

Information and Guidance on Prescribing in Transgender Health

This document brings together various pieces of information, guidance, and service specifications into one place. It is intended to provide a helpful resource and source of information and advice for practices.

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- 1. Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Patients under the Specialist Gender Identity Service for Adults

NHS England is the responsible commissioner for the specialised element of the gender dysphoria pathway, which in England is delivered through specialist Gender Identity Clinics, including the Nottingham Centre for Transgender Health. There is a detailed service specification for <u>Gender Identity Services for Adults (Non-Surgical</u>) and <u>Gender Identity Services for Adults (Surgical Interventions)</u>, Integrated Care Boards (ICBs) have a supporting role to play, but are not directly involved in the commissioning of this pathway.

NHS England Service Specification

The NHS England service specification for adults (Appendix J: Current arrangements for prescribing endocrine treatment p30-31) states that the service:

- The gender specialist registered medical practitioner may recommend endocrine and other pharmacological interventions, will assess the risks, benefits and limitations of pharmacological interventions for the individual, and will ensure that that the individual meets the relevant eligibility criteria set out in the World Professional Association for Transgender Health Standards of Care (2011): Persistent, well-documented gender dysphoria; Capacity to make a fully informed decision and to consent for treatment and if significant medical or mental concerns are present, they must be reasonably well-controlled
- Will obtain written consent to the interventions under consideration from the individual and provide a copy of the consent to the individual and their GP.
- Provide the GP with patient-specific 'prescribing guidance', which will consist of a written
 treatment recommendation, and adequately detailed information about necessary pretreatment assessments, recommended preparations of medications, and advice on
 dosages, administration, initiation, duration of treatment, physical and laboratory
 monitoring, interpretation of laboratory results and likely treatment effects.
- Will give GPs advice on dose titration and the introduction of additional pharmacological interventions by the provider.
- Respond promptly to requests by GPs for advice regarding the interpretation of laboratory results and medication use.



- Individuals receiving endocrine and other pharmacological interventions recommended by the Provider will have these reviewed by a gender specialist medical practitioner from the specialist multi-disciplinary team at least once in twelve months, until the individual is discharged from the service. More frequent review should be provided according to clinical need, particularly after treatment initiation or following significant changes in regimen. The purpose of clinical monitoring during hormone use is to assess the degree of feminisation / masculinisation and the possible presence of adverse effects of medication.
- The Lead Clinician will provide the GP with written advice when the individual is discharged. They will give advice on the individual's future need for endocrine and other pharmacological interventions, the anticipated duration of treatment (which may be lifelong), the regimen recommended for on-going use, its intended effects and possible side-effects, long-term monitoring recommendations, and how they might access further information in the future.

The services specification notes that

Most recommendations will be for medications to be used outside the indications approved by the Medicines and Healthcare Products Regulatory Agency. The General Medical Council advises GPs that they may prescribe 'unlicensed medicines' where this is necessary to meet the specific needs of the patient and where there is no suitably licensed medicine that will meet the patient's need.

General Medical Council Guidance (GMC)

The GMC has a collection of resources available within its ethical hub on Trans healthcare. This includes a section on prescribing and mental health and bridging prescriptions.

GMC guidance states that GPs should collaborate with a Gender Identity Clinic (GIC) and/or an experienced gender specialist to provide effective and timely treatment for trans patients. This may include:

- prescribing medicines on the recommendation of an experienced gender specialist for the treatment of gender dysphoria, and
- following recommendations for safety and treatment monitoring.

It also advises that once the patient has been discharged by a GIC or experienced gender specialist, the prescribing and monitoring of hormone therapy can be carried out in primary care without further specialist input. However, it is reasonable for a GP to expect the GIC or specialist to remain available to provide timely support and advice where necessary.

Royal College of General Practitioners

RCGP has useful <u>information</u> which provides an overview of the key issues facing genderquestioning and transgender patients, general practice, and the broader health system. It establishes the RCGP's position on the role of a GP in providing care to patients experiencing gender dysphoria. It also covers the policy principles underpinning this position. Recommendations for ensuring these patients receive equal access to the highest standard of care are also laid out.



2. Children and Young People's Gender Services

NHSE commissioned a full independent review of children and young people's gender services in 2020. The Cass review has now been <u>published</u> and NHSE has already made significant changes in this area and will be introducing a different model of care and expanding service provision in this area.

Key changes include:

- Managed closure of the Gender Identity Development Service at the Tavistock and Portman NHS Foundation Trust on 31 March 2024
- Establishing two new children and young people's gender services based in the North West (a partnership between Alder Hey Children's and Royal Manchester Children's Hospital) and London (a partnership between Great Ormond Street Hospital, Evelina London and South London & Maudsley NHS Foundation Trust). These are the first of up to eight regional centres, that will be commissioned over the next two years.
- Publication of a <u>new interim service specification</u>. The new service specification reflects the fundamentally different approach to the assessment, diagnosis and treatment of children and young people presenting with gender incongruence as a result of the Cass review.
- New evidence-based clinical policy on puberty suppressing hormones (also called puberty blockers) restricting their use.
- New <u>legislation</u> to restrict prescribing and supply of puberty suppressing hormones to children and young people under 18, comes into force on 1st January 2025. It applies to prescriptions written by UK private prescribers and prescribers registered in the European Economic Area (EEA) or Switzerland. This means that no new patients under 18 can be prescribed these medicines for the purposes of puberty suppression in those experiencing gender dysphoria or incongruence under the care of these prescribers. Patients already established on these medicines by a UK prescriber for these purposes can continue to access them. They will also remain available for patients receiving the drugs for other uses, from a UK-registered prescriber. NHSE has produced <u>guidance</u> for prescribers on this legislation change which includes a useful table (on p4-9) that provides advice to prescribers on the prescribing of GnRH analogues for 'puberty suppression' and 'gender affirming' for various patient groups.

Next steps include:

- NHS England will review the use of gender affirming hormones, using a similar process that was followed to review the use of puberty suppressing hormones. In the meantime, the Cass review has suggested that new providers should be 'extremely cautious' when considering whether to refer young people under 18 years for consideration of hormone intervention.
- NHS England will publish a separate, but related service specification by June 2024 that defines access into the new children and young people's gender services.



 NHS England will commission the required professional training curriculum and competencies framework, not just for staff working in the new gender services but also for clinicians working in secondary care, primary and community care.

Key Policies and Service Specifications Published by NHSE

Interim Specialist Service for Children and Young People with Gender Incongruence

This sets out how care will be provided to children and young people, and their families, who express gender incongruence and who are likely to benefit from clinical support.

Clinical Policy: Puberty suppressing hormones for children and young people who have gender incongruence / gender dysphoria

This includes the NHSE commissioning position that 'puberty suppressing hormones (PSH) are not available as a routine commissioning treatment option for treatment of children and young people who have gender incongruence / gender dysphoria.'

A review on the use of puberty-blocking medicines in children concluded that further evaluation and data are required to know the impact, benefits and detriments of puberty-blocking medicines and a review of the ethical and safeguarding issues surrounding their use is also required. This will be examined as part of a clinical trial. Children and young people will only have access to puberty-blocking medicines via the clinical trial.

<u>Prescribing of gender affirming hormones (masculinising or feminising hormones) as part of the children and young people's gender service</u>

This states that NHSE will commission gender affirming hormones (GAH) therapy for young people who meet the eligibility and readiness criteria from around their 16th birthday.

Treatment and Prescribing Outside of the NHSE Service Specification

The NHSE interim service specification states the following regarding 'prescribing from unregulated sources and unregulated providers.

Children, young people, and their families are strongly discouraged from sourcing puberty suppressing or gender affirming hormones from unregulated sources or from on-line providers that are not regulated by UK regulatory bodies.

If a practice is approached to take on the prescribing that has been initiated outside of an NHSE Children and Young Person's Gender Service, then the practice should be fully aware of the recommendations within the NHSE <u>interim service specification</u> (section 8.2, p16-18).

Referrals for Children and Young People

These are being managed by the <u>National Referral Support Service for the NHS Gender</u> Incongruence Service For Children And Young People.



3. Advice on Situations outside of the Adult Specialised Commissioned Services (Prescribing following Private Consultation)

The earlier guidance relates to prescribing following an NHS consultation. However, due to lengthy waiting times in accessing NHS Gender Identity Services, practices are often faced with requests to prescribe in scenarios that are not covered in the current NHS England service specification.

This section has been produced with reference to the available published documents from NHSE and GMC, but also uses the advice that would be given regarding any request to prescribe on the NHS following a private consultation. NHSE have also provided some guidance in this <u>area.</u>

Important background principles

NHS Gender Identity Assessments:

The current service specification and advice from Nottingham Centre for Transgender Health means that patients who have been referred will only be considered for prescribing medication after a full assessment. This takes place over a minimum of 2 face to face meetings.

Converting private prescriptions to an FP10 - generic rules

Patients who choose to be treated privately should be entitled to NHS services on exactly the same basis of clinical need as any other patient and should not be put at any advantage or disadvantage – this means a prescription on the NHS would be appropriate if a GP considers there is clinical need AND that an NHS patient would be treated in the same way.

In terms of equity, we would expect the same principles to be applied when considering requests from patients who are accessing private transgender services. Therefore, consideration would need to be given as to whether the clinical service offered by the private provider prior to commencing medication was equivalent to that offered in an NHS Gender Identity Service. See local guidance on the NHS and Private Interface Prescribing Guidance.

General Medical Council Guidance (GMC)

The GMC information in section 1, is also relevant here, with resources available within its ethical hub and the section on <u>prescribing</u> and <u>mental health and bridging prescriptions</u>.

Again it is worth noting that GMC guidance states that GPs should collaborate with a Gender Identity Clinic (GIC) and/or an experienced gender specialist to provide effective and timely treatment for trans patients. This may include:

- prescribing medicines on the recommendation of an experienced gender specialist medical or non-medical prescriber for the treatment of gender dysphoria, and
- following recommendations for safety and treatment monitoring.

A recommendation to prescribe from a private gender clinic, should be from a suitably experienced medical or non-medical prescriber. The GMC advises that an experienced gender specialist will have evidence of relevant training and at least two years' experience working in specialised gender dysphoria practice such as an NHS gender identity clinic.

The GMC also states, if you are unsure whether a specialist working outside the NHS is suitably qualified, you are not obliged to follow their recommendations. As <u>Good medical practice</u> says – you must only prescribe drugs or treatment if you are satisfied they serve the patient's needs.



Private Providers of Gender Identity Services for Adults

In the UK there are a number of private gender identity services, these appear to range from those mirroring the NHS offer – for example one clinic is led by a psychiatrist (who also works at an NHS gender clinic) along with a multidisciplinary team (including endocrinologist and psychologists) to those offering different levels of assessment. Some clinics offer an online service only, do not have GMC registered GPs and are not UK based. We would strongly advise against prescribing following recommendations from these clinics.

The following advice has been developed by a local practice and is intended as a pragmatic guide for practices to use if they receive a request to prescribe transgender medicines on FP10 by an adult patient who is not using an NHS Gender Identity Clinic.

Scenario	Response	Reason		
Pre-NHS assessment Patient not taking anything, wanting GP to prescribe	NO	Patient hasn't had formal NHS level assessment. Refer to NHS GIC if not already done so		
Pre-NHS assessment Pre NHS assessment, wanting GP to prescribe — saying that risk of suicide if prescription not done	NO	Patient needs to be referred to Crisis team if thought to be at high risk. Refer to NHS GIC if not already done so		
Pre-NHS assessment Pre NHS assessment and obtaining medicines from the Internet – wanting GP to prescribe	NO unless NHS GIC advise and fulfils other criteria	See GMC guidance on bridging prescriptions. To date NHS GIC have been unwilling to advise prescribing prior to seeing patient, but GP should write for each case where they think the GMC criteria apply. Refer to NHS GIC if not already done so. Note the GIC are unable to expedite an appointment but may be able to provide advice about hormone treatment. If the patient is at high risk of suicide refer to Crisis team.		
Pre-NHS assessment Obtaining or has obtained prescribed medicines from abroad	MAYBE	If the patient has had a gender assessment which appears to the GP to be equivalent to NHS GIC - YES If the GP feels the assessment is not equivalent to NHS GIC - NO. See GMC guidance on bridging prescriptions. To date NHS GIC have been unwilling to advise prescribing prior to seeing patient, but GP should write for each case where they think the GMC criteria apply. Refer to NHS GIC if not already done so. Note the GIC are unable to expedite an appointment but may be able to provide advice about hormone treatment. If the patient is at high risk of suicide refer to Crisis team.		
Pre-NHS assessment Obtaining medicines from private UK GIC after private assessment	MAYBE Depends on which clinic	Private providers where assessment appears to be equivalent to NHS clinics – YES BUT need to confirm that part of the assessment has included review by a senior medical gender specialist.		
		Private providers where assessment is not equivalent to that obtained through NHS GIC –		



Scenario	Response	Reason
		NO as assessment not equivalent to that obtained through NHS GIC. Consider GMC advice on bridging prescriptions but would need to fulfil the 3 criteria including the NHS GIC writing back recommending the lowest appropriate doses. Otherwise, patient will need to continue to obtain their medications from the private clinic until reviewed by NHS GIC. Refer to NHS GIC if not already done so.
Under NHS GIC Care Undergoing medical transition	YES	The GMC advise that practices must co-operate with GICs and gender specialists in the same way that you would co-operate with other specialists, this includes: • prescribing medicines recommended by a gender specialist for the treatment of gender dysphoria. • following recommendations for safety and treatment monitoring • making referrals to NHS services that have been recommended by a specialist.
Previously Under NHS GIC Care After medical transition	YES	Once the patient has been discharged by a GIC or gender specialist, the prescribing and monitoring of hormone therapy can be carried out successfully in primary care without further specialist input. From the patient's perspective, management in primary care is far easier, and there is no specific expertise necessary to prescribe for and monitor patients on hormone therapy. However, NCTH can offer advice and access to specialised endocrinologists should there be any complications or change.
Private GIC Undergoing medical transition – UK or abroad	MAYBE	Private providers where assessment appears to be equivalent to NHS clinics – YES BUT need to confirm that part of the assessment has included review by a senior medical gender specialist. Private providers where assessment is not equivalent to that obtained through NHS GIC – NO as assessment not equivalent to that obtained through NHS GIC. Consider GMC advice on bridging prescriptions but would need to fulfil the 3 criteria including the NHS GIC writing back recommending the lowest appropriate doses. Otherwise, patient will need to continue to obtain their medications from the private clinic until reviewed by NHS GIC. Refer to NHS GIC if not already done so.
Private GIC Post transition – UK or abroad	MAYBE	Once the patient has been discharged by a GIC or gender specialist, the prescribing and monitoring of hormone therapy can be carried out



Scenario	Response	Reason	
		successfully in primary care without further specialist input.	
		If the GP feels that the patient has been under the care of an appropriate gender specialist and the treatment has been equivalent to that within the NHS, then - YES	
		If the GP feels the assessment was not equivalent to NHS GIC - NO Consider GMC advice on bridging prescriptions but would need to fulfil the 3 criteria including the NHS GIC writing back recommending the lowest appropriate doses. Otherwise, patient will need to continue to obtain their medications from the private clinic until reviewed by NHS GIC.	

What would an NHS gender clinic be expected to provide?

Training: An experienced medical gender specialist will have evidence of relevant training and at least two years' experience working in a specialised gender dysphoria practice such as an NHS GIC. If you are unsure whether a specialist working outside the NHS is suitably qualified, you are not obliged to follow their recommendations.

Structure:

Nominated senior clinical lead, plus a leadership role for the service overall. They should have evidence of appropriate experience and expertise in specialised gender dysphoria practice; management experience; and significant evidence of continued professional development.

A specialist multi-disciplinary team of professionals, with expertise in:

- clinical aspects of gender identity development, diagnosis of gender identity-related bio-psycho-social concerns, and the management of gender dysphoria
- sex development, and endocrine intervention in the treatment of gender identityrelated bio-psycho-social concerns and gender dysphoria
- physical health care needs that are specific to individuals with gender dysphoria
- mental health care needs that are specific to individuals with gender dysphoria
- social inclusion and care needs that are specific to individuals with gender dysphoria.
- gender-specific voice and communication development
- specific psychological therapy, relevant trans, and gender-diverse population
- knowledge of neuro-developmental conditions, including autism spectrum condition, and of adjustments to facilitate optimal communication with affected people.
- Good professional knowledge of trichology
- Good professional knowledge of the care needs of individuals who are receiving specialised gender-related surgical procedures.

Governance:

A robust system of corporate governance, including a nominated senior manager who provides guidance, oversight, and accountability.



Lead Clinical Role

A registered medical practitioner or clinical or counselling psychologist allocated for the duration of the patient's care.

Pathway

Patients receiving endocrine and pharmacological interventions are reviewed at least annually.

Endocrine Treatments

NHS Gender Services would ensure that the recommending gender specialist medical practitioner will assess the risks, benefits, and limitations of pharmacological interventions for the individual, and that they meet the relevant eligibility criteria set out in the World Professional Association for Transgender Health Standards of Care (2011):

- · Persistent, well-documented gender dysphoria
- Capacity to make a fully informed decision and to consent for treatment.
- If significant medical or mental concerns are present, they must be reasonably wellcontrolled.

NHS Gender Services would be expected to provide the GP with patient-specific 'prescribing guidance', as well as advice on the individual's future need for endocrine and other pharmacological interventions, the anticipated duration of treatment (which may be life-long), the regimen recommended for on-going use, its intended effects and possible side-effects, long-term monitoring recommendations, and how they might access further information in the future.

Additionally, they will obtain written consent to the interventions under consideration from the individual and provide a copy of the consent to the individual and their GP.

The above information may be helpful in assessing whether a private clinic is offering a service that is of a similar level to that which would be offered on the NHS. We would also recommend that advice should only be accepted from healthcare professionals who are registered with their regulatory body.

See Also Appendix 1 – Suggested checklist for practices asked to prescribe by a private Gender Identity Clinic

Further Information and Advice for GP practices

Contact your primary care Medicines Optimisation Team for further information and guidance, including advice on situations that fall outside of the specialised commissioned service such as recommendations from private clinics, or regarding the NHSE children and young people's service specification and associated documents.

Resources

- GMC advice for doctors treating trans and non-binary patients
- NHS gender dysphoria information for patients
- World Professional Association for Transgender Health standards of care
- The NHS Children and Young People's Gender Service (London)
- The NHS Children and Young People's Gender Service (North West)



Appendix 1 Private Gender identity Clinics - suggested checklist for practices asked to prescribe by a patient (over 18 years) or private Gender Identity Clinic

If a practice is considering taking on prescribing recommended by a private GIC, then we recommend that they should make reasonable efforts to ensure that an appropriately qualified GMC registered specialist has made a careful assessment equivalent to an NHS assessment. The practice may want to consider the points listed below to help aid their decision making. This could include asking the GIC to private extra information if there is insufficient detail in any referral documentation.

Criteria	Yes	No
Is the Consultant on the appropriate GMC specialist register, a member of the relevant Royal College and based in the UK?		
Is the requestor an appropriate gender specialist? E.g. do they hold (or has held in the past) a substantive NHS Consultant post within a Gender Identity Clinic?		
Is there a clear written plan for how often the patient will be reviewed by the private consultant?		
Will the consultant / clinic be available for ongoing support and advice?		
Is the medication proposed to be prescribed in accordance with Nottinghamshire Area Prescribing Committee guidance in Transgender Health?		
Has fertility been discussed and informed consent obtained?		
Is the patient aged over 18? If no, see section 2 for more detailed information restricting NHS prescribing in this area, and the need for caution if asked to prescribe following private consultation.		
Has the advice on the prescribing of GnRH analogues for 'puberty suppression' and 'gender affirming' for various patient groups in Appendix 1 of NHSE's <u>guidance</u> been checked?		

If the answer to any of these is no, then the practice may wish to proceed with caution.