Australian Informed Consent Standards of Care for Gender Affirming Hormone Therapy



Acknowledgment of Country

This document was developed, written and reviewed by many people, including those living and working on the lands of the Dharug, Gadigal, Jagera, Larrakia, Kokatha, Mirning, Ngunnawal, Palawa, Turrbal, Whadjak, Wirangu and Wurundjeri.

AusPATH respectfully acknowledges the First Peoples, the owners and Traditional Custodians of all the lands upon which we live and work.

We pay our respects to the Elders past and present, and extend our respect to all Aboriginal and Torres Strait Islander Peoples reading these guidelines.

We want to particularly acknowledge and pay our respects to all gender diverse Aboriginal people, known as Sistergirls, Brotherboys and trans mob, and who must always be centred and elevated, for they are our past, present and future.

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With thanks to









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Who is AusPATH

The Australian Professional Association for Trans Health (AusPATH) is Australia's peak body for professionals involved in the health, rights and wellbeing of all trans people – binary and non-binary.

Initially established in 2009 as ANZPATH (Australian and New Zealand Professional Association for Transgender Health), the organisation changed its name and governance structure in April 2019 to better reflect its national reach and representation.

The Boards of AusPATH and PATHA (the Professional Association for Trans Health Aoteoroa) enjoy a close relationship and we advocate together on shared aims.

AusPATH have the following aims:

AusPATH's principal purpose is to promote the health and well-being of all trans people - binary and non-binary. This is achieved through the organisation's aims:

- Provide education on the health, rights and wellbeing of all trans people – binary and nonbinary to health professionals
- Develop best practices and supportive policies
- Share information and promote communication and collaboration amongst health professionals
- Encourage, promote and disseminate relevant research
- Maintain a network of supportive and informed professional service providers

We provide:

- Communication
- Up to date information on clinical, research and educational developments, advocacy opportunities and community events.
- Advice
- Seek advice through our members only email list.
- Support
- Meet and network with other professionals working in trans health across Australia. AusPATH hosts a biennial conference, as well as training and education events.

Find us:

Web: <u>auspath.org.au</u> Facebook: <u>/auspathorg</u> Instagram: <u>auspathorg</u>

Foreword from the AusPATH President and Vice-President

On behalf of the Board of Directors and Sub-Committees of the Australian Professional Association for Trans Health (AusPATH), we are proud to offer our members, communities, and clinicians across Australia these new Australian Informed Consent Standards of Care for Commencing and Managing Gender Affirming Hormone Therapy.

As President and Vice President of AusPATH, and most importantly as community-connected, evidence informed and well-respected leaders in trans health, we know that these national guidelines will save lives.

These Standards of Care are intended to assist and enable clinicians across Australia to better meet the medical gender affirmation needs of their trans women, trans men and non-binary patients. Doctors and trans communities have been calling for these guidelines for many years, and we are proud to be finally able to deliver a set of guidelines which unapologetically centre the trans person seeking hormonal intervention and empower the clinician to facilitate this access.

Through the combined decades of clinical, research and community development experience of AusPATH members, we know that those seeking gender affirming hormones greatly benefit from medical care that is local, accessible and grounded in human rights.

The trans experience is increasingly understood as ancient and we see evidence of gender diversity across all Indigenous cultures. It stands to reason that if the longest living continuous cultures on Earth are our Aboriginal and Torres Strait Islander peoples, then it is also this place that boasts the longest living continuous trans cultures.

Our own First Nations peoples of Sistergirls and Brotherboys have lived on country and in community for millennia; many tribes and nations have language, dance and ceremony that recognise and affirm them. Humans have always found ways to be who they are, and trans people are no different. In 2022 the evidence is clear that medical gender affirmation, for those who seek it, is clinically relevant and medically necessary. Access to hormones improves quality of life and strengthens wellbeing, and denial of care dramatically impacts the health of trans people of all genders.

These guidelines reflect the consensus of AusPATH's active membership, and as Australia's peak body for professionals involved in the health, rights and wellbeing of all trans people, binary and non-binary, it is entirely appropriate AusPATH to develop and publish them. The AusPATH Board is proud to have majority trans Directors, with all Sub-Committees inclusive of trans health professionals. AusPATH's Board and Sub-Committees also include incredible cis allies.

As with any set of guidelines, it is important that they remain up to date. Accordingly, they are intended to be revised and updated on a regular basis as new evidence emerges regarding best practice.

We wish to thank Thorne Harbour Health and their Equinox Gender Diverse Health Centre for allowing us to adapt the 2020 update to their *Protocols for the Initiation of Hormone Therapy for Trans and Gender Diverse Patients.* We also thank ACON for supporting this work, for allowing us to take guidance and imagery from TransHub, and for designing this document so beautifully.

Our list of acknowledgements can be found at the end of this document, but we wish to loudly thank the many trans health experts and gender affirming doctors, nurses and allied health professionals (trans and cis) across Australia who have contributed to these Standards of Care. Thank you, too to the many thousands of trans people across Australia who have trusted and guided us since our inception. AusPATH exists for you.

Dr Fiona Bisshop MBBS FRACGP BSc (Hons) AusPATH President

Mr Teddy Cook AusPATH Vice-President

Introduction

Trans people, including women, men, non-binary people, Sistergirls, Brotherboys and those with cultural identities other than man or woman, experience their gender as different to that presumed for and assigned to them at birth (Coleman et al., 2012; World Medical Association, 2017). This contrasts with cisgender (cis) people, whose gender is the same as that presumed for and assigned to them at birth.

Being trans is not a new experience of gender, indeed the trans experience can be traced throughout human history and is widely regarded as simply one aspect of the richness of human diversity, rather than a mental disorder (American Psychological Association, 2015; World Medical Association, 2017; World Health Organization, 2022).

Many trans people become aware of their gender in childhood or adolescence, and many others come to know themselves later in life (Coleman et al., 2012; Heylens et al., 2014; Zaliznyak et al., 2020). A recent Australian survey found that 2.3% of highschool aged young people sampled are trans (Fisher et al., 2019). The adult trans population in Australia is difficult to estimate, largely due to the absence of adequate measures in the Census of Population and Housing, including in 2021.

When a trans person chooses to reveal their gender, a supportive environment allows for social, medical and legal affirmation.

Social affirmation (names, pronouns, hairstyles, clothes) has been shown to provide benefits to the health and wellbeing of many trans people, especially trans youth (Olson et al., 2016; Durwood et al., 2017; Russell et al., 2018). Medical affirmation can involve a broad range of healthcare support, delivered by way of a gender affirming approach to healthcare (Keo-Meier & Ehrensaft., 2018). Legal affirmation involves the updating of legal identity across institutions and with the state (Scheim et al., 2020). Gender affirming healthcare is **the** widely accepted standard in the field. It emphasises affirming language, psychological and peer support, support for social affirmation, medical and/or legal affirmation, as medically necessary and clinically relevant (Keo-Meier & Ehrensaft., 2018).

There is a significant, and growing, body of evidence to show that medical affirmation leads to improved quality of life and better mental health outcomes (White et al., 2016; AusPATH, 2021; Turban et al., 2022).

Transgender Europe's (2019) Guidelines to Human Rights-based Trans-Specific Healthcare shares the human rights principles of gender affirming healthcare, which include:

- The principle of non-discrimination
- The principles of bodily integrity, bodily autonomy and informed consent
- The principle of freedom from torture and degrading and inhuman treatment
- · The principle of free self-determination of gender
- The principles of quality, specialised and decentralised care
- The principles of the right to decide on number and spacing of own children
- · The principle of the best interest of the child

These human rights principles align with the Yogyakarta Principles (2007) and Yogyakarta Principles+10 (2017).

There are many ways trans people experience and affirm their gender, and the path of gender affirmation is unique to each individual. Services seeking to offer gender affirming healthcare will have an opportunity to work across a wide range of binary and non-binary identities and gender expressions. To nurture affirming medical spaces, it is imperative services understand that **trans patients are the experts of their own lives and the final authority on their own gender**. This can be demonstrated early by ensuring all staff, from admin to specialists, first offer their own name and pronouns, and then always use each patient's chosen name and pronouns.

In this document "clinicians" refers to medical practitioners including General Practitioners, specialists and nurse practitioners.

Clinicians should ask all patients seeking gender affirming hormone therapy what their affirmation goals are, listen to them, and then engage with them in a way that helps them understand the available options. Although trans people may attend clinical services seeking medical care, it is important to avoid pathologising the trans experience; being trans is not a mental illness, it is an aspect of human variation, and hormones and surgery are not necessarily desired by all trans people.

Using plain language when communicating medical information supports people in developing an understanding of the benefits and risks of hormone therapy across their lifespan. By providing comprehensive education about hormones and general health, clinicians can support patients in making informed decisions about all aspects of their general health and wellbeing.

Informed consent models of hormone prescribing resist the notion that a doctor can determine the validity of a person's gender, and instead centre the trans person in the decision-making process, whilst ensuring that the patient understands and can consent to the potential impacts that gender affirming hormone therapy may have on their body and life.





The informed consent model of care is sometimes called affirmation enablement or ethical affirmation.

Working in partnership with trans people and respecting their right to self-determination, autonomy and agency are the foundations of providing high quality and culturally safe services.

Purpose And Scope

These guidelines offer expert Australian consensus on commencing gender affirming hormone therapy, using the informed consent approach, for trans people seeking medical affirmation.

They are a starting point from which a trans person seeking medical gender affirmation services, with their clinician, can arrive at a care plan appropriate to their goals and needs.

The guidelines are designed to support clinicians to initiate and manage gender affirming hormone therapy, and to help reduce barriers and improve health outcomes for trans people of all genders.

These guidelines are not intended to and do not provide legal advice. The below is accurate as at March 2022.

Like any treatment, gender affirming hormonal therapy can be commenced and managed by clinicians with the informed consent of people with legal capacity to give consent to treatment. The position for adolescents and young people aged under 18 is more complex, as is the situation for those without medical decision-making capacity or who may be placed in care or under guardianship orders.

For adolescents aged under 18, the default position is that treatment can commence when there is no dispute between parents (or those with parental responsibility), the medical practitioner and the young person themselves with regard to:

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- The competence of the adolescent (sometimes referred to as *Gillick* competence); or
- A diagnosis of gender dysphoria; or
- Proposed treatment for gender dysphoria.

In the case of *Re Imogen (No. 6)* [2020] FamCA 761 the Family Court of Australia said that any dispute as to competence, diagnosis or treatment (including between the parents) requires a mandatory application to be made to the Family Court. The case suggested that the absence of consent to treatment from either parent meant that court approval would be required from the Family Court.

However, the interaction of *Re Imogen(2020)* with particular state and territory laws regulating medical consent has not yet been finally considered by a court.

For example, the South Australian Consent to Medical Treatment and Palliative Care Act 1995 (SA) allows a person 16 years and over to make decisions about their own medical treatment as if they were an adult (s 6). The Act also allows treatment for children under 16 years if the parent or guardian consents, or the child consents and:

- the medical practitioner who is to administer the treatment is of the opinion that the child is capable of understanding the nature, consequences and risks of the treatment and that the treatment is in the best interest of the child's health and well-being; and
- that opinion is supported by the written opinion of at least one other medical practitioner who personally examines the child before the treatment is commenced (s 12).

In NSW, the Civil and Administrative Tribunal (NCAT), under *The Children and Young Persons* (*Care and Protection*) *Act 1998* (NSW), s 175, must generally provide consent to certain non-urgent treatments for children under 16 years, including treatments that are reasonably likely to result in infertility (unless that infertility is consequential to life-saving treatment or an unwanted consequence). When and if this NCAT requirement applies is not fully resolved and legal advice is recommended before treatment, particularly if the treatment is reasonably likely to result in permanent infertility or sterilisation of the person: see also Re Kelvin [2017] FamCAFC at [84], Re Bernadette [2010] FamCA 94 at [111].

That is why, unless there is agreement among the parents (or those with parental responsibility), the adolescent and medical practitioner regarding competence, diagnosis and treatment, a Family Court order is required for access to gender affirming puberty blockers, hormone treatment and surgery for an adolescent under 18 years, unless another legal order or basis can be relied upon.

The Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents have been endorsed by AusPATH and are available on the <u>AusPATH website</u> and on the <u>Royal Children's Hospital</u> website. The informed consent model can be used with adolescents, provided the legal requirements set out above are met.

Informed consent models for prescribing gender affirming hormone therapy have been developed and tailored to meet the needs of trans communities around the world, thus avoiding further pathologisation and increasing selfdetermination and autonomy.

These models can be successfully adapted to reflect local resources, service availability and community wishes. Informed consent enables trans people to access hormone therapy with their clinician, without endocrine or mental health specialist consultations where not indicated, thus avoiding the long wait periods and costs usually associated with those services. Informed consent approaches to commencing gender affirming hormones are well suited to settings of primary care, sexual health, community health, adolescent health, Aboriginal communitycontrolled health services, LGBTQ+ and trans community-controlled health services, multicultural health and within settings of incarceration.

The Australian Commission on Safety and Quality in Healthcare (2020) define informed consent as follows:

Informed consent is a person's decision, given voluntarily, to agree to a healthcare treatment, procedure or other intervention that is made:

- Following the provision of accurate and relevant information about the healthcare intervention and alternative options available; and
- With adequate knowledge and understanding of the benefits and material risks of the proposed intervention relevant to the person who would be having the treatment, procedure or other intervention.

Informed consent in medical gender affirmation means respecting and valuing the trans experience and the rights of trans people, working in partnership with individuals and communities, and clinicians developing the skills and confidence they need to undertake this valuable, rewarding and lifesaving work.

When a clinician delivers gender affirming medical care using informed consent, they play a central role in facilitating access to hormones, including conducting mental health, safety and risk assessments, and, when required, organising referral for secondary consultation. The GP remains the primary treating physician for most patients, without requiring additional referral. Trans patients are more likely to stay linked with medical services when medical gender affirmation is integrated with primary care (Ker et al., 2020).

The informed consent model is not a new concept and was formalised in 2014 by the Callen Lorde Community Health Centre in New York. In their Protocols for the Provision of Hormone Therapy, Callen-Lorde Community Health Centre (2014), state that hormonal affirmation is "a cooperative effort between patient and provider. We strive to establish relationships with patients in which they are the primary decision makers about their care, and we serve as their partners in promoting health".

Informed consent recognises the trans person as the experts of their own needs and experience,

while respecting that medical professional(s) can utilise their expertise to enable effective and safe treatment. Together, they can optimise the health and wellbeing of the person requiring access to gender affirming treatment in a timely manner.

All doctors can be a gender affirming doctor. Gender affirming medicine is a part of general medical care within the primary health care system. All people should be offered trans-affirming and culturally safe support throughout the process of exploring or affirming their gender. This may include peer support, connection to community groups, counselling, social work, psychology and psychiatry services.

A 'gender assessment' with a psychiatrist is not required and is not a mandatory requirement prior to commencing medical gender affirmation. A genital examination is never a necessary part of the assessment process and is more likely to be a distressing experience for the patient.

In situations where mental illness or substance use may impair the ability of the patient to provide informed consent, a mental health professional opinion may be needed. Examples include active psychosis related to gender, cognitive or intellectual impairment, dementia, brain injury, untreated personality disorder, and dissociative identity disorder (where the system of alters disagree on identity, or affirmation goals). Complex mental health issues should be addressed, and the patient supported, prior to commencing hormone therapy.

Clinicians who are new to hormone prescribing may find it helpful to seek guidance from an experienced medical practitioner in this field of healthcare. Annual training days are provided by AusPATH, and membership is highly recommended. You can also read more about hormone prescribing and Informed Consent on <u>TransHub</u>.

For patients requesting surgery for gender affirmation, the WPATH Standards of Care (edition 7) (Coleman et al., 2012) recommend a surgical readiness referral, conducted by one or more mental health professionals, depending on the surgery sought. WPATH guidelines state that medical professionals should accept letters from mental health professionals with a Masters degree or equivalent, and training from any discipline that prepares them for clinical practice, this includes "psychology, psychiatry, social work, mental health counseling, marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling" (Coleman et al., 2012).

Medical Guidelines

These guidelines and templates offer approaches clinicians can follow to use the informed consent model when commencing and managing gender affirming hormone therapy (GAHT) for their trans patients - binary and non-binary. This process may be completed in one or two appointments, or may require more, depending on patient needs and clinician confidence.

STAGE 1. INTRODUCTION

PROVIDER: Clinicians and clinic staff

GOALS OF THE SESSION:

To welcome and affirm patients to the service.

- Ensure a trans-affirming, culturally safe clinic environment, including but not limited to respectful staff, affirming intake forms and posters, and all-gender bathrooms.
- Complete clinic registration paperwork including chosen name and pronouns.
 - Ensure forms allow cis and trans patients to meaningfully reflect their gender. A template can be found in the appendix
 - Offer your own and then collect name, pronouns and gender (self-determined by patient)
 - o Useful questions include
 - 'How do you describe your gender?'
 - 'My pronouns are ***, what pronouns do you use?'
 - If a patient's name and gender is different to what is listed with Medicare, it's essential to collect this separately and to specify that it is for billing purposes only. The limitations of medical information systems shouldn't negatively impact trans patients.
- Outline the staged approach to informed consent
 - Offer information regarding trans peer support and community groups (locally or online).
- Reassure the patient that you will work with them and can advocate for them.

STAGE 2. INITIAL MEDICAL REVIEW

PROVIDER: Clinician

GOALS OF THE SESSION:

To take a comprehensive medical history and organise baseline investigations.

Medical history to include:

- Gender history
 - Ask open questions and allow the patient to share about their gender as they wish. This may include asking about their gender experience or history, and any impact this has had on their on their life, mental health, relationships, work, schooling?
- Social history
 - Including housing, partners, occupation.
 - Is there a support network in place (friends, family, community groups)?
 - For Sistergirls, Brotherboys, multicultural and multifaith trans patients – are they connected to culture and community?
 - Ask about Medicare and visa status. Most gender affirming hormones are available on the PBS however those without Medicare cover need to pay for hormones privately.
 - Ask about current care, support and legal needs.
- Past medical and surgical history
 - Enquire about relative contraindications to hormone therapy such as migraines with aura, hormone sensitive cancers, uncontrolled hypertension, DVT.
- Relevant sexual health history
 - $\circ\;$ Sensitive and appropriate questioning.
- Family history
 - Ask about cancer, blood clots, cardiovascular disease.

- Medications
 - reassure that previous 'self-medicating' with hormones does not restrict access.
 - ask about prescription and over the counter medications.
- Allergies
- Vaccination history
- · Smoking, alcohol and drug history

Mental health assessment to include:

- Be clear and reassuring about why this information is being collected, offer a referral for mental health and/or peer support as needed/requested.
- Any mental health history including depression, anxiety, psychosis, bipolar, ADHD, complex trauma.
- Any hospitalisations.
- Risk assessment ask sensitively about self-harm or suicidal thoughts.
 - Trans people have some of the highest rates of suicidality and suicide attempts in Australia access to medical gender affirmation for those who seek it is medically necessary, clinically relevant suicide prevention.
 - Depression, anxiety, and suicidality are not contraindications to hormone therapy. In most cases mental health can be exacerbated by denial or delay, and improves following initiation of gender affirming hormones.
 - Trans people can experience problems with food-intake or have eating disorders, this may or may not be related to gender and body, so always ask sensitively.
 - Offer support, advocacy and referrals where required.



Examination:

- Baseline weight (if acceptable to the patient), blood pressure (BP) height and pulse.
- Genital examination is neither required nor recommended when working with patients commencing medical gender affirmation, unless requested by the patient.
- Adopt a trauma informed approach to any examination. Ask sensitively, gain consent, and explain fully what each examination would involve.

Initial investigations:

- Baseline blood tests including, but not limited to
 - full blood count (FBC)
 - $\circ~$ liver function tests (LFT)
 - urea and electrolytes (U+E)
 - $\circ~$ follicle stimulating hormone (FSH)
 - \circ luteinising hormone (LH)
 - \circ estradiol (E2)
 - \circ testosterone (TEST)
 - human chorionic gonadotropin (hCG) (if indicated or requested)
 - vitamin D (if clinically indicated)
 - coagulopathy is not required nor recommended
- Consider ECG, fasting glucose, lipids, HbA1c if cardiovascular risk factors are present.

- o Offer a sexual health screen.
 - Take a Parts and Practices approach, which focuses on the body parts a person has, and what they're doing with them, rather than making assumption about gender, sexuality, or the language used.
 - Find more <u>here</u>
- Use a trauma-informed approach.
- Don't make assumptions.
- Explain why intimate sexual questions may need to be asked during a sexual health risk assessment.
- $\circ~$ Ask open questions in order to ascertain risk.
- Discuss Pre-Exposure Prophylaxis (PrEP) for HIV prevention if indicated.
- Inform the patient that GAHT is not contraception, and discuss options if contraception is required.
- Offer cervical screening if patient has a cervix, has ever been sexually active, and is aged 25y - 74y.
 - This can be self-collected if client prefers, and there are no current symptoms of break through bleeding, discharge or significant pain. Discuss options with the patient based on their comfort.
- Consider bone density scan, particularly if risk factors present for osteoporosis.

STAGE 3. HORMONE EDUCATION AND HARM REDUCTION

PROVIDER: Clinician

GOALS OF THE SESSION

Spend time talking through hormones and their effects, to ensure patient can make a fully informed decision about commencing feminising or masculinising gender affirming hormone therapy.

Discussion regarding hormone therapy to include:

- Patient's goals and expectations of hormone therapy.
- Patient's understanding of hormone therapy, allowing adequate time for questions, concerns and discussion.
- Likely effects and potential side effects of hormones.
- Limitations of hormones (things that will not change) e.g. voice, face and neck structure, balding patterns from endogenous testosterone at puberty, height
- Likely timeline of expected changes.
- Potential irreversible changes with hormone therapy such as balding, deep voice with testosterone, breast growth, loss of fertility with estrogen.
- Emphasise importance of monitoring and regular medical care and review.
- Contraception needs.
- Counsel regarding fertility preservation options:
 - Estrogen may lead to permanent loss of fertility
 - Offer referral for sperm analysis and freezing prior to initiation hormones (usually through a local fertility service).

- Ask about fertility needs. Research is very limited but there is some evidence that semen volume and spermatogenesis may be reduced by some gender affirming processes such as feminising hormones and tucking.
- Continued use of estrogen is likely to impair fertility, at the same time, estrogen alone can not be recommended as contraception for people presumed male at birth.
- Trans people have varying relationships with their bodies, it's important not to make assumptions and only ask questions that are relevant.
- Assess and document capacity to provide informed consent. If patient can give informed consent, then the clinician can prescribe and monitor in the community setting.
- Provide written information including plain language fact sheets, templates are provided in the Appendix.

STAGE 4. HORMONE INITIATION

PROVIDER: Clinician

GOALS OF THE SESSION

Provide initial prescription for hormone therapy.

General principles when prescribing gender affirming hormones:

- Start with low doses for first 1-3 months to minimise side effects and complications. Titrate upward over time.
- Trans people come in all shapes, shades, sizes, ages and abilities, so individualised approaches to hormonal affirmation is important.
- Clinical response, including physical changes, should be considered along with hormone levels.
- Patients are often highly educated and aware of their hormone needs and goals, so actively listening and incorporating patient views, desires and needs into affirmation plans is important.
- Monitor and review blood results and patient wellbeing every three months, especially during the first 12 months.
- Acknowledge that some trans people may prefer to use lower doses of hormones (sometimes called micro dosing) to achieve their individual goals. These goals may change over time and their hormone requirements may also change.



Prescribing Feminising Hormones

- Feminising medications usually include a combination of estrogen and an androgen-blocker.
- Some trans feminine people choose not to use anti-androgens
- A general principle is to start at low doses of estrogen and titrate upwards

The following tables outlines formulations available in Australia:

Estrogens

Hormone	Route	Trade name	Starting dose	Max dose
Estradiol	PO	Progynova Zumenon Estrofem	2-4mg, OD	8mg, OD
Estradiol	GEL	Sandrena	lg, OD	2g, OD
Estradiol	Patch	Climara Estradot	50-100mcg, twice weekly	200mcg, twice weekly
Estradiol	Implant	N/A (compounded)	100mg, 6-12 months	200mg, 6-12 months

Anti-Androgens and Progesterone

Product	Route	Trade name	Starting dose	Max dose
Spironolactone	РО	Aldactone Spiractin	50mg, BD	200mg, OD
Cyproterone	PO	Androcur	12.5mg, OD	25mg, OD
Progesterone	РО	Prometrium	100mg, OD	200mg, OD

Prescribing Masculinising Testosterone

- There are several different formulations of testosterone available, and patient preference should determine which is used.
- Some people may wish to learn to self-inject a short-acting preparation such as testosterone enanthate (Primoteston) or testosterone esters (Sustanon), or they may prefer to visit the clinic for long-acting testosterone undecanoate (Reandron).
- To access PBS-subsidised testosterone a second opinion is required from an endocrinologist, sexual health physician, or urologist. This may be a face to face or telehealth consultation, or GPs may consult with one of these specialists on behalf of their patient, depending on local services available.

The following table describes the testosterone formulations available in Australia:

Formulation	Route	Trade Name	Dose*
Testosterone undecanoate 1g/4ml	Instramuscular injection	Reandron	1000mg, 10-12 weekly (first two doses six weeks apart)
Testosterone enanthate 250mg/1ml	Instramuscular injection	Pimoteston	250mg, 2-4 weekly
Testosterone esters 250mg/1ml	Instramuscular injection	Sustanon	250mg, 2-4 weekly
Testosterone 1% gel sachet 50mg/5g	Transdermal	Testogel	50mg/5g, OD
Testosterone 5mg gel patch	Transdermal	Androderm	5mg/24 hour patch, 5mg OD
Testosterone 1% gel pump pack 12.5mg/1.25g	Transdermal	Testogel	12.5mg/actuation, 50mg OD
Testosterone 2% gel pump pack 23mg/1.25g	Transdermal	Testavan	23mg, OD
Testosterone 5% cream 50mg/1ml	Transdermal	Androforte	2ml, 100mg OD

Testosterones

*Some patients may prefer to start at a lower dose and titrate up, others will prefer a full dose from commencement.

STAGE 5.

ONGOING MONITORING & SUPPORT

PROVIDER: GP, practice nurse, peer worker, allied health worker

GOALS OF THE SESSION

Provide continuity of care to optimise health outcomes.

Care Plans

- Regular medical review and support
- Consider Chronic Care Management Plans
 - GP Management Plan (721)
 - Team Arrangement Plan (723)
 - o Reviews (732)
 - Masculinising and Feminising templates can be found in the appendix.
 - Chronic Care Management Plans must be individualised for each patient to ensure Medicare compliance.

Hormone monitoring

The Australian Position Statement on the Hormonal Management of Adult Transgender and Gender Diverse Individuals states that "treatment should be adjusted based on clinical response" (Cheung et al., 2019). This acknowledges that the clinical management of gender affirming hormones should be individualised, and requires partnership between a treating physician and the trans patient.

Recommended ranges should be used as a guide, rather than a rule. This means prescribing gender affirming hormones based on how a patient responds to treatment and alongside risk factors, rather than based solely on specifically targeted levels.

As a guide, and based on patient needs and goals:

- For masculinising therapy, aim for trough total testosterone levels at the lower end of the endogenous testosterone 'male' reference range (10-15 nmol/L)
- For feminising therapy, aim for estradiol levels in the endogenous estrogen 'female' reference range (250-1000 pmol/L) and total testosterone levels to < 2 nmol/L (although some patients may prefer a higher testosterone level).

Levels should be monitored at baseline, every 3-4 months for the first year, and then annually once levels are adequate and stable. During the first year, request both reference ranges to assist with monitoring (Cheung et al., 2020).

Blood testing to include but not limited to:

- full blood count (FBC)
- urea and electrolytes (U+E)
- renal (RFT) and liver function test (LFT)
- o glucose
- estradiol (E2)
- testosterone (TEST)
- Luteinising hormone (LH)
- \circ lipids
- Weight (if acceptable to the patient) and blood pressure 6 monthly.
- Monitor for complications of hormone therapy including DVT, acne, polycythaemia (HCT > 0.50), sleep apnoea.
- Check in on general health, encourage smoking cessation and increased body movement, community connection and emotional nourishment.

Affirmation

- Referrals as required eg. speech pathology, surgery, dietitian.
- Information about hair removal services.

• Assist with change of gender marker if desired on documents such as Medicare, birth certificate, driving licence, passport (regulations differ in different states and countries).

Mental health support

- Check in routinely regarding mental health, wellbeing, and care and support needs.
- Refer to peer and community groups for advocacy and support.
- Consider mental health care plan if required or wanted, and refer to LGBTQ+-trusted and transaffirming services and clinicians.

Screening

- Consider bone density scan, particularly if risk factors for osteoporosis present.
- Sexual health screens as required.
- Routine cancer screening based on age and organs present (cervix, prostate, breast/chest, bowel).
- Cervical screening 5 yearly for anyone with cervix 25y-74y.
- Mammogram 2 yearly from 50y-69y for patients with natal breast tissue or after 5 years of feminising hormones.
- Chest examinations 2 yearly for people aged 50y-69y after top surgery who may have residual breast tissue.

Nursing or Peer Worker Support

- Hormone education and counselling.
- Health checks, care plans.
- Provide patient with syringes, needles, sharps disposal container if required.
- Ensure immunisations are up to date, consider Hep A, B, HPV and COVID vaccine.
- Consider practice nurse session for safe hormone injection technique if appropriate (not recommended to self-inject testosterone undecanoate but may be appropriate for testosterone enanthate or testosterone ester preparations).

Disclaimer

These prescribing protocols are guidelines only. Each patient is an individual with their own needs and goals.



Acknowledgments

These guidelines are adapted from the Thorne Harbour's Equinox Gender Diverse Health Centre Protocols for the Initiation of Hormone Therapy, an informed consent guideline, initially developed by Dr P Cundill and Jeremy Wiggins in 2017.

Version 2 was developed in 2020 by Dr P Cundill, Dr Adam Brownhill and Peter Locke. Version 2.0 has been reviewed by the Thorne Harbour Health Trans & Gender Diverse Advisory Group

Version 2.1 has been reviewed by ACON's Trans Health Equity Team and endorsed by AusPATH

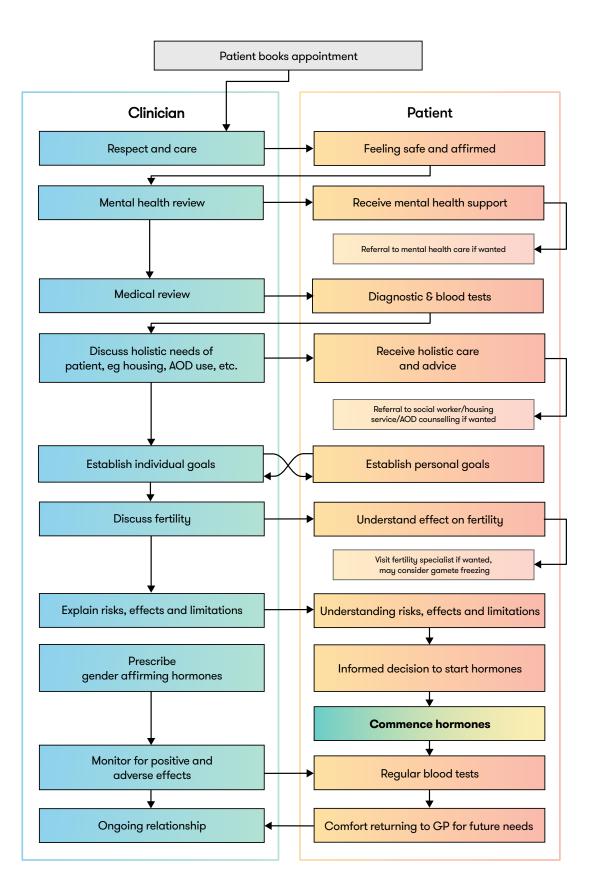
We would like to thank and acknowledge the Callen Lorde Community Health Center in New York City, NY, USA for granting permission to reference and adapt their hormone protocols to our local context.

We would also like to acknowledge the following individuals who were involved in a range of clinical and community consultations.

Thank you to:

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Appendix 1 - Gender Affirming Hormones Clinician & Patient Journey



Appendix 2 - Key Links

- TransHub Clinicians
- Hormone therapy for trans and gender diverse patients in the general practice setting
- <u>Position statement on the hormonal management of adult transgender and gender</u> <u>diverse individuals</u>

Appendix 3 - Gender Affirming Feminising Hormone Therapy Templates

- Patient Information Sheet
- Consent Form
- Chronic Care Management Plan Feminising

Patient Information Sheet: Feminising Hormone Therapy

Typical changes from Estrogen (varies from person to person)

Average timeline	Effect of Estrogen
1–3 months after starting estrogen	 softening of skin decrease in muscle mass and increase in body fat redistribution of body fat to buttocks and hips decrease in sex drive fewer instances of waking up with an erection or spontaneously having an erection; some trans women also find their erections are less firm during sex, or can't get erect at all decreased ability to make sperm and ejaculatory fluid
Gradual changes (maximum change after 1–2 years on estrogen)	 nipple and breast growth slower growth of facial and body hair slowed or stopped balding decrease in testicular size

Typical changes from Anti-Androgens (varies from person to person)

Average timeline	Effect of blocking Testosterone
1–3 months after starting anti-androgens	 decreased testosterone in the body decrease in sex drive fewer instances of waking up with an erection or spontaneously having an erection; some trans women also have difficulty getting an erection even when they are sexually aroused decreased ability to make sperm and ejaculatory fluid
Gradual changes (usually at least 2 years)	 slower growth of facial and body hair slowed or stopped balding slight breast growth (reversible in some cases, not in others)

Consent Form - Feminising Hormone Therapy

The informed consent model of care respects your fundamental human right to self-determination and bodily autonomy. The purpose of this document is to indicate, in writing, that you consent to starting or continuing feminising hormone therapy as part of a gender affirmation process. This form may be signed by any person who is able to make an informed decision over the age of 18, or with the co-signatures of all primary legal guardians.

This document relates to the hormones estrogen and progesterone, as well as testosterone blocking medications. Your doctor will make a medical decision, in consultation with you, about the medications that are best for you, keeping in mind your overall health during your gender affirmation process. Your doctor will discuss with you all of the information relating to starting hormone therapy. You are asked to read and understand the following information, and raise any questions you have with your doctor.

A physical genital examination, for the purpose of commencing gender affirming hormones, is not required, unless you request an examination.

I,_____, on the date_____, acknowledge that I have

read and understood the following information in consultation with my doctor_____

Tick the boxes to acknowledge the following:

Changes expected whilst on feminising hormone therapy:

Permanent changes:

- Breast and nipple development
- Decreased testicular size
- Atrophy (shrinkage) of the penis leading to possible penile pain with erections

Reversible changes:

- Softening of skin
- · Decreased muscle mass and increased body fat
- Decreased libido
- · Reduced spontaneous morning erections
- Reduced ability to achieve or sustain an erection
- · Reduced ability to ejaculate and reduced volume of ejaculatory fluid
- Slowed or stopped balding
- Slowed rate of growth of facial and body hair
- Improved cholesterol

I acknowledge the following side effects of feminising hormone therapy:

- Headaches
- Nausea
- Fluid retention and bloating
- Breast and nipple tenderness
- Mood disturbance, such as teariness, depression or anxiety
- Fatigue

I acknowledge the following potential risks of feminising hormone therapy:

- Blood clots, deep vein thrombosis or potentially fatal pulmonary embolism
- Stroke
- Increased risk of heart disease or heart attack
- Raised blood pressure
- Liver damage

- Osteoporosis
- Potentially increased risk of breast cancer
- Development of prolactinoma (a rare brain tumour that results in milk production from the breasts)
- Difficultly controlling blood sugars in people with diabetes
- Meningioma (a rare benign growth in the lining of the brain, seen in some people on high dose cyproterone)

I understand that feminising hormone therapy affects everyone differently, and that there is no way to predict exactly how my body will change. Some of the long term effects of feminising hormone therapy are not yet known.

I acknowledge that continuing to smoke whilst taking estrogen increases my risk of developing a blood clot, deep vein thrombosis or a potentially fatal pulmonary embolism.

I have been advised by my doctor to consider storing sperm in case I decide to have children at a later date, I have been given the opportunity to delay medical gender affirmation until I have stored sperm if I wish to.

I have been informed that the use of feminising hormones does not guarantee infertility, and that contraception should be used to avoid unwanted pregnancy if I have sex with someone who could become pregnant.

I understand that gender affirming hormone therapy means that I will need to see my doctor and have blood tests at regular intervals throughout my life. Appointments will be more frequent at first, and then every 6-12 months when my hormone levels are stable. I am ready to make this commitment to my health.

I acknowledge that gender affirming hormones are only a part of my overall health, and that a range of preventative health activities are recommended so that I remain happy and healthy in my affirmed gender. These include but are not limited to:

- Monthly breast self-examination. I should tell my doctor if I discover any new lumps
- Regular breast mammograms from an appropriate age, in consultation with my doctor
- Quitting smoking
- Immunisations
- Regular STI screening, depending on my level of risk
- HIV prevention, depending on my level of risk
- Regular physical activity, including resistance exercise for bone health
- Healthy eating

I can choose to stop gender affirming hormone therapy at any time. If I choose to stop taking hormones, it is best that I do this in consultation with my doctor, to ensure that I remain safe and healthy.

Patient name:	
Signature:	Date:
Parent/guardian name:	
Signature:	Date:
Doctor name:	
Signature:	Date:

TransHub Templates	
GENDER AFFIRMING CARE MANAGEMENT PLAN - FEMINISING PREVENTATIVE HEALTH CARE PLAN TEAM CARE ARRANGEMENT	
Important Note: Chronic Care Management Plans must be individualised for each patient to ensure Medicare compliance.	GP Management Plans (721):/ // (date of service) Team Care Arrangements (723):/ // (date of service) Reviews (732):/ // (date of service)
PATIENT DETAILS	ALLERGIES
	No known allergies/adverse reactions.
GENDER DETAILS GP	HISTORY LIST
Gender identity: Gender presumed at birth: M Pronouns:	<i>Inactive:</i> Date Condition Comment
MEDICATIONS	

GENDER AFFIRMING CARE MANAGEMENT PLAN TEMPLATE - REVIEW DUE:

Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
Gender incongruence - physical aspected (marked & persistent incongru-ence between experienced & as-signed gender) <i>Reference: ICD-11 (Version 04/2019)</i>	Affirmation of experienced gender through medical &/or surgical treatment and supported social &/or legal gender affirmation as desired	Other health care providers:	 Regular review of goals for gender affirmation Regular monitoring of treatment for efficacy, side effects & concerns Healthy lifestyle measures to support physical & mental health & reduce risk of chronic disease
	Gender affirming hormonal treatment - oestrogen replacement	Other health care providers:	$\hfill\square$ Inform patient that no genital or chest exam is necessary in order to access hormonal affirmation
	Ostrogen replacement for gender affirmation	Results:	 Education re expected physical & mental changes & limitations of therapy Regular review with GP for clinical monitoring & dose adjustment
	<u>goals</u> :		 Endocrine/ sexual health physican review, if ap-propriate Oestrogen replacement details:
			 Formulation: Target oestrogen: insert patient name >'s target = (outline reasons if difference in targets) Patient education re risks of high dose oestrogen if electing for higher targets
			 Other gender affirming medical treatment: Progesterone Anti-androgens
			 Target testosterone: AusPATH target < 2nmol/L (but above zero) Higher if wishing to maintain erectile function
			Discuss with Dr any treatment concerns

Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers	ACTION ("TO DO") LIST:
	Gender affirming hormonal	Other health care providers:	Education re notential side effects of treatment
	treatment - side effects		
	- - -		
	Early identification & management of treatment side offects	Results:	 Regular blood tests
			Discuss with Dr any treatment concerns
	goals:		 Low libido/ reduced erectile fx. Increase testosterone target (if a concern)
			 Increased metabolic risk Regular blood tests / BP check Healthy lifestyle interventions including regular exercise & healthy diet, consider exercise physiologist/ dietician review as appropriate
			 Penile atrophy / pain Consider topical low dose testosterone
			 Possible elevated VTE (clot) risk Education on clot symptoms Urgent medical review if calf swelling or pain, chest pain or shortness of breath
	Gender affirming hormonal treatment - fertility affects	Other health care providers:	 Discussion of current & future fertility plans Discuss with Dr any fertility concerns
	ldentification & appropriate	Results:	 Consider sperm freezing if appropriate, (long term hormonal therapy may cause sterility)
	of appropriate contraception		 Contraception (condoms, vasectomy, orchiectomy) & STI protection (condoms, PrEP) as indicated
	goals:		

Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
	Other gender affirming treatment Identification of & facilitation of treatment for other goals of gender affirmation including surgery, vocal training, prosthetics, etc. as appropriate <u>goals</u> :	Other health care providers: Results:	 Surgical referral, if/ when appropriate - oestrogen therapy may need to be ceased peri Speech therapy referral, if/when appropriate Permanent hair removal Termanent hair removal Safe use of genital tucking - remove for sleeping, monitor skin for rashes/ infection/ pain/ bruising Breast prostheses - remove for sleeping, monitor skin for rashes/ infections with Dr any treatment concerns/ needs
Gender incongruence - psychological aspects <i>Reference: Pride in Sport Australia,</i> <i>cited Nov. 2016</i> Other causes of mental distress: - Depression - Anxiety - Other mental health disorder:	Identification & appropriate management of any mental distress caused by gender incongruence, esp. if persistent despite gender affirmation, in order to improve symptom control and quality of life management of any co-morbid mental health disorder to achieve & maintain symptom control & improve QOL	Other health care providers: Results:	 Regular review with GP Psychotherapy with psychologist if appropriate Online resources: https://headtohealth.gov.au/ www.acon.org.au Establish/ maintain healthy sleep habits Healthy diet, consider dietician review 30 mins(+) moderate intensity exercise daily, con-sider exercise physiology Meditation/ mindfulness as appropriate Discuss with Dr any med side effects or concerns Lifeline: 13 11 14

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Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
FOR EXAMPLE	Achieve glycaemic control with diet,	Other health care providers:	Regular review with GP 3 monthly
	exercise and medications (where appropriate) to prevent development		Healthy diet, consider dietician review
Diabetes Mellitus	or progression of diabetic complications	Recutre.	Group allied health services for T2DM
(Poor glucose control increases risk	Regular multidisciplinary team		Diabetes educator, if appropriate
ot cardiovascular, kigney and eye disease and nerve damage)	assessment for the prevention/ early		Skin / skin cancer check
			\Box 30 mins moderate intensity exercise daily (or more)
	Standard targets: HbΔ1c < 7%/ 53 mmol/mol		Smoking cessation if smoker
kejerence: касыр general practice management of type 2 diabetes	Total chol. <4.0, HDL ≥1.0, LDL <2.0,		□ Limit alcohol intake (≤2 standard drinks daily, at least 2 alcohol free days per week)
2016-18	non-HDL <2.5, TGs<2.0 BP < 140/90 (< 130/80 if proteinuria)		Foot check: at least yearly
	Urine Alb:Cr <3.5 women, <2.5 men		Eye check: at least yearly
			□ Discuss with Dr any med side effects or concerns

PREVENTATIVE HEALTH CARE PLAN

Health Care Need/ Issue/ Condition	Management Goals	ACTION ("TO DO") LIST:
Sexual Health	Determination of sexual health risk & provision of individualised risk reduction strategies & screening plan	 Use of appropriate protection with any new, untested sexual partners PrEP, if appropriate STI screening recommendations (see www.stiguidelines.org.au): See your doctor if any genital or sexual symptoms
Eye Health	Prevention and early detection of eye disease	 Eye check with optometrist at least every 2 years (more frequently as recom-mended) Report any sudden change in vision or any concerns about your vision
Oral Health	Maintenance of good oral hygiene for the prevention and early detection of dental disease	 Vearly dental checks, or more frequently if advised Brushing teeth twice a day with fluoride toothpaste & daily flossing Smoking cessation if smoker Avoid sugary snacks and drinks Dentist (if any): Last dental check:

Health Care Need/ Issue/ Condition	Management Goals	ACTION ("TO DO") LIST:
Skin Health	Early detection and removal of skin cancers Maintenance of good skin integrity	 Consider yearly skin checks with GP Be aware of changes in your skin; if any new or changing skin lesions see your GP Be 'sun smart' by wearing hats, protective clothing, sunglasses and sunscreen (reapply every 2 hrs) www.sunsmart.com.au
Preventative Health & Screening	Achieve and maintain best possible physical and mental health, maintain independence and prevent disease through health diet, regular exercise, not smoking, limiting alcohol intake and appropriate screening Vaccinations attended:	 ☐ Aggressive cardiovascular disease management through lifestyle measures (listed below) & medication where appropriate ☐ Smoking cessation if smoker ☐ Regular exercise - MINIMUM 30 mins moderate intensity 5+ days/ wk ☐ Health diet high in (non-starchy) vegies, unrefined grains & moderate healthy fats ☐ Limit alcohol in take (≤2 standard drinks daily, at least 2 alcohol free days per week)
	Screening attended:	 Influenza (flu) – annually Whooping cough/ tetanus – every 10 years Pneumococcal – at age 65 (or younger if high risk) Shingles – at age 70
	Outstanding:	 □ Hep A & meningococcal, if appropriate □ Vaccination recommended prior to travel Cancer screening:
		 Prostate cancer check Breast cancer: Mammogram every 2 years ages 50-74 years BreastScreen NSW: 13 20 50 Skin cancer: skin check annually if risk factors such as family history or sunburns Bowel cancer: poo test for blood 2 yearly from age 50, colonoscopy if appropriate

Template created 2019 by Dr Holly Inglis.. Recommendations based on the RACGP Guidelines for Preventative Activities in General Practice 9th Edition, 2016 unless otherwise stated.

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(date of service) (date of service) Team Care Arrangement reviews: _ Team Care Arrangement: _

Treatment / Service Goals & Actions for	SERVICES THE PRACTICE NURSES WILL PROVIDE - e.g. wt checks, needs to be included to be able to claim 10997			
Health Care Need/ Issue/ Condition (to be) addressed by provider	LIST CONDITION			
Treatment / Service Provided	Nursing care			
Collaborating providers & details (as listed in GPMP)	Practice nurses NB to Drs: Nurses to not qualify as 'collaborating providers' for the TCA	1. Collaborating provider:	2. Collaborating provider:	Other collaborating providers:

Signed copies of this final page to be forwarded to collaborating providers

For collaborating providers - please fax back to

, if any changes suggested to current team care arrangements

PATIENT CONSENT FOR GPMP/TCA

I, <insert patient name>, acknowledge that:

- My doctor has explained to me (and/or my carer) the purpose of & the steps involved in preparing my care plan & I have agreed to the preparation of the plan
- My doctor has discussed with me & we have agreed upon management goals for my health care which will be reviewed regularly
- My doctor has offered me (and/or my carer) a copy of my health care plan

If a team care arrangement has been undertaken:

- My doctor has explained the steps involved the development of the team care arrangements to me (and/or my carer)
- My doctor has discussed with me the collaborating providers in my team care arrangement, their services & treatments, & I agree to my team care arrangement
 - I agree to the involvement of other care providers and to for them to share clinical information without restrictions
- My doctor has offered me (and/ or my carer) a copy of my team care arrangement

signature:

signature:

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Appendix 4 - Gender Affirming Masculinising Hormone Therapy Templates

- Patient Information Sheet
- Consent Form
- Chronic Care Management Plan Masculinising
- GP testosterone consultation form for PBS Authority

Patient Information Sheet: Masculinising Hormone Therapy

Typical changes from Testosterone (varies from person to person)

Average timeline	Effect of testosterone
1–3 months after starting testosterone	 decreased estrogen in the body increased sex drive vaginal dryness lower/bottom growth (clitoris) - typically 1-3 cm increased growth, coarseness, and thickness of hairs on arms, legs, chest, back, & abdomen oilier skin and increased acne increased muscle mass and upper body strength redistribution of body fat to the waist, less around the hips increased sweating and change in body odour mood changes may occur
1–6 months after starting testosterone	• menstrual periods stop
3–6 months after	 voice starts to crack and drop within first 3-6 months, but may take at least a year to finish changing
l year or more after starting testosterone	 gradual growth of facial hair (usually 1-4 years) possible balding

Consent form - Masculinising hormone therapy

The informed consent model of care respects your fundamental human right to self-determination and bodily autonomy. The purpose of this document is to indicate, in writing, that you consent to masculinising hormone therapy as part of a gender affirmation process. This form may be signed by any person who is able to make an informed decision over the age of 18, or with the co-signatures of all primary legal guardians.

This document relates to the hormone testosterone. Your doctor will discuss with you all of the information relating to starting hormone therapy. Please read and understand the following information, and raise any questions you have with your doctor.

A physical genital examination, for the purpose of commencing gender affirming hormones, is not required, unless you request an examination.

I,_____, on the date_____, acknowledge that I have

read and understood the following information in consultation with my doctor_____

Tick the boxes to acknowledge the following:

Changes expected whilst on masculinising hormone therapy

Permanent changes:

- Increased facial and body hair
- Deepened voice
- Enlargement of erectile genital tissue (phallus / clitoris)
- Possible balding

Reversible changes:

- Increased libido
- Body fat redistribution
- Coarser and oilier skin
- Acne of face, chest and back
- Stopping of menstrual periods
- Vaginal dryness
- Raised cholesterol
- Increased blood pressure
- Mood changes

I acknowledge the following potential side effects and risks of masculinising hormone therapy. My doctor will continue to monitor my health and address any issues if and when they develop.

- Polycythaemia increased number of red blood cells, resulting in "thickened" blood
- Increased risk of cardiovascular disease
- Difficulty controlling blood sugars if diabetic
- New or worsened obstructive sleep apnoea
- Osteoporosis
- Liver damage
- Increased salt and water retention

I understand that masculinising hormone therapy affects everyone differently, and that there is no way to predict exactly how my body will change. Some of the long term effects of masculinising hormone therapy are not yet known.

I have been advised to consider storing eggs in case I decide to have children at a later date, I have been given the opportunity to delay medical gender affirmation until I have stored eggs if I wish to.

I have been informed that the use of masculinising hormones do not guarantee infertility, and that contraception should be used when having sex that puts me at risk of pregnancy. I have been advised that getting pregnant whilst taking testosterone could put the baby at serious risk.

It is my responsibility to educate myself about safe sex. I should take active steps to protect myself from getting HIV or other sexually transmitted infections. My doctor can guide me make the best choices.

I understand that gender affirming hormone therapy means that I will need to see my doctor and have blood tests at regular intervals throughout my life. Appointments will be more frequent at first, and then every 6-12 months when my hormone levels are stable. I am ready to make this commitment to my health.

I acknowledge that gender affirming hormones are only a part of my overall health, and that a range of preventative health activities are recommended so that I remain happy and healthy in my affirmed gender. These include but are not limited to:

- Cervical screening tests at appropriate intervals, as recommended by my doctor
- Regularly checking my chest / breasts for lumps, even if I have had a mastectomy
- Mammograms from age 50, as recommended by my doctor
- Regular STI screening, depending on my level of risk
- Quitting smoking
- Immunisations
- Regular physical activity if clinically recommended, including resistance exercise for bone health
- Healthy eating

I can choose to stop gender affirming hormone therapy at any time. If I choose to stop taking hormones, it is best that I do this in consultation with my doctor, to ensure that I remain safe and healthy.

Patient name:		
Signature:		
Parent/guardian name:		
Signature:		
Doctor name:		
Signature:	Date:	

GP Testosterone Consultation Form for PBS Authority

GP Details					
Patient Details					
Name:					
Name with Medicare (if different):					
Date of birth:					
Gender:	Man	W	/oman	Non-binary	
Pronouns:					
Gender recorded at birth:	М	F	х	Prefer not to say	
Gender History					
Hx incongruence / dysphoria					
Treatment goals (Medical, surgical, fertility, other)					
Treatment history (Medical, surgical, fertility, other)					
Medical History					
Medical history					
Medications					
Allergies					
Surgical history					
Family history					
Social history					
Mental health					
Sexual health					

Substance use	
Immunisations	
Preventative health	
Examination	
ВР	
Height/Weight	
Cardiovascular/other	
Investigations	
Baseline bloods & hormones (E2/T/LH)	
Sexual health screen	
Thrombophilia screen (FHx / high risk)	
ECG >40yo / high risk	
BMD >50yo / high risk	
Management Plan	
Testosterone therapy	Medication and dose: Titrate to trough level within male ranges
Referrals if indicated (mental health, fertility, endocrine)	
Other	

PBS Indication

Clinical Criteria: Patient must have an established pituitary or testicular disorder.

Treatment Criteria: Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Doctors	
Treating CD	Name:
Treating GP	Signature:
Specialist confirming	Name:
patient meets PBS criteria for testosterone therapy	Specialty:
Tor testosterone therapy	Signature:

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GENDER AFFIRMING CARE MANAGEMENT PLAN - MASCULINISING PREVENTATIVE HEALTH CARE PLAN TEAM CARE ARRANGEMENT

Important Note: Chronic Care Management Plans must be individualised for each patient to ensure Medicare compliance.

GP Management Plans (721)	Plans (72:	1):		(q	(date of service)
Team Care Arrangements (723):	ements (723):	_//_		(date of service)
Reviews (732):	/	/	(date of	date of service)	

PATIENT DETAILS		ALLERGIES
		No known allergies/adverse reactions.
GENDER DETAILS	GP	HISTORY LIST
Gender identity: Gender presumed at birth: F Pronouns:		<i>Inactive:</i> Date Condition Comment

MEDICATIONS

GENDER AFFIRMING CARE MANAGEMENT PLAN TEMPLATE - REVIEW DUE:

Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
Gender incongruence - physical aspected (marked & persistent incongruence between experienced & assigned gender) <i>Reference: ICD-11 (Version 04/2019)</i>	Affirmation of experienced gender through medical &/or surgical treatment and supported social &/or legal gender affirmation as desired	Other health care providers:	 Regular review of goals for gender affirmation Regular monitoring of treatment for efficacy, side effects & concerns Healthy lifestyle measures to support physical & mental health & reduce risk of chronic disease
	Gender affirming hormonal treatment - testosterone replacement	Other health care providers:	 Inform patient that no genital or chest exam is necessary in order to access hormonal affirmation Education re expected physical & mental changes & limitations of therapy
	Testosterone replacement for gender affirmation	Results:	 Regular review with GP Endocrine/ sexual health physican review, if appropriate Testosterone replacement details:
	goals:		
			 Regular blood tests, initially 6-12 weekly, then as advised/ symptomatically Discuss with Dr any treatment concerns
	Gender affirming hormonal treatment - side effects	Other health care providers:	 Education re potential side effects of treatment Targeted management of side effects as appropriate
	Early identification & management of treatment side effects	Results:	 Regular blood tests Discuss with Dr any treatment concerns
	<u>goals</u> :		 Acne Topical treatment: Referral to dermatologist for isotretinoin
			 Persistent uterine bleeding Rule out pathological causes (CST, USS, STI testing as indicated) Consideration of hormonal IUD
			 Polycythemia Regular monitoring of red cell count/ oct Use of male normal values Smoking cessation Treatment modification/ haematology input as indicated
			 Vaginal dryness / atrophy Vaginal moisturisers, e.g. Replens/ Sylk Topical oestrogen Surgical management if appropriate

Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
	Gender affirming hormonal treatment - fertility affects	Other health care providers:	 Discussion of current & fertility concerns Discuss with Dr any fertility concerns
	Identification & appropriate management of fertility goals & use of appropriate contraception	Results:	 Consider egg freezing if appropriate Contraception as indicated (testosterone & amenorrhoea is not sufficient for contraception) including barrier methods, IUD & surgery
	goals:		
	Other gender affirming treatment	Other health care providers:	Surgical referral, if/ when appropriate
	Identification of & facilitation of treatment for other goals of gender		 Speech therapy referral, if/when appropriate Safe use of chest binding - use properly sized commercial binder, remove for
	affirmation including surgery, vocal training, chest binding, etc. as	Kesults:	sleeping, max. 8-12 hrs, Power's 4 finger check; review if pain, rashes or other concerns
	goals:		Prostheses - remove for sleeping, careful daily washing if skin contact; review with GP if symptoms of urinary tract infection (burning, stinging or blood in urine) or skin irritation
			Discuss with Dr any treatment concerns/ needs
Gender incongruence -	Identification & appropriate	Other health care providers:	Regular review with GP
psychological aspects	management of any mental distress caused by gender incongruence,		Psychotherapy with psychologist if appropriate
Reference: Pride in Sport Australia, cited Nov. 2016	esp. if persistent despite gender affirmation, in order to improve symptom control and quality of life	Results:	 Online resources: https://headtohealth.gov.au/ www.acon.org.au
Other causes of mental distress:			Establish/ maintain healthy sleep habits
- Depression - Anxiety	Identification & appropriate		
- Other mental health disorder:	mental health disorder to achieve		
	& maintain symptom control &		
			Lifeline: 13 11 14

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Health Care Need/ Issue/ Condition	Management Goals	OTHER care providers Results/ appointments	ACTION ("TO DO") LIST:
FOR EXAMPLE	Achieve glycaemic control with diet, exercise and medications (where	Other health care providers:	Regular review with GP 3 monthly
Diabetes Mellitus	appropriate) to prevent development or progression of diabetic complications	Results.	Healthy diet, consider dietician review Group allied health services for T2DM
(Poor glucose control increases risk	Regular multidisciplinary team		Diabetes educator, if appropriate
or cargiovascular, kigney and eye disease and nerve damage)	assessment for the prevention/ early detection of diabetic complications		Skin / skin cancer check
	C+2		\Box 30 mins moderate intensity exercise daily (or more)
	Januaru targets. HbA1c < 7%/ 53 mmol/mol		Smoking cessation if smoker
rejerence: ractor general practice management of type 2 diabetes	Total chol. <4.0, HDL ≥1.0, LDL <2.0,		\Box Limit alcohol intake (s2 standard drinks daily, at least 2 alcohol free days per week)
2016-18	BP < 140/90 (< 130/80 if proteinuria)		Foot check: at least yearly
	Urine Alb:Cr <3.5 women, <2.5 men		Eye check: at least yearly
			\Box Discuss with Dr any med side effects or concerns

PREVENTATIVE HEALTH CARE PLAN

Health Care Need/ Issue/ Condition	Management Goals	ACTION ("TO DO") LIST:
Sexual Health	Determination of sexual health risk & provision of individualised risk reduction strategies & screening plan	 Use of appropriate protection with any new, untested sexual partners PrEP, if appropriate STI screening recommendations (see www.stiguidelines.org.au): See your doctor if any genital or sexual symptoms
Eye Health	Prevention and early detection of eye disease	 Eye check with optometrist at least every 2 years (more frequently as recommended) Report any sudden change in vision or any concerns about your vision
Oral Health	Maintenance of good oral hygiene for the prevention and early detection of dental disease	 Yearly dental checks, or more frequently if advised Brushing teeth twice a day with fluoride toothpaste & daily flossing Smoking cessation if smoker Avoid sugary snacks and drinks Dentist (if any): Last dental check:

Health Care Need/ Issue/ Condition	Management Goals	ACTION ("TO DO") LIST:
Skin Health	Early detection and removal of skin cancers Maintenance of good skin integrity	 Consider yearly skin checks with GP Be aware of changes in your skin; if any new or changing skin lesions see your GP Be 'sun smart' by wearing hats, protective clothing, sunglasses and sunscreen (reapply every 2 hrs) www.sunsmart.com.au
Preventative Health & Screening	Achieve and maintain best possible physical and mental health, maintain independence and prevent disease through health diet, regular exercise, not smoking, limiting alcohol intake and appropriate screening Vaccinations attended:	 ☐ Aggressive cardiovascular disease management through lifestyle measures (listed below) & medication where appropriate ☐ Smoking cessation if smoker ☐ Regular exercise - MINIMUM 30 mins moderate intensity 5+ days/ wk ☐ Health diet high in (non-starchy) vegies, unrefined grains & moderate healthy fats ☐ Limit alcohol in take (≤2 standard drinks daily, at least 2 alcohol free days per week) <i>Vaccination</i>:
	Screening attended:	 Influenza (flu) – annually Whooping cough/ tetanus – every 10 years Pneumococcal – at age 65 (or younger if high risk) Shingles – at age 70 Hep A & meningococcal, if appropriate
	Outstanding:	 Vaccination recommended prior to travel Cancer screening: Cervical cancer: screening ages 25-74
		At least every 5 yrs (if last test after Dec 2017 - Zyrs if below), more frequently as advised; see Dr if abnormal vaginal bleeding Breast cancer: Mammogram every 2 years ages 50-74 years BreastScreen NSW: 13 20 50 Skin cancer: skin check annually if risk factors such as family history or sunburns Bowel cancer: poo test for blood 2 yearly from age 50, colonoscopy if appropriate

Template created 2019 by Dr Holly Inglis.. Recommendations based on the RACGP Guidelines for Preventative Activities in General Practice 9th Edition, 2016 unless otherwise stated.

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Team Care Arrangement: __

_ (date of service) (date of service) Team Care Arrangement reviews: ____

Treatment / Service Goals & Actions for	SERVICES THE PRACTICE NURSES WILL PROVIDE - e.g. wt checks, needs to be included to be able to claim 10997			
Health Care Need/ Issue/ Condition (to be) addressed by provider	LIST CONDITION			
Treatment / Service Provided	Nursing care			
Collaborating providers & details (as listed in GPMP)	Practice nurses NB to Drs: Nurses to not qualify as 'collaborating providers' for the TCA	1. Collaborating provider:	2. Collaborating provider:	Other collaborating providers:

Signed copies of this final page to be forwarded to collaborating providers

For collaborating providers - please fax back to

____, if any changes suggested to current team care arrangements

PATIENT CONSENT FOR GPMP/TCA

I, <insert patient name>, acknowledge that:

- My doctor has explained to me (and/or my carer) the purpose of & the steps involved in preparing my care plan & I have agreed to the preparation of the plan
- My doctor has discussed with me & we have agreed upon management goals for my health care which will be reviewed regularly
- My doctor has offered me (and/or my carer) a copy of my health care plan

If a team care arrangement has been undertaken:

- My doctor has explained the steps involved the development of the team care arrangements to me (and/or my carer)
- My doctor has discussed with me the collaborating providers in my team care arrangement, their services & treatments, & I agree to my team care arrangement
- I agree to the involvement of other care providers and to for them to share clinical information without restrictions
- My doctor has offered me (and/ or my carer) a copy of my team care arrangement

signature:

signature:

References

American Psychological Association. (2015). Guidelines for psychological practice with transgender and gender nonconforming people. American Psychologist, 70(9), 832-864. <u>https://doi. org/https://doi.org/10.1037/a0039906</u>

AusPATH. (2021, June 26). Public Statement on Gender Affirming Healthcare, including for Trans Youth – AusPATH. https://auspath.org. au/2021/06/26/auspath-public-statement-ongender-affirming-healthcare-including-for-transyouth/

Australian Commission on Safety and Quality in Healthcare. (2020). Informed consent in health care. Australian Commission on Safety and Quality in Healthcare. <u>https://www.safetyandquality.gov.</u> <u>au/sites/default/files/2020-09/sq20-030 - fact</u> <u>sheet - informed consent - nsqhs-8.9a.pdf</u>

Re Bernadette [2010] FamCA 94

Callen-Lorde Community Health Centre. (2014). Protocols for the Provision of Hormone Therapy. https://callen-lorde.org/graphics/2018/04/Callen-Lorde-TGNC-Hormone-Therapy-Protocols.pdf

Cheung, A. S., Lim, H. Y., Cook, T., Zwickl, S., Cinger, A., Chiang, C., & Zajac, J. D. (2020). Approach to interpreting common laboratory pathology tests in transgender individuals. *J Clin Endocrinol Metab*, *106*(3), 893-901. <u>https://doi.org/10.1210/clinem/</u> <u>dgaa546</u>

Cheung, A. S., Wynne, K., Erasmus, J., Murray, S., & Zajac, J. D. (2019). Position statement on the hormonal management of adult transgender and gender diverse individuals. *Medical Journal* of Australia, 211(3). 211(3), 127-133. <u>https://doi.</u> org/10.5694/mja2.50259

Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W. J., Monstrey, S., Adler, R. K., Brown, G. R., Devor, A. H., Ehrbar, R., Ettner, R., Eyler, E., Garofalo, R., Karasic, D. H., Mayer, G... Zucker, K. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *The international journal of transgenderism*, *13*(4), 165-232. https://doi.org/10.1080/15532739.2011.700873

Consent to Medical Treatment and Palliative Care Act 1995. (SA) https://www.legislation. sa.gov.au/lz?path=%2FC%2FA%2FCONSENT%20 TO%20MEDICAL%20TREATMENT%20AND%20 PALLIATIVE%20CARE%20ACT%201995. Durwood, L., McLaughlin, K. A., & Olson, K. R. (2017). Mental Health and Self-Worth in Socially Transitioned Transgender Youth. Journal of the American Academy of Child and Adolescent Psychiatry, 56 (2), 116-123.e112. https://doi. org/10.1016/j.jaac.2016.10.016

Fisher, C. M., Waling, A., Kerr, L., Bellamy, R., Ezer, P., Mikolajczak, G., Brown, G., Carman, M., & Lucke, J. (2019). 6th national survey of Australian secondary students and sexual health 2018. https:// gdhr.wa.gov.au/-/2018-6th-national-survey-ofaustralian-secondary-students-and-sexual-health

Heylens, G., Elaut, E., Kreukels, B. P. C., Paap, M., Cerwenka, S., Richter-Appelt, H., Cohen-Kettenis, P., Haraldsen, I. R., & De Cuypere, G. (2014). Psychiatric characteristics in transsexual individuals: multicentre study in four European countries. *Br J Psychiatry*, 204(2), 151-156. <u>https://doi.org/10.1192/</u> <u>bjp.bp.112.121954</u>

Re Imogen (No. 6) [2020] FamCA 761

Kenny Rodriguez-Wallberg, Juno Obedin-Maliver, Bernard Taylor, Norah Van Mello, Kelly Tilleman & Leena Nahata (2022): Reproductive health in transgender and gender diverse individuals: A narrative review to guide clinical care and international guidelines, International Journal of Transgender Health, DOI: 10.1080/26895269.2022.2035883

Keo-Meier, C and Ehrensaft, D. (2018). Introduction to the gender affirmative model. In Keo-Meier, C and Ehrensaft, D (Eds) The Gender affirmative model: An interdisciplinary approach to supporting transgender and gender expansive children. (pp 3-20). American Psychological Association. http://www.jstor.org/stable/j.ctv1chrwv9.4

Ker, A., Fraser, C., Lyons, A., Stephenson, C., & Fleming, T. (2020). Providing gender-affirming hormone therapy through primary care: service users. *Journal of primary health care*, 12(1), 72-78. https://doi.org/10.1071/HC19040

Re Kelvin [2018] FamCAFC at [84].

Olson, K. R., Durwood, L., DeMeules, M., & McLaughlin, K. A. (2016). Mental Health of Transgender Children Who Are Supported in Their Identities. *Pediatrics*, *137* (3), e20153223-e20153223. https://doi.org/10.1542/peds.2015-3223 Russell, S. T., Pollitt, A. M., Li, G., & Grossman, A. H. (2018). Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behavior Among Transgender Youth. *Journal of Adolescent Health*, 63 (4), 503-505. https://doi.org/https://doi.org/10.1016/j. jadohealth.2018.02.003

Transgender Europe. (2019). Guidelines to human rights-based trans-specific healthcare, 2019. <u>https:// tgeu.org/guidelines-to-human-rights-based-trans-</u> specific-healthcare/

Turban, JL., King D., Kobe J., Reisner SL., Keuroghlian AS. (2022). Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. *PLOS ONE* 17(1), e0261039. <u>https://doi.org/10.1371/journal.</u> pone.0261039

The Children and Young Persons (Care and Protection) Act 1998 (NSW). <u>https://legislation.nsw.gov.au/view/whole/html/inforce/2021-12-08/act-1998-157#ch.2</u>

Scheim, A. I., Perez-Brumer, A. G., & Bauer, G. R. (2020). Gender-concordant identity documents and mental health among transgender adults in the USA: a cross-sectional study. *The Lancet Public Health*, 5(4), e196-e203. <u>https://doi.org/https://doi.</u> org/10.1016/S2468-2667(20)30032-3

White Hughto, J. M., & Reisner, S. L. (2016). A Systematic Review of the Effects of Hormone Therapy on Psychological Functioning and Quality of Life in Transgender Individuals. *Transgender health*, 1(1), 21-31. <u>https://doi.org/10.1089/</u> <u>trgh.2015.0008</u>

World Health Organization. (2022). WHO/Europe brief – transgender health in the context of ICD-11. https://www.euro.who.int/en/health-topics/ health-determinants/gender/gender-definitions/ whoeurope-brief-transgender-health-in-thecontext-of-icd-11

World Medical Association. (2017). WMA Statement on Transgender People. <u>https://www.wma.net/</u> policies-post/wma-statement-on-transgenderpeople/

Yogyakarta Principles. (2007). The Yogyakarta Principles: Principles on the Application of International Human Rights Law in Relation to Sexual Orientation and Gender Identity. https://yogyakartaprinciples.org/ Yogyakarta Principles. (2017). The Yogyakarta Principles Plus 10: Additional Principles and State Obligations on the Application of International Human Rights Law in Relation to Sexual Orientation, Gender Identity, Gender Expression and Sex Characteristics to Complement the Yogyakarta Principles. https://yogyakartaprinciples.org/wpcontent/uploads/2017/11/A5_yogyakartaWEB-2.pdf

Zaliznyak, M., Bresee, C., & Garcia, M. M. (2020). Age at First Experience of Gender Dysphoria Among Transgender Adults Seeking Gender-Affirming Surgery. JAMA Network Open, 3(3), e201236. https://doi.org/10.1001/jamanetworkopen.2020.1236

