN5135 Gender Affirming care should NOT be covered by Medicare* which closed on 28 June 2023 and received 63,060 signatures. Further information about this petition can be found at: www.aph.gov.au/e-petitions/petition/EN5135. The Department is currently drafting a response for the Minister which is due on 12 September 2023 (MC23-014763 refers).
- Whilst noting the ASPS MSAC application anticipates Medicare funding would be provided to adults between 18 and 50 years of age, following a recent Four Corners investigation into gender-affirmation care of young patients at Westmead Children's Hospital in Sydney, the NSW government advised that it will commission a review by the Sax Institute into the way gender-affirming care is delivered across the state to assist in the establishment of a new care framework for clinicians (www.abc.net.au/news/2023-07-11/nsw-gender-affirmation-care-investigation-review/102585936.)

Attachments:

- A. MSAC Application 1754.
- B. MSAC Executive Committee outcome for MSAC Application 1754

Minister	Minister Butler
PDR Number	MB23-002667
Subject	Department initiated brief - MSAC application 1754 - patient consultations and surgical procedures for gender affirmation in adults with gender incongruence
Contact Officer	Nigel Murray s22 s22
Clearance Officer	Daniel McCabe s22 s22
Division/Branch	Health Resourcing Medicare Benefits & Digital Health
Has Budget Branch been consulted if there are financial implications?	Choose an item
Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>

SENATE QUESTIONS ON NOTICE

Question Number: 2220
Date Asked: 05 July 2023
Tabling Due Date: 04 August 2023

Question:

SENATOR Pauline Hanson asked the Minister for Health and Aged Care upon notice, on 05 July 2023:

In an email, made public via FOI, (FOI 4366 – Released Document – Email to Minister Butler’s Office with quick points on gender dysphoria <https://www.health.gov.au/resources/foi-disclosure-log/foi-4366-released-document-email-to-minister-butlers-office-with-quick-points-on-gender-dysphoria>) from the Department to Minister Butler’s office on 30 November 2022 outlining ‘quick points on gender dysphoria that includes information pertaining to the use of puberty blockers and the care and treatment of young people experiencing gender dysphoria in Australia,’ there appears to be an incomplete reference.

In the document, on page 4, under item g. ‘whether puberty blockers are reversible as claimed,’ the advice provided by the Department is ‘puberty suppression relieves distress and is reversible in its effect’ this claim is accompanied by a footnote reference '5', however the corresponding footnote at the bottom of the document is blank.

Please provide the source intended to be referenced by the Department to support the claim puberty suppression is reversible in its effect.

Answer:

Minister Butler – The answer to the honourable senator's question is as follows:

The intended references to support the claim that puberty suppression is reversible in its effect are:

- Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2017;102:3869-3903. Available at www.academic.oup.com/jcem/article/102/11/3869/4157558?login=true
- Telfer MM, Tollit MA, Pace CC, Pang KC. Australian standards of care and treatment guidelines for transgender and gender diverse children and adolescents. Med J Aust. 2018;209: 132-136. Available at www.onlinelibrary.wiley.com/doi/full/10.5694/mja17.01044

- Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgender Health. 2022;23:sup1, S1-S259. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC9553112

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Parliamentary Questions on Notice Clearance Sheet

DETAILS	
Responsible Minister:	Minister Mark Butler
PDR Number:	PQ23-000063
Question Number:	2220
Senator	Pauline Hanson
Question Title:	Use of puberty blockers and the care and treatment of young people experiencing gender dysphoria
Due to Parl Coord:	20 July 2023
Due Date for Tabling:	04 August 2023
Division / Agency	Primary and Community Care Population Health
Contact SES Officer:	Name: Celia Street Work No: §22 Mobile No: §22
Contact Action Officer:	Name: Tiali Goodchild Work No: §22 Mobile No: §22
Date sent to MO	20 July 2023 (MPS Use Only)
MO Advisor	(MO Use Only)
Minister's Clearance:	Cleared / Not Cleared
	Minister's Signature _____ Date ____/____/____

Comments:

Senate Committee: Community Affairs Committee**QUESTION ON NOTICE****Budget Estimates 2023-2024****Outcome: 1 - Health Policy, Access and Support****PDR Number: SQ23-001148****Question Subject:** Gender affirming care and surgery**Type of Question:** Written**Senator:** Malcolm Roberts**Question:**

1. Is any medical procedure that would be used by a person who is transitioning commencing from the point of puberty blockers, covered by medicare? For clarity I am asking about the medical lifecycle of modern trans treatment including doctor's visits, specialists and surgeons, drugs used at any point in the process, medical devices used in surgery or patient care.
2. How much did these items cost the taxpayers in the latest period you have, 2022 would be good.
3. Is any medical procedure that would be used by a person de-transitioning, putting themselves back the way God made them, covered by medicare?

Answer:**1. *Pharmaceutical Benefits Scheme***

Medicines used in gender-affirming hormone therapy are available on the Pharmaceutical Benefits Scheme (PBS). Estrogen containing products are available in many cases as unrestricted benefits (PBS medicines can be prescribed by a doctor within their scope of practice for unrestricted health reasons) while testosterone containing products are mainly available as Authority Required listings (prior approval for prescription required from Services Australia or the Department of Veteran Affairs as appropriate).

Gonadotropin releasing hormone (GnRH) analogues (sometimes referred to as 'puberty blockers') are available on the PBS for the treatment of certain cancers and precocious puberty (early puberty). A PBS benefit is not currently available for the administration of GnRH analogues as part of a gender affirmation process.

Medicare Benefit Schedule - consultations

Medicare rebates are available for services listed on the Medicare Benefit Schedule (MBS) when a service has been deemed clinically relevant by a doctor for the treatment of their patient. There are a wide range of MBS services for GP, allied health and specialist patient consultations (for example, consultations with psychiatrists, paediatricians and endocrinologists) that may be billed as part of the gender affirmation process. These MBS items are used to support consultations for a wide range of health conditions, so there is no data about what proportion of these consultations relate to gender affirmation processes.

Medicare Benefit Schedule - surgical, and medical devices

Medicare rebates are available for surgical services listed on the Medicare Benefit Schedule (MBS) when a service has been deemed clinically relevant by a doctor for the treatment of their patient. There are a range of MBS services for surgical procedures (for example gynaecological, and plastic surgery procedures) and funding for devices may be covered by private health insurance as part of the gender affirmation process. These MBS procedural items may be used for a range of clinical reasons, not only gender affirmation processes.

2. It is not possible to provide the number of gender affirmation services funded through Medicare each year. There are no specific MBS items for gender affirmation services, and data for the billing of an MBS item generally does not include the reason why a consultation or procedure has been performed for an individual patient.

Similarly, it is not possible to determine through PBS claims data the number of medicines administered for the purpose of gender-affirming hormonal therapy, as the applicable medicines are used for a broad range of patient treatments.

3. There are MBS services that could be applicable if the patient's doctor deems a service to be clinically relevant to the care of the patient.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT (1982) (FOI)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2022-2023

Outcome: 2 - Individual Health Benefits

PDR Number: SQ23-001138

Question Subject: Concerns regarding the regulation of puberty blocker/cross sex hormone**Type of Question:** Written**Senator:** Matthew Canavan**Question:**

At least one private indemnity insurer has recognised that hormone treatment of minors in the private setting represents an incalculable and unacceptable risk and will not offer indemnity for this use of medicine.

3. Is the TGA aware of local and international concerns about the puberty blocker / cross sex hormone regime and the paucity of supporting evidence leading to a deliberate restriction on their use in numerous western nations?
4. If the TGA does not assume responsibility to regulate the use of these medications, who should the responsibility fall to?

Answer

The Therapeutic Goods Administration (TGA) is aware that the use of gender affirming care in minors is undertaken within strict clinical guidelines in most Western nations. One reason for this is to ensure medications for puberty suppression or gender affirming hormone treatment are not used inappropriately.

- The Royal Children's Hospital Melbourne have published the *Australian Standards of Care and Treatment Guidelines for trans and gender diverse children and adolescents* (2020)¹ (the Australian Guidelines) which outlines a comprehensive clinical assessment and decision framework for the use of puberty suppressing and gender affirming hormone agents for children and adolescents. They recommend an individualised approach in which the views of clinicians, the patient and their family are considered.

¹ www.rch.org.au/adolescent-medicine/gender-service/

- National guidelines in several countries are updated in order to optimise care for minors who may need puberty suppression and/or gender affirming hormone treatment. For example, the English NHS has recently provided updated guidance on the requirements for commissioning services providing gender affirming care to minors².
- The TGA is aware that a number of states in the USA have passed laws prohibiting or severely restricting access to gender affirming care for children and adolescents. However, this does not constitute a national consensus in the USA.
- The TGA notes that although medications used for puberty suppression or gender affirming hormone care are included in the Australian Register of Therapeutic Goods (ARTG), they are not approved for gender-affirming hormone care or treatment of gender dysphoria, and are therefore being used 'off-label'. These include medicines containing leuporelin acetate, which are approved for the treatment of children with central precocious puberty (see SQ23-001187).
- Off label prescribing is a clinical decision made at the discretion of the prescriber who is responsible for obtaining informed consent from their patient or patient's guardian. Informed consent takes into account the risks and benefits of that treatment verses other available treatments or no treatments at all, based on the individual circumstances.
- The TGA does not regulate the use of therapeutic goods or clinical practice, and does not generally provide advice or input into clinical guidelines.
- Medical practitioners who engage in 'off label' prescribing are required to do so in accordance with Good Medical Practice, the code of conduct published by the Medical Board of Australia, which regulates practitioners in partnership with the Australian Health Practitioner Regulation Agency (AHPRA) to ensure public safety.
- The appropriateness of clinical decision making is also overseen by a number of authorities. This includes organisations involved in accrediting practitioners (such as AHPRA), setting hospital care standards (such as state and territory health departments) and the specialist training organisations for clinicians (such as the Royal Australasian College of Physicians).

² www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/implementing-advice-from-the-cass-review/

Senate Estimates Questions on Notice Clearance Sheet

DETAILS	
Responsible Minister:	Minister Mark Butler
Hearing:	Budget Estimates
Committee:	Community Affairs Committee
Senator:	Matthew Canavan
PDR Number:	SQ23-001138
Topic:	Concerns regarding the regulation of puberty blocker / cross sex hormone
Due to Parl Coord:	22 June 2023
Due Date to Cttee:	14 July 2023
Division/Agency:	Health Products Regulation Medicines Regulation
Contact SES Officer:	Name: Tracey Duffy Work No: §22 Mobile No: §22
Contact Action Officer:	Name: Andrew Simpson Work No: §22 Mobile No: §22
Date sent to MO	28 June 2023 (MPS Use Only)
MO Advisor	(MO Use Only)
Noted in Minister's Office:	Noted
	Signature _____ Date ____/____/____

Comments:

Senate Committee: Community Affairs Committee**QUESTION ON NOTICE****Budget Estimates 2022-2023****Outcome: 1 - Health Policy, Access and Support****PDR Number: SQ23-001187****Question Subject:** Puberty blocking agents - Lupron and leuprorelin**Type of Question:** Spoken, Hansard page 97, 01 June 2023**Senator:** Matthew Canavan**Question:**

Senator CANAVAN: I think they've exhausted that. They are trying, these people that we've spoken to, but they're just struggling there. I just want to move on to—I'm not sure what area this would come into. It's hard to know. I wanted to ask about the use of puberty-blocker drugs and ongoing controversies around that.

Professor Murphy: Puberty blocking agents?

Senator CANAVAN: Yes. Some of them may wait for the TGA later but there's a broader question here. I'm not sure if you saw the reporting on the weekend. There have been reports that some eminent legal professionals have written to the Family Court, or a court, I think in New South Wales, saying that the previous Family Court decisions on these matters, have not properly taken into account medical advice, and they're seeking courts to reopen the investigations here, especially given conclusions around Tavistock over in the United Kingdom and other developments. Is there any work being done in the department of health about the latest evidence on the long-term impacts of the use of puberty blockers, especially for adolescent or pre-adolescent children?

Professor Murphy: No specific work. This is a really challenging and contested area, and we've certainly discussed it at estimates in the past. I think our position is that where these services are provided by very expert multidisciplinary clinic services, such as the Royal Children's in Melbourne, we have to rely on the best clinical advice we have. We have concerns like some of those reviews expressed in the media, that where individual practitioners are undertaking this sort of therapy outside of that comprehensive multidisciplinary clinic strategy—but even within a service such as the Royal Children's Hospital, which is probably the largest one in Australia, it is a highly contested area. Again, the Commonwealth department doesn't really have a policy role in how health services—they have their own governance structures that look at those things. We certainly provide MBS and PBS funding. We'd have to take on notice which of those drugs might be on the PBS for—

Senator CANAVAN: In particular I want to ask about Lupron or—it goes by different names; there's also leuporelin. It's a drug primarily to treat prostate cancer and some other cancers.

Professor Murphy: Yes. It's an androgen blocker.

Senator CANAVAN: So you're aware of that and I'm getting it right to some degree. Has that been approved for use to block or stop or limit puberty development by the TGA?

Professor Murphy: You'd have to take that question to the TGA about whether what its registration is. I don't think you would know, Ms Shakespeare, would you?

Answer:

- Three products containing the active ingredient leuporelin acetate have been approved by the Therapeutic Goods Administration (TGA) and included in the Australian Register of Therapeutic Goods (ARTG).
- Two of these products, Eligard and Lucrin Depot, have been approved to treat children with Central precocious puberty (CPP) and prostate cancer. The third, Bi Eligard is approved only for the treatment of prostate cancer. Further information about approved indications for these medicines are listed below.
- As mentioned, two of the medicines containing leuporelin acetate are included in the ARTG for the treatment of children with CPP, which refers to early activation of the hypothalamic-pituitary-gonadal (HPG) axis.
- Precocious puberty refers to development of puberty that occurs earlier than normal, for example when puberty begins before the age of 8 years in girls, and before the age of 9 years in boys.
- These medicines are not approved for limiting normal puberty development or for gender-affirming hormone care – please also see response to SQ23-001138.

Medicines containing leuporelin acetate

1. Eligard

Prostate cancer indications:

- palliative treatment of advanced prostate cancer
- treatment of high-risk localised and locally advanced hormone-dependent prostate cancer in combination with radiotherapy

Central precocious puberty (CPP) indications:

- Treatment of children 2 years of age and older with CPP

2. Lucrin Depot and Lucrin Depot Paediatric PDS injection

Lucrin Depot

- Palliative treatment of metastatic or locally advanced prostate cancer

Lucrin Depot Paediatric 3-Month

- Treatment of children with CPP

3. Bi Eligard composite pack (comprised bicalutamide tablets and leuprorelin injections)

- bicalutamide is indicated for treatment of advanced prostate cancer in combination with LHRH agonist therapy
- leuprorelin is indicated for the palliative treatment of advanced prostate cancer

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Senate Estimates Questions on Notice Clearance Sheet

DETAILS	
Responsible Minister:	Minister Mark Butler
Hearing:	Budget Estimates
Committee:	Community Affairs Committee
Senator:	Matthew Canavan
PDR Number:	SQ23-001187
Topic:	Puberty blocking agents - Lupron and leuprorelin
Due to Parl Coord:	28 June 2023
Due to Committee:	14 July 2023
Division / Agency:	Health Products Regulation Medicines Regulation
Contact SES Officer:	Name: Andrew Simpson Work No: [REDACTED] Mobile No: [REDACTED]
Contact Action Officer:	Name: Tracey Duffy Work No: [REDACTED] Mobile No: [REDACTED]
Date sent to MO	11 July 2023 11 July 2023 (MPS Use Only)
MO Advisor	(MO Use Only)
Noted in Minister's Office:	Noted Signature_____ Date ____/____/____

Comments:



Australian Government

Department of Health and Aged Care

Information Brief

MB23-001628

Version (1)

Date sent to MO: 30/05/2023

To: Minister Butler

cc: Assistant Minister Kearney

Subject: MDA national changed indemnity insurance policy conditions on gender affirming treatment for minors

Comments:			
Contact Officer:	Nigel Murray	Assistant Secretary, MBS Policy and Specialist Programs Branch, MBD&DH Division	Ph: s22 Mobile: s22
Clearance Officer:	Daniel McCabe	First Assistant Secretary, Medical Benefits and Digital Health Division	Ph: s22 Mobile: s22

Key Issues:

- On 23 May 2023, Ms Nicky Bath, Chief Executive Officer of LGBTIQ Health Australia, emailed Minister Butler's Office to highlight changes to MDA National's medical indemnity policy. The changed policy inserts an exclusion for claims "arising from aspects of gender transitioning treatment for under 18-year-olds".
- The proposed policy states:

We will not cover you or make payment under your Policy when:

26.28 the claim against you arises in any way out of:

- your assessment that a patient under the age of 18 years is suitable for gender transition; or*
- you initiating prescribing of gender affirming hormones for any patient under the age of 18 years.*

- On 23 May 2023, Mr Ian Anderson, Chief Executive Officer of MDA National (MDAN), (a mutual organisation providing indemnity insurance to its members) advised the Department that its members had expressed a number of concerns about the significantly increased demand that has created pressure on GPs to prescribe cross sex hormones. These concerns include:

- whether the usual consent will be sufficient for children given the life changing, permanent effects of such procedures; and
 - in the event of a claim, the reliance on medical opinion influencing a minor's permanent lifelong decision.
4. This caused MDAN to investigate the underwriting risk of potential claims for gender treatment of minors. MDAN concluded that they are unable to:
 - quantify (and price) the risk, quantum, and frequency of claims; or
 - source appropriate data, despite seeking data sources in the United Kingdom and other European countries.
 5. The results of this investigation prompted the MDAN decision to change their medical indemnity cover in respect of treatment for gender issues of minors. Mr Anderson stressed that restructuring the policy in its current form is purely an underwriting decision and is not based on any medical ethic viewpoint.
 6. Mr Anderson has clarified that the MDAN exclusion does not apply to GPs prescribing puberty blockers, including repeat prescriptions, for the first phase of treatment for gender transition. The exclusion applies to the prescription of cross-sex hormones as part of the second phase of treatment but does not extend to the provision of repeat prescriptions of cross-sex hormones.
 7. MDAN is limiting the restriction to claims arising in relation to services provided to minors (under 18); a cohort they consider would potentially generate the highest number of claims. The change will take effect from 1 July 2023.
 8. MDAN is still receiving a variety of feedback from its members. Mr Anderson advised that some members forwarded an email they received from AusPath (the Australian Professional Association for Trans Health) to MDAN in which AusPath expressed its disappointment in MDAN's decision and indicated that they were intending to challenge the exclusion. MDAN believe the way AusPath described their position is factually incorrect and are continuing to communicate with their members as to the effect of the exclusion. Some members have expressed concern about this area of practice and support the MDAN decision. A small handful of members have expressed disappointment with the position and have signalled they will move to another insurer.
 9. Should an insured doctor object to the exclusion policy included in MDA National's policy, the onus would be on the doctor to find another insurer given it is a condition of their registration that they must hold medical indemnity insurance to practise.
 10. While the MDAN has not received any claims on this issue, they are aware of claims emerging with other indemnifiers in Australia and overseas although none appear to be contemplating a similar policy change at present.

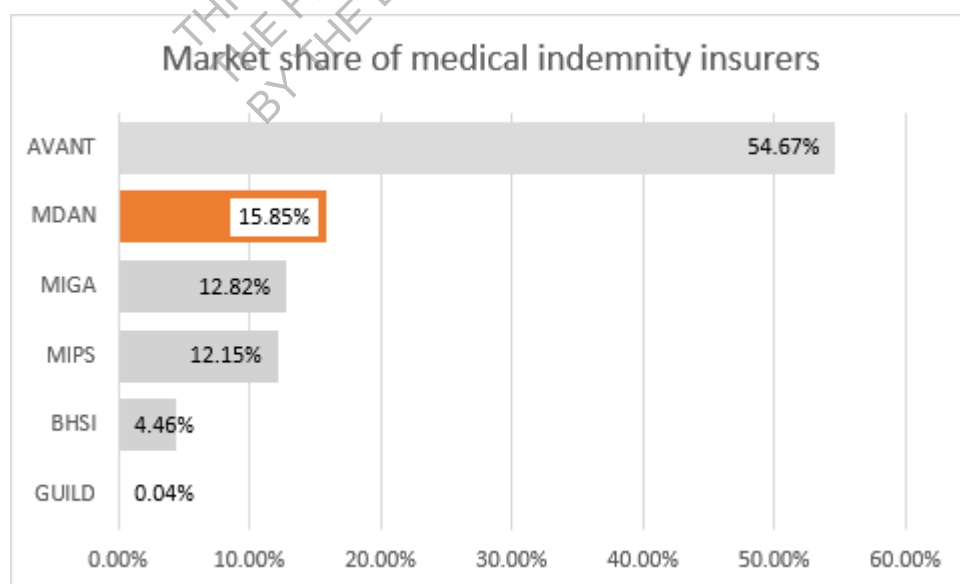
Medical professional standards

11. There are no Medical Board of Australia (MBA) issued professional standards that relate to specific treatments or care. There is, however, more generic advice and Guidelines, as discussed in point 13 below, that relates to what is considered good medical practice. The MBA would rely on these guidelines if medical board intervention was required.

12. The MBA's Good Medical Practice: a code of conduct for doctors in Australia (Code) requires doctors to work within their scope of practice, have adequate knowledge and skills to provide safe clinical care and provide treatment options based on the best available information.
13. In determining what is safe clinical care and what is the best available evidence, doctors should have regard to relevant Australian standards of care.
14. The Australian standards of care and treatment guidelines for transgender and gender diverse children and adolescents clearly outlines the role of the GPs in the assessment and care of adolescents with gender dysphoria.
15. The role of the GP includes:
 - Provision of information and education to the adolescent and their parents/carers regarding options for medical transitioning including risks and benefits of puberty suppression and gender affirming hormones.
 - Prescribing and administration of medication for puberty suppression or gender affirming hormones in collaboration with a paediatrician, adolescent physician, or paediatric endocrinologist.
16. The Code also requires that doctors refer a patient to appropriate treatment and care elsewhere if they are unable to provide the treatment/care themselves (whether due to limited scope of practice, inability to prescribe or personal objections to providing care).
17. MDAN has advised that a number of its members with experience in gender affirming treatments consider that the best model of care for the assessment and treatment of children is within a multi-disciplinary team with the resources and supports of a significant hospital.

Background:

18. MDAN is a mutual medical defence organisation, established in 1925. Mr Anderson also Chairs the Insurance Council of Australia Medical Indemnity Committee.
19. The table below illustrates the market shares of the six private underwriters (insurers) calculated by the Australian Government Actuary for the 2021-22 financial year.



Budget/Financial Implications:

Nil

Impact on Rural and Regional Australians:

This policy change will impact on individuals under 18 seeking gender transforming treatment throughout Australia.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Minister	Minister Butler
PDR Number	MB23-001628
Subject	**URGENT one day turnaround** Department Initiated Information Brief: MDA National changed policy on gender affirming treatment for minors
Contact Officer	Nigel Murray s22 s22
Clearance Officer	Daniel McCabe s22 s22
Division/Branch	Health Resourcing Medicare Benefits & Digital Health

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

OFFICIAL – COMMERCIAL-IN-CONFIDENCE



Australian Government

Department of Health and Aged Care

Information Brief

MB23-001628

Version (1)

Date sent to MO: 30/05/2023

To: Minister Butler

cc: Assistant Minister Kearney

Subject: MDA national changed indemnity insurance policy conditions on gender affirming treatment for minors

Comments:

Noted
[Signature]
5/6

Contact Officer:	Nigel Murray	Assistant Secretary, MBS Policy and Specialist Programs Branch, MBD&DH Division	Ph: s22 [REDACTED] Mobile: s22 [REDACTED]
Clearance Officer:	Daniel McCabe	First Assistant Secretary, Medical Benefits and Digital Health Division	Ph: s22 [REDACTED] Mobile: s22 [REDACTED]

Key Issues:

- On 23 May 2023, Ms Nicky Bath, Chief Executive Officer of LGBTIQ Health Australia, emailed Minister Butler's Office to highlight changes to MDA National's medical indemnity policy. The changed policy inserts an exclusion for claims "arising from aspects of gender transitioning treatment for under 18-year-olds".

- The proposed policy states:

We will not cover you or make payment under your Policy when:

26.28 the claim against you arises in any way out of:

- your assessment that a patient under the age of 18 years is suitable for gender transition; or*
- you initiating prescribing of gender affirming hormones for any patient under the age of 18 years.*

- On 23 May 2023, Mr Ian Anderson, Chief Executive Officer of MDA National (MDAN), (a mutual organisation providing indemnity insurance to its members) advised the Department that its members had expressed a number of concerns about the significantly increased demand that has created pressure on GPs to prescribe cross sex hormones. These concerns include:

OFFICIAL

OFFICIAL

- whether the usual consent will be sufficient for children given the life changing, permanent effects of such procedures; and
 - in the event of a claim, the reliance on medical opinion influencing a minor's permanent lifelong decision.
4. This caused MDAN to investigate the underwriting risk of potential claims for gender treatment of minors. MDAN concluded that they are unable to:
 - quantify (and price) the risk, quantum, and frequency of claims; or
 - source appropriate data, despite seeking data sources in the United Kingdom and other European countries.
 5. The results of this investigation prompted the MDAN decision to change their medical indemnity cover in respect of treatment for gender issues of minors. Mr Anderson stressed that restructuring the policy in its current form is purely an underwriting decision and is not based on any medical ethic viewpoint.
 6. Mr Anderson has clarified that the MDAN exclusion does not apply to GPs prescribing puberty blockers, including repeat prescriptions, for the first phase of treatment for gender transition. The exclusion applies to the prescription of cross-sex hormones as part of the second phase of treatment but does not extend to the provision of repeat prescriptions of cross-sex hormones.
 7. MDAN is limiting the restriction to claims arising in relation to services provided to minors (under 18); a cohort they consider would potentially generate the highest number of claims. The change will take effect from 1 July 2023.
 8. MDAN is still receiving a variety of feedback from its members. Mr Anderson advised that some members forwarded an email they received from AusPath (the Australian Professional Association for Trans Health) to MDAN in which AusPath expressed its disappointment in MDAN's decision and indicated that they were intending to challenge the exclusion. MDAN believe the way AusPath described their position is factually incorrect and are continuing to communicate with their members as to the effect of the exclusion. Some members have expressed concern about this area of practice and support the MDAN decision. A small handful of members have expressed disappointment with the position and have signalled they will move to another insurer.
 9. Should an insured doctor object to the exclusion policy included in MDA National's policy, the onus would be on the doctor to find another insurer given it is a condition of their registration that they must hold medical indemnity insurance to practise.
 10. While the MDAN has not received any claims on this issue, they are aware of claims emerging with other indemnifiers in Australia and overseas although none appear to be contemplating a similar policy change at present.

Medical professional standards

11. There are no Medical Board of Australia (MBA) issued professional standards that relate to specific treatments or care. There is, however, more generic advice and Guidelines, as discussed in point 13 below, that relates to what is considered good medical practice. The MBA would rely on these guidelines if medical board intervention was required.

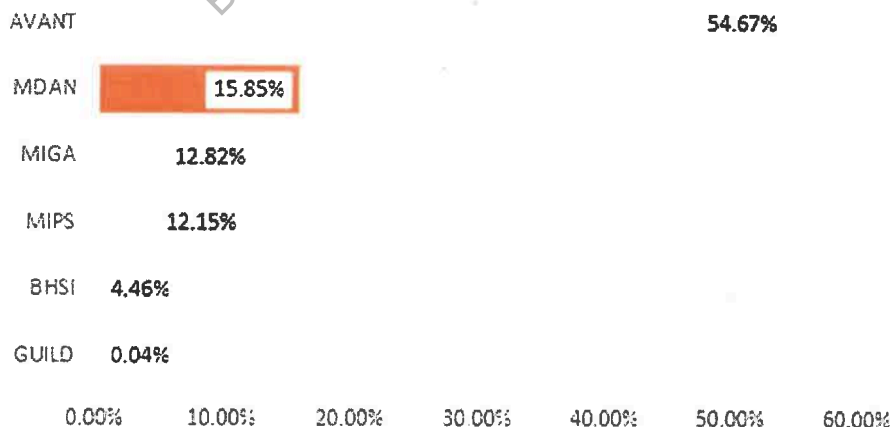
OFFICIAL

12. The MBA's Good Medical Practice: a code of conduct for doctors in Australia (Code) requires doctors to work within their scope of practice, have adequate knowledge and skills to provide safe clinical care and provide treatment options based on the best available information.
13. In determining what is safe clinical care and what is the best available evidence, doctors should have regard to relevant Australian standards of care.
14. The Australian standards of care and treatment guidelines for transgender and gender diverse children and adolescents clearly outlines the role of the GPs in the assessment and care of adolescents with gender dysphoria.
15. The role of the GP includes:
 - Provision of information and education to the adolescent and their parents/carers regarding options for medical transitioning including risks and benefits of puberty suppression and gender affirming hormones.
 - Prescribing and administration of medication for puberty suppression or gender affirming hormones in collaboration with a paediatrician, adolescent physician, or paediatric endocrinologist.
16. The Code also requires that doctors refer a patient to appropriate treatment and care elsewhere if they are unable to provide the treatment/care themselves (whether due to limited scope of practice, inability to prescribe or personal objections to providing care).
17. MDAN has advised that a number of its members with experience in gender affirming treatments consider that the best model of care for the assessment and treatment of children is within a multi-disciplinary team with the resources and supports of a significant hospital.

Background:

18. MDAN is a mutual medical defence organisation, established in 1925. Mr Anderson also Chairs the Insurance Council of Australia Medical Indemnity Committee.
19. The table below illustrates the market shares of the six private underwriters (insurers) calculated by the Australian Government Actuary for the 2021-22 financial year.

Market share of medical indemnity insurers



Budget/Financial Implications:

Nil

Impact on Rural and Regional Australians:

This policy change will impact on individuals under 18 seeking gender transforming treatment throughout Australia.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

**Australian Government****Department of Health and Aged Care****Ministerial Information Request****MB23-000709****Version (1)****Date sent to MO: 7/03/2023****To: Assistant Minister Kearney****cc: Minister Butler****Subject/Issue: MIR: RCH Gender Clinic (Dreyfus MP obo §47F)**

Comments:			
Contact Officer:	<i>Tiali Goodchild</i>	<i>Assistant Secretary, Health Equity Branch, Population Health Division</i>	Ph: §22 Mobile: §22
Clearance Officer:	<i>Celia Street</i>	<i>First Assistant Secretary, Population Health Division</i>	Ph: §22 Mobile: §22

Key Government Initiatives

- The Australian Government recognises the challenges the LGBTIQ+ community may experience in accessing health care. The Government acknowledges these individuals have unique and often complex health needs and are at an increased risk of poorer physical and mental health outcomes compared to the general population.
- The Government has announced the development of a 10 Year National Action Plan for the Health and Wellbeing of LGBTIQ+ people to provide guidance on reforms needed to make improvements across the health system.
 - The Action Plan will be designed with the support of an Expert Advisory Group and national consultations focused on understanding health priorities of the LGBTIQ+ community including trans and gender diverse children and young people.
- The Government also announced a \$26 million investment in health and medical research (through the Medical Research Future Fund) focusing on LGBTIQ+ communities. The intended outcome of the research funded by this grant opportunity is to improve the health and wellbeing of Australians by improving the physical and mental health of:
 - sexuality diverse people including those who live in regional, remote and rural areas;

- sexuality and/or gender diverse people experiencing intersectional disadvantage;
- transgender and gender diverse children, adolescents and young adults; and
- people born with innate variations of sex characteristics.

Background Gender Support Services

- The provision of care for gender services is led by Australian states and territories.
- Specialist gender services across a number of jurisdictions provide care to young people based on a multidisciplinary approach tailored to individual circumstances and needs. Decisions regarding clinical care are shared between the clinicians, the young person and their family.
- Supporting children experiencing gender dysphoria requires a developmentally appropriate approach that is safe, supportive and holistic.
- This support requires an understanding of the child and their family through a comprehensive exploration of the child's developmental history, gender identity, emotional functioning, intellectual and educational functioning, peer and other social relationships, family functioning as well as immediate and extended family support, in a safe and therapeutic environment (based on the Australian Standards of Care and Treatment Guidelines for trans and gender diverse children and adolescents).
- Individual practitioners, including paediatricians, psychiatrists and clinical psychologists provide treatment and care in the private sector, and may be accessed through referral from a General Practitioner. A number of practitioners have a special interest in this area and bring additional expertise.
- The clinical treatment of children and adolescents experiencing gender dysphoria is a complex and evolving area in which it is recognised that longer term evidence to inform treatment protocols is still developing and research continues to grow.

Minister	Assistant Minister Kearney
PDR Number	MB23-000709
Subject	MIR: RCH Gender Clinic (Dreyfus MP obo ^{s47F})
Contact Officer	Tiali Goodchild Ph: ^{s22} Mobile: ^{s22}
Clearance Officer	Celia Street Ph: ^{s22} Mobile: ^{s22}
Division/Branch	Primary and Community Care Population Health

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTF)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

s22

From: s22
Sent: Wednesday, 30 November 2022 11:03 AM
To: s22
Cc: s22; s47E(d)
Subject: FW: URGENT - FW: Standing order 77 letter received (Senator Hanson) [SEC=OFFICIAL]
Attachments: SKM_C3350i22112918490.pdf
Importance: High

FYI all for your records, we will head back to the office now.

From: s22
Sent: Wednesday, 30 November 2022 11:02 AM
To: s47E(d); s22 @Health.gov.au; s22 @health.gov.au'
 s22 @health.gov.au>
Cc: STREET, Celia <s22 @health.gov.au>; GOODCHILD, Tiali <s22 @health.gov.au>; s47E(d)
 s47E(d) @health.gov.au; s47E(d) @health.gov.au>
Subject: FW: URGENT - FW: Standing order 77 letter received (Senator Hanson) [SEC=OFFICIAL]
Importance: High

Hi s22

Sorry for the delay. We suggest using [MB22-003296](#) which includes talking points and background on the key issues.

Also suggest relying heavily on the RACP 2020 advice if possible, it is outlined in the brief and available here [racp-letter-hon-greg-hunt-minister-for-health-gender-dysphoria-in-children-and-adolescents.Pdf](#)

Let us know if you need additional input. Celia and Tiali are in other meetings, but have agreed this approach.

Kind regards,

s22

**Director – Preventive Policy Section
 Health Equity Branch**

Population Health Division | Primary and Community Care Group
 Australian Government, Department of Health and Aged Care
 T: s22 @health.gov.au

Location: s22

PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Sent from [WorkSpace ONE Boxer](#)

----- Forwarded message -----

From: s47E(d) [redacted] <[redacted]@Health.gov.au>

FOI 4713 Document 15

Date: 30 November 2022 at 9:46:40 am AEDT

Subject: URGENT - FW: Standing order 77 letter received (Senator Hanson) [SEC=OFFICIAL]

To: GOODCHILD, Tiali <[redacted]@health.gov.au>, [redacted]
[redacted] <[redacted]@Health.gov.au>

Hi [redacted]

Further to our chat just now, the MO needs the below by 10.45 pls. Happy for a direct email back to me and [redacted]

Kind regards

[redacted]

Departmental Liaison Officer

Office of the Hon Mark Butler MP

Minister for Health and Aged Care

E: [redacted] <[redacted]@health.gov.au> T: [redacted]

T: [redacted]

Suite [redacted] PO Box 6022

Parliament House, Canberra ACT 2600

From: [redacted] <[redacted]@health.gov.au>

Sent: Wednesday, 30 November 2022 9:45 AM

To: [redacted] <[redacted]@Health.gov.au>

Cc: [redacted] <[redacted]@Health.gov.au>, [redacted] <[redacted]@Health.gov.au>

Subject: FW: Standing order 77 letter received (Senator Hanson) [SEC=OFFICIAL]

As discussed, we are after high level TPs on the Government's response to the attached motion (max 1 page) by 10:45 p.m. I am available to chat by at 10 a.m.

Kindly,

[redacted]

Parliamentary and Budget Adviser

Office of the Hon Mark Butler MP

Minister for Health and Aged Care

T: [redacted]

E: [redacted] <[redacted]@health.gov.au>

Suite [redacted] PO Box 6022

Parliament House, Canberra ACT 2600

[redacted]

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE



s22

From: STREET, Celia
Sent: Wednesday, 30 November 2022 1:56 PM
To: s47E(d)
Cc: GOODCHILD, Tiali; s22 s22 s47E(d)
Subject: Gender dysphoria - response points [SEC=OFFICIAL]
Attachments: Gender dysphoria - response points.docx

Hi s22

Please find attached quick points on gender dysphoria as requested.

Thanks to the team.

Happy to discuss

Kind regards

Celia

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

The use of puberty blockers in Australia, with particular reference to:

- a. the causes of the increase in rapid onset of gender dysphoria in children, including friendship groups, peer contagion, gender clinic staff and social media;**
 - An increase in onset of gender dysphoria has been observed around the world. The causes are unknown.
 - While there is an increase in younger people presenting with gender dysphoria, the existence of 'rapid onset gender dysphoria' is disputed and is not a formal diagnosis.
 - A public inquiry will not increase the evidence available to understand the cause of the increase.
 - A better way forward would be to progress research on the long-term outcomes of the care and treatment of gender dysphoria. I have asked my Department to explore opportunities for this research to be undertaken.
- b. the experiences of parents of young people who have been prescribed puberty blockers, including their experience with the medical system;**
 - In Australia, treatment for gender dysphoria is a matter for young people and their parents or guardians to agree and consent to, in consultation with their clinicians. If there is a disagreement about the diagnosis, treatment or capacity of the minor to provide informed consent, the family court has ruled this requires an application to the court to resolve the dispute consistent with the child's best interests.
 - In Australia, specialist gender services across a number of jurisdictions provide care to young people that is based on a multidisciplinary approach that is tailored to individual circumstances and needs. Puberty blocking treatments are prescribed after a thorough multidisciplinary clinical and psychosocial assessment and a careful and well documented consent process which includes provision of information about potential benefits and side effects.
- c. the experiences of young people who have been prescribed puberty blockers, including their experience with the medical system;**
 - See response for b.
 - There are differences between the mental health and wellbeing of transgender and gender diverse people and cisgender people. Transgender people aged 14-25 are fifteen times more likely to have attempted suicide.¹ 48.1% of transgender and gender diverse people aged 14 to 25 reported they had attempted suicide in their lifetime.²
 - Evidence suggests that trans children who have socially transitioned demonstrate rates of depression, anxiety and self-worth comparable to their cisgender peers.³⁴

¹https://assets.nationbuilder.com/lgbtihealth/pages/549/attachments/original/1648014801/24.10.21_Snapsh of MHSP Statistics for LGBTIQ People - Revised.pdf?1648014801

² Strauss, P., Cook, A., Winter, S., Watson, V., Wright Toussaint, D., & Lin, A. (2017). Trans pathways: The mental health experiences and care pathways of trans young people. Summary of results. Telethon Kids Institute;

³ Olson K, Durwood L, DeMeules M, McLaughlin K. Mental health of transgender children who are supported in their identities. *Pediatrics*. 2016;137(3):e20153223. Cited from the Australian Standards of Care and Treatment Guidelines For trans and gender diverse children and adolescents.

⁴ 4. Durwood L, McLaughlin KA, Olson KR. Mental health and self-worth in socially transitioned transgender youth. *J Am Acad Child Adolesc Psychiatry*. 2017;56(2):116-123 e112. Cited from the Australian Standards of Care and Treatment Guidelines For trans and gender diverse children and adolescents.

- The number of children in Australia who later socially transition back to their gender assigned at birth is not known, but anecdotally appears to be low and no current evidence of harm in doing so exists.

d. the medical oversight of general practitioners prescribing puberty blockers;

- In Australia, decisions on clinical care are shared between clinicians, the young person and their family. Care to young people is based on a multidisciplinary approach, tailored to individual circumstances and needs.
- Puberty blocking treatments are prescribed after a thorough multidisciplinary clinical and psychosocial assessment and a careful and well documented consent process which includes provision of information about potential benefits and side effects.
- For patients under 16 years of age consideration of puberty blockers generally occurs in a tertiary setting and is considered by a multidisciplinary specialist team.
- General practitioners would typically be involved as part of the multidisciplinary team.

e. the results of longitudinal studies of young people prescribed puberty blockers;

- Research shows that puberty suppression typically relieves distress for young people experiencing gender dysphoria.
- The main concern with the use of puberty blockers is the possible impact on bone mineral density. Bone mineral density is measured at the commencement of treatment and monitored throughout treatment.
- A public inquiry will not increase the evidence available to comprehensively understand the health and wellbeing outcomes of young people prescribed puberty blockers.

f. whether the decision of the England and Wales High Court in Bell v Tavistock[2020] EWHC 3274, which held that it was highly unlikely that a child under the age of 16 could give consent to being prescribed puberty blockers, should apply in Australia;

- There are different care pathways in Australia as compared with the UK. Specialist gender services across a number of Australian jurisdictions provide care to young people based on a multidisciplinary approach, tailored to individual circumstances and needs.
- In Australia, treatment for gender dysphoria is a matter for young people and their parents or guardians to agree and consent to, in consultation with their clinicians. If there is a disagreement about the diagnosis, treatment or capacity of the minor to provide informed consent, the family court has ruled this requires an application to the court to resolve the dispute consistent with the child's best interests.

Background

- In September 2020, the National Health Service (NHS) England commissioned an independent review, led by Dr Hillary Cass, of gender identity services for children and young people.
- Dr Cass' recommendations emphasised the need to move away from the current model of a sole provider, and to establish regional services that provide holistic clinical care, better support for multidisciplinary care and which address prolonged waiting lists in the United Kingdom.
- In response, the NHS is moving to establish two Early Adopter services by mid-2023. The services will be led by specialist children's hospitals. Once established, they will assume clinical responsibility for and management of all patients at the Tavistock clinic – including those on the waiting list – as part of a managed transition.

g. whether puberty blockers are reversible as claimed;

- Puberty suppression relieves distress and is reversible in its effects.⁵

h. whether affirming gender dysphoria as a primary condition is always helpful in the absence of investigating prior trauma, mental illness and other conditions; and

- Gender dysphoria is a term used to describe the distress experienced by a person when their gender identity is different from their sex at birth.
- Care to young people is based on a multidisciplinary approach, tailored to individual circumstances and needs.
- Prior trauma, mental illness and other conditions would be considered in the clinical and psychosocial evaluation of a young person presenting with gender dysphoria.

i. any other related matters.

Details on the clinical standards in place in states and territories, especially around consent

- The Australian Standards of Care and Treatment Guidelines For trans and gender diverse children and adolescents (Ver 1.3) have been developed and endorsed by the Australian Professional Association for Trans Health (AusPATH).
- These standards aim to maximise quality and care provision to trans and gender diverse children and adolescents across Australia. The recommendations are based on available evidence including clinical consensus and were developed in consultation with professionals from multiple disciplines working with these young people across Australia and New Zealand, as well as young people and their families.
- The Standards provide a detailed outline of the roles of each member of the multidisciplinary team, for example, mental health professionals, paediatricians, adolescent physicians or endocrinologists, GPs, nurses and bioethicists and some allied health professionals.

Arguments and evidence that demonstrate no connection to autism or other conditions

- The AusPATH Standards of Care acknowledge that Autism Spectrum Disorder (ASD) has been demonstrated to be associated with gender diversity and many children presenting to specialist gender services have co-existing ASD.
- A diagnosis of ASD will be taken into account in the therapeutic approach for young people experiencing gender dysphoria.
- Clinical guidelines for the management of co-existing ASD and gender dysphoria are available.⁶

Possible harm caused to trans kids through public inquiries

- The RACP has advised Government of a need for caution in relation to a national inquiry.
- A national inquiry would not increase the scientific evidence available regarding gender dysphoria but would further harm already vulnerable patients and their families through increased media and public attention.
- Considerations of care and treatment of medical conditions should be based on medical evidence and advice from medical and other health professionals who have specific expertise in the condition in question, as well as the affected patient population.

⁵

⁶ Strang JF, Meagher H, Kenworthy L, et al. Initial clinical guidelines for co-occurring autism spectrum disorder and gender dysphoria or incongruence in adolescents. J Clin Child Adolesc Psychol. 2018;47(1):105-115



Australian Government

Department of Health and Aged Care

Event Brief

MB22-003386

Version (1)

Date sent to MO: 11/11/2022

To: Assistant Minister Kearney

cc: Minister Butler

Subject: EVENT BRIEF + SPEECH - THE DREAMLIFE OF GEORGIE STONE

Comments:			
Contact Officer:	Tiali Goodchild	Assistant Secretary, Health Equity Branch, Population Health Division	Ph: s22 Mobile: s22
Clearance Officer:	Celia Street	First Assistant Secretary, Population Health Division	Ph: s22 Mobile: s22

Date / Time: Tuesday 22 November 2022, 5.00-7.30pm AEST

Meeting Type/Location: Australian Parliament House, Main Committee Room

Traditional Custodians: Ngunnawal and Ngambri peoples

Purpose: To hear about the needs of trans and gender diverse Australians and to indicate the Government's support for this LGBTIQ+ community at a screening of the documentary *The Dreamlife of Georgie Stone*.

Desired Outcomes: To acknowledge Georgie Stone and other panel members' contribution to improve the wellbeing of trans and gender diverse people and convey the Government's commitment to work in partnership with the LGBTIQ+ community to improve health outcomes.

Key Attendees/Speakers:	Title:	Organisation	Mobile number
Maya Newell (she/her) (Event Organiser)	Director and Producer	Unquiet Collective	Not provided
Jeremy Wiggins (he/him)	CEO	Transcend Australia	s47F
Georgie Stone (she/her)	OAM	Patron, Transcend Australia	
Rebekah Robertson (she/her)	OAM	Founder, Transcend Australia	
Michelle Telfer (she/her)	Associate Professor	Director, Gender Service Royal Children's Hospital Melbourne	
Eloise Brook (she/her)	Dr	NSW Gender Centre	
Rosalind Croucher	Emeritus Professor	President, Australian Human Rights Commission	

Louise Pratt (she/her)	Senator	Senator for Western Australia	
Zoe Daniel (MP) (she/her)	Ms	Member for Goldstein	

Biographies are at [Attachment A](#).

Key Matters/Issues:

- The documentary and the associated campaign seek to raise awareness of the importance of gender affirming health care, the challenges in accessing care and to build support for public access to gender services and gender affirming health care for trans, gender diverse and non-binary young people in Australia.
- Trans and gender diverse children and their families are a particularly disadvantaged cohort of the LGBTIQ+ community and it is important to ensure they have access to appropriate care and support.
- The Australian Government wants to achieve improved access to care and support and better health, mental health, and wellbeing outcomes for the LGBTIQ+ community, including the trans and gender diverse community.
- The Government is committed to working in partnership with the LGBTIQ+ community, on the unique health issues and barriers to access that LGBTIQ+ Australians face to ensure future action is informed by the lived experience of the diverse LGBTIQ+ population.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (FOI)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Discussion Guide:

You have been invited to respond to the film and share the Government's approach and considerations on access to health care for trans and gender diverse young people. A speech has been prepared for you to deliver at Attachment B.

- Promoting health equity and delivering better outcomes for all Australians, including the LGBTIQ+ community is a priority for the Government.
- The Government is investing in measures to increase support and better understand the needs of LGBTIQ+ Australians including:
 - a national consultation with LGBTIQ+ people, in partnership with community-led organisations supported by one-off funding, to consult on the unique health and mental health issues and barriers to access and care faced by LGBTIQ+ Australians; and
 - funding to boost QLife's peer support workforce to help them to reach more LGBTIQ+ Australians.
- The measures aim to acknowledge, prioritise, and address the unique needs and lived experience of LGBTIQ+ communities and the health disparities they experience.
- Welcome Transcend Australia and other panel members' participation in the national consultation and extend the invitation to other attendees such as LGBTIQ+ people, their families and those providing services and support to the LGBTIQ+ community.
- It is important that the lived experience of trans and gender diverse people and their families are heard in the national LGBTIQ+ consultation to inform how we can improve access and outcomes for those seeking gender affirming care.
- The Government acknowledges that challenges may be experienced by those accessing gender affirming care including long wait times and unforeseen out-of-pocket medical expenses that can add to the stress faced by trans and gender diverse children and their families.
- Ensuring all Australians have access to timely and affordable, high quality health care by providing Medicare benefits (rebates) for private services and free hospital services for public patients in public hospitals is a priority for the Australian Government.
- The Government provides assistance through MBS items for a wide range of surgical procedures that may be performed as part of the gender affirmation process and assistance for high out-of-pocket expenses through the Original Medicare Safety Net and the Extended Medicare Safety Net.
- The Government also invests in a range of mental health and wellbeing programs and supports for LGBTIQ+ Australians, including core funding for the delivery of QLife, investments for LGBTIQ+ suicide prevention activities and funding for the digital platform Qheadsapce.

Proposed Objective and/or Desired Outcomes:

- Emphasise the Government's commitment to work in partnership with the LGBTIQ+ community to better understand needs and to identify future reforms to improve health care access and health outcomes for LGBTIQ+ Australians.

Stakeholder information:

- Transcend Australia is a registered charity established in 2012 by Georgie's mother Rebekah Robertson as the first parent led peer support network for families of transgender children in Australia. Its purpose is to support, affirm and celebrate the lives of trans, gender diverse and non binary children and their families and carers by advocating for improvements to systems and services, developing resources and enhancing partnerships to stand up for the rights of these young people.

Stakeholder Objective:

- To promote the film and the goals of the associated campaign including:
 - Celebrate trans, gender diverse and non-binary young people and tackle transphobia by sharing the film widely with parliamentarians
 - Amplify the voices of trans, gender diverse and non-binary youth in the debates that are about them and impact them
 - Increase understanding and compassion for the issues trans, gender diverse and non-binary young adults face and build support for access to gender services for trans, gender diverse and non-binary young people with a focus on the critical importance of gender affirming health care for trans and gender diverse young people.
- The impact campaign for the film, designed in partnership with Georgie, her family and Transcend Australia includes the following political goals:
 - Build support for publicly available access to gender services for trans, gender diverse and non-binary young people;
 - Support schools and service providers to be more culturally safe for trans, gender diverse and non-binary young people;
 - Support advocacy to allow trans, gender diverse and non-binary young people to record their gender identity on legal identity documents;
 - Support advocacy for a national Human Rights Charter/ Act; and
 - Support campaigns to ban unethical and damaging conversion therapy practices led mostly by religious institutions

Sensitivities or Contentious Issues:

- Increased concern in Australia about the provision of gender affirming health care, psychological assessment of both children and adults consenting to gender affirming surgery as adults and renewed calls for a national enquiry following the closure of the United Kingdom's Tavistock gender clinic causes distress to the trans and gender diverse community.
- Sensitivities related to appropriate use of language include:
 - 'Trans, gender diverse and non-binary' are preferred inclusive phrasing.
 - Use the term 'assigned male at birth' instead of 'born a boy' or 'used to be a boy'
 - Use 'affirming medical or health care' when referring to medical care of Georgie or other trans and gender diverse people.
 - Do not use the term 'surgery' without including 'gender affirming surgery'.

Budget/Financial Implications: Nil**Background:**Documentary - The Dreamlife of Georgie Stone

- Georgie Stone is the star and creative Producer of the documentary *The Dreamlife of Georgie Stone* launched worldwide on Netflix on 22 September 2022.
- The film spans 19 years and documents the story of Georgie, an Australian transgender teen, and her family navigating medical pathways, reforming Australian law to enable better access to health care for trans youth and building and dreaming of a greater future for herself and young people similar to her.
- Key messages and principles the film aims to convey on the Dreamlife website¹ include:
 - Georgie's story does not represent all transgender experiences. This film is her story, and only one of many diverse stories about transgender people.

¹ [The Dreamlife of Georgie Stone | Home \(dreamlifefilm.com\)](https://www.dreamlifefilm.com/)

- “We know who we are” – we must listen to and lead with the voices of trans, gender diverse and non-binary people.
- Trans, gender diverse and non-binary youth need:
 - agency over their own bodies, narratives and lives;
 - to be safe from prejudice and discrimination; and
 - support from their families and communities to thrive.
- The film is not about becoming a girl or a woman, it is about Georgie becoming herself.

Gender affirming health care

- Gender affirming treatment is a complex medical process requiring close consultation with a treating practitioner and care that is tailored to individual circumstances and needs.
- In Australia the provision of care for children and young people experiencing gender dysphoria² is led by states and territories, who provide the relevant services, including specialist gender services in tertiary hospitals in some jurisdictions and multidisciplinary services in primary, secondary and tertiary systems in others. Decisions on clinical care are shared between clinicians, the young person and their family.
- Under Australian law, the consent of parents or legal guardians is required where a minor is unable to give informed consent for a gender-affirming medical treatment. If there is a dispute about the diagnosis, treatment or capacity of the minor to provide informed consent, the Family Court has ruled this requires an application for the court to resolve the dispute consistent with the child’s best interests.
- There is no singular or overarching Medicare Benefits Schedule (MBS) item that captures all the procedures involved in gender affirmation surgery.
- The Australian Society of Plastic Surgeons and other relevant clinical colleges have put forward a proposal to improve access to Medicare benefits for people who seek to receive gender affirmation treatment as a private patient. This proposal is under consideration by the Department of Health and Aged Care.
- Anyone considering gender affirmation surgery should closely consult with their treating practitioner concerning the specific treatments they require, and if seeking private treatment, consider what level of health insurance hospital cover is most appropriate.




Attachments:





- A. Biographical details of key attendees
- B. Speech for Assistant Minister Kearney
- C. Event summary

² Gender dysphoria is a term used to describe the distress experienced by a person when their gender identity is different from their sex at birth.

Attachment A

Biographies

<p>Maya Newell (she/her)</p> 	<p>Maya Newell is an Australian director and filmmaker who directed <i>The Dreamlife of Georgie Stone</i>. Maya grew up in an LGBTIQ+ family and she is passionate about social justice, and advocates for gender equality. Her career includes award-winning short documentaries <i>Two</i>, <i>Growing Up Gayby</i> and feature length documentaries <i>Gayby Baby</i> and <i>In My Blood It Runs</i>.</p> <p>In 2015 she made <i>Gayby Baby</i> with Charlotte Mars, which screened at festivals internationally. It was nominated for an AACTA Award and an AWGIE, and won Best Documentary at the ATOM awards. The film sparked a national debate after it was banned from being screened in Australian schools and was significant in the movement for marriage and adoption equality in Australia.</p>
<p>Jeremy Wiggins (he/him)</p> 	<p>Jeremy Wiggins was appointed Chief Executive Officer of Transcend Australia in 2021. Throughout his career, Jeremy has led the development of multiple health services and programs for trans, gender diverse and non-binary communities.</p> <p>Jeremy is passionate about working with gender diverse communities and codesigning programs with the communities they aim to serve. He currently serves as Co-Chair of the Victorian Government's Trans and Gender Diverse Community Health Service. He has also worked as a Youth Worker and is dedicated to upholding the rights and voices of young people.</p>
<p>Georgie Stone (OAM) (she/her)</p> 	<p>Georgie Stone is an Australian actor, writer, producer and transgender rights advocate who tells her own story in the documentary <i>The Dreamlife of Georgie Stone</i>. Georgie has been at the forefront of advocacy for the rights of trans, gender diverse and non binary children working from a young age to remove the systematic discrimination that negatively impacts them. Her work has been widely recognised and includes a 2020 Medal of the Order of Australia and a 2017 Young Peoples Human Rights Medal.</p> <p>Georgie is Transcend Australia's inaugural Patron and a former Director of the Transcend Board. In 2019, she began studying a Bachelor of Arts at the University of Melbourne.</p>

<p>Rebekah Robertson (OAM) (she/her)</p> 	<p>Rebekah Robertson is Georgie Stone's mother and the founder of Transcend Australia. Rebekah is a champion of rights for transgender and gender diverse children and led the fight for law reform around access to medical treatment for transgender adolescents. She received a Medal of the Order of Australia in 2020 for service to the trans and gender diverse community. Rebekah is committed to justice and equality for trans young people and LGBTIQ+ young people. Rebekah was nominated for Straight Ally of the Year in the 2016 GLOBE Community Awards.</p>
<p>Associate Professor Michelle Telfer (she/her)</p> 	<p>Associate Professor Michelle Telfer is the Director of the Royal Children's Hospital Gender Service in Melbourne. Before her role as a doctor, she was an Olympic Gymnast. When she retired from Gymnastics at age 18, Michelle developed an interest in sports medicine and psychiatry. She then found her passion for adolescent medicine and working with transgender children. Michelle now leads a multidisciplinary team that supports transgender children and adolescents. In this role, she is responsible for overseeing the treatment of hundreds of trans children and teenagers.</p>
<p>Dr Eloise Brook (she/her)</p> 	<p>Eloise Brook is the Health and Communications Manager at the Gender Centre in NSW. The Gender Centre is the peak NSW multidisciplinary centre of excellence providing a broad range of specialised services that enables the exploration of gender identity and alleviation of gender dysphoria.</p> <p>Eloise is a writer, trans activist and academic. She has written on the formation of queer families on television, and is working on research projects including trans people in public health and developing models for media representation of trans in the media. Eloise utilises her academic knowledge, community understanding and personal experience to better represent the issues of transgender Australians.</p>
<p>Emeritus Professor Rosalind Croucher (AM) (she/her)</p> 	<p>Rosalind commenced her seven year term as President of the Australian Human Rights Commission on 30 July 2017.</p> <p>Prior to joining the Commission, Rosalind was President of the Australian Law Reform Commission (2009–2017) and Commissioner (2006–2009), where she led a number of significant law reform inquiries. In 2015 she was appointed a Member of the order of Australia for significant service to the law as an academic, to legal reform and education, to professional development and to the arts.</p>

Attachment C

SUMMARY SHEET**Event: Screening of The Dreamlife of Georgie Stone and panel discussion**

Date:	22 November 2022
Arrive:	5.00pm
Depart:	7.30pm
Duration:	2.5 hours

Person the Minister is to be met by

Name:	TBC
Title:	
Contact phone	

Order of Events:

5.00pm	All arrive – welcomed by Senator Pratt's staff
5.15pm	Photos with all hosts and key delegation
5.30pm	Acknowledgement of Country and welcome - Parliamentary Friends of LGBTIQ+ Australians
5.35pm	Speech – Zoe Daniel MP
5.40pm	Speech – Jeremy Wiggins, CEO, Transcend Australia
5.50pm:	Speeches – Rebekah Robertson OAM and Georgie Stone OAM
6.00pm:	Film screening (29 mins)
6.30pm	Reflections by the Hon Ged Kearney MP (5 mins)
6.35pm	Panel Discussion <ul style="list-style-type: none"> ○ Moderated by Senator Louise Pratt ○ Panel members: Georgie Stone OAM, Rebekah Robertson OAM, Associate Professor Michelle Telfer, Jeremy Wiggins, Dr Eloise Brooke
7.15	Photos and mingle
7.30pm	Close

Minister	Assistant Minister Kearney
PDR Number	MB22-003386
Subject	Event brief + speech - The Dreamlife of Georgie Stone
Contact Officer	Tiali Goodchild s22 s22
Clearance Officer	Celia Street s22 s22
Division/Branch	Health Products Regulation Medicines Regulation

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE



Australian Government

Department of Health and Aged Care

Ministerial Information Request

MB22-003296

Version (1)

Date sent to MO: 6/10/2022

To: Minister Butler

cc: Assistant Minister Kearney

Subject/Issue: Urgent inquiry into the treatment of gender-confused children in Australia
(Shorten MP obo^{s47F})

Comments:

Contact Officer:	s22	A/g Assistant Secretary, Health Equity Branch	s22
Clearance Officer:	Belinda Roberts	A/g First Assistant Secretary, Population Health Division	s22

Standard word response:

- Delivering better health outcomes for all Australians, including children, young people and their families is a key priority for the Australian Government.
- It is important each child and family, including transgender and gender diverse children, have access to the care and support they need for the best possible health, now and in the future.
- The clinical treatment of children and adolescents experiencing gender dysphoria is a complex and evolving area in which it is recognised that longer term evidence to inform treatment protocols is still developing.
- In Australia, the provision of gender services is led by states and territories, who are responsible for the relevant services. Specialist gender services are located in a number of jurisdictions. It is important that care provided to young people is based on a multidisciplinary approach tailored to their individual circumstances and needs. Decisions regarding clinical care are shared between the clinicians, the young person and their family.
- While I hear your concerns, I note that in 2020 the Royal Australian College of Physicians (RACP) provided advice to the then Minister for Health on the treatment of gender dysphoria in Australia. The RACP advice noted that a national inquiry would not increase the scientific evidence available regarding gender dysphoria but would further harm vulnerable patients and their families.

Background:

- In Australia the provision of care for children and young people experiencing gender dysphoria¹ is led by states and territories, who provide the relevant services, including specialist gender services in tertiary hospitals in some jurisdictions and multidisciplinary services in primary, secondary and tertiary systems in others.
- Decisions regarding clinical care are shared between clinicians, the young person and their family. Under Australian law, parents or guardian consent is required for access to gender-affirming medical treatment. If there is a disagreement about the diagnosis, treatment or capacity of the minor to provide informed consent, the Family Court has ruled this requires an application for the court to resolve the dispute consistent with the child's best interests.

Royal Australian College of Physicians advice

- On 6 March 2020, the Royal Australasian College of Physicians (College) provided advice² to the then Minister for Health on the treatment of gender dysphoria in Australia. The advice was informed by consultation with expert College bodies including paediatricians, endocrinologists and groups with specialist research and bioethics expertise.
- The College's advice noted a national inquiry would not increase the scientific evidence available regarding gender dysphoria but would further harm vulnerable patients and their families through increased media and public attention.
 - The College's advice acknowledges that gender dysphoria in childhood and adolescence is an emerging area of health care and as such existing evidence on the health and wellbeing outcomes of clinical care is limited.
 - The College suggested three ways forward:
 - development of a national framework for service provision and outcomes monitoring led by the Government in partnership with states and territories;
 - funding for research on long-term outcomes for the care and treatment of gender dysphoria; and the development of an outcomes data base; and
 - evidence-based fact sheets aligned to guidelines for all patients and their families to support informed consent.
 - s47E(d)

Closure of the National Health Service Tavistock Clinic

- Increased concern about care in Australia follows the closure of the United Kingdom's National Health Service (NHS) Tavistock gender clinic.
- In September 2020, NHS England commissioned an independent review, led by Dr Hilary Cass, of gender identity services for children and young people.
- In February 2022, Dr Cass published an interim report, followed by a letter outlining her recommendations, which was published in July 2022. Dr Cass emphasised the need to move away from the current model of a sole provider, and to establish regional services that provide holistic clinical care. The model aims to better support multidisciplinary treatment and care and address prolonged waiting lists for access to treatment in the United Kingdom.
- In response, the NHS is moving to establish two Early Adopter services by mid-2023. The services will be led by specialist children's hospitals and, once established, will assume clinical responsibility for and management of all patients at the Tavistock clinic – including those on the waiting list – as part of a managed transition.³

¹ Gender dysphoria is a term used to describe the distress experienced by a person when their gender identity is different from their sex at birth.

² 2020 RACP advice to then Minister for Health available at [racp-letter-hon-greg-hunt-minister-for-health-gender-dysphoria-in-children-and-adolescents.pdf](https://www.racp.edu.au/~/media/Files/2020/06/racp-letter-hon-greg-hunt-minister-for-health-gender-dysphoria-in-children-and-adolescents.pdf)

³ www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/implementing-advice-from-the-cass-review/

Minister	Minister Butler
PDR Number	MB22-003296
Subject	MIR: urgent inquiry into the treatment of gender-confused children in Australia (Shorten MP obo ^{s47F})
Contact Officer	s22
Clearance Officer	Belinda Roberts s22 s22
Division/Branch	Primary and Community Care Population Health

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------

s22

From: s47E(d)
Sent: Tuesday, 4 October 2022 1:09 PM
To: s22 s47E(d)
Cc: s47E(d)
Subject: MB22-003296 - RE: I am writing to call for an urgent inquiry into the treatment of gender confused children in Australia (Case Ref: BS138719) [SEC=OFFICIAL]

Categories: s47F

MB22-003296

Thanks heaps!

MPS – can we please have an MIR from PHD?

s47F (who uses the MIRs) says great idea about using for future corro 😊

Kind regards

s22

Departmental Liaison Officer

Office of the Hon Mark Butler MP
 Minister for Health and Aged Care

E: s47E(d) @health.gov.au T: 02 6277 7220

s22

Suite s22 | PO Box 6022
 Parliament House, Canberra ACT 2600

From: s22 @Health.gov.au>

Sent: Tuesday, 4 October 2022 1:03 PM

To: s47E(d) @Health.gov.au>

Cc: s47E(d) @health.gov.au>

Subject: RE: I am writing to call for an urgent inquiry into the treatment of gender confused children in Australia (Case Ref: BS138719) [SEC=OFFICIAL]

Good afternoon s22

Thanks for your email.

Yes, this does sit within the remit of our Health Equity Branch for a response.

If the MO would prefer this be a D response, we will want to run our draft standard words by you to ensure that the Minister's office is comfortable with the approach as we get a few corro on this matter and imagine we will continue to get them so want to ensure our standard words are pitched correctly.

If you raise this as an M response or a MIR, we will still use this response for any future correspondence on the matter.

Thanks again for checking.

Kind regards

s22

Executive Officer to Belinda Roberts, A/g First Assistant Secretary
Population Health Division

Primary and Community Care Group
Australian Government, Department of Health and Aged Care

Tel: s22 @health.gov.au

Location s22

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47E(d) @Health.gov.au>

Sent: Tuesday, 4 October 2022 12:50 PM

To: s47E(d) @health.gov.au>

Subject: FW: I am writing to call for an urgent inquiry into the treatment of gender confused children in Australia (Case Ref: BS138719) [SEC=OFFICIAL]

Hey s22

Is this something Pop Health would look at?

Kind regards

s22

Departmental Liaison Officer

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s47E(d) health.gov.au T: 02 6277 7220

T: s22

Suite s22 | PO Box 6022

Parliament House, Canberra ACT 2600

From: s47F @Health.gov.au>

Sent: Tuesday, 4 October 2022 12:43 PM

To: s47E(d) @Health.gov.au>

Subject: FW: I am writing to call for an urgent inquiry into the treatment of gender confused children in Australia (Case Ref: BS138719) [SEC=OFFICIAL]

Hello

Can the Department please advise who the relevant Minister would be – not sure if this falls within our portfolio?

Kind regards,

s47F

Caucus Liaison Officer

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

M: s47F

E: s47F @health.gov.au

Suite s47F | PO Box 6022

Parliament House, Canberra ACT 2600

s22

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982 (CTH)
BY THE DEPARTMENT OF HEALTH AND AGED CARE



Australian Government

Department of Health and Aged Care

Ministerial Information Request

MB22-003696

Version (1)

Date sent to MO: [Click or tap to enter a date.](#)

To: Minister Butler

Subject/Issue: MIR - Letter to Federal Health Minister re gender affirming surgery - October 2022

Comments:			
Contact Officer:	Nigel Murray	Assistant Secretary, MBS Policy and Specialist Services Branch, Medical Benefits Division	Ph: ^{s22} Mobile: ^{s22}
Clearance Officer:	Travis Haslam PSM	A/g First Assistant Secretary, Medical Benefits Division	Ph: ^{s22} Mobile: ^{s22}

Response:

- Gender affirmation is a complex medical process and there is no singular or overarching Medicare Benefits Schedule (MBS) item that captures all the procedures involved in gender affirmation surgery.
- There are existing MBS items available for a wide range of surgical procedures which may be performed as part of the gender affirmation process, if the treating practitioner deems these to be clinically relevant for the care of the patient.
- In addition, there are MBS items for specialist consultations including with plastic and reconstructive surgeons and psychiatrists, which are available for patients undergoing gender affirmation surgery.

- The existing MBS items can be billed by the treating practitioner if they are deemed clinically relevant for the treatment of the individual patient and the requirements of the item descriptor are met in full.
- The Australian Society of Plastic Surgeons (ASPS) and other relevant clinical colleges have put forward a proposal to improve access to Medicare benefits for people who seek to receive gender affirmation treatment as a private patient. This proposal is currently under consideration by the Department, noting the change or introduction of new MBS items will require consideration by the Medical Services Advisory Committee (MSAC).
- MSAC is an independent, expert advisory group which provides advice to the Australian Government based on an assessment of the comparative safety, clinical effectiveness, and cost effectiveness of procedures. Further information about MSAC can be found at www.msac.gov.au.

Background:

- Gender incongruence (or dysphoria) is a condition where there is a marked and persistent incongruence between an individual's experience of gender and the assigned gender at birth (WHO 2016). Statistics on the number of Australians who use puberty blockers, hormones or seeking gender affirming surgeries is limited. A survey of 859 young transsexual people by Telethon Kids Institute reported that 20 per cent of respondents would like gender affirming surgery when they are old enough.¹
- Two petitions were lodged with the House of Representatives requesting Medicare funding for the treatment of gender dysphoria with gender affirmation surgery:
 - [Petition EN3307 - Gender affirming surgery should be covered by Medicare](#) (148,182 signatures. Petition closed on 27 October 2021)
 - [Petition EN2668 - Have transgender surgeries covered by Medicare](#) (89 signatures. Petition closed on 9 June 2021).

The former Government's position to these petitions was a health technology assessment (HTA) by MSAC would be required for any new gender affirmation treatment services. No public commitment was provided to consider the broader issues facing patients with gender dysphoria, such as affordability and access to public and/or private health insurance.

- Since May 2022, you have received multiple correspondence relating to the affordability and equity of services relating to gender affirmation treatment (MC22-009234, MC22-012054, MC22-009805, and MC22-009746 refers).
- On 5 June 2022, the Hon Ged Kearney MP, Assistant Minister for Health and Aged Care announced in a radio interview the Department's work in progressing specific

¹ Strauss, P., Cook, A., Winter, S., Watson, V., Wright Toussaint, D., Lin, A. (2017). Trans Pathways: the mental health experiences and care pathways of trans young people. Summary of results. Telethon Kids Institute, Perth, Australia.

MBS funding for gender affirming services. While this is true in terms of MSAC consideration of the principle of the ASPS proposal, no broader work on the issue of access to gender affirming services has commenced.

Current access to gender affirming surgery

- The Australian Government is committed to ensuring that all Australians are able to access timely and affordable, high quality health care by providing Medicare benefits (rebates) for private services listed on the Medicare Benefits Schedule (MBS) and free hospital services for public patients in public hospitals.
- As a general principle, medical treatment provided in the private sector can also be provided in a public hospital, including gender affirmation surgery. However, decisions about which procedures are provided in public hospitals and waiting times are matters for each state government and its hospital network.

Affordability for private gender affirming surgery

- Patients have reported facing high out of pocket costs for private gender affirmation surgery, up to \$50,000. While the Government is responsible for setting Medicare fees and rebates, practitioners operate their practices as private businesses and are free to determine whether they bulk bill some or all their patients or charge a co-payment.
- Doctors are encouraged to consider the personal circumstances of their patients when determining the fees they charge and patients always have the option of discussing their financial concerns with their treating practitioner.
- The Government recognises that unforeseen out-of-pocket expenses can add to the distress for those who suffer from gender dysphoria and provides assistance to patients who incur high out-of-pocket medical expenses through both the Original Medicare Safety Net and the Extended Medicare Safety Net (EMSN).
- The EMSN provides benefits of up to 80% of out-of-pocket costs for eligible out-of-hospital services once an annual threshold of out-of-pocket expenses is reached. The current EMSN threshold for Commonwealth Concession Card holders and FTB Part A participants in 2022 is \$717.90 and the general public threshold is \$2,249.80. Thresholds are indexed annually on 1 January in line with the Consumer Price Index. Both safety nets are calendar year programs, renewing on 1 January each year. More information is available at: www.servicesaustralia.gov.au/medicare-safety-nets.

Private Health Insurance

- For MBS services provided in-hospital privately, Medicare will pay 75% of the MBS fee and if the patient has private health insurance and depending on the level of insurance, health insurers are required to pay the gap between the benefit and the schedule fee. Where doctors charge above the MBS fee, patients are responsible for any additional amounts. Health funds can pay more than 25% of the MBS fee, and many do so via "gap cover arrangements". In this circumstance, patients will either have no gap to pay, or will be informed in advance about any gap. Doctors can

choose, on a case-by-case basis, whether they wish to use a health insurer's gap cover arrangements. Policy holders are strongly encouraged to have early discussions with their health insurer the availability of gap cover arrangements for the treatments they require.

- Private health insurance policies are categorised into Gold, Silver, Bronze and Basic tiers, to help people choose the level of cover that best suits their needs. What is and is not covered in these tiers is based on minimum standard clinical categories. It would be important for anyone considering gender affirmation surgery to closely consult with their treating practitioner concerning the specific treatments they require, and if seeking private treatment, consider what level of health insurance hospital cover is most appropriate.
- All health insurers are prevented from discriminating against policy holders on the basis of the treatments they may require, however a number of Australian health insurers note their particular commitment to transgender members and provide specific advice on cover which provides for gender affirmation surgery.
- The *Private Health Insurance Act* (2007) provides the maximum waiting periods private health insurers can apply to policy holders. Waiting periods are designed to ensure equality among insured persons. For the treatment of pre-existing conditions, which gender affirmation surgery would likely be considered, health insurers are able to apply a waiting period of up to 12 months. For any policy holder who decides to change health insurers or health insurance products, information about 'portability rules' is available on the Private Health Insurance Ombudsman website by searching for 'the right to change'. Portability rules ensure policy holders do not have to re-serve already served waiting periods.

THIS DOCUMENT HAS BEEN RELEASED UNDER THE FREEDOM OF INFORMATION ACT 1982 (C111) BY THE DEPARTMENT OF HEALTH

Minister	Minister Butler
PDR Number	MB22-003696
Subject	MIR - Letter to Federal Health Minister re gender affirming surgery - October 2022
Contact Officer	Nigel Murray s22 s22
Clearance Officer	Penny Shakespeare s22 s22
Division/Branch	Health Resourcing Medical Benefits

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	-------------------------------------------------------------------------------------------