



Information and Guidance on Prescribing in Transgender Health

Contents

- 1. Primary Care Responsibilities in Prescribing and Monitoring Hormone Therapy for Patients under the Specialist Gender Identity Service for Adults
- 2. Gender Identity Service for Children and Adolescents
- 3. Advice on Situations outside of the Specialised Commissioned Services (Prescribing following Private Consultation)
- 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 (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.

Information and Guidance on Prescribing in Transgender Health		
V3.0	Last reviewed: July 2022	Review date: May 2024



- 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 <u>prescribing</u> and <u>mental health and bridging prescriptions</u>.

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

In June 2019 RCGP published a position statement on <u>The role of the GP in caring for gender-questioning and transgender patients</u> this contains useful information and links for general practice.



Last reviewed: July 2022 Review date: May 2024 V3.0

Nottinghamshire Area Prescribing Committee

2. Gender Identity Service for Children and Adolescents

NHS England has a highly specialised service for Gender Identity Development (GID) for children and adolescents up to their 18th birthday. Note that NHSE state that the service specification for the Gender Identity Development Service for Children and Adolescents must be read in conjunction with the amendments that have been made following the High Court rulings as described below.

A new regional model for gender care has been announced for children and young people. NHS England are establishing two new early adopter services - one in London and one in the Northwest. It is hoped that these services will be operational by Spring 2023 to serve all patients across England. Once operational, these services will take over clinical responsibility for all GIDS patients and those on the waiting list; the current GIDS contract (based at the Tavistock Centre in London) will be brought to a close. The London-based service will be formed as a partnership between Great Ormond Street Hospital for Children and Evelina London Children's Hospital, with specialist mental health support provided by South London and Maudsley NHS Foundation Trust. The Northwest-based service will be formed as partnership between Alder Hey Children's NHS Foundation Trust and Royal Manchester Children's Hospital, who both provide specialist Children and young people's mental health services.

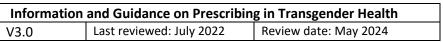
Gender Identity Service Specification

The specification states the following:

- It should be noted that the research evidence around the long term impacts of some treatments is limited and still developing and that by no means all clients with gender dysphoria choose to have physical interventions.
- Adolescents with continuing gender dysphoria will be able to have physical interventions via the service provided they fulfil the eligibility and readiness criteria for these. National and international guidelines recommend the use of hormone blockers (gonadotropinreleasing hormone agonists GnRH) in adolescence to suppress puberty. For some individuals, this is followed later with cross-sex hormones, which are sex steroids of the experienced gender, also referred to as gender affirming hormones. If individuals fulfil additional criteria, they may have various types of gender affirming surgery from the age of 18 through adult gender identity clinics.
- Clients will be able to access care locally, including accessing prescribed hormone treatments by their local GP, with oversight from the Service's Paediatric and Adolescent Endocrine Liaison Team.

The specification references a separate NHS England policy 'Prescribing of Cross Sex Hormones as part of the Gender Identity Development Service for children and adolescents for access criteria to cross sex hormones'. This also states that 'hormone therapy will be prescribed by the client's GP on the advice of the specialist multi-disciplinary team'.

Note that this document also notes that clinical contra-indications include 'selfadministration of hormone blockers or cross sex hormones without an NHS prescription'.





High Court Ruling September 2021

Over the last year there have been three court rulings about consent to the use of hormone blockers:

- In December 2020, three judges in the High Court ruled that it is doubtful that children under the age of 16 years are able to consent to treatment with hormone blockers.
- In March 2021, the Family Division of the High Court ruled that parental consent may form a legal basis to prescribe hormone blockers to children under-16 and suggested it may be appropriate to consider additional safeguards in the clinical decisionmaking process.
- In September 2021, the December 2020 ruling was overturned by the Court of Appeal.

The most recent ruling confirms that children under the age of 16 may, depending on their presentation, be assessed as legally competent to give informed consent – without the need to obtain a best interest order from the court.

For those aged 16 and 17 the courts have maintained a position that they are presumed to be able to give legally effective consent to treatment for hormone blockers or cross-sex hormones.

Assuring a safe and robust decision-making process for hormone blockers

Healthcare decisions always involve weighing up the potential benefits and risks of treatment. For hormone blockers, that includes reflecting on the limited scientific evidence base for their use in this context (see NICE evidence review). This underlines the importance of patients, their families or carers, and clinicians having full information when making decisions and in ensuring the Gender Identity Development Service (GIDS) follows a safe and robust clinical process.

Given this, prior to the most recent court ruling measures were already in place to help provide assurance that the clinical decision-making process is robust and to ensure patients and their parents are fully informed before they give consent to a referral by GIDS for hormone blockers. Since early 2021, patients at the GIDS undergo a revised and thorough clinical review to ensure a patient is fully informed during decisions and to help clinicians assess their suitability for referral to the endocrinology clinic. Further information about the process is available on the GIDS website.

Where a patient, their parent(s) or carer, and clinicians are of the view that referral to an endocrinology clinic for hormone blockers is appropriate, the GIDS' decision-making process for under-16s will be reviewed by an independent Multi-Professional Review Group which was established in August 2021.

Multi-Professional Review Group (MPRG)

The MPRG provides assurance about the Children and Young People's Gender Identity Development Service decision-making process. The role of the group is not to endorse or refuse treatment but to ensure all of the necessary steps have been taken, and all relevant information has been provided to the patient and their parents/carers. Patients do not need to meet the review group. The template form the Group uses to assess decisions is available here.



Information and Guidance on Prescribing in Transgender Health V3.0 Last reviewed: July 2022 Review date: May 2024

Nottinghamshire Area Prescribing Committee

The MPRG is established on an interim basis and is chaired by Professor Judith Ellis OBE – previously Chief Nurse at Great Ormond Street Hospital for Children and a previous Chief Executive of the Royal College of Paediatrics and Child Health. The group is meeting regularly.

There is no requirement on GIDS to submit cases to the MPRG in regard to 16 and 17 year olds.

The MPRG will also retrospectively audit a sample of decisions at the related endocrine clinic for confidence in their processes.

Prescribing in Primary Care

The current Gender Identity Development Service (https://gids.nhs.uk/ based at the Tavistock Centre in London) have stated that it is expected that GPs will continue to prescribe to this cohort. This expectation is likely to continue with the transition to new regional centres for gender care.

3. Advice on Situations outside of the 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 area.

Important background principles

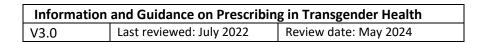
NHS Gender Identity Assessments:

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 meetinas.

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 a 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.





General Medical Council Guidance (GMC)

The information from the GMC 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</u> prescriptions.

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.

In terms of recommendation to prescribe from a private gender clinic, this 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 a 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

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 a 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	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 – 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 cooperate 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 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 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

Information and Guidance on Prescribing in Transgender Health		
V3.0	Last reviewed: July 2022	Review date: May 2024



- 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.

Checklist for practices asked to prescribe by private gender clinic

Is the provider a reputable company?	Check internet for complaints, news articles etc.
Does the service appear to meet GMC good practice?	Provision of shared care +/- adequate information to enable prescribing safely In the following questions consider need to check other medical staff employed by the clinic, not just the requestor.
Is the requestor an appropriate gender	Check name of requestor on GMC website





specialist?	for registration details:
Training and experience? Does the requestor have any current formal links with NHS gender identity clinic (GIC)?	Check clinic website for any indication of training and experience in managing gender identity.
What professional associations does the requestor belong to?	Check clinic website for evidence of membership to relevant professional association and check membership is current.
Has the requestor spent any previous time spent in NHS GIC?	Check clinic website for any indication of previous NHS GIC experience
Does the requestor undertake CPD?	Information may be available on gender clinic website.
Is there documented support of two gender specialists (including one medic)	Information should have been provided in clinic letter for individual patient
Has the patient been subject to multi- disciplinary team recommendation?	Information should have been provided in clinic letter for individual patient
Will the clinic be available for ongoing support and advice	This may include medication related queries
Has fertility been discussed and informed consent obtained?	Information should have been provided in clinic letter for individual patient

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 adolescents service specification and prescribing policy 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
- Children and adolescents under the age of 18 years