



# **Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy**

Version 2



## Acknowledgement of Country

This document was developed, written and reviewed by many people, including those living and working on the lands of the Awabakal, Bidjigal, Bunurong Boon Wurrung, Dharawal, Dharug, Gadigal, Garigal, Gundungurra, Jagera, Meanjin, Palawa, Turrbal, Wadawurrung, Wangal, Wiradjuri, and Wurundjeri Woiwurrung peoples.

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

We pay our respects to the Elders past, present, and emerging, and extend our respect to all First Nations peoples, Sistergirls, Brotherboys, and trans mob reading this document. We recognise the longstanding presence of gender diversity in First Nations cultures, acknowledging the significant roles that Sistergirls, Brotherboys, and other gender-diverse people have held in communities on these lands long before colonisation.

# AusPATH

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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 well-being of all trans individuals - binary and non-binary. AusPATH was established in 2009 as the Australian and New Zealand Professional Association for Transgender Health (ANZPATH). In 2019, the name and governance structure were changed to better reflect its national reach and representation and the Professional Association for Trans Health Aotearoa (PATHA) was formed.

The Boards of AusPATH and PATHA enjoy a close relationship and advocate together on shared aims.

## Aims of AusPATH

- Provide education to health professionals on the health, rights, and well-being of all trans people, binary and non-binary.
- Develop best practice and supportive policies.
- Share information and promote communication and collaboration among health professionals.
- Encourage, promote, and disseminate relevant research.
- Maintain a network of supportive and informative professional service providers.

## AusPATH provides:

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

Find us at [www.auspath.org.au](http://www.auspath.org.au)

To become a member, please fill out the application form online at <https://auspath.org.au/become-a-member/>. Membership fees apply, with different membership tiers available.

Suggested reference: AusPATH. (2025). Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy. Version 2. Australia: Australian Professional Association for Trans Health.

Suggested citation: AusPATH, 2025

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## Foreword: AusPATH President and Vice-President

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On behalf of the AusPATH Board of Directors and Executive, we are delighted to introduce the *Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)*.

The original *Australian Informed Consent Standards of Care for Gender Affirming Hormone Therapy (AusPATH SOC 2022)* were published on the 31st March 2022. Released to coincide with Trans Day of Visibility, AusPATH SOC 2022 represented a milestone for gender-affirming care within Australia. By explicitly endorsing an informed consent model of care for gender-affirming therapies, AusPATH SOC 2022 recognised the fundamental human rights of trans and gender diverse people to autonomy and self-determination, changing the landscape for gender-affirming care in Australia.

The original standards of care (SOC) were developed to support clinicians working in Australia to confidently, safely, and compassionately provide high quality medical care to their trans and gender diverse individuals. They highlighted the essential role of general practitioners and other primary care providers in the provision of gender-affirming medical treatments. In doing so, they marked an important step away from the historical pathologisation of trans and gender diverse identities, and a move towards increased access to medically necessary care.

In addition to guiding choices around hormone therapies and other medical treatments, the SOC assisted primary care practitioners to provide culturally and psychosocially safe medical care. This was a significant contribution to healthcare in Australia, increasing the accessibility of essential medical care for a population that have historically faced significant barriers to health, and consequently, poorer health outcomes when compared with their cisgender peers.

Trans and gender diverse health care is an exciting and evolving field of medicine, with new advances in our understanding of treatments, treatment options, and the health needs of trans and gender diverse people developing over time. Since the publication in 2022 of the original informed consent SOC, progress in research has furthered our understanding of the needs of trans and gender diverse people. Over the same period, new clinical questions and challenges have gained prominence, such as optimal treatment approaches for non-binary individuals.

This new update to the SOC seeks to address the clinical questions and concerns that arise in the provision of gender-affirming hormone care. Compiling the most up-to-date research available, and with input from multiple clinical experts in this field, the new AusPATH SOC 2025 provides a comprehensive summary of the current evidence base, and outlines contemporary clinical recommendations for the provision of gender-affirming care in Australia.

For clinicians, researchers, and other professionals working in the field of trans and gender diverse healthcare, the primary goal of the work that we do is to improve the health, safety and wellbeing of trans and gender diverse people. These updated SOC will support us to do exactly that. They are an invaluable resource for professionals working in trans health in Australia. As the peak organisation representing this professional body, AusPATH are proud to be publishing the *Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)*.

Professor Ashleigh Lin (President) and Dr Portia Predny (Vice President)

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## Foreword: AusPATH Standards of Care Review Committee

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On behalf of the Australian Professional Association for Trans Health (AusPATH), we are proud to present to AusPATH members, as well as to communities and clinicians across Australia, the *Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)*.

In March 2022, the original AusPATH *Australian Informed Consent Standards of Care for Gender Affirming Hormone Therapy* was released. Prior to this, there were no local standards to refer to, and the contemporaneous *World Professional Association for Trans Health Standards of Care (WPATH SOC)(Version 7)* firmly centred mental health professionals in assessments for gender-affirming hormone therapy (GAHT). The AusPATH SOC 2022 provided meaningful Australian standards that supported the clinical care of transgender and gender diverse (TGD) individuals, and placed primary care practitioners, such as ourselves, at the forefront of GAHT provision. Importantly, they acknowledged TGD individuals as experts in their own lives and gender experiences. These inaugural SOC were empowering and facilitated accessible GAHT without requiring non-GP specialist involvement or other mental health professional input where unnecessary.

In the foreword of the original AusPATH SOC 2022, President Dr Fiona Bisshop, and Vice-President Mr Teddy Cook explained that the SOC were intended to be revised and regularly updated as new evidence emerged regarding best practice. As research continues to advance, evidence continues to emerge regarding the benefits and safety of GAHT, and we aim to capture the latest information in this first major update.

As GPs working in this space, we have updated the SOC to reflect how care is currently provided in primary care and present the evidence to support this care. We also recognise that there were aspects of TGD health that were not addressed in AusPATH SOC 2022 to the extent desired, and we have endeavoured to include information on different populations and specific clinical scenarios that may be encountered in the primary care setting when providing GAHT.

Our goal in developing AusPATH SOC 2025 has been to align with the *National Health and Medical Research Council Standards for Guidelines* and to meet the following benchmarks:

- relevancy and usefulness in decision making (Standard 1)
- focus on health and related outcomes (Standard 5)
- evidence-informed (Standard 6)
- actionable recommendations (Standard 7)
- up-to-date (Standard 8)
- accessibility (Standard 9)

We have also met the standards for transparency (Standard 2) and the identification and management of conflicts of interest (Standard 4), with all contributors declaring no conflicts and receiving no financial compensation for their work. Areas for development for future iterations include establishing a dedicated guideline development group (Standard 3) and as more evidence emerges in this field, subsequent versions would benefit from graded evidence and recommendations. By enhancing these areas, future versions will continue to uphold clinical rigour while maintaining meaningful community engagement.

The political climate into which AusPATH SOC 2025 is being released must be acknowledged. During the drafting of this document, major political shifts have taken place in Australia and internationally, with gender-affirming healthcare increasingly coming under threat. Policies that restrict access to care for TGD people have emerged in some jurisdictions, creating fear and uncertainty for individuals and the clinicians who support them. In this environment, it is more important than ever for the healthcare community to stand together with resilience and unity, ensuring that TGD people continue to receive safe, evidence-based, affirming care.

We would like to acknowledge on whose shoulders we stand in presenting version 2 of the AusPATH SOC. Both the Thorne Harbour Health, Equinox Gender Diverse Health Centre, *Protocols for the Initiation of Hormone Therapy for Trans and Gender Diverse Patients (2020)*, and the hormone protocols of the Callen-Lorde Community Health Centre, New York City, NY, USA were central to the development of AusPATH SOC 2022. We deeply thank all the contributors to those guidelines and the contributors to AusPATH SOC 2022.

For their contributions to the *Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)*, we would like to acknowledge the following (in alphabetical order):

Dr Sophia Berkemeier, Dr Fiona Bisshop, Ms Crystal Boza, Professor Ada Cheung, Dr Michelle Dutton, Dr Michelle Hannan, Dr Adam Brownhill, Dr Michelle McRae, Dr Brendan Nolan, Mx Emerson Österberg, Dr Portia Predny, Professor Darren Russell, Dr Bronwyn Thorpe, Professor Katie Wynne, Dr Gemma Urch and the AusPATH Board.

Dr Mihal Guttman-Jones and Dr Holly Inglis

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# Table of Acronyms

ACRONYM	TERM
5ARI	5-alpha reductase inhibitors
ADHD	Attention-deficit hyperactivity disorder
AGA	Androgenic alopecia
ASD	Autism spectrum disorder
ASHM	Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
AusPATH	Australian Professional Association of Trans Health
CMI	Consumer Medicines Information
CVD	Cardiovascular disease
CPA	Cyproterone acetate
DXA	Dual-energy x-ray absorptiometry
ECG	Electrocardiogram
GAHT	Gender-affirming hormone therapy
GAS	Gender-affirming surgery
GP	General practitioner
HIV	Human immunodeficiency virus
MBS	Medicare Benefits Schedule
OSA	Obstructive sleep apnoea
PATHA	Professional Association for Trans Health Aotearoa
PBS	Pharmaceutical Benefits Scheme
PI	Product information
POME	Pulmonary oil microembolism
PrEP	Pre-exposure prophylaxis
RACGP	Royal Australian College of General Practitioners
T2DM	Type 2 diabetes mellitus
TGD	Transgender and gender diverse
SNAP	Smoking, nutrition, alcohol, and physical activity
SOC	Standards of care
VTE	Venous thromboembolism
WHI	Women's Health Initiative
WPATH	World Professional Association for Trans Health

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# Executive Summary

## Purpose

The AusPATH *Australian Standards of Care for Informed Consent Gender-Affirming Hormone Therapy, Version 2 (2025)* (AusPATH SOC 2025) is intended to provide a benchmark for Australian clinicians providing gender-affirming care and hormone therapy. The recognition of overlooked populations, the need for increased clinical guidance for primary care practitioners in specific clinical scenarios, and the need for AusPATH SOC to more accurately reflect primary care workflows have prompted this new version.

Gender and its exploration are a normal part of the vast canvas of the human experience, and general practitioners (GPs) and other primary care providers, as community-based practitioners with their broad experience, are best placed to provide gender-affirming hormone therapy (GAHT). The purpose of these standards of care (SOC) is to empower GPs and other practitioners to provide safe and effective GAHT for transgender and gender diverse (TGD) adults (those aged 18 years and over) in the primary care setting. By firmly placing GAHT for adults in the primary care setting, AusPATH SOC 2025 aims to help reduce barriers and improve health outcomes for TGD individuals.

While the latest AusPATH SOC 2025 is written by GPs for use by GPs and other providers working in community care, such as nurse practitioners and Aboriginal health care workers, it is also intended to apply broadly to other services, including sexual health clinics, custodial settings, Aboriginal Community Controlled Health Services, hospital settings, and any other clinical setting where GAHT is provided.

## Scope

The AusPATH SOC 2025 offers expert Australian consensus on the initiation and management of GAHT in the Australian primary care setting under the informed consent model of care for TGD adults seeking hormonal affirmation. It provides support for the management of commonly encountered clinical scenarios for those on GAHT.

For those under the age of 18 years, those in care, or those under guardianship orders, the medicolegal context that clinicians must navigate with regard to capacity to consent is more complex. For those under the age of 18 years, rules vary by state and are undergoing change. It is incumbent on the provider to be aware of the legal context in which they practise. Principles for the initiation and management of GAHT outlined in these SOC can be used with post-pubertal adolescents provided the legal requirements for where you are practising, and the guidelines outlined in the *Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents*<sup>1</sup> are met.

It should be noted that at time of publication guidelines for the care of those under the age of 18 years are under review. Multidisciplinary care should be considered for the care of individuals under the age of 18 years, those in care, or those under guardianship orders, in primary care settings.

## **What is new**

AusPATH SOC 2025 includes several important changes to language and structure. Terminology has been revised to be more inclusive and affirming. The term 'transgender and gender diverse', and its acronym, TGD, has been adopted to encompass the broad spectrum of gender identities beyond cisgender. We acknowledge that not all individuals identify with this term or with the use of acronyms more generally. Acronyms can at times feel clinical, reductive, or imposed by institutions, and the diversity of language and identity across communities is recognised. We also recognise that language is constantly evolving.

As a clinical document intended for use in healthcare settings, some shared terminology is necessary for clarity; however, terminology has been chosen with care and consideration. We have also limited the use of the term 'patient' to avoid pathologising language, and replaced 'feminising' and 'masculinising' hormonal care with 'estradiol-based' and 'testosterone-based' care, respectively, to better reflect individualised approaches and affirming language.

The structure of the AusPATH SOC has also been updated. This current version now includes an executive summary, a purpose section, and a scope section, with the main body text presented in three parts to enhance clarity, usability, and clinical relevance.

- Part 1 now provides important contextual background regarding the provision of GAHT and situates AusPATH SOC 2025 within the Australian primary healthcare system.
- Part 2 is adapted from the original five stages and outlines the clinical assessment of individuals seeking GAHT. The partitioning into five stages has been removed to reflect the flexibility required in the application of the AusPATH SOC in primary care settings. Information on sexual health, fertility, principles of hormone prescribing, hormone education, and non-hormonal gender affirmation has been updated and expanded, and there are updated and new tables regarding side effects, dosages, and hormone formulations.
- Part 3 is a new section with contributions from multiple experts in the field that addresses specific clinical scenarios and key considerations for primary care providers of GAHT.

Finally, the appendices have been revised with updated resources and consent forms.

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# Part 1. Background

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## Informed consent model of care

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Informed consent, as per the Australian Commission on Safety and Quality in Healthcare, is:

*A person's decision, given voluntarily, to agree to a health care 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.*<sup>2</sup>

General practitioners (GPs) engage with informed consent in every patient encounter. It is the medicolegal and ethical foundation of the care we provide. We ensure individuals receive relevant information regarding their health care choices while assessing their capacity to understand the information provided and make decisions about their health. Central to informed consent is autonomy, that is, an individual's right to make their own choices about their own body and life, provided they have sufficient and appropriate information. As GPs, our role is to facilitate and respect these choices. The principle of bodily integrity, bodily autonomy and informed consent is a human rights principle, as per *Transgender Europe's 2019 Guidelines to Human Rights-based Trans-Specific Health Care* and align with the *Yogyakarta Principles (2007)*<sup>3</sup> and the *Yogyakarta Principles+10 (2017)*<sup>4</sup> of human rights. Informed consent is a RACGP standard for general practice.<sup>5</sup>

The informed consent model for gender-affirming hormone therapy (GAHT) emerged as an alternative to the 'standard care' model outlined by the *World Professional Association of Trans Health (WPATH)* which has traditionally placed greater emphasis on the role of mental health professionals in assessing gender dysphoria and facilitating gender role changes.<sup>6</sup> The original 1979 standards of care (SOC) advised mental health professionals not to rely on individuals' accounts of their experience as they were 'potentially unreliable or invalid sources of information' and should instead be validated independently.<sup>7</sup> Until the last two iterations of the WPATH SOC, it was recommended that those seeking GAHT be prescribed a period of 'real-life' experience in their identified gender before any medical intervention, a requirement which was impractical, infantilising, and potentially dangerous.<sup>7</sup>

In contrast, the informed consent model recognises that gender incongruence of adulthood is not a mental health disorder and emphasises the individual's expertise in their own lives. Under this model, the threshold for initiation of GAHT is simply informed consent. Mental health professionals still play an important role but are engaged when requested by the individual or when significant coexisting mental health concerns require management before initiating hormonal care. This model separates supportive mental health care from the assessment of gender incongruence.<sup>7</sup> The two most recent iterations of the WPATH SOC; SOC 7 (2012)<sup>6</sup> and SOC 8 (2022)<sup>8</sup> acknowledge the informed consent model as a valid approach to adult GAHT, recognising the diversity of clinical environments and individuals seeking treatment.

The informed consent model does not mean 'hormones on demand'. Rather it rejects the idea that a medical professional must validate an individual's gender experience. Instead, it centres the adult seeking treatment in their own medical decision-making while ensuring they receive appropriate information regarding the benefits, risks and side effects of GAHT. This model allows transgender and gender diverse (TGD) individuals to obtain care from their GP without requiring non-GP specialist input or separate mental health professional consultations where they are not clinically indicated. This approach reduces costs, shortens wait times, and improves accessibility. The informed consent model of care for GAHT is associated with high satisfaction<sup>9</sup> and access to gender-affirming hormone therapy has been shown to be associated with reduced gender dysphoria, depression, and suicidality.<sup>10</sup>

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## Gender dysphoria vs gender incongruence

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'Gender dysphoria' and 'gender incongruence' are terms often used to describe experiences related to gender identity, but they are distinct concepts. Gender dysphoria refers to the psychological distress that can arise when an individual's gender identity differs from their birth-registered sex. This distress can manifest as significant discomfort or anxiety and may necessitate clinical intervention to alleviate. 'Gender incongruence' is a broader term describing a mismatch between a person's gender identity and the birth-registered sex. It encompasses the internal sense of one's gender not aligning with their birth sex, but does not inherently include the distress component that defines gender dysphoria. Thus, individuals may have gender incongruence with or without gender dysphoria. AusPATH SOC 2025 recommends primary care practitioners adopt a supportive, informed approach, offering hormone therapy, counselling, or other interventions based on the individual's self-identified needs rather than rigid diagnostic criteria. This approach respects individuals' autonomy and facilitates timely access to necessary care without the additional burden of a formal diagnosis. We have minimised our use of the term 'patient' in AusPATH SOC 2025 to further destigmatise and demedicalise an experience that is innately human.

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## Beyond the binary

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In addition to the binary framework of cisgender and transgender individuals, the concept of gender includes non-binary identities. Non-binary individuals may not exclusively identify as man or woman; instead, their gender identity exists outside these traditional categories. They may identify as a blend of genders, a different gender, or no gender and this identification may be fluid. Pronouns such as they/them/theirs are frequently used while others may use neopronouns, such as xe/xem/xyr.

Research has shown that non-binary individuals face specific challenges related to social recognition, acceptance, and access to healthcare. They may encounter difficulties with legal documentation and societal expectations that predominantly recognise binary genders and many report high levels of invalidation of their gender experience.<sup>11</sup> Non-binary individuals also face significant barriers to accessing GAHT, including healthcare providers failing to recognise their gender as valid, refusing to acknowledge or support their need for GAHT, or individuals having to educate the clinicians from whom they are seeking treatment. Additionally, they often feel pressured to present themselves within a binary gender framework, either as transmasculine or transfeminine, in order to access GAHT. As a result, non-binary individuals are more likely to delay care due to fears about how they will be treated within the health system.<sup>8</sup>

It is important for primary care practitioners to avoid limiting their understanding of gender to a linear spectrum, with traditional perceptions of masculinity and femininity positioned at either end. This perspective risks viewing non-binary individuals as 'partial articulations' of a more complete transgender manhood or womanhood.<sup>8</sup> Instead, by recognising gender as a non-linear spectrum that embraces diverse experiences beyond traditional and Western conceptualisations, primary care practitioners can create space for individuals to determine how they wish to be seen and addressed. This approach also fosters trusting therapeutic relationships and ensures the needs of those seeking care are met.

Non-binary individuals can be supported through the acknowledgment and respect of their gender identities, the implementation of inclusive practices in medical settings, and advocacy for legal reforms that recognise diverse gender identities. These SOC emphasise the importance of personalised care that honours an individual's self-identified needs and preferences.

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## Individuals with innate variations of sex characteristics

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Individuals with innate variations of sex characteristics (which may be known clinically as intersex or individuals with differences of sex development) are individuals whose physical sex characteristics do not fit typical medical or social norms for male or female bodies. Some individuals with innate variations of sex characteristics are also gender diverse and may pursue GAHT to align their physical characteristics with their gender identity. Others, including those who are cisgender, may seek GAHT or gender-affirming procedures to address the effects of earlier, non-consensual medical interventions or for other personal or medical reasons. These experiences can be shaped by complex interactions with the healthcare system, including barriers to access, lack of recognition in policy, and a history of involuntary or traumatic treatment.

It is important to recognise that people with innate variations of sex characteristics variations may have unique anatomical and physiological needs that impact the safety and effectiveness of hormonal or surgical interventions. For example, some individuals may have atypical genital or reproductive anatomy or respond to hormones in unexpected ways. While AusPATH SOC 2025 focuses on the needs of transgender and gender diverse populations, it may also serve as a resource for healthcare providers supporting people with innate variations of sex characteristics variations seeking GAHT.

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## Intersectionality in gender-affirming healthcare

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Clinicians providing gender-affirming healthcare for TGD individuals should be aware of the overlapping marginalisations often present in individuals seeking their care. Intersectionality describes how various social identities, including but not limited to gender and sexual identity, race, socioeconomic status, disability, and cultural background, intersect to create distinct and compounding challenges.<sup>12</sup> The perception of discrimination in healthcare settings further exacerbates these challenges, discouraging individuals from seeking necessary care.<sup>13</sup>

In gender-affirming care, understanding and addressing the impact of an individual's intersecting identities is necessary to deliver holistic and culturally sensitive support. This includes actively creating a welcoming and inclusive environment, ensuring accessible communication, and acknowledging systemic inequities that affect an individual's health outcomes. Taking an intersectional approach improves wellbeing, builds trust, and allows clinicians to deliver care that is more effective and equitable.

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## Gender-affirming care for First Nations individuals

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For Australian GPs, understanding intersectionality is important when addressing the experiences of First Nations TGD individuals, who often face multiple layers of marginalisation. These individuals may encounter discrimination not only due to their gender identity but also because of their Aboriginality, and may experience worse health and wellbeing because of overlapping inequities.<sup>14</sup> Systemic barriers to care also include a higher proportion of First Nations people living in rural and remote areas, where affirming services are less accessible, and the decision to travel for services is impacted by distance, cost, access to transport, separation from community and cultural safety.<sup>12</sup> Some Indigenous TGD individuals choose to relocate from Country to more socially accepting areas with better access to affirming care, but this can lead to disconnection from their land, culture, and community, which can negatively impact their wellbeing.<sup>12,14</sup> GPs can improve the quality of care for First Nations individuals by recognising culture, creating safe and welcoming clinic environments, providing trauma-informed care, seeking further education about how to provide appropriate healthcare for Indigenous communities and First Nations TGD people specifically, and advocating for systemic change.

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## Trauma-informed care

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Trauma-informed care is a framework for healthcare provision that recognises and responds to the widespread impacts of trauma on individuals. It acknowledges that trauma, whether it stems from abuse, violence, discrimination, intergenerational impacts or other distressing events, can affect a person's physical, emotional, and psychological health.

The RACGP first principles of trauma informed care are:

- prioritise safety
- foster the capacity to soothe physiological arousal
- validate the person and their perceptions
- collaborate and empower
- connect and stay involved<sup>15</sup>

In practice, this involves creating a safe and supportive environment, establishing trust between clinicians and those seeking care, providing individuals with choices in their care, collaborating on treatment plans, and empowering individuals by validating their experiences and promoting autonomy in their healthcare decisions. In doing so, it helps avoid re-traumatisation and improve outcomes. Trauma-informed care is central to the AusPATH SOC 2025.

Trauma-informed care is especially important for TGD individuals, many of whom experience trauma related to their gender identity, including discrimination, rejection, and violence.<sup>16</sup> Misgendering, deadnaming, invasive questioning, and medical gatekeeping are common healthcare experiences that can retraumatise individuals or deter them from seeking care and are associated with increased suicide attempts.<sup>17</sup> A trauma-informed approach for TGD individuals involves recognising these past traumas and creating a supportive, non-judgemental environment that affirms their identities and avoids pathologisation. By building trust, offering choices, and collaborating with individuals to create care plans that respect their autonomy, healthcare providers can ensure that TGD individuals receive compassionate, equitable, and effective care.

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## The Australian primary care context

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Primary care is the initial and ongoing point of contact with the healthcare system for the Australian population, making it an ideal environment for delivering inclusive and accessible GAHT. Placing GAHT within the primary care scope of practice ensures that TGD individuals are able to receive timely, comprehensive and longitudinal support. Primary care practitioners are uniquely positioned to provide routine services such as hormone therapy management, mental health support, and preventive healthcare in a consistent and familiar setting, as well as coordinating multidisciplinary care where indicated.

Incorporating gender-affirming care into primary care is fundamental for addressing the health disparities faced by TGD individuals, especially those in regional and remote areas. Evidence shows that these populations experience higher rates of mental health issues and barriers to accessing healthcare due to stigma and discrimination. The La Trobe University 2021 national report, *Writing Themselves In 4: The Health and Wellbeing of LGBTQIA+ Young People in Australia*, found that those in rural or regional settings reported lower rates of peer support and higher rates of verbal harassment, psychological distress, suicidal ideation, and suicide attempts compared with the already high rates of their urban counterparts.<sup>18</sup> The introduction of the telehealth sexual health item numbers has broadened the reach of GAHT providers, allowing telehealth appointments without the requirement of an initial face-to-face appointment.

Better education and training of doctors in health issues affecting TGD individuals is the most frequently identified top priority for government funding amongst TGD individuals.<sup>16</sup> AusPATH SOC 2025 aims to educate and support primary care practitioners in providing GAHT for those who seek it. While AusPATH SOC 2025 offers comprehensive guidelines for initiating and managing ongoing GAHT support and management, there are many ways for primary care practitioners to utilise these SOC to develop inclusive and safe practices. It is an RACGP standard for general practice to provide respectful and culturally appropriate care for all individuals.<sup>5</sup> AusPATH SOC 2025 includes steps to ensure that clinic and personal practice meet these college standards. While some may not be confident in initiating GAHT themselves, AusPATH SOC 2025 provides recommendations for ongoing care and oversight of hormonal care for those on long-term stable treatment. Lastly, for primary care practitioners not actively working in this space, AusPATH SOC 2025 provides clinical support for the general primary care and overall health of individuals on GAHT, as well as guidance on clinical scenarios encountered within this population in the primary care setting.



## Respectful and culturally safe practices and practise

The *RACGP Standards for General Practice* highlights the importance of respecting and accommodating diverse identities as a core aspect of general practice.<sup>5</sup> Working collaboratively with transgender and gender-diverse (TGD) individuals, respecting their rights to self-determination, autonomy, and agency, is fundamental to creating gender-affirming environments and delivering high-quality healthcare.

### Creating gender-affirming environments

Steps to create a gender-affirming service include, but are not limited to, the following:

- Train all staff, both clinical and non-clinical, to ensure they understand and correctly use names, pronouns, and gender-inclusive language.
- Design intake forms that enable all individuals to accurately reflect their name (if it is different from their legal/Medicare name), gender identity, and pronouns - ensure this information is documented accurately in your medical software.
- Offer bathrooms that are accessible to all gender identities.
- Use signage that reflects and welcomes diverse gender identities.

### Gender-affirming consultations

During a consultation, ways to create a respectful and culturally safe environment include:

- Introducing yourself with your name and pronouns.
- Reassuring the individual that you will work with them and advocate for their needs
- Confirm the individual's pronouns and name, if different from legal/Medicare name. If they are unsure, reassure them that this is a safe space to explore different pronouns or names without judgement, and that details can be updated at any time.
- Clearly explaining the use of legal names for billing and Medicare purposes as well as any limitations with your medical software systems. This can help reduce potential distress and ensure transparency in the care process.
- Outlining how the provision of gender-affirming hormone therapy (GAHT) works under the informed consent model.
- Offering information about local and online TGD peer support and community groups, helping individuals connect with supportive networks.
- Adopting a principle of asking rather than assuming when gathering history. This applies to all aspects, including gender identity, pronouns, sexuality, religion, and other personal details.
- Adopting a trauma-informed approach to examinations by explaining each procedure and its purpose. Always obtain consent before physical contact, and allow individuals to decline any examination or procedure until they feel comfortable and safe.

Refer to [\*Appendix A\*](#) for further resources on fostering an affirming clinic environment.

## Clinical assessment

A comprehensive clinical assessment is crucial for the safe provision of GAHT. Individuals should undergo a thorough evaluation, similar to any other medical presentation, including their presenting issue, medical and surgical history, mental health background, social history, family history, and other relevant information for safe prescribing. Examination for GAHT should adopt a trauma-informed approach, and should include general observations and other systems examinations as indicated by the individual's history. Initial investigations should include standard tests, with additional assessments based on the individual's history and examination.

## Gender history

When taking a gender history, the following can help engender a respectful and collaborative conversation tailored to the individual's needs and goals:

- Explore their gender experience using open-ended questions, such as 'If you are comfortable, could you share your gender experience with me?'
- Explore their goals and expectations regarding GAHT. Consider asking questions such as:
  - What are your gender-affirmation goals?
  - How would you like to achieve these goals?
  - What changes are you hoping to achieve with hormones?
  - Are there any changes you do not want to happen?
- Inquire about any previous gender-affirming hormonal and non-hormonal care, whether prescribed or otherwise, and discuss their experiences with these treatments.
- Assess their knowledge about GAHT and address any fears or concerns they may have regarding any potential treatment.

## Medical history

Undertake a routine medical history, which may include:

- past medical history
- relative contraindications to hormone therapy, such as:
  - hormone dependent cancers
  - uncontrolled liver disease
  - current pregnancy
- surgical history (gender-affirming and other surgeries)
- medications
- allergies
- immunisations
- relevant screening history
- family history
- social history and any important cultural priorities
- lifestyle assessment [hard copy version] (smoking, nutrition, alcohol, physical activity or SNAP history)<sup>19</sup> [digital version] (Smoking, nutrition, alcohol, physical activity (SNAP))<sup>19</sup>

## Mental health history

TGD communities experience higher rates of mental health disorders and suicidality, especially young TGD individuals.<sup>1,17-18,20-22</sup> Reassure individuals that the information collected about their mental health is to ensure their safety, facilitate access to services if needed, and provide support throughout the gender-affirmation process.

Mental health history may include:

- any formal or suspected diagnoses
- history of neurodiversity, including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD), diagnosed or suspected
- current and/or previous medications for mental health
- assessing their current use of mental health services and any desire to connect with additional mental health care providers
- a risk assessment including current risk of non-suicidal self-injury and/or suicidality and any past suicide attempts
- identifying any symptoms or history of eating disorders

It is important to note that mental health conditions, including eating disorders and neurodiversity, are not contraindications for initiating GAHT under the informed consent model, provided they do not currently impair the individual's capacity to consent. Conditions that may impair capacity to consent, such as acute psychosis, intellectual disability, or dementia, should be stabilised and/or the appropriateness of GAHT should be assessed in a multidisciplinary team setting with guardian input, if applicable.

## **Relevant sexual health history and fertility plans**

GAHT can affect sexual function and libido and may reduce fertility, however, it is not a form of contraception. It is important to address these topics comprehensively, offering individuals the option to discuss, write down their replies, or defer certain topics until they are comfortable.

Sexual history may include:

- Use of ACON TransHub Sexual Health *Parts and Practices Model* (see also Part 3, *Sexual Health* for further discussion) to gather information about sexual history, focusing on the body parts involved and practices, and how the body parts are used, rather than making assumptions about gender or sexuality.
- If relevant and appropriate, discuss the need for sexual health screening and any related preventive measures such as pre-exposure prophylaxis (PrEP) for HIV prevention.
- Discussion of current contraception needs, emphasising that while GAHT can reduce fertility, it does not prevent pregnancy, and effective contraception is necessary if applicable.
- Exploration of fertility goals and plans, ensuring individuals understand the implications of GAHT on their reproductive options. Encourage consideration of long-term plans for having children and document preferences and decisions regarding fertility preservation.

## **Examination**

Adopt a trauma-informed approach to examinations. Ask questions sensitively, obtain consent, and thoroughly explain what each examination will involve to ensure the individual's comfort and understanding. For more information, refer to the [RACGP Guidelines](#) on trauma-informed care.<sup>15</sup>

Examination may include the following:

- vital signs, including blood pressure and pulse rate
- measurement of weight and height if the individual is comfortable with these assessments
- targeted systems examinations as indicated by reported symptoms
- genital examination is neither required nor recommended for the initiation of GAHT, unless there are specific symptoms that need assessment

## Initial investigations

Consider conducting the following baseline blood tests:

- full blood count
- electrolytes and kidney function
- liver function tests
- estradiol and testosterone
- luteinising hormone and follicle stimulating hormone concentrations
- prolactin (see Part 3. [Prolactinoma](#) for further discussion)
- human chorionic gonadotropin (if indicated or requested)
- vitamin D (if clinically indicated, noting that there is a high prevalence of vitamin D deficiency in the TGD population).<sup>23</sup>

Routine coagulopathy screening and karyotyping are not required or recommended.

Additional tests to consider based on individual risk factors and history:

- lipids, HbA1c, fasting glucose, and ECG if cardiovascular disease risk factors are present
- sexual health screening tests if appropriate or indicated by the individual's history
- routine screening tests appropriate for the individual's age and relevant organs present

## Gender-affirming hormone education

Education and counselling are essential components of providing GAHT. These discussions empower individuals to make informed decisions about their care, respecting their autonomy and personal goals. Healthcare providers should assess the individual's level of knowledge, as some may already be well-informed about GAHT, and offer clarification or additional information as needed.

Key topics to discuss include what changes can and cannot be expected with GAHT, the effects of GAHT on fertility and sexual function, and personalised support strategies. Providing comprehensive information and directing individuals to resources such as [TransHub](#) can enhance their understanding and support their decision-making process.

## General considerations for GAHT

The following should be discussed with the individual:

- GAHT requires ongoing adherence to exogenous hormone regimens, which involve regular medical visits and may incur associated financial costs.
- The expected effects of GAHT, including the potential for irreversible changes, and provide information on the typical timeline for these changes (see [Figure 1](#)).
- The potential side effects and risks associated with GAHT, ensuring individuals are fully informed (see [Table 1](#) and [Table 2](#)).
- The limitations of GAHT, highlighting which changes can and cannot be expected (see [Table 1](#) and [Table 2](#)).
- Some individuals may choose to stop GAHT, which is safe. Support their decision and reassure them that stopping or pausing GAHT is not a contraindication to restarting therapy in the future (see Part 3. [Cessation of gender-affirming hormone therapy](#) for further discussion).
- Responses to GAHT are highly individual, and blood hormone levels do not reliably correlate with clinical outcomes.
- The possibility of considering surgical or other cosmetic interventions as part of their gender-affirmation process, if that is their preference.

## Effects of GAHT on fertility

The following should be discussed with the individual:

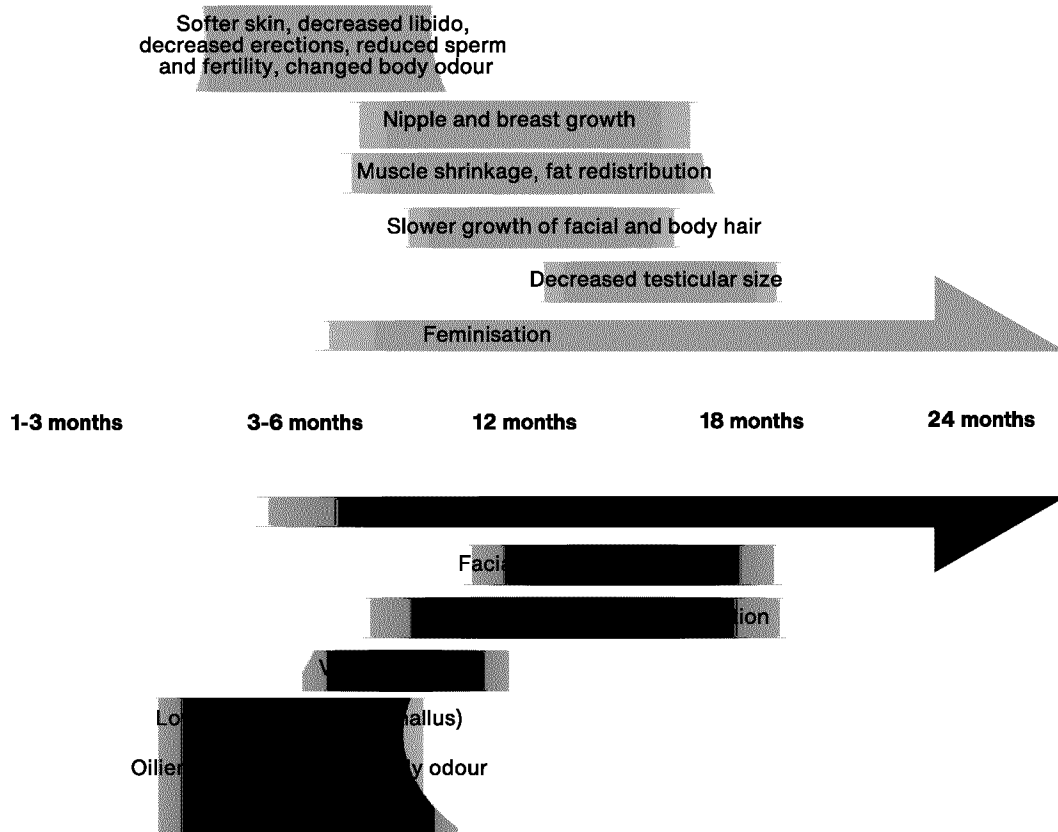
- GAHT may reduce fertility and could lead to irreversible infertility, although evidence on its permanence is lacking.
- Stopping GAHT may restore fertility, this is not guaranteed and can vary among individuals. Discuss the implications for future family planning and the potential need for referral to fertility specialists.
- Provide counselling on fertility preservation options, such as sperm or egg freezing, before starting hormones. Differences in cost and invasiveness between egg and sperm preservation procedures impacts their acceptability. If fertility preservation is chosen, GAHT initiation may need to be delayed. Fertility preservation is not mandatory before beginning GAHT.
- Discuss how adoption is a complex process in Australia and may require careful planning.

## Effects of GAHT on sexual function and sexuality

The following should be discussed with the individual:

- Changes in libido are very common with GAHT. Less commonly, people may report changes in sexuality and sexual attraction after starting GAHT.
- Although GAHT may reduce fertility, it is not a contraceptive. Contraception is recommended to prevent pregnancy.
- Testosterone is a teratogen. Individuals should be informed about the importance of using adequate contraception before, during, and for a time after discontinuing testosterone to prevent foetal effects (see Part 3 *Sexual Health* for further discussion).

**Figure 1. Timeline of GAHT changes**



**Table 1. Changes, side-effects, risks, and limitations of estradiol-based GAHT**

Potential permanent changes <sup>a</sup>	Reversible changes	Side effects and potential risks <sup>b</sup>	Limitations
Breast and nipple development	Decreased/changed distribution of muscle mass and body fat	Breast and nipple tenderness	Balding will not typically reverse but limited regrowth may be possible with medical treatment
Infertility	Slowed rate of facial and body hair growth	Drug specific risks (see <i>Consumer Medicine Information</i> (CMI) for each medication)	Body hair will continue to grow but may grow more slowly and finely; existing body hair will not disappear
Reduction in genital size	Softer skin	Fatigue	Skeletal structure, height, and size of hands and feet will not change
	Sexual function changes include decreased/reduced: <ul style="list-style-type: none"> <li>• libido</li> <li>• spontaneous morning erections</li> <li>• ability to achieve or sustain an erection</li> <li>• ability to ejaculate</li> <li>• changed consistency/volume of ejaculatory fluid</li> </ul>	Hyperprolactinaemia and possibly prolactinoma	Vocal pitch will not change; speech pattern and intonation will not change but can be modified with speech therapy
		Mood and emotional changes	
		Meningioma (higher CPA doses)	
		Painful erections	
		Increased breast cancer risk compared with cis men (remains lower than cis women); prostate cancer risk may be reduced	Breast development is typically modest, may be limited to an A-cup and breasts are positioned more laterally and caudally on the chest. <sup>24</sup> While a majority of individuals are nonetheless satisfied, a significant proportion go on to seek breast augmentation surgery. <sup>25</sup>
		Venous thromboembolism	

<sup>a</sup> Potential permanent changes are listed in alphabetical order.

<sup>b</sup> For further discussion on selected risks, Part 3.

**Table 2. Changes, side-effects, risks, and limitations of testosterone-based GAHT**

Potential permanent changes <sup>a</sup>	Reversible changes	Side effects and potential risks <sup>b</sup>	Limitations
Deepening of voice	Coarser and oilier skin	Acne	Skeletal structure, height, and size of hands and feet will not change
Enlargement of erectile genital tissue (phallus/clitoris)	Growth of new facial and body hair	Drug specific risks (see CMI for each medication)	
Hair head loss and balding in some people	Increased libido	Fatigue	Speech pattern and intonation will not change but can be modified with speech therapy
Facial and body hair growth	Increased muscle growth and masculinisation of body fat distribution	Increased blood pressure and cholesterol	Volume of breast tissue will not reduce; this can be addressed with top surgery if desired
	Menstrual cessation	Intracranial hypertension	
		Mood changes	
		New or worsened obstructive sleep apnoea	
		Pelvic pain	
		Polycythaemia	
		Reduced breast cancer risk compared with cis women	
		Teratogenic effects if taken during pregnancy	
		Vaginal/lower dryness	

<sup>a</sup> Potential permanent changes are listed in alphabetical order.

<sup>b</sup> For further discussion on selected risks, Part 3.

## Prescribing and monitoring GAHT

Prescribing and monitoring GAHT requires a personalised approach that considers the unique goals of the individual. Effective management involves regular clinical assessments and responsive adjustments to treatment plans, ensuring safe and supportive care throughout the hormone therapy process.

### Principles for prescribing gender-affirming hormones

The following should be considered when prescribing GAHT:

- TGD individuals have diverse needs requiring an individualised and person-centred approach.
- There are multiple methods for initiating GAHT, with no single approach demonstrating superior outcomes over others. The choice should be guided by individual preferences and clinical considerations.
- Some TGD individuals, including non-binary people, may prefer lower doses of hormones to achieve their personal goals. It is important to note that a low dose does not equate to no dose, and specific changes cannot be selectively controlled in terms of their extent.
- Regular clinical reviews are best practice to ensure ongoing health and well-being of those on GAHT. Monitoring should focus on both clinical response and safety.
- Clinical response, including reported physical changes, is a key consideration when assessing progress. Blood tests should be used primarily for safety monitoring and identifying potential side effects.

### Hormone monitoring

Cheung et al. in their position statement in the *Medical Journal of Australia* on the hormonal management of adult transgender and gender diverse individuals emphasise that treatment should be adjusted based on clinical response.<sup>26</sup> This approach requires a partnership between the provider and the individual receiving GAHT.

Hormone levels should be used as safety guides rather than strict targets, ensuring treatment is responsive to individual needs and risk factors. Clinical progress and blood test results should be reviewed every 3–4 months during the first year of treatment and then annually once stable.<sup>27</sup>

## Principles of estradiol-based GAHT

Estradiol-based GAHT involves the use of oestrogen and androgen blockers (also known as antiandrogens or T-blockers) to induce physical changes that align with an individual's gender experience.

### Hormonal regimen approaches

Therapy can begin with estradiol alone, followed by the addition of antiandrogens, or both can be started simultaneously. Some clinicians choose to initiate with mid-to-higher dose oestrogen, while others may prefer to start with a lower dose and titrate up every 2–3 months based on clinical outcomes. There is no evidence to support one approach over another and shared decision making is recommended. Antiandrogen monotherapy is an option for those requesting it; however, prolonged antiandrogen monotherapy beyond 12 to 18 months should be used with caution and consider endocrinology input due to potential risks to bone density and cardiovascular health.

## Choice of oestrogen formulation

The choice of oestrogen formulation (see [Table 3](#)) should be personalised and based on individual medical history and personal preferences:

- Estradiol dosing is typically significantly higher than those used for menopausal hormonal therapy<sup>28</sup> and pharmaceutical benefits scheme (PBS) authority scripts can be obtained for increased quantities where the individual is on doses higher than the standard, non-authority PBS listing.
- Non-binary individuals and those not wishing for full dose estradiol-based GAHT should be counselled that breast development can occur at very low levels of estradiol and with anti-androgens. As a result, some slower or later features of estradiol-based GAHT, such as skin softening, feminisation of body shape, or reduction of body hair, may not be achievable without some degree of breast development. Parenteral formulations may not be suitable for those who do not desire full-dose estradiol-based GAHT, as maintenance of lower serum estradiol concentrations may be difficult with these formulations.
- Slack et al.<sup>29</sup> found, in their 2024 retrospective chart analysis of 2,126 trans individuals on oestrogen, a low prevalence of venous thromboembolism (VTE) at 0.8%, compared with a reported estimated incidence of 0.1–0.2% in the general population,<sup>30</sup> and that when adjusted for age, race and several comorbidities, VTE was not associated with any one risk factor including exogenous oestrogen. They suggest that those with underlying risk factors contributing to VTE risk, such as age and cardiometabolic comorbidities may benefit from increased surveillance and VTE risk mitigation.
- Transdermal estradiol via patches or gel may be preferred for individuals at risk of VTE, such as those with known thrombophilia, obesity, age over 45, smokers, hyperlipidaemia, diabetes mellitus, or a history of VTE, as studies in cisgender women show transdermal preparations do not increase VTE risk, unlike oral estradiol.<sup>30</sup> It is unclear whether this lower risk is due to bypassing hepatic metabolism or decreased delivery of estradiol.<sup>31</sup> Recent data indicates a similar VTE risk for injectable intramuscular estradiol compared with oral estradiol,<sup>29</sup> and the VTE risk of estradiol implants is unknown.
- Non-oral estradiol is also preferred for those at risk of cardiovascular and cerebrovascular events, such as those with migraine with aura and uncontrolled hypertension.
- Patches may cause skin irritation in some users. This can be managed with topical steroid creams post application or steroid powder sprays, e.g., steroid metered dose inhaler (private script) prior to application, or changing to another oestrogen formulation.
- Estradiol implants are only available as compounded products and are not approved by the Therapeutic Goods Association (TGA). Private fees apply and they must be obtained from pharmacies that are able to sterilise the pellet. Individuals should be counselled by the prescriber regarding the use of compounded medicinal products.
- Estradiol implants are not recommended for initiating therapy but are preferred by many individuals for maintenance. They often produce higher serum estradiol concentrations, particularly in those who have not reached target levels with other formulations. Estradiol levels should be monitored to guide the timing of implant replacement. Modelling by Measure et al. (2023), based on a study of 38 individuals who received 88 implants, estimated that serum estradiol concentrations reach a level of  $\leq 250$  pmol/L approximately 4 months after the first 100 mg implant and 13 months after subsequent implants.<sup>32</sup>

- Estradiol injections, administered either intramuscularly or subcutaneously, are infrequently used in Australia due to accessibility of implants which offer a more stable estradiol dosing. Estradiol injections are also a compounded product and are not approved by the TGA.
- The 2017 *Endocrine Society Clinical Practice Guidelines* suggest dosing of 5–30 mg second weekly or 2–10 mg weekly of estradiol cypionate or valerate interchangeably. However, Rothman et al.<sup>33</sup> noted serum estradiol concentration well above the target range advised by the same guidelines and recommended initiating doses of 5 mg or lower to avoid this. Similarly, Slack et al.<sup>31</sup> found that intramuscular estradiol was the most potent compared with oral or transdermal routes of delivery in reducing serum testosterone but also the highest risk of suprathreshold serum estradiol concentrations.

### Choice of androgen blocker

There is little comparative data evaluating clinical feminisation to support one antiandrogen over another. Angus et al.<sup>34</sup> found no difference in measurements of breast development between spironolactone and cyproterone acetate. Individual preference and tolerance should guide choice (see [Table 4](#)).

#### Cyproterone acetate (CPA):

- CPA is a potent centrally acting antiandrogen favoured for strong androgen suppression. Efficacy can be monitored by checking total testosterone.
- A meta-analysis based on four retrospective observational studies (n = 165,988 individuals taking CPA) did not find a statistically significant increase in meningioma overall; however, all four studies included found an association between high dose CPA (defined as > 50 mg daily for two studies, and > 10 g accumulative for another) and meningiomas.<sup>35</sup>
- Weill et al. in their 2021 retrospective observational cohort study, found the incidence of treated meningioma for those exposed to CPA compared with those not exposed was 23.8 and 4.5 per 100,000, respectively.<sup>36</sup> Their study included analysis of data from 10,876 transgender women, which found three treated meningiomas in the exposed group compared with zero in the non-exposed group. Importantly, those three individuals had been exposed to very high daily doses of 100–150 mg daily for 3–4.5 years.<sup>36</sup>
- It has been demonstrated that 10 mg daily is as effective as higher doses at reducing testosterone with fewer side effects<sup>37</sup> while titrating CPA to testosterone concentration allows for effective suppression of testosterone with the lowest CPA dose.<sup>38</sup> In Australia, 50 mg is the lowest dose CPA tablet available. A quarter tablet, or 12.5 mg, twice a week is a commonly prescribed dose.
- CPA may cause hepatotoxicity, ranging from mild transient liver enzyme elevations to, very rarely, severe liver injury generally occurring at high doses typically used in prostate cancer treatment. Baseline liver function tests are recommended before starting CPA, with periodic monitoring during treatment.

#### Spironolactone:

- Spironolactone acts as an androgen receptor antagonist, inhibits androgen synthesis, and increases testosterone clearance, while also functioning as a potassium-sparing diuretic through its antagonism of mineralocorticoid receptors.
- Efficacy is assessed clinically as spironolactone may not necessarily lower serum testosterone concentrations to within the cisgender female range (< 2 nmol/L).<sup>39</sup>
- As it is a potassium-sparing diuretic, it may cause self-limiting polyuria, polydipsia and/or postural hypotension. Care should be taken in those with renal impairment or on renin-angiotensin system inhibitors due to the risk of hyperkalaemia. This is otherwise very uncommon in healthy individuals.<sup>40</sup>

- Spironolactone has been associated with upper gastrointestinal bleeding in large population studies. Russo et al. found rates of upper gastrointestinal bleeding to be 4.8% in those exposed to spironolactone compared to 3.2% in those who had not (hazards ratio 1.94).<sup>41</sup> Gulmez et al. found the rates of upper gastrointestinal bleeding to be 2.5% in those taking spironolactone compared to 0.6% in those who were not (odds ratio 2.7).<sup>42</sup> This odds ratio increased to 5.4 for those on 100 mg and 13.1 for those aged 55–75 years. Bleeding risk was not modified by the use of antithrombotic or non-steroidal anti-inflammatories.<sup>42</sup>
- As spironolactone is frequently used in the treatment for those with liver and heart disease such as cirrhosis and heart failure, the applicability of these data to otherwise healthy TGD individuals is unknown, but clinicians should be aware of the possible risk.

#### Bicalutamide:

- Bicalutamide is a selective anti-androgen used in the treatment of prostate cancer. It has had very limited use in the care of TGD with very little data available and it is not endorsed in major clinical guidelines.
- WPATH SOC 8<sup>8</sup> advises against routine use. Gender-affirming hormone therapy guidelines from the University of California, San Francisco<sup>43</sup> and Fenway Health<sup>44</sup> advise a high degree of caution and to consider more established anti-androgen therapies first. Cases of liver toxicity, fulminant liver failure and lung toxicity including fatalities have been reported with bicalutamide use.<sup>45-47</sup>
- Bicalutamide is a peripheral androgen receptor antagonist that functions differently from spironolactone, as it does not inhibit androgen production but instead blocks androgen receptor activation. A case series of 24 individuals on estradiol-based GAHT found that with bicalutamide at 25–50 mg daily, the median testosterone concentration was 7.7 nmol/L (range: 0.7–17.5 nmol/L). One case of asymptomatic liver transaminitis was reported.<sup>48</sup>
- Due to the lack of data, AusPATH SOC 2025 does not recommend for or against its use other than to state that bicalutamide should not be considered first-line, should be used with careful appraisal of the risks with individuals, and involve regular liver function testing through-out its use.

**Table 3. Oestrogens**

Oestrogen	Brand name(s)	PBS listed <sup>a</sup>	Available doses	Common dosing ranges <sup>b</sup>
<b>Oral</b>				
Estradiol hemihydrate	Estrofem Zumenon	No 2 mg only	1 mg, 2 mg 1 mg, 2 mg	2–8 mg daily, in single or divided dosing <sup>d</sup>
Estradiol valerate <sup>c</sup>	Progynova	Yes	1 mg, 2 mg	
<b>Transdermal</b>				
Estradiol 0.1% gel	Sandrena	Yes	1 g (1 mg estradiol) sachets	1–2 sachets daily
Estradiol 0.06% gel	Estrogel	Yes	80 g metered-dose pump, 1.25 g (0.75 mg estradiol)/pump actuation	1–4 pump actuations daily
Estradiol patch	Estraderm MX Estradot Estramon	Yes	25 mcg, 37.5 mcg, 50 mcg, 100 mcg/24 hrs patches	50–200 mcg/24 twice weekly
<b>Parenteral</b>				
Estradiol pellet (subcutaneous)	N/A (compounded medication)	No	50 mg, 100 mg pellets	50–200 mg every 6–12+ months
Estradiol cypionate or valerate (intramuscular or subcutaneous injection)	N/A (compounded medication)	No	As per individual compounding pharmacy	2–10 mg weekly <sup>f</sup>

<sup>a</sup> A PBS authority script may be obtained if increased quantities are required.

<sup>b</sup> There is no evidence to guide individual starting doses and it appears safe to start at any dose within that range. Many clinicians start at low to mid-range doses and titrate up every 2–3 months to clinical effect. Shared decision making is recommended.

<sup>c</sup> Estradiol valerate is the most commonly available and used oral oestrogen in Australia.

<sup>d</sup> There is no guidance on whether single or divided dosing is 'better', individual preference is suggested.

<sup>e</sup> Patches are described as dose administered over 24 hrs but last for 3–4 days.

<sup>f</sup> As per the 2017 Endocrine Society Clinical Practice Guidelines and Nolan and Cheung, 2025,<sup>39</sup> noting that care is required to avoid suprathreshold dosing.

**Table 4. Anti-androgens**

Drug	PBS listed	Standard dosing ranges	Potential side effects
Spironolactone	Yes	50–200 mg daily	Hyperkalemia, diuresis, polydipsia, hypotension, GI upset, rash
Cyproterone	Yes	12.5 mg once weekly – 25 mg daily <sup>a</sup>	Depression, hepatitis, hyperprolactinaemia, meningioma (associated with long-term use at high doses)

<sup>a</sup> High dose CPA has been associated with meningiomas and regular dose review and reduction where appropriate is recommended. 12.5 mg alternate daily or twice a week dosing are commonly used.

### Monitoring estradiol-based GAHT

The clinical value of regular monitoring of serum hormone levels remains unclear. It can serve as a useful safety measure to avoid potential risks associated with prolonged deviations from the target hormone ranges. When performed, trough estradiol concentration should be used where feasible.<sup>26</sup> However, this may be difficult where individuals split their dosing across the day. Individuals administering their oral estradiol sublingually or those on oestrogen injections are also challenging to monitor due to faster peaks and increased overall periodicity, although there is no data indicating this increased cycling is otherwise harmful or beneficial.<sup>49</sup> See [Table 5](#) for further information on estradiol monitoring.

Current available recommendations for target serum estradiol ranges are based on expert opinion and lack supporting data:<sup>26</sup>

- The 2017 Endocrine Society Guidelines<sup>49</sup> and the 2022 WPATH SOC 8<sup>8</sup> recommend a target serum estradiol range of 100–200 pg/ml (367–734 pmol/L), to align with mid-cycle estradiol ranges for cisgender menstruating women.
- Cheung et al.<sup>26</sup> in their Australian position statement recommend a range of 250–600 pmol/L and the 2022 version of the AusPATH SOC recommends 250–1000 pmol/L.<sup>50</sup>
- The 2016 *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*, developed by the University of California, San Francisco, do not state a specific target range, but suggest that maintaining serum estradiol concentration within the cisgender menstruating female range ‘makes sense clinically’ in order to minimise risks and side effects and recommend using local laboratory estradiol assay reference ranges.<sup>43</sup>
- The 2021 *Medical Care of Transgender and Gender Diverse Adults* guidelines by Fenway Health follow the Endocrine Society’s recommended reference range, but suggest that in younger individuals with low cardiovascular risk, concentrations in the upper end of the physiologic range (300–400 pg/mL, 1101–1468 pmol/L) may be reasonably safe.<sup>44</sup>

Higher serum estradiol concentrations are associated with higher bone mineral density but have not been shown to enhance breast development or result in more feminine body composition changes, in the context of adequate testosterone suppression.<sup>51</sup> The optimal serum estradiol concentration that achieves feminisation without significantly increasing side effects or complications, if such a concentration exists, remains unknown.<sup>27</sup> Treatment should be adjusted to clinical response, noting that feminisation is typically slow.<sup>26</sup>

For those wishing to have complete testosterone suppression, the total testosterone target is < 2 nmol/L. However, as noted above, efficacy of spironolactone should be assessed clinically due to its peripheral action and total testosterone in those on spironolactone may not accurately reflect the antiandrogen effect. Some individuals may prefer a higher testosterone, including those seeking maintenance of erectile function and some non-binary individuals. Limited data suggest that adequate testosterone suppression is an important factor in clinical feminisation, but further studies are needed.<sup>51</sup> In the absence of data to support target serum estradiol concentrations, some clinicians may prefer to prioritise testosterone suppression in place of estradiol dose up-titration to reduce risk of adverse effects.<sup>27</sup>

For individuals with effective testosterone suppression, the minimum estradiol concentration required to maintain bone health remains uncertain. However, bone loss is likely at levels below 182 pmol/L.<sup>52</sup> AusPATH SOC 2025 recommends maintaining estradiol concentrations above 250 pmol/L, in accordance with Cheung et al.<sup>26</sup> with the understanding that this threshold may be revised as further evidence emerges. AusPATH SOC 2025 does not recommend a specific upper limit for serum estradiol but note the upper levels recommended by other guidelines as outlined above, while acknowledging the lack of evidence underpinning these recommendations. Instead, AusPATH SOC 2025 outlines clinical approaches to 'supratherapeutic' serum estradiol concentrations as these may be commonly encountered:

- Serum estradiol concentrations greater than 600 pmol/L or 734 pmol/L are more likely to be encountered with parenteral routes of estradiol administration.
- Consider possible underlying causes including timing of test relative to estradiol administration (trough concentration should be checked where feasible),<sup>26</sup> contamination from topical oestrogen at the phlebotomy site, and high-dose biotin supplementation.<sup>53</sup>
- Assess individuals for side effects of high serum estradiol including mood swings, emotional instability, breast tenderness, hot flushes, night sweats, fatigue, and weight gain and whether these are causing distress or harm.<sup>54</sup>
- Assess for the presence of risk factors such as smoking, cardiovascular disease, history of VTE, and poor renal function that may place an individual at higher risk of adverse effects.
- For those at higher risk of adverse events or those wishing to reduce their potential risk of adverse effects a gradual reduction in estradiol dosing may warrant consideration and should be undertaken in a collaborative manner.
- Counsel individuals seeking higher serum estradiol concentration regarding the lack of association between high serum estradiol and clinical feminisation outcomes and the lack of safety data for prolonged 'supratherapeutic' dosing.
- For those with poor clinical response despite adequate testosterone suppression and serum estradiol within mid-cycle estradiol ranges for cisgender menstruating women, a trial of higher serum estradiol concentrations could be considered. Since this approach lacks evidence, careful assessment of individual risk and detailed informed consent is suggested.

**Table 5: Estradiol monitoring**

<b>Estradiol</b>	<b>Recommended monitoring</b>
Oral estradiol	Trough estradiol concentration just prior to next dose Split dosing and sublingual administration will affect concentration
Transdermal estradiol patches	Limited guidance available Consider testing prior to new patch application as peaks may occur after new patch application and allows for consistency in timing of testing
Transdermal estradiol gel	Trough estradiol concentration just prior to next dose Expected to reach a steady-state after 3–5 days but not always observed Venipuncture from non-application arm recommended Split dosing will affect concentration
Estradiol implants	No data to guide testing Typically 3 monthly after the first implant for 12 months to guide initial implant replacement, then less frequently for subsequent implants
Estradiol injections	No data to guide testing. Consider peak and trough testing or check mid-way between doses <sup>44</sup>

## **Principles of testosterone-based GAHT**

Testosterone-based GAHT involves the use of testosterone to induce physical changes that align with an individual's gender experience.

- Several formulations of testosterone are available (see [Table 6](#)), with the choice tailored to the individual's preferences and goals.
- For those seeking full masculinisation, testosterone can be initiated at the full therapeutic dose of any preparation.
- For those seeking slow or submaximal masculinisation, such as some non-binary individuals, testosterone 1% gel offers the flexibility of administering lower doses, typically 1–3 pumps, titrated to individual preference and clinical effects. It should be noted that 'low' testosterone dosing does not equate to no testosterone and it is possible to achieve testosterone concentrations in cisgender male range with 1% testosterone gel.<sup>55</sup>
- Individuals seeking submaximal doses of testosterone-based hormone therapy should be counselled that it is not possible to select for some changes, such as voice deepening, and not others, such as clitoral growth. As voice deepening is irreversible, some individuals may choose to cease therapy once this occurs.
- Product information for testosterone gels advises that they are to be applied to the shoulders or arms. Absorption of testosterone gel appears more consistent and effective when applied to the shoulders and upper arms compared to other body sites.<sup>56</sup> Gels should be applied to areas of the body that can be easily covered by clothing to reduce the risk of transfer to others via skin-to-skin contact. Individuals should shower before intimate or skin-to-skin contact. For specific details refer to the individual product CMI.

- Injectable testosterone is available in short- and long-acting formulations. Testosterone undecanoate (Reandron) is the most commonly used due to less frequent dosing and a lower risk of supra-therapeutic concentrations compared with short-acting formulations.
- Short-acting injectable testosterone is not PBS subsidised. It may be self-administered. Appropriate dosing intervals vary person to person. Regular blood tests in the initiation phase are recommended to establish the required time interval to achieve appropriate trough concentration.
- Intramuscular testosterone injections carry a rare risk of pulmonary oil microembolism (POME), a transient condition causing shortness of breath and coughing. Healthcare providers should be aware of this risk, its clinical presentation, and appropriate management strategies (see Part 3. *Pulmonary Oil Microembolism* for further discussion).
- For intramuscular testosterone, the delivery base may be relevant in guiding formulation decisions for individuals with allergies or sensitivities. Testosterone undecanoate (Reandron) and testosterone enanthate (Primoteston) are delivered in a base of castor oil, while testosterone esters (Sustanon) are delivered in a base of peanut oil.
- An authority is required to access a PBS script for testosterone:
  - The authority is for 'androgen deficiency' under the criteria of 'an established pituitary or testicular disorder'.
  - The individual must have a second opinion from an endocrinologist, urologist or sexual health physician. This can be a face-to-face or telehealth consultation, or prescribers can prescribe in consultation with the non-GP specialist. The consultation only needs to occur once and the name of the non-GP specialist can be used on all subsequent prescriptions. Prescribers are permitted to provide an authority script if the individual has an appointment to be assessed by one of these non-GP specialists.

**Table 6. Testosterones**

Testosterone	Brand name	PBS listed <sup>a</sup>	Common dose ranges
<b>Topical</b>			
Testosterone 1%	Testogel: 12.5 mg/actuation pump	Yes	1–8 pumps (12.5–100 mg) daily <sup>b</sup>
	50 mg/5 g sachets	Yes	1–2 sachets (50–100 mg) daily <sup>b</sup>
Testosterone 2%	Testavan: 23 mg/actuation pump	Yes	1–3 pumps (23–69 mg) daily
Testosterone 5%	Androforte: 50 mg/mL cream	Yes <sup>c</sup>	1–4 mL (50–200 mg) daily
<b>Injectable (intramuscular)</b>			
Testosterone undecanoate	Reandron: 1000 mg/4 mL	Yes	250–1000 mg 10–14 weekly (first two doses 6 weeks apart) <sup>c</sup>
Testosterone enanthate	Primoteston: 250 mg/1 mL	No	0.5–1 mL (125–250 mg) 2–4 weekly
Testosterone esters	Sustanon 250: 250 mg/1 ml	No	0.5–1 mL (125–250 mg) 2–4 weekly

<sup>a</sup> All testosterone scripts required an authority script to access it on the PBS.

<sup>b</sup> Maximum dose stated is as per the product CMI. Please note that it is frequently possible to achieve a trough testosterone in the target range for full masculinisation using 4 pumps of Testogel or 2 mL of Androforte.

<sup>c</sup> Reandron dosing interval may vary depending on trough concentration and can range from as little as 7 weeks to more than 20 weeks. Intervals of 10–14 weeks are typical.

## Monitoring testosterone-based GAHT

Gender-affirming hormone therapy management guidelines from WPATH, the Endocrine Society, the University of California, San Francisco, and Fenway Health all recommend targeting testosterone ranges within the cisgender male range of 320–1000 ng/dL (11.1–34.7 nmol/L). It is recommended that clinicians refer to their local laboratories for reference intervals for the specific assay used. Serum total testosterone concentration is typically checked at the trough timepoint, that is, just prior to the next dose, aiming for a trough concentration in the lower end of the male reference range of approximately 10–20 nmol/L. See [Table 7](#) for further information.

Haematocrit should be monitored alongside serum testosterone, with greater clinical emphasis placed on haematocrit values when assessing treatment. While elevated serum testosterone concentration may be accepted in the context of normal haematocrit and acceptable clinical outcomes, haematocrit concentration should remain below 0.5 L/L. Persistent concentrations above 0.5 L/L can be managed through addressing risk factors such as smoking, and obstructive sleep apnoea, if present, increasing the dosing interval, reducing doses, and/or switching to a topical formulation (see Part 3. [Polycythemia](#) for further discussion).

**Table 7. Timing of testosterone monitoring**

Testosterone	Recommended timing of total serum testosterone measurement
Testosterone undecanoate	Trough concentration just prior to the next injection Do not test or adjust treatment until after initial 3 injections
Testosterone 1% gel	Trough concentration just prior to application of the gel
Testosterone 2% gel	Measure 2–4 hours after application (as per product information) If testosterone < 17.3 nmol/L – increase by 1 pump actuation <sup>a</sup> If testosterone > 36.4 nmol/L – decrease by 1 pump actuation
Testosterone 5% cream	Trough concentration just prior to application of the cream
Testosterone enanthate and testosterone esters	Measure midway between injections or measure peak and troughs to ensure concentration remain in cisgender male reference ranges <sup>b</sup>

<sup>a</sup> If seeking full dose therapy.

## Ongoing monitoring of GAHT

Routine monitoring may include the following blood tests:

- full blood count
- electrolytes and kidney function (this is important if on spironolactone, PrEP, or renal impairment present)
- liver function tests
- testosterone
- estradiol (estradiol-based GAHT only)

Additional monitoring tests to consider based on individual risk factors and history:

- vitamin D
- prolactin (see Part 3. *Prolactinoma* for further discussion)
- metabolic monitoring
- sexual health screening tests if appropriate or indicated by the individual's history
- routine screening tests appropriate for the individual's age and relevant body parts

## Reference ranges

Gender-affirming hormone therapy may cause significant changes in body composition within 3–6 months of commencement. Thus, it is essential to be aware of the duration of therapy and dosing in order to guide appropriate choice of binary gender reference ranges when assessing results. In the first year, it may be useful to request both physiological male and female reference ranges to assist with monitoring or have a cheat sheet for standard reference ranges for your laboratory available. Nolan and Cheung (2025)<sup>39</sup> offer a detailed review of evidence for the impact of GAHT on laboratory parameters with sex-specific reference ranges and the clinical implications, which are summarised in *Table 8*. Current data is based on binary trans people on full dose GAHT. Individuals on lower dose GAHT may have values that fall between physiological male and female ranges, and individual interpretation is required.

**Table 8. Sex-specific laboratory tests and recommended reference ranges**

Test	Recommended reference range to use	Information
Haemoglobin (Hb) Haematocrit (Hct)	Affirmed gender	Serum Hb reflects the affirmed gender by 6 months Serum Hct aligns with the affirmed gender after 3 months for testosterone-based hormone therapy and 6 months for estradiol-based hormone therapy
Estimated glomerular filtration rate (eGFR)	Affirmed gender	eGFR is calculated using serum creatinine concentration, age, and sex, based on the assumption that individuals registered male at birth typically have higher muscle mass, which contributes to higher serum creatinine levels. After three months, GAHT leads to significant changes in lean body mass, which have been associated with changes in serum creatinine concentration and eGFR in some, but not all, studies. Assessing longitudinal trends in renal function may be more informative than relying on single measurements.
Cardiac troponin and b-type natriuretic peptide	Insufficient data to make recommendations	Clinical history, physical examination, ECG changes, and serial troponin measurements should be prioritised when results fall between the upper limits of sex-specific reference ranges.
Iron studies	Affirmed gender, except for pregnant and menstruating individuals use female reference ranges <sup>57</sup>	Further studies are required
PSA	Insufficient data to make recommendations	The prostate remains in situ post gender-affirming bottom surgery for those registered male at birth. GAHT lowers PSA to concentrations similar to hypogonadal men undergoing androgen deprivation therapy for prostate cancer and prostate cancer risk is lower in those on estradiol-based hormone therapy compared with cisgender men, but a risk remains. <sup>58</sup> At the time of publication there are no consensus guidelines on PSA screening for those registered male at birth on estradiol-based hormone therapy and it is unclear if lower thresholds for biopsy should be utilised.

## Additional clinical monitoring

In addition to monitoring for clinical progress, assess for and ask about complications and side effects of GAHT, including acne, DVT, sleep apnoea, unwanted hair growth or hair loss and manage as per standard practice (see [Table 1](#) and [Table 2](#)). Check in with individuals regularly regarding their goals for GAHT, whether their current regimen is meeting those goals, and whether there are any changes to their goals. Some individuals may choose to stop GAHT which is safe (except in the case of oophorectomy/orchiectomy where exogenous sex steroid is necessary) and they should be supported in doing so. Stopping or pausing GAHT is not a contraindication to restarting.

Additional monitoring is not specific to GAHT and should follow the latest [RACGP Guidelines for Preventive Activities in General Practice](#).<sup>59</sup> This may include:

- regular blood pressure checks
- encouraging smoking cessation
- increasing body movement
- encouraging community connection and emotional nourishment
- cancer screening based on organs present (see section Part 3. [Cancer screening](#) for further discussion).

## Medical risk reduction

Management of medical risks is an important aspect of holistic gender-affirming care, and primary care providers are uniquely positioned to support the overall health of TGD individuals.

Strategies for medical risk reduction in GAHT may include:

- Regular check-ins with individuals to assess personal safety and mental well-being, ensuring timely intervention if needed.
- Facilitating access to mental health services and social support networks where appropriate.
- Addressing cardiovascular disease risk factors, including high blood pressure, cholesterol, and lifestyle factors (see [SNAP guidelines](#)).<sup>19</sup>
- Supporting smoking cessation.
- Providing sexual health screenings and discussing the use of PrEP if appropriate.
- Engaging gender-affirming non-GP specialists for support in complex medical contexts, such as haematology input for individuals with a history of, or who develop VTE while on treatment, or hepatology for those with liver disease.

## Non-Hormonal Gender Affirmation

Non-hormonal gender affirmation is an important way to support individuals as they navigate transition. It encompasses a range of interventions that do not involve hormone treatments but are equally significant in affirming one's gender. Primary care providers are well-placed to guide and facilitate access to these resources.

Non-hormonal gender affirmation may include the following:

- Using correct pronouns for individuals and documenting pronouns in medical software.
- Assisting with legal changes, which may include:
  - birth certificate amendments (which vary by State and Territory)
  - passport gender marker changes ([B14 form](#)), including considerations for selecting an 'X' marker and potential travel implications
  - Medicare card gender marker changes; GPs can write a supporting document verifying the individual's gender

- Facilitating connections to affirming professionals who can assist with specific non-hormonal affirmation needs, such as:
  - speech therapists for voice and communication training
  - dietitians for nutritional support, particularly in the context of gender affirmation goals
  - exercise physiologists for fitness plans that align with gender identity.
- Supporting individuals seeking affirming surgery by providing referrals and facilitating WPATH-compliant assessments with mental health professionals, if required by the individual's chosen surgeon.
- Offering information on hair removal options, including laser and electrolysis, and hair loss prevention strategies for those seeking to maintain or modify their hair pattern.
- Engaging individuals in discussions about available peer support groups, mental health resources, and community networks. This is particularly important for those who may not pursue medical or surgical pathways.
- Acknowledging and incorporating cultural identities and practices.



**Part 3. Beyond hormones: —  
clinical scenarios and key considerations**

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## Androgenic alopecia

Androgenic alopecia (AGA), also known as pattern hair loss, is the most common form of hair loss, affecting over 50% of individuals over the age of 40 years, though rates within the TGD population remain unknown.<sup>60</sup> AGA is an autosomal dominant condition in which terminal hairs are gradually replaced by shorter, finer, miniaturised hairs, eventually leading to hair follicle reduction and permanent hair loss.<sup>61</sup> Clinically, AGA presents as bitemporal thinning of the frontal scalp hair that spreads to the vertex, or as diffuse thinning between the frontal and vertex scalp, making the scalp more visible through the hair. This condition has been shown to cause significant psychological distress in cisgender populations.<sup>61</sup> Most treatment data for AGA comes from studies on cisgender populations, with research on TGD populations being limited, primarily focusing on European cohorts.<sup>60</sup> Testosterone-based gender-affirming hormone therapy (GAHT) can alter the distribution and pattern of hair growth, which may be perceived by the individual as affirming, neutral, or distressing.

### Testosterone-based hormone therapy

Due to differing tissue responses to androgens, testosterone-based GAHT causes hair follicles in the beard, axilla, and pubic areas to increase in size, while those on the frontal, temporal, and vertex scalp tend to miniaturise.<sup>62</sup> Risk factors for developing AGA in individuals on testosterone-based hormone therapy include age, family history, and likely the duration of treatment. Cocchetti et al. reported worsening hair loss during the first 12 months of testosterone therapy, but the overall risk of significant AGA development was low.<sup>63</sup> AGA appears to increase with duration of testosterone therapy, though rates of moderate to severe AGA at 10 years in those on testosterone-based GAHT remain lower than in the general population.<sup>63</sup>

For those seeking treatment, the use of 5-alpha-reductase inhibitors (5ARI) and spironolactone may need to be balanced with affirmation goals, as they theoretically could impact the development of desired secondary sex characteristics. Delaying treatment might also be considered, as AGA typically takes over 12 months to manifest. A small retrospective case review found that low-dose finasteride in trans men resulted in modest improvements in hair loss, with no reports of sexual side effects.<sup>64</sup> As with testosterone, the use of 5ARI or spironolactone is contraindicated in pregnancy. Non-hormonal treatment options include wigs, camouflage, topical and oral minoxidil, low-level laser light therapy, micro-needling, platelet-rich plasma, and hair transplantation.

### Estradiol-based hormone therapy

It is unclear what effect estradiol has on hair growth.<sup>62</sup> Current, low-level evidence, suggests that estradiol-based hormone therapy may improve AGA, and combination treatment rather than antiandrogens alone is more effective.<sup>62</sup> Tang et al. demonstrated a significant increase in hair counts with associated improved hair-related quality of life within the first 6 months of estradiol-based hormone therapy.<sup>65</sup> Spironolactone and cyproterone acetate (CPA) both inhibit testosterone and have been demonstrated to improve AGA in transwomen.<sup>62,66</sup> It is unclear whether additional blockade with 5ARIs is of additional benefit, but they are commonly used. It should be noted that the use of 5ARI in cis men has been associated with sexual side effects, depression and suicidal thoughts.<sup>61</sup> Non-hormonal options are the same as for those on testosterone-based hormone therapy.

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## Bone health and GAHT

Oestrogen and testosterone are critical for bone formation during adolescence and early adulthood and play a key role in bone turnover throughout life. Individuals seeking GAHT may present with lower bone mass prior to starting hormone therapy, influenced by factors such as vitamin D insufficiency, smoking, reduced physical activity, and a higher prevalence of eating disorders.<sup>67-69</sup>

### Transgender women

Approximately 20% of transgender women have lower bone density before initiating hormone therapy compared to cisgender men.<sup>70</sup> Although oestrogen therapy improves bone density initially, a gradual decline can occur, particularly if estradiol concentrations fall below 180 pmol/L, leading to reduced lumbar spine density.<sup>52,71,72</sup> A nationwide Dutch cohort study reported that in trans women under 50 years, the fracture incidence was approximately 2.4%, similar to that in cisgender men and somewhat higher than that in cisgender women. In those aged 50 and over, incidence rose to around 4.4%, aligning with rates seen in cisgender women and exceeding those in age-matched cisgender men.<sup>73</sup>

### Transgender men

Bone density in transgender men is generally comparable to cisgender women and remains stable over time according to observational studies.<sup>71</sup> Current data does not suggest an increased fracture risk. Data from cis men suggests maintaining a testosterone concentration above 7 nmol/L is important.<sup>74</sup> However, for individuals with ovaries, despite increased testosterone concentration, oestrogen concentration typically decreases only slightly (20–60 pmol/L), likely offering additional bone protection.<sup>57</sup>

### Non-binary individuals

Data is lacking for non-binary individuals. Extrapolating from data in transgender men, adequate sex hormone concentrations for bone health in individuals on testosterone-based GAHT would be expected from the background estradiol, although if there were concerns about bone health, maintaining a testosterone concentration above 7 nmol/L is warranted, based on data from cisgender men.<sup>74</sup> This should be balanced with the individual's goals. For individuals on estradiol-based GAHT, maintaining either an endogenous testosterone above 7 nmol/L or exogenous estradiol above 180 pmol/L would be important for bone health. Adequacy of GAHT with regard to bone health can be assessed by checking for suppressed luteinising hormone level, except for those on cyproterone due to its central action.

### Osteoporosis screening and risk reduction

Osteoporosis screening with dual-energy x-ray absorptiometry (DXA) of the lumbar spine, total hip, and femoral neck does not need to be performed routinely but may be considered if there are individual risk factors.

Risk factors for osteoporosis should be screened for and managed appropriately, including:

- smoking
- excessive alcohol use
- long-term steroid use
- personal or family history of low trauma fractures
- rheumatoid arthritis
- disordered eating behaviours
- nutritional inadequacies
- prolonged GnRH analogue therapy
- androgen blockade without oestrogen therapy
- inadequate oestrogen therapy

Encourage risk reduction measures for osteoporosis, including:

- ensuring adequate calcium and vitamin D intake
- encouraging regular weight-bearing, strength, and resistance exercises.
- providing guidance on lifestyle factors and nutrition as appropriate
- maintaining sufficient concentrations of oestrogen or testosterone for bone health

Where DXA is performed, the International Society for Clinical Densitometry, 2019,<sup>75</sup> recommends calculating T-scores using a female normative database for TGD individuals aged 50 years and older. For those under 50 years, the Z-score should be calculated using the database for the affirmed gender.<sup>75</sup> For non-binary individuals, the sex registered at birth is used due to limited evidence.

## **Management of osteopenia and osteoporosis**

If osteopenia is identified, address all modifiable risk factors and repeat DXA scans every 1–2 years. For individuals with progressive bone loss or osteoporosis, including fragility fractures, assess and treat for secondary causes. Pharmacological treatment to prevent or treat osteoporosis should align with general population recommendations (see [\*RACGP osteoporosis guidelines\*](#))<sup>76</sup> and assessed with a repeat DXA scan within a year to assess treatment response.<sup>77-78</sup>

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## **Cardiovascular disease risk and GAHT**

### **Estradiol-based GAHT and CVD risk**

Individuals on estradiol-based GAHT may experience higher rates of cardiovascular disease (CVD) compared with the general population. A large cohort study found increased rates of stroke in individuals on estradiol-based GAHT compared with cisgender men and women.<sup>79</sup> The study also reported higher rates of myocardial infarction in those on estradiol-based GAHT compared with cisgender women; however, these rates did not exceed those observed in cisgender men. Similar findings of increased stroke and myocardial infarction risk in individuals on estradiol-based GAHT were reported by Nota et al.<sup>80</sup> The data do not clarify whether these findings are related to higher-risk oestrogen formulations, such as ethinyl estradiol or oral estradiol valerate.

## **Testosterone-based GAHT and CVD risk**

Testosterone-based GAHT may be associated with an increased risk of CVD compared with cisgender women. A systematic review and meta-analysis by van Zijverden et al. found that transgender men have a 1.3 times higher risk of stroke compared with cisgender women.<sup>81</sup> However, this risk remains lower than that observed in cisgender men.<sup>79</sup>

Evidence regarding the risk of myocardial infarction remains inconclusive. One potential contributor to increased CVD risk in those on testosterone-based GAHT, is the effect of testosterone on haemoglobin and haematocrit concentrations, which are known to rise in both cisgender and transgender men using testosterone. This can lead to erythrocytosis, which in turn, may increase the risk of venous thromboembolism (VTE) and stroke. However, the evidence remains inconclusive regarding whether erythrocytosis directly translates to higher rates of these adverse events.<sup>82</sup>

## **Obstructive sleep apnoea and testosterone therapy**

Testosterone therapy has been associated with an increased risk of sleep-disordered breathing and obstructive sleep apnoea (OSA) in both cisgender men and individuals on testosterone-based GAHT. A cohort study of 422 cisgender men receiving testosterone therapy for hypogonadism demonstrated a 16.5% increased risk of developing OSA at 2 years,<sup>83</sup> while studies indicate that testosterone therapy worsens pre-existing OSA in cisgender men.<sup>84</sup> Limited evidence suggests a similar trend in individuals on testosterone-based GAHT, though further research is needed to establish prevalence and risk factors.

The largest existing study involved 94 individuals completing screening questions before and one year into testosterone-based GAHT, finding a higher prevalence of snoring at one year.<sup>85</sup> Additionally, case reports describe individuals who developed new or worsened OSA following initiation of testosterone-based GAHT, further suggesting a potential link.<sup>86-87</sup>

## **Metabolic health and GAHT**

GAHT influences body composition and insulin sensitivity, with differing effects based on hormone type. Individuals on estradiol-based GAHT typically experience an increase in fat mass and a decrease in lean body mass, while individuals on testosterone-based GAHT generally see increases in lean body mass and overall weight, with a reduction in fat mass.<sup>88</sup> Testosterone-based GAHT is associated with improved insulin sensitivity, while estradiol-based GAHT is linked to a decrease in insulin sensitivity, though the clinical significance of this remains uncertain.<sup>89</sup> Despite these metabolic changes, current evidence does not establish a direct link between GAHT and increased risk of diabetes.

Regarding type 2 diabetes mellitus (T2DM), a cohort study of 2869 individuals on estradiol-based GAHT found a higher risk of T2DM compared with cisgender women, but not compared with cisgender men.<sup>90</sup> The same study found no increased risk of T2DM in 1514 individuals on testosterone-based GAHT compared with either cisgender men or women. While these findings suggest that GAHT itself may not directly increase the risk of T2DM, further research is needed to clarify long-term metabolic effects.

## Assessing cardiovascular disease risk in individuals on GAHT

Clinicians should assess CVD risk factors in individuals seeking GAHT and encourage modifiable risk factor reduction. When using CVD risk calculators, the University of California, San Francisco, Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People recommend considering both the age at which GAHT was initiated and its duration when selecting a binary gender required by the calculator, or using an average of the risk calculations based on birth-registered sex and affirmed gender.<sup>43</sup> The Australian cardiovascular disease risk calculator utilises birth-registered sex (see [AusCVDRisk](#)).

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## Cancer screening

Cancer screening should be guided by the individual's organs and routine screening as recommended by the Australian National Screening Program, regardless of gender identity or GAHT status,<sup>59</sup> and is summarised in [Table 9](#). Breast cancer risk trends slightly towards the affirmed gender for those on GAHT. That is, those on estradiol-based GAHT have a higher risk of breast cancer than cis men but lower than cis women, and those on testosterone-based GAHT have a lower risk of breast cancer than cis women.<sup>91</sup> Prostate cancer risk is significantly lower in those on estradiol-based GAHT compared with cis men.<sup>92</sup> Routine cervical screening should be offered to all individuals with a cervix. In 2022, self-collection of cervical screening swabs was introduced for all participants of the Australian National Cervical Screening Program, reducing barriers to screening for those who may not be comfortable with or do not wish to have speculum examination.<sup>93</sup> If a speculum examination is indicated, topical estradiol applied for several weeks prior to the examination may alleviate discomfort due to vaginal atrophy, but dysphoria may still persist and should be acknowledged, when present, and accommodated. Breast cancer screening should be offered to those in the appropriate age groups and who have been on estradiol-based GAHT for more than 5 years. There are no recommendations for those on testosterone-based hormone therapy who have had chest surgery beyond chest awareness and seeking medical attention if there changes are noted. Currently, Australia also has national screening programs for bowel and lung cancer and recommendations are unchanged for TGD individuals.

**Table 9. Summary of cancer screening guidelines**

Organ	Who	Specific screening recommendations
Bowel	All individuals	Unchanged, follow national guidelines
Breasts	Individuals with breasts	Offer screening to those aged 50–74 years for those with natal breasts and those who have been on estradiol-based therapy > 5 yrs
	Post chest reconstruction for individuals registered female at birth	No specific recommendations beyond chest awareness and seeking medical attention for changes
Cervix	Individuals with a cervix	Offer screening to those aged 25–74 with a cervix; self-collection available
Lung cancer	All individuals	Unchanged, follow national guidelines
Prostate	Individuals with a prostate	No specific recommendations beyond routine recommendations for those with a prostate
Skin	All individuals	No specific recommendations beyond routine recommendations, support individuals in accessing an affirming provider

## Cessation of GAHT

Cessation of hormone therapy may, or may not, be motivated by a change in gender identity or transition status. The decision to cease GAHT is multifaceted and should not be automatically equated with dissatisfaction, regret, or the belief that being transgender was not the underlying cause of a person’s distress or body discomfort.

Factors influencing the cessation of hormonal affirmation can include:

- External factors such as persistent social stigma, lack of support, difficulties associated with transitioning, workplace challenges, and experiences of harassment or discrimination.<sup>94</sup>
- Internal factors such as increasing comfort identifying as one’s birth-registered sex, realisation that gender dysphoria is connected to other issues such as trauma or mental health issues, availability of non-medical alternatives to manage dysphoria, persistence of dysphoria despite affirmation, shifts in personal beliefs, or resolution of other distress contributors.<sup>95</sup>
- Other reasons such as health concerns, dissatisfaction with physical changes, unwanted or intolerable side effects, decisions about fertility and/or pregnancy, and challenges related to accessing affirming healthcare.<sup>95</sup>

Capturing the precise rates of hormone discontinuation is difficult due to limited longitudinal follow-up and dropout. As access to hormonal affirmation expands, it is likely that rates of discontinuation will rise, particularly given that GAHT is typically intended to be lifelong. Support for individuals who choose to discontinue hormonal affirmation should include support for psychosocial as well as medical needs.

## **Psychosocial support**

Adopt a person-led, non-judgmental approach to explore the factors behind an individual's decision to cease medical affirmation, with a focus on achieving a fulfilling life.

This support can include:

- Validating the challenges of cessation of therapy, such as societal misunderstanding, stigma, isolation, and lack of resources, while supporting the identification of non-medical alternatives for managing persisting gender dysphoria.
- Providing psychological support for adjusting after hormone cessation, addressing issues like disclosure, stigma, anxiety, grief, regret, and acceptance of irreversible physical changes.
- Assisting in navigating potential rejection, disconnection, or loneliness, particularly concerning community loss, while addressing underlying stressors contributing to the decision to stop hormones.
- Emphasising the importance of regular, long-term follow-ups to ensure comprehensive care post GAHT.

## **Medical support**

This support can include:

- Providing guidance on safely stopping, changing, or resuming hormonal affirmation
- offering advice on managing side effects or complications, and explore less invasive gender-affirmation options if needed.
- Assessing reproductive capacity if relevant to hormone cessation.
- Discussing options for reversing physical changes if there is dissatisfaction with outcomes from hormonal affirmation.

This approach ensures that individuals considering or undergoing cessation of GAHT receive comprehensive medical and psychosocial support, with respect for their autonomy and individual needs. Compassionate care and ongoing follow-up are essential for those who choose to stop hormone therapy, helping to safeguard their psychological and physical wellbeing. As gender identity and expression may evolve over time, it is important to approach these changes with empathy and respect. A strong therapeutic alliance offers stability and support, serving as a protective factor as individuals navigate the complexities of their gender experience across their lifespan.

## Gynaecological and pelvic health

### Menstrual suppression

Individuals on full-dose testosterone-based hormone therapy are generally expected to become amenorrhoeic within approximately 6 months, though this timeframe can vary.<sup>96</sup> For those seeking menstrual suppression, progestins may be used as an adjunct to testosterone-based hormone therapy, or as monotherapy for individuals who choose not to take testosterone or are awaiting access to it. *Table 10* outlines medication options and dosages. Surgical options include endometrial ablation, which is permanent but not a contraceptive, and hysterectomy, with or without gonadectomy. It is important to fully assess any persistent bleeding to determine whether it is normal menses or abnormal uterine bleeding, such as irregular cycles, intermenstrual, or postcoital bleeding, and investigate appropriately.

**Table 10. Medical options for menstrual suppression**

Medication	Brand name	Dose	Comments
Norethisterone	Primolut	Start 5–10 mg BD Titrate down to lowest effective dose to maintain amenorrhea, ideally 5 mg daily	Slightly increased VTE risk Not a contraceptive
Oral medroxyprogesterone acetate	Provera Ralovera	Start 5–10 mg BD Titrate down to lowest effective dose to maintain amenorrhea, ideally 10 mg daily	Increased risk of VTE Not a contraceptive
Progestogen-only pills - levonogestrel - norethisterone - drospirenone	Microlut Noriday Slinda	Once daily tablet	May not reliably induce amenorrhoea Breakthrough bleeding possible Is a contraceptive May cause breast tenderness or engorgement, which may be intolerable
Intramuscular medroxyprogesterone acetate	Depo-Provera Depo-Ralovera	3 monthly injection	Potential for weight gain and mood changes Variable efficacy in achieving amenorrhoea Is a contraceptive
Levonorgestrel intrauterine system	Mirena Kyleena	Intrauterine device	Requires invasive insertion, with sedation preferred for some Initial irregular bleeding is common Is a contraceptive

## Pelvic pain in those registered female at birth

Pelvic pain in those on testosterone-based hormone therapy is very common, with self-reported rates above 70%.<sup>97</sup> Risk factors include persistent menstruation, current or past history of post-traumatic stress disorder, and experiences of pain with orgasm.<sup>97</sup> Acute causes of pelvic pain (< 6 months) may include infection, postoperative complications, eg, adhesions post hysterectomy, and directly as a result of testosterone, but the pathophysiology of the latter is not understood. Management options include treatment of any infection, testosterone dose adjustment and non-steroidal anti-inflammatories. Chronic causes of pelvic pain (> 6 months) include postoperative complications, pelvic floor dysfunction, endometriosis, musculoskeletal causes and psychological/trauma related. Management of chronic pelvic pain depends on the cause and can include medications such as amitriptyline for central sensitisation, pelvic floor physiotherapy with an affirming provider, endometriosis management, and progestogen menstrual suppression. Surgical options are available for endometriosis and adenomyosis. Involvement of an affirming gynaecologist is recommended.

## Vaginal atrophy management

Testosterone-based GAHT leads to reduced oestrogen concentration in the vagina, causing several changes that can result in long-term discomfort and pain. Atrophic changes occur in up to 80% of individuals on testosterone-based GAHT,<sup>98</sup> and are similar to those seen in postmenopausal cisgender women. These changes include cytological alterations,<sup>99</sup> increased vaginal pH, and shifts in the microbiome, notably a reduction in lactobacilli and an increase in intestinal flora.<sup>100</sup> These atrophic changes can lead to vaginal dryness, dyspareunia, and an increased risk of bacterial vaginosis. Additionally, the thinning of the vaginal tissue may heighten susceptibility to sexually transmitted infections due to the potential for microtraumas during sexual activity.

The recommended treatment for vaginal atrophy is topical oestrogens applied directly to the vagina. In individuals on testosterone-based GAHT, the use of topical estradiol has been associated with an increased prevalence of lactobacilli, which is crucial for maintaining vaginal health.<sup>101</sup> Data from postmenopausal cisgender women indicates that topical oestrogen can alleviate symptoms of dryness and dyspareunia, lower vaginal pH, and boost the prevalence of *Lactobacillus* species.<sup>102</sup> The typical regimen involves applying topical estradiol nightly for 2 weeks, followed by twice-weekly applications for maintenance. For those who cannot tolerate vaginal administration, vulval application is an alternative, although absorption may be reduced.

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## Hair removal

TGD individuals may wish to remove hair for various reasons, which may be for gender affirmation or for other motivations. Options for hair removal are outlined in [Table 11](#). Frequently hair removal is sought by individuals registered male at birth. While estradiol-based GAHT will typically lead to a reduction in terminal hair growth velocity and density, affecting the body hair more than the facial hair, this reduction does not typically reach values typical for cisgender women.<sup>103</sup> US-based population studies have demonstrated that almost 90% of individuals registered male at birth engage with or desire to have gender-affirming hair removal with gender-affirming hair removal being associated with improvements in mental health outcomes and reduced psychological distress.<sup>104</sup> Testosterone therapy causes increases in facial and body hair and reduced which may be affirming for some individuals while others may wish to remove excess or unwanted hair. Injectable forms of testosterone show higher rates of body and facial hair growth compared with topical formulations.<sup>63</sup>

**Table 11. Hair removal options**

Method	Details	Potential side effects
<b>Temporary options</b>		
Shaving	Self-administered	Skin irritation Folliculitis Laceration
Depilatory creams	Chemical hair removal Self-administered	Skin irritation Risk of chemical burn to the skin
Waxing	Can be self-administered or at salon	Pain Skin irritation Burns
Mechanical removal	More suited to smaller areas Can be self-administered or at salon	Pain Skin irritation
Eflornithine	Facial cream that can reduce hair growth Compounded only Costly Takes 4–8 weeks to see effect	Stinging, burning, irritated skin Acne Dry or red skin Skin rashes
<b>Permanent options</b>		
Intense pulsed light	Light-induced hair follicle damage Permanent hair reduction Requires multiple treatments Works best with dark hair/pale skin Home devices are available Costly Less effective than laser hair removal	Pain Redness Swelling Blisters, burns, scarring
Laser hair removal	Laser-induced hair follicle damage Permanent hair reduction Requires multiple treatments Works best with dark hair/pale skin Home devices are available Costly	Pain Redness Swelling Blisters, burns, scarring
Electrolysis	Hair follicle destruction via electrical current Effective for all skin types and colours Requires multiple treatments at specialised salon Costly	Pain Redness Swelling

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## Medicare Benefits Schedule and Pharmaceutical Benefits Scheme considerations

The Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) are key components of Australia's healthcare system, with the MBS providing subsidies for a range of medical services and procedures, and the PBS offering subsidised medications to reduce the cost of pharmaceuticals for Australian residents.

Consultations for gender-affirming care with GPs are eligible for standard time-based consultation items, noting that in November 2023, Item 123 was introduced for face-to-face consultations lasting more than 60 minutes. Telehealth item numbers are also available for GAHT appointments, as these are normal primary care consultations. For individuals who have not been seen face-to-face before, at the time of publication, the sexual health item numbers are exempt from the 12-month face-to-face rule, and as gender incongruence of adulthood is a sexual health condition as per the International Classification of Diseases,<sup>105</sup> consultations related to gender incongruence of adulthood are eligible for these MBS item numbers. Individuals with gender incongruence of adulthood on GAHT are also eligible for GP chronic care items. The MBS does undergo periodic revision and clinicians are advised to refer directly to the MBS for up-to-date information.

Individuals on GAHT with Medicare cards are eligible for subsidised medications under the PBS. GPs will frequently need to write authority scripts in two contexts:

- Individuals on estradiol-based GAHT who need an increased quantity of medications above what is available on the general PBS.
- Individuals on testosterone-based GAHT needing testosterone.

Accessing government services via Provider Digital Access (PRODA) can speed up the process of obtaining these scripts. From September 2023, the Australian government increased the quantity that individuals could access on a single prescription. Clinicians should not use a 60-day supply as a 30-day supply for individuals as this will affect an individual's PBS safety net contributions and may be declined by the pharmacist. PBS authorities for testosterone scripts are discussed in Part 2. *Principles of testosterone-based GAHT.*

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## Neurodivergence in gender-affirming care

Neurodivergence refers to a condition when an individual experiences the world, learns, communicates, interacts, and engages differently from what is typically considered 'neurotypical' in psychological frameworks. This includes individuals with autism, ADHD, mental health conditions, learning disabilities, and acquired brain injuries. Although data varies, more than 10% of the general population is thought to be neurodivergent.<sup>106</sup> Research indicates that neurodivergent individuals are three to six times more likely to report gender diversity compared to neurotypical individuals.<sup>107-108</sup> While there is no causal link between neurodivergence and gender variance, it is essential to recognise that many TGD neurodivergent people experience heightened levels of minority stress. They may also face greater challenges in accessing systems designed for neurotypical, cisgender populations. Neurodivergent individuals often encounter barriers to accessing medical support, which can extend to gender-affirming care. Fears that their neurodivergence will prevent them from receiving appropriate care may lead to a reluctance to disclose their neurodivergence.<sup>109</sup> This can result in 'masking', where individuals modify their behaviour to appear neurotypical in order to feel safer, secure access to services, and avoid further trauma.<sup>110</sup>

## Supporting neurodivergent TGD individuals in clinical practice

Healthcare providers can take the following steps to create inclusive and accessible healthcare environments for neurodivergent individuals:

- Reassure the individual that neurodivergence does not prevent access to gender-affirming care.
- Ask how their neurodivergence impacts their ability to access services and what adjustments would support them during the consultation.
- Recognise that power imbalances in healthcare settings may cause individuals to mask their neurodivergence until they feel safe.
- Acknowledge that each person's experience of neurodivergence is unique, and adjustments will vary.
- Understand that many neurodivergent people have had traumatic experiences in the healthcare system, so building trust may take time.

Accommodations that may be helpful include:

- Providing printed and emailed copies of referrals, scripts, and test orders.
- Encouraging the individual to take notes during consultations or providing written summaries of key information.
- Offering handouts or links to resources for further information.
- Welcoming the presence of a support person during appointments, especially when complex medical information is discussed.
- Allowing the individual to regulate in ways they find helpful, such as using fidget toys, support animals, headphones, sunglasses, and/or stimming.
- Explaining each step of a consultation or procedure in detail, including what sensations they might experience and the reasons behind each action. Always seek consent at every step.

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## Older adults and GAHT

There are increasing numbers of older adults receiving GAHT. Some commenced GAHT long ago, when discrimination, non-acceptance, and significant barriers to healthcare were societal norms. Others have initiated their GAHT in older age, with greater societal acceptance and improved access to healthcare. Older adults may desire to initiate or continue GAHT when their endogenous hormone production has changed or chronic issues have developed. There is no current data to guide hormone concentration targets in older individuals. Decisions about hormone therapy should be individualised based on the personal goals and health needs.

### Testosterone-based GAHT

Individuals with ovaries who are on testosterone-based GAHT continue to produce significant concentrations of oestrogen during the pre-menopausal stage.<sup>111-112</sup> Most people with ovaries reach menopause between the ages of 40 and 60. However, in those receiving testosterone therapy, estradiol concentrations appear to remain stable regardless of ovarian function, likely due to aromatisation of exogenous testosterone.<sup>112</sup> These sustained oestrogen levels, despite the natural decline associated with menopause, may help preserve bone density and cardiovascular health in older adults. Currently, there is no evidence to suggest that testosterone doses need to be reduced with age.<sup>113</sup>

## Estradiol-based GAHT

Individuals on estradiol-based GAHT generally aim to achieve cisgender female premenopausal concentrations of estradiol and testosterone. As individuals on estradiol-based GAHT age, the potential risks and benefits of continuing to aim for these cisgender female physiological ranges should be discussed,<sup>113</sup> while being cognisant that research suggests it is primarily the concomitant use of progestins that mediate the cardiovascular, thromboembolic, and breast cancer risks in cisgender women using long-term menopausal hormone therapy.<sup>114-115</sup> Transdermal oestrogen is the preferred the route of administration for GAHT in people over 45 years of age to minimise VTE risk<sup>8</sup> but whether the target concentration of serum estradiol should be lowered in older adults is currently unknown.<sup>116</sup> When considering androgen blockade, the possible association of spironolactone with upper gastrointestinal bleeding demonstrated in the general population, especially in people on higher doses (100 mg) and those over 55 years of age, should be discussed.<sup>41-42</sup> Additionally, the cumulative lifetime use of CPA should be monitored due to the established risk of meningioma at high accumulative doses (see Part 2. *Principles of estradiol-based GAHT* for further discussion).<sup>35-36</sup>

Current longitudinal studies generally include younger populations, but an increasing proportion of older adults are represented as these groups age.<sup>113,117-118</sup> This emerging data will provide more information about the potential levels of risk from GAHT in this age group where, as in the general population, cardiovascular disease, diabetes, renal impairment, fragility fracture, and cancer become more frequent with age.<sup>116</sup> Cognitive impairment and dementia may also be concerns for older adults. GAHT for these older individuals may require a multidisciplinary approach involving primary care practitioners, endocrinologists, sexual health physicians, and geriatric medicine physicians. If the older individual is receiving support within the aged care system or resides in an aged care facility, advocacy should be offered to ensure a safe and inclusive environment.

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## Penile pain and erectile dysfunction

Penile pain may be reported by individuals undergoing estradiol-based GAHT. This type of pain, while recognised, is not well-documented in medical literature. It is hypothesised that the pain may result from penile atrophy and/or fibrosis of the penile tissue, potentially involving the tunica albuginea, the tough fibrous layer of connective tissue that surrounds the corpora cavernosa. These changes can occur after several months or years of GAHT. The pain may also be related to androgen blockade. Clinically, the pain can range from mild to moderately severe and may intensify during erections and penetrative intercourse. Diagnosis is clinical, with no specific investigations useful for diagnosis. GPs should inform individuals of this known side effect of estradiol-based GAHT.

There is currently no data to guide the management of penile pain associated with estradiol-based GAHT. The following strategies are anecdotal and may be trialled according to individual preference and acceptability:

- Androgen blocker reduction may allow serum testosterone concentration to increase to typical female concentrations or slightly above, which may help reduce pain.
- Regular erections and genital use through masturbation, vacuum erection device, or intercourse several times a week may gradually alleviate pain.
- Penile vacuum pumps have been reported to reduce pain, although others find that it increases discomfort.
- Low-dose topical testosterone cream applied to the genitals can decrease pain, likely by reducing atrophy caused by low testosterone concentration. Any cream-based testosterone product can be used at a low dose, though some may prefer testosterone products marketed for women, such as 1% testosterone cream. Regular monitoring of wellbeing and serum testosterone concentration can help guide dosing.

## Erectile dysfunction

Reduced libido, decreased spontaneous erections, and decreased overall erectile function are known side effects of estradiol-based GAHT. The degree as to which an individual experiences these side effects varies and may be influenced by the duration and dose of hormone therapy, baseline testosterone concentration, and psychological factors. For some individuals, these changes are desirable; for others, they may cause distress. Managing erectile dysfunction in those on estradiol-based GAHT requires a nuanced approach that balances gender-affirming care goals with their sexual function needs.

Options for management include:

- Hormone dose adjustment by lowering the dose of oestrogen or anti-androgens can aid in the maintenance of a level of sexual function that meets an individual's desires by slightly increasing the serum total testosterone. This approach must be balanced with the individual's feminisation goals and may cause increased androgenisation.
- Phosphodiesterase type 5 inhibitors such as sildenafil (Viagra) or tadalafil (Cialis) can be effective in managing erectile dysfunction in individuals on estradiol-based GAHT
- These medications enhance blood flow to the genital area, helping to achieve and maintain an erection. They do not address libido directly but can help maintain sexual function.
- Testosterone supplementation may be useful in cases of orchiectomy or complete testosterone suppression due to oestrogen monotherapy. Low-dose testosterone supplementation may be considered after thorough discussion with the individual. Regular monitoring of wellbeing and serum testosterone concentration should guide dosing adjustments.
- Psychosexual support from a mental health professional experienced in gender-affirming care can be beneficial. Addressing psychological aspects of sexual function, such as body image and gender dysphoria, plays a critical role in managing the sexual side effects of estradiol-based GAHT.
- Exploring and adapting to alternative forms of sexual expression that do not rely on erectile function can also be a fulfilling option for many individuals on estradiol-based GAHT. This may include focusing on non-penetrative sex, sensual touch, and other forms of intimacy that align with the individual's gender identity and sexual preferences.

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## Prolactinoma

Following the initiation of estradiol-based GAHT, serum prolactin concentration may rise above the normal range. This increase is primarily associated with CPA and will normalise with its discontinuation.<sup>119</sup> There have been case reports of prolactinomas in individuals on estradiol-based GAHT using both CPA and spironolactone.<sup>120</sup> There is no clear evidence to support routine prolactin monitoring as part of the ongoing care of the individual on GAHT and it is an individual provider's choice to monitor or not. The University of California, San Francisco, *Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People*,<sup>40</sup> recommend against routine serum prolactin testing, as it is unlikely to change clinical management. This is because the management of asymptomatic incidental prolactinomas is typically expectant only and detection of incidental hyperprolactinaemia may lead to costs or harms as a consequence of further investigation. Some clinicians may choose to monitor serum prolactin as prolactinoma symptoms may not be clinically apparent and tumours may resolve with limited treatment courses.

Testing of serum prolactin concentration is strongly recommended if there are symptoms of hyperprolactinaemia, such as excessive galactorrhoea, or symptoms of a pituitary tumour, such as new onset headaches, visual disturbances, or anterior pituitary hormone deficiency (e.g. secondary adrenal insufficiency, central hypothyroidism and growth hormone deficiency).<sup>27</sup>

A minimal amount of galactorrhoea may be experienced by some individuals on estradiol-based GAHT, particularly early on. Provided it is non-bloody, minimal, and from more than one duct, it is physiological and does not warrant further investigation unless additional features are present. For those choosing to monitor prolactin, advise individuals to have blood taken in the morning, ideally 3–4 hrs after waking, and avoid strenuous exercise prior to testing.

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## Polycythemia

Polycythemia, also known as erythrocytosis, is the most common adverse effect of testosterone therapy. It refers to an increase in red cell mass, detected through elevated haemoglobin and haematocrit (the ratio of the volume of red blood cells to total volume of blood) concentrations. In the context of testosterone-based GAHT, laboratory reference ranges for cisgender males should be used. A haematocrit greater than 0.5 L/L (or greater than the upper limit of the male physiological range for a given laboratory) is considered abnormal and warrants further evaluation.

Polycythaemia is of clinical concern because of complications associated with hyperviscosity, specifically thrombosis which may clinically manifest as digital infarcts, cerebral ischaemic infarcts and venous thrombosis.<sup>121</sup> In those on testosterone-based GAHT, individuals with polycythemia will be asymptomatic and be identified on routine blood tests. Polycythemia vera (primary polycythaemia) is very rare (9 in 1 million cases)<sup>122</sup> and is seldom seen before the age of 40. Diagnosis is confirmed via JAK2 mutation studies if clinically suspected, routine testing is not recommended.

When polycythaemia is detected, other contributing factors should be assessed, including smoking, chronic kidney disease, lung disease, and obstructive sleep apnoea. Among testosterone formulations, short-acting intramuscular testosterone carries the highest risk of polycythemia. Management of polycythemia once any underlying contributing factors have been excluded, may require a reduction in the testosterone dose or increase in the dosing interval, if applicable. As transdermal testosterone is associated with a lower risk of polycythemia, it offers an alternative for those developing polycythaemia on intramuscular formulations.<sup>123</sup> Venesection (therapeutic phlebotomy) should be reserved for primary polycythemia, as there is no evidence supporting its use in TGD populations. Additionally, it may lead to iron deficiency and appears to provide temporary relief only as it is not addressing the underlying cause.

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## Progesterone

Progestogens are a class of hormones that include synthetic progestogens (progestins) and the naturally occurring hormone progesterone, which is produced by the adrenal cortex and gonads. Historically, progestogens were commonly used in GAHT due to use of the combined oral contraceptive pill in standard care. However, this is no longer standard practice, as ethinyl estradiol carries a higher risk of VTE compared to the estradiol formulations now used in GAHT.

Some individuals on estradiol-based GAHT may request the addition of progesterone to their regimen, often citing potential benefits for breast and/or areola development, mood improvement, and libido enhancement. However, progesterone is not involved in pubertal breast development in cisgender women; its role is mainly in lobular alveolar development during lactation.<sup>27</sup> Additionally, the two most common anti-androgens, spironolactone and particularly CPA, already have progestogenic effects, making the impact of additional progesterone unclear.

The current evidence on progesterone use in estradiol-based GAHT is limited. Nolan et al. 2022,<sup>124</sup> in a 3-month prospective case-control study, did not find any benefit of 100 mg of micronised progesterone on sleep quality, psychological distress or breast development. Bahr et al.,<sup>125</sup> found the addition of progesterone to estradiol-based GAHT was associated with greater satisfaction with breast development and improved mental health in their retrospective cohort study. Further high quality studies are underway.<sup>126</sup>

Concerns about progestogen use in GAHT often stem from findings in the Women's Health Initiative (WHI) study, which linked synthetic progestins to increase risk of breast cancer and higher rates of CVD events. However, there are key differences between the WHI population and TGD individuals on GAHT. The WHI studied postmenopausal cisgender women, many of whom were more than ten years post-menopause. The WHI study used conjugated equine estrogens combined with medroxyprogesterone (MDA), both of which are not used in standard GAHT. TGD individuals on GAHT are typically younger and have a lower baseline risk of breast cancer. Additionally, the risk of CVD and breast cancer in the WHI study was small and there was no effect on overall mortality.

If used, micronised progesterone is generally preferred over synthetic progestins due to a better safety profile, including lower risk of breast cancer<sup>127</sup> and VTE,<sup>128</sup> at least in cisgender post menopausal women. Individuals should be informed about potential side effects of progesterone, including negative mood effects such as depression, weight gain, bloating, and acne. As progestogens can cause sleepiness, it is best taken at night. Some individuals may opt to administer it rectally, though there is no data to support specific routes of administration. Commonly used doses are 100–200 mg nightly. Given the lack of strong evidence for benefits, clinical review after 3–6 months to assess effectiveness and determine ongoing use.

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## **Pulmonary oil microembolism**

Pulmonary oil microembolism (POME) is a rare clinical event associated with the administration of oil-based testosterone injections. POME has primarily been reported through case studies, case series, and post-marketing safety analyses, primarily in cisgender men and diagnostic criteria are not consistently standardised. The condition is thought to result from the inadvertent intravascular delivery of the oil-based formulation, which travels to the lungs and leads to respiratory symptoms such as coughing and shortness of breath.<sup>129</sup> The incidence of POME is low. In a large post-marketing safety analysis, its occurrence was noted in less than 0.1% of injections annually.<sup>129</sup> However, depending on the study and definitions, rates have varied between < 0.1% and 2.1%.<sup>129-134</sup> POME typically presents within 30 minutes of an intramuscular injection of oil-based testosterone. Common symptoms include cough and dyspnoea, with additional complaints of throat irritation, malaise, hyperhidrosis, chest pain, dizziness, and paraesthesia.<sup>129</sup> Most episodes resolve spontaneously within 30 minutes to 3 hours, often without medical intervention, though oxygen therapy may be provided if required. However, treatment details are often underreported.

It is essential to distinguish POME from anaphylaxis, a very rare but potentially life-threatening reaction to testosterone injections. Anaphylaxis is an IgE-mediated hypersensitivity reaction, typically triggered by repeated exposure to an allergen, and characterised by systemic symptoms such as rash, bronchospasm, cardiovascular (hypotension, syncope) and gastrointestinal (vomiting, abdominal pain) involvement and cardiovascular involvement.<sup>135</sup>

To our knowledge, only one case of testosterone anaphylaxis has been reported in the English-language medical literature.<sup>136</sup> In contrast, POME predominantly manifests with respiratory symptoms, without the systemic features typical of anaphylaxis. Nonetheless, any suspected anaphylaxis should be urgently managed according to established emergency guidelines, due to the severe outcomes if untreated.

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## Sexual health

Sexual health, as defined by the World Health Organization, is a state of physical, emotional, mental, and social wellbeing in relation to sexuality, encompasses intimacy, gender, sexual orientation, reproductive health, and safety.<sup>137</sup> Sexual healthcare is a core component of primary care, yet TGD individuals face significant barriers to accessing inclusive and affirming care due to gaps in provider education and understanding.<sup>138</sup> Inclusive sexual history taking, prescribing pre-exposure prophylaxis (PrEP), and contraception for TGD individuals, and understanding the impact of GAHT on sexual function and libido can enhance quality of care, build trust, and strengthen the therapeutic relationship.

### Sexual health history

Traditional sexual history often relies on questions like ‘do you have sex with men, women, or both?’ which can lead to assumptions about anatomy and sexual practices. The ‘parts and practices’ approach focuses on anatomy and sexual behaviours, asking questions such as, ‘Do you have sex with people with a penis, vagina, or both?’ and ‘Do you engage in penetrative sex, and if so, which body parts are involved?’ Further questions may include, ‘Do you use any protections during sex, such as contraception, barrier methods, or PrEP?’

When detailed questioning is necessary, it is important to explain why the information is required and how it will improve care. For some individuals, discussing genitalia may provoke gender dysphoria. It is appropriate to ask about preferred language for body parts, or alternatively, use non-gendered terms like genitalia, gonads, erectile genital tissue, or chest/upper body (see TransHub *Trans-affirming clinical language*). Further guidance can be found on the [ACON TransHub website](#) regarding sexual health history taking for TGD individuals.

Understanding different relationship structures can also enhance care. While many prefer monogamous relationships, others engage in polyamory or other non-traditional relationship structures. When discussing sexual activity with an individual, avoid assumptions about exclusivity. It is important to ask whether the individual has other relationships, whether they have sex outside of those relationships, whether their partners have other partners, and to screen for relationship health as would be standard in any clinical discussion of relationships. As well as validating non-traditional relationship structures, it is important to acknowledge that the emotional and psychological dynamics of non-monogamous relationships can be different from monogamous ones, although neither relationship structure is intrinsically better or worse for emotional and psychological health. The dynamics of any relationship can affect satisfaction, mental health and stress, all of which can impact on overall wellbeing. By addressing both the physical and emotional aspect of an individual’s relationship(s), healthcare providers can offer more holistic and affirming care.

## Contraception

While GAHT may reduce fertility, it is not a form of contraception, and contraception should be discussed with individuals at risk of pregnancy. For individuals with a penis, all standard contraceptive options are effective. For those choosing condoms, appropriate sizing should be considered in cases of genital atrophy. It is safe to conceive using sperm from an individual on estradiol-based GAHT.

For those on testosterone-based GAHT, it is important to note that testosterone is a teratogen, and pregnancy should be avoided to prevent foetal effects. If pregnancy occurs while on testosterone, medical or surgical termination may be an option for these individuals. If in doubt, urgent obstetric opinion is strongly encouraged. Contraception options include standard barrier and progestin-only methods. Progestin-only contraception is used as per non-TGD individuals, with counselling and shared decision making regarding the various methods.

Long-acting forms, such as the etonogestrel implant (Implanon) and levonorgestrel intrauterine device (Mirena or Kylena) are more effective and mitigate user error but the requirement of intrauterine placement may be unacceptable for some individuals. Consider if an individual would prefer sedation for any pelvic procedures. Oestrogen-containing contraceptives are not considered first line for individuals on testosterone-based GAHT due to the potential for unwanted feminising effects, but may be used by some. Emergency contraception is safe for all individuals at risk of unintended pregnancy, including those on GAHT. Regular reviews of contraceptive needs are recommended as sexual practices and relationships evolve.

## Pre-exposure prophylaxis

Pre-exposure prophylaxis (PrEP) is a highly effective strategy for HIV prevention and has significantly reduced HIV acquisition rates in Australia.<sup>139</sup> PrEP should be offered to TGD individuals who are at risk of HIV acquisition, including those having sex with men who have sex with men. The prescription of PrEP should be tailored to the individual's sexual practices and HIV risk factors, regardless of gender identity. TGD individuals on GAHT can safely use PrEP, as it does not interact with hormone therapy, and it should be prescribed according to the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine Australian PrEP Guidelines.<sup>140</sup> Note that the guidelines recommend against on-demand PrEP for TGD individuals who are taking GAHT and people with vaginas. Daily PrEP is recommended for all of these population groups. Routine monitoring of kidney function, HIV status and sexually transmitted infection screening is necessary during PrEP use. It is important to engage in shared decision-making with individuals regarding the use of PrEP, depending on their sexual practices and preferences, to ensure optimal protection and adherence.

## Surgery

A range of gender-affirming surgery (GAS) is available, offering physical changes that hormone therapy alone cannot achieve. These surgeries are associated with significant improvements in mental health, quality of life, and relief from gender dysphoria.<sup>141</sup> However, access to surgery remains challenging for many individuals due to a combination of factors, including long wait times and financial barriers. Most procedures are not covered by the MBS and those that are, are rarely performed in the public system, meaning individuals often face significant out-of-pocket costs. In Australia and internationally, there is a growing number of surgeons performing gender-affirming surgeries but their approach to consent varies. Some perform certain surgeries under the informed consent model; others, particularly for genital surgery, require individuals to obtain an assessment from a qualified mental health professional, in accordance with the WPATH SOC 8,<sup>8</sup> to confirm gender dysphoria and assess capacity to consent. *Table 12* and *Table 13* provide an overview of common gender-affirming surgeries.

Individuals undergoing GAS, or any major surgical procedure, are at risk of VTE. The perioperative management of VTE prophylaxis and hormone therapy should be individualised, taking into account the risks of bleeding, thrombosis, and the potential adverse effects of hormone deprivation. These decisions should be made in collaboration with the surgical team to ensure optimal outcomes. The modified Caprini score is the most commonly used tool for assessing VTE risk in surgical patients, though it does include oestrogen use without stratifying based on the administration route. Those at intermediate to high risk (i.e., score > 3) are recommended to have VTE chemoprophylaxis. There is insufficient evidence to support routine perioperative discontinuation of estradiol-based therapy and withholding GAHT may cause significant negative impacts on the individual.<sup>142-</sup>  
<sup>143</sup> Continuation of GAHT is particularly important during and following gonadectomy. For individuals with moderate to high modified Caprini scores, a shared decision-making approach regarding anticoagulation and/or withholding GAHT should be utilised, tailoring treatment decisions to the individual's personal goals and desired outcomes.<sup>143</sup>

**Table 12. Common feminisation procedures**

<b>Procedure</b>	<b>Description</b>
Breast augmentation ('top surgery')	Placing implants under the breast tissue to increase breast size. The type and size of the implants are determined by factors such as desired increase in size, breast structure, skin thickness and elasticity, and overall body shape.
Orchiectomy ('bottom surgery')	Surgical removal of testicles. The individual will no longer be able to synthesise endogenous testosterone and thus will not require antiandrogens but will require exogenous sex hormones until at least menopausal age.
Vaginoplasty ('bottom surgery')	Creation of a neovagina, labia and clitoris by using penile and scrotal skin. The urethra is shortened and repositioned, and the testicles are removed to complete the genital reconstruction. Various techniques are used, and the surgery can be done in one or two stages. The individual is required to use a dilator regularly to maintain the volume of the internal vaginal cavity. Permanent hair removal on some areas of skin may be recommended preoperatively by the surgeon to reduce hair growth in neovagina and vestibule.
Labiaplasty/zero-depth vaginoplasty ('bottom surgery')	A labiaplasty is similar to a vaginoplasty in the creation of external genitalia, but no vaginal canal is formed. Instead, a vaginal dimple is created, giving the appearance of a vaginal opening without requiring dilation.
Facial feminisation	Involves a range of procedures to achieve a more feminine appearing face. Procedures include forehead contouring, rhinoplasty, cheek contouring, genioplasty and lip augmentation.
Laryngeal shave	Flattening of the thyroid cartilage (Adam's Apple).
Vocal feminisation surgery or glottoplasty	Shortening of the vocal cords to achieve a higher pitched voice. This surgery requires intensive speech therapy for optimal results.
Body contouring	Body contouring involves cosmetic procedures that enhance body shape and appearance by altering its size or form. It is commonly done on areas like the waist, abdomen, thighs, buttocks, and arms, using techniques such as fat removal, skin tightening, or implants.
Hair replacement surgery	Hair replacement surgery uses various techniques, like grafts and scalp-reduction, to restore hair fullness.

**Table 13. Common masculinisation procedures**

<b>Procedure</b>	<b>Description</b>
Chest reconstruction ('top surgery')	Removal of breast tissue. Creates a more masculine appearing chest with several different surgical methods based on breast size.
Hysterectomy	Removal of the uterus and cervix.
Oophorectomy	Removal of the ovaries. The individual will no longer be able to synthesise endogenous oestrogen and will require exogenous sex hormones at least until menopausal age.
Metoidoplasty	The construction of a penis from existing genital tissue. The resulting penis is typically 3–6cm long. Testosterone-based hormone therapy is a prerequisite of this surgery.
Phalloplasty	Creation of a full sized penis from a skin flap (skin, underlying tissue, nerves, arteries and veins) and lengthening of the urethra. There are a range of techniques used and the surgery is multi-staged.
Scrotoplasty	Construction of a scrotum out of the labia majora and silicone testicular implants. Scrotoplasty often accompanies phalloplasty or metoidoplasty.

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# **Appendix A. Resources**

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## *Australian*

### ASHM

- [ASHM & Acon's Trans and Gender Diverse Sexual Health Care e-learning](#)

### HealthPathways

- Refer to local HealthPathways, if available

### TransHub

- [10 tips for clinicians](#)
- [Creating welcoming environments](#)
- [Trans-affirming clinical language](#)

## *Other*

### The Fenway Institute (USA)

- [Affirmative Care for Transgender and Gender Non-Conforming People: Best Practices for Front-line Health Care Staff](#)

### TransHub

- [For clinicians](#)

### Trans Health Research

- [Professional resources](#)
- [Community resources](#)

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## **Appendix B. Consent forms**

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## **Estradiol-based gender-affirming hormonal therapy consent form**

The informed consent model of care respects your fundamental human right to self-determination and bodily autonomy. This document relates to estradiol-based hormone therapy, which includes the hormone estradiol and testosterone blocking medications. The purpose of this document is to indicate, in writing, that you fully understand and consent to estradiol-based hormone therapy as part of a gender-affirmation process. Your provider will discuss with you all of the information relating to starting estradiol-based hormone therapy. In consultation with you, your provider will make a medical decision about which medications are best for you, keeping in mind your overall health during your gender-affirmation process. You are asked to read and understand the following information, and raise any questions you have with your provider.

I, *<Full name>*, in consultation with my provider *<Provider name>*, acknowledge that I have read and understood the following information, and I have been given sufficient opportunity to address all questions:

*Tick the boxes to acknowledge you understand the following:*

I understand that there are permanent changes that can be expected while taking estradiol-based hormone therapy. I understand that these changes may be present for the rest of my life, even if I choose to stop treatment:

- Breast and nipple development
- Decreased testicular size
- Possible permanent infertility with long-term treatment

I understand that there are reversible changes that can be expected while taking estradiol-based hormone therapy:

- Softening of skin
- Decreased muscle mass and increased body fat
- Slowed or stopped balding
- Slowed rate of growth of facial and body hair; however, existing body hair will not disappear
- Sexual function changes: decreased libido, reduced spontaneous morning erections, reduced ability to achieve or sustain an erection, reduced ability to ejaculate, reduced volume and changed consistency of ejaculatory fluid

I understand that there are possible side effects of estradiol-based hormone therapy. Many of these side effects can be managed. If side effects occur, I will discuss the with my provider:

- Fatigue
- Headaches
- Nausea
- Fluid retention and bloating
- Breast and nipple tenderness
- Painful erections
- Shrinkage of genitals
- Emotional changes, moodiness and increased sensitivity, teariness, and possible exacerbation of pre-existing depression and anxiety

I understand that there are potential risks of estradiol-based hormone therapy. I understand that research is ongoing to fully understand the extent and likelihood of these risks, and that some of the long term effects are not yet known. My provider will continue to monitor my health and address any issues if and when they develop:

- Increased risk of stroke
- Blood clots - deep vein thrombosis or potentially fatal pulmonary embolism
- Liver damage
- Reduced bone density and increased risk of osteoporosis
- Potentially increased risk of certain cancers, including breast cancer
- Increased risk of gastrointestinal bleeding (associated with spironolactone)
- Increased risk of certain types of benign brain tumours (rare, associated with cyproterone)

I understand that estradiol-based hormone therapy affects everyone differently, and that there is no way to predict exactly how, or how much, my body will change. I also understand that some characteristics of my body will not change with estradiol-based hormone therapy.

I understand that estradiol-based hormone therapy reduces fertility and risks permanent infertility with long term use. I have discussed my future fertility with my provider, and have been given the opportunity to delay starting estradiol-based hormone therapy until after I have stored sperm.

I understand that estradiol-based hormone therapy 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 my sexual practices may evolve during my gender affirmation process, which could affect my risk of acquiring HIV or other sexually transmitted infections. I have been encouraged to discuss sexually transmitted infection prevention strategies with my GP to support my health and wellbeing.

I understand that being on estradiol-based hormone therapy means that I will need to see my provider 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 estradiol-based hormone therapy is 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:

- Regular breast self-examination. I should tell my provider if I discover any new lumps
- Regular breast mammograms from an appropriate age, in consultation with my provider
- Quitting smoking
- Staying up to date with immunisations
- Regular sexual health screening and HIV prevention, depending on my level of risk
- Regular physical activity, including resistance exercise for bone health
- Healthy eating

I understand that 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 provider, to ensure that I remain safe and healthy.

Name:

Signature:

Date:

## Testosterone-based gender-affirming hormonal therapy consent form

The informed consent model of care respects your fundamental human right to self-determination and bodily autonomy. This document relates to testosterone therapy, and its purpose is to indicate, in writing, that you fully understand and consent to testosterone therapy as part of a gender affirmation process. Your provider will discuss with you all of the information relating to starting testosterone therapy. In consultation with you, your provider will make a medical decision about which medications are best for you, keeping in mind your overall health during your gender affirmation process. You are asked to read and understand the following information, and raise any questions you have with your provider.

I, <Full name>, in consultation with my provider <Provider name>, acknowledge that I have read and understood the following information, and I have been given sufficient opportunity to address all questions:

*Tick the boxes to acknowledge you understand the following:*

I understand that there are permanent changes that can be expected while taking testosterone. I understand that these changes may be present for the rest of my life, even if I choose to stop testosterone:

- Increased facial and body hair
- Deepened voice
- Enlargement of erectile genital tissue (phallus/ clitoris)
- Hair loss / balding of head in some people

I understand that there are reversible changes that can be expected while taking testosterone:

- Increased libido
- Body fat redistribution
- Increased muscle mass
- Coarser and oilier skin
- Stopping of menstrual periods

I understand there are possible side effects of testosterone. Many of these side effects can be managed. If side effects occur, I can discuss the with my provider:

- Acne
- Vaginal / lower dryness
- Pelvic pain
- Fatigue
- Fluid retention
- Increased blood pressure and cholesterol
- Mood changes: irritability, emotional reactivity, possible worsening of pre-existing depression or anxiety

I understand there are following potential risks of testosterone therapy. Research is ongoing to fully understand the extent and likelihood of these risks. My provider will continue to monitor my health and address any issues that develop:

- Polycythaemia: an increased number of red blood cells, resulting in 'thick' blood. Severe polycythaemia increases the risk of heart attack and stroke. Smoking is the biggest risk factor for developing polycythaemia whilst on testosterone.
- Increased risk of stroke
- New or worsened obstructive sleep apnoea

I understand that testosterone therapy affects everybody differently, and there is no way to predict exactly how, or how much, my body will change. I also understand that some characteristics of my body will not change with testosterone.

I understand that testosterone therapy reduces fertility while in use but does not reliably prevent pregnancy, and therefore cannot be used as a form of contraception. I am aware that becoming pregnant while taking testosterone may result in serious birth defects and that, in such cases, termination of pregnancy may be recommended. I have been advised to use effective contraception during any sexual activity that could lead to pregnancy, and my contraceptive options have been discussed with me where appropriate.

I understand that although return to fertility after stopping testosterone is often possible, it is not guaranteed. I have discussed my future fertility with my provider, and have been given the opportunity to delay starting testosterone until after I have stored eggs.

I understand that my sexual practices may evolve during my gender affirmation process, which could affect my risk of acquiring HIV or other sexually transmitted infections. I have been encouraged to discuss sexually transmitted infection prevention strategies with my GP to support my health and wellbeing.

I understand that testosterone therapy means that I will need to see my provider 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 testosterone therapy is 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 provider
- Regularly checking my chest/breasts for lumps, even if I have had top surgery
- Regular chest/breast mammograms from an appropriate age, in consultation with my provider, if appropriate
- Quitting smoking
- Staying up to date with immunisations
- Regular sexual health screening and HIV prevention, depending on my level of risk
- Regular physical activity, including resistance exercise for bone health
- Healthy eating

I understand that I can choose to stop testosterone therapy at any time. If I choose to stop taking testosterone, it is best that I do this in consultation with my provider, to ensure that I remain safe and healthy.

Name:

Signature:

Date:

