

April 2025

GUIDANCE TO PRIMARY CARE ABOUT UNREGULATED PROVIDERS WHO SUPPLY HORMONE MEDICATIONS TO CHILDREN AND YOUNG PEOPLE FOR GENDER INCONGRUENCE

This guidance document advises General Practitioners against shared care agreements with unregulated providers in relation to hormone medication to children and young people under 18 as a response to gender incongruence / gender dysphoria.

A GP **must refuse** to support the private prescribing or supply of GnRH analogues.

A GP **should refuse** to support an unregulated provider in the prescribing or supply of alternative medications that may be used to suppress pubertal development.

A GP **should refuse** to support an unregulated provider in the prescribing of exogenous hormones.

A GP should always be prepared to refer their patient for an appropriate non-routine investigation under an NHS contract where there is a concern that the child or young person may come to harm as an outcome of a medication from unregulated sources.

In all cases, safeguarding measures should be considered where the administration of a medicine from an unregulated source presents an immediate safety risk.

Introduction

In its role of direct commissioner of specialised services for gender incongruence / gender dysphoria, NHS England has received requests from Integrated Care Boards, General Practitioners (GP) and other primary care professionals for advice on how to respond to requests that are made by **unregulated** providers for a shared care approach to the prescribing, administration and monitoring of hormone interventions as a treatment option for gender incongruence or gender dysphoria.

The hormone interventions are (see Appendix A):

- gonadotrophin releasing hormone (GnRH) analogues and other medications that may be used to suppress pubertal development
- exogenous hormones (testosterone / oestrogen) used for the purpose of masculinisation or feminisation

An unregulated provider is one that is not registered with, or regulated by, a UK health regulator such as the *Care Quality Commission* or *Health Inspectorate Wales*.

Advice



Where a medical intervention as a treatment option for gender dysphoria or gender incongruence is proposed for a child or young person under 18 years by a healthcare professional working for / with an unregulated healthcare provider, the absence of regulatory oversight should reasonably cause a GP to **decline** a proposal for a shared care arrangement.

This advice reaches to any unregulated provider operating in the field of gender dysphoria / gender incongruence for children and young people, including online providers. GPs are specifically cautioned against a shared care agreement with two unregulated providers who have published statements that oppose the restrictions that have been put in place by NHS England and, separately, the Government around the supply of gonadotrophin releasing hormone analogues to children and young people under 18 years of age:

- *GenderGP*
- *Anne Transgender Healthcare Ltd*

Reasons for the Advice

Unregulated healthcare services pose a risk to patient safety as they are not subject to the same level of scrutiny as registered services.

It is well established that a prescribing professional is responsible for the prescriptions they sign and for their decision and actions when supplying and administering medicines¹. If a clinician prescribes at the recommendation of another, they must satisfy themselves that the prescription is needed, appropriate for the patient and within the limits of their competence. The clinician should question any recommendation which is considered unsafe².

When engaged in a pathway of care of a patient jointly with an unregulated provider, a GP has a professional obligation to verify the safety of care that an unregulated provider or unregulated health professional provides to that patient. For example, the General Medical Council³ requires a GP to ensure that they are confident that systems are in place to verify the safety and quality of the care when making a referral of their patient to an unregulated service. Diligence in this regard is also essential for patient safety when an unregulated provider or unregulated healthcare professional seeks to delegate responsibility for prescribing or monitoring a medication to a GP.

Recent advice to dispensing professionals from the General Pharmaceutical Council is equally relevant to GPs who are asked to agree a shared care arrangement:

“It is not enough for a prescription to be legally valid; that is just one consideration alongside others, including judgement as to whether a prescription is clinically appropriate. In some cases, prescriptions may have been issued by overseas gender clinics and prescribers who are not under the jurisdiction of UK regulators, which creates additional risk. We expect pharmacies to have taken active steps to assure themselves that all prescribers, including those from overseas, comply with relevant UK regulatory and professional guidance⁴”.

Recently, the NHS and the Government have taken steps to curtail access to certain medical interventions (gonadotrophin releasing hormone analogues) for children and young people under 18 years of age with gender incongruence or gender dysphoria because of the lack of evidence about safety, risks, benefits and outcomes.

¹ [General Medical Council's "Good Practice in Proposing, Prescribing Providing and Managing Medicines and Devices", 2021](#)

² Ibid

³ [Delegation and Referral - Professional Standards - GMC](#)

⁴ General Pharmaceutical Council; Gender Identity: Pharmaceutical Care for Children and Young People (updated January 2025).

Additionally, the NHS has accepted the recommendations of the [Cass Review](#) (April 2024) that exogenous hormones should not be prescribed to children under 16 years of age, and only to young people aged 16 or 17 where the clinician making the prescribing recommendation can demonstrate extreme caution in clinical decision making, such as to justify not waiting until the young person turns 18 years, and where the prescribing recommendation has been approved by a national MDT.

It is within this context that GPs and other prescribing professionals are cautioned against a shared care approach with unregulated providers who continue to offer access to - or facilitate access to - hormone interventions to children and young people under 18 years of age as a response to gender dysphoria or gender incongruence.

GPs may wish to familiarise themselves with the background to the Cass Review and the recent Government legislation (Appendix B).

NHS England's [interim service specification](#) for NHS Children and Young People's Gender Services (June 2023; for revision in 2025) is clear on the approach to 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.

Where the [NHS Children and Young People's Gender] Service is not able to accept responsibility for prescribing, the Service will not offer clinical supervision for the management of the endocrine intervention and will not enter into shared care arrangements with a health professional who is making recommendations for prescribing / is prescribing to the child or young person.

In such cases The [NHS Children and Young People's Gender] Service will make the child or young person and their family aware of the risks, contraindications and any irreversible or partially reversible effects of the intervention; and will make the GP or local health professional (as appropriate) aware and suggest that the GP or local health professional considers what safeguarding protocols may be appropriate for the individual child or young person's wider circumstances including the extent to which the parents / carers are able to protect or safeguard the child or young person.

Safeguarding procedures may be necessary regardless of the endeavours and best intentions of the parents / carers in reducing risk of harm.

Safeguarding protocols should be initiated immediately where the child or young person is at risk of immediate, serious harm.

It would also be important for the GP or local health professional to explore what regulatory bodies may need to be informed if healthcare professionals registered with a UK professional body are prescribing medication contrary to NHS protocols.

GenderGP

GenderGP is a private online service providing gender affirming interventions to individuals in the UK. It offers a remote diagnostic service across all age ranges.

GenderGP is outside the reach of the UK health regulators as the company is registered overseas and its relevant activities are performed overseas. *GenderGP* may either ask the patient's GP to initiate prescribing or, more usually, has used prescribers overseas who issue prescriptions directly to individuals for dispensing by pharmacies in the UK. In either case *GenderGP* may ask the patient's GP to accept responsibility for regular monitoring. It is known that many GPs refuse a shared care agreement with *GenderGP* because of its unregulated status and because of uncertainties about clinical expertise.

Past regulatory action and judicial rulings suggest that the activities of *GenderGP* may present an ongoing safety risk to children and young people in the UK:

- In 2018 Health Inspectorate Wales successfully prosecuted through the Magistrates Court one of the founders of *GenderGP* (Dr Helen Webberley, a medical professional) for illegally providing online gender healthcare services which required registration by the Care Standards Act 2000. The prosecution followed a period in which the doctor had refused to stop providing relevant services to patients.
- The business was subsequently registered outside of the UK, beyond the jurisdiction of Health Inspectorate Wales or the Care Quality Commission.
- In response to the Government's legislation that places restrictions on the supply of GnRH analogues, *GenderGP* has promoted the administration of synthetic testosterone to natal girls from 8 years of age, as an alternative drug

for the purpose of puberty suppression. This is contrary to the NHS England clinical commissioning policy that prohibits the prescribing of exogenous hormones to children under 16 years of age because of the very limited evidence about the effects, harms and outcomes to young people under 16 years, though compromised fertility is a known likely outcome. *GenderGP* also promotes the use of raloxifene for pre-pubescent girls while noting that this is “an oestrogen blocker that hasn’t been widely tested in young people”.

- In a published judgment in May 2024, the President of the Family Division of the High Court stated the following, in a case concerning testosterone treatment offered to a 16-year old, and prescribed, by *GenderGP*⁵:

“There must be very significant concern about the prospect of a young person...accessing cross-hormone treatment from any off-shore, online, unregulated private clinic. The evidence relating to GenderGP that is currently available from [named expert witness] ... gives rise to additional serious concerns as to the safety of patients accessing cross-hormone treatment from that particular clinic Whilst further evidence may, of course, alleviate the concerns that I have described, on the experience in these proceedings thus far, I would urge any other court faced with a case involving GenderGP to proceed with extreme caution before exercising any power to approve or endorse treatment that that clinic may prescribe”.

Anne Trans Healthcare Ltd

Anne Trans Healthcare Ltd is a UK based company, though its clinical team is based overseas. It is not registered with the Care Quality Commission.

It describes itself as “a subscription service which coordinates therapeutic and medical support for individuals experiencing gender incongruence through referrals to healthcare professionals”. It offers access to overseas healthcare professionals, and its website states that it offers services which include “puberty blockers for individuals of all ages, including those under 18.” As has been noted above, and subject to narrow exceptions, the sale or supply by private prescription of GnRH analogues to children and young people under 18 years for the purposes of puberty suppression and as a treatment for gender incongruence and/or gender dysphoria contravenes the Government’s restrictions on their prescription and is contrary to the aims of the NHS clinical policy position.

⁵ Re J (Transgender: Puberty Blocker and Hormone Replacement Therapy) [2024] EWHC 922 (Fam)

The company's published terms and conditions has the disclaimer that "*Anne is not responsible for the quality of care, advice, or any prescriptions or medication provided to you/the Minor (if applicable) by any Independent Healthcare Professional*". Nevertheless, the company's website suggests that GPs may be approached to support patients in the monitoring of these medicines through a shared care approach: "*we are very happy to work with GPs who are open to shared care agreements*".

Summary

As a general principle, a GP should consider each request for shared care on a case-by-case basis to satisfy themselves that the request is from a reputable company that provides a safe and effective service; and that the circumstances of the request for the particular individual meets the general principles of the General Medical Council's "*Good Practice in Prescribing and Managing Medicines and Devices*". A GP may decline to accept responsibility for prescribing, monitoring and testing if the GP is not assured that the provider offers a safe service.

- Suppression of pubertal development

A GP **must refuse** to support the private prescribing or supply of GnRH analogues. It is a criminal offence for a healthcare professional to privately prescribe or dispense this drug to patients under the age of 18 as a puberty-suppressing treatment option for gender incongruence or gender dysphoria unless that treatment had begun before 3rd June 2024.

A GP **should refuse** to support an unregulated provider in the prescribing or supply of alternative medications that may be used to suppress pubertal development.

- Exogenous Hormones

Where the prescribing recommendation is made by a healthcare professional working for, or working with, an unregulated provider, a GP should reasonably conclude that the absence of regulatory oversight and scrutiny is a cause for concern such that a request for shared care **should** be **refused**. In such cases, the young person and family should be advised against sourcing medications from the provider, and the risks explained to them.

If the GP has concerns that declining responsibility would pose a clinical risk to the child or young person, the decision to decline a shared care agreement should be weighed against the ongoing risk posed by administration of a medicine from an unregulated source. In such cases, consider a referral to appropriate local services.

If a GP decides that an existing shared care arrangement for exogenous hormones should be discontinued:

- The young person and family should be advised against continued sourcing of medications from the provider, and the risks explained to them.
- The GP should inform the unregulated provider and the young person / family in writing that the shared care agreement is no longer in place.
- Where the young person or family decide to continue with the medication contrary to the GP's advice, the GP should arrange for a final set of test results to be sent to the provider that is prescribing, with a written request for that provider to establish alternative means of regular monitoring and testing. This approach is consistent with the general principle that clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring⁶.
- The GP should consider the individual's need for further professional support, such as a referral to children and young people's mental health services and / or to the specialist NHS gender pathway.

Irrespective of whether a shared care agreement is in place, a GP should always be prepared to refer their patient for an appropriate non-routine investigation under an NHS contract where there is a concern that the child or young person may come to harm as an outcome of a medication from unregulated sources (for example, monitoring bone density; or venous thromboembolism).

In all cases, safeguarding measures should be considered where the administration of a medicine from an unregulated source presents an immediate safety risk.

Referral to the NHS Children and Young People's Gender Service

Details of the referral arrangements into the NHS Children and Young People's Gender Service are available [here](#). Waiting times are expected to remain long while the NHS builds additional clinical capacity through a new configuration of providers. However, the sourcing of medications from unregulated providers cannot be defended as an appropriate response to the long waiting times for NHS services.

Referrals into the NHS Children and Young People's Gender Service are made through NHS secondary care mental health teams for children and young people or NHS paediatric services. Children and young people who were on the national waiting list between 1 April and 31 August

⁶"Responsibility for prescribing between Primary & Secondary/Tertiary Care", NHS England (2018)

2024 will have been contacted by the NHS and offered an assessment by local NHS mental health services while they remain on the waiting list⁷.

Individuals who are sourcing unregulated medicines and who are seen by the NHS Children and Young People's Gender Service will be advised to discontinue the medicine. The NHS Children and Young People's Gender Service will not accept prescribing responsibility or enter into a shared care agreement with a private provider⁸.

Adult Patients Over 18 years

The advice in this document supersedes previous advice set out in the NHS circular "*Primary Care Responsibilities In Regard to Private Online Medical Service Providers to Prescribe Hormone Treatments for Transgender People*", 2018 ([Appendix C](#)) in so far as it relates to children and young people under 18 years of age.

The advice in this document does not extend to adult patients over 18 years of age.

However, in recognition that unregulated healthcare services pose a potential risk to patient safety across all age ranges, NHS England will address the management of adults who source medications outside of the NHS-commissioned gender dysphoria service, including the management of those who are using atypical levels of medications, within its current work to establish a clinical commissioning policy for exogenous hormones in 2025/26.

In the meantime, the general principles described in the 2018 circular should continue to be the basis for how a GP determines how to respond to a request for shared care for management of a hormone intervention by a private provider in relation to an adult patient (extract below):

"GPs are therefore advised to consider each request on a case-by-case basis to satisfy themselves that (i) the request is from a reputable company that provides a safe and effective service; and (ii) the circumstances of the request for the particular individual meets the general principles of the General Medical Council's "Good Practice in Prescribing and Managing Medicines and Devices"; and (iii) that the health professional making the request is an appropriate "gender specialist" (the term that is used in the General Medical Council guidance).

⁷ From 1 September 2024 all referrals to the national wait list for CYP Gender Services are made through NHS mental health teams or NHS paediatric teams

⁸ This approach will be described in NHS England's amended service specification for CYP Gender Services in 2025 subject to the outcome of public consultation.

A GP may decline to accept responsibility for prescribing, monitoring and testing if the GP is not assured that the provider offers a safe service, or is not assured that the request has been made by an appropriate gender specialist as long as the GP is also satisfied that declining responsibility would not pose a significant clinical risk to the individual’.

END

Queries about the advice offered in this document should in the first instance be submitted to: england.casework@nhs.net

APPENDIX A
The Interventions

Name	Purpose	NHS / Government Action: Summary
<p>Gonadotrophin releasing hormone analogues:</p> <p>(also known as hormone blockers; puberty blockers and puberty suppressing hormones).</p>	<p>Taking these hormones stops the progress of puberty. The GnRH analogues act by competing with the body's natural gonadotrophin releasing hormone. This competition blocks the release of two gonadotrophin hormones important in puberty called Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland.</p> <p><i>GenderGP</i> has promoted the use of raloxifene as an alternative means of puberty suppression; this drug is used to treat and prevent osteoporosis and reduce the risk of invasive breast cancer in high-risk postmenopausal women.</p>	<p>NHS clinical policy (March 2024) prevents prescribing to children and young people under 18 for gender dysphoria outside of clinical trial.</p> <p>Government legislation prevents private prescribing to children and young people for puberty suppression in connection with gender incongruence and/or gender dysphoria under 18 years of age subject to narrow exceptions.</p>
<p>Feminising and masculinising hormones:</p> <p>(also known as cross-sex hormones; and gender affirming hormones).</p>	<p>These are sex hormones given as part of a medical transition for gender dysphoric individuals (testosterone for transgender males and oestrogen for transgender females).</p>	<p>NHS clinical policy (March 2024) permits prescribing to young people from 16 years of age, alongside specialist psychological support, where a diagnosis of gender dysphoria has been confirmed by a specialist NHS team:-</p> <p>that can demonstrate that 'extreme caution' has been applied in clinical decision making; and</p> <p>that includes a consultant paediatric endocrinologist; and</p> <p>where the prescribing recommendation has been approved by a national MDT.</p>

Appendix B: The Cass Review; and recent Government legislation

- In April 2024 the independent Cass Review delivered its final report on how the NHS should care for children and young people with gender dysphoria or gender incongruence. The Review represents the most comprehensive analysis of the available evidence.
- The Review found that children and young people with gender incongruence present with higher levels of neurodiversity, co-occurring mental health issues and adverse childhood experiences.
- The Review proposes a new and fundamentally different model of care that is less reliant on medical intervention and focused more on psychosocial and psychological support, within an integrated, multi-disciplinary pathway.
- NHS England and the Government have committed to implementing the Review's recommendations.
- In March 2024 the former children's Gender Identity Development Service at the Tavistock and Portman NHS Foundation Trust was brought to a managed close by NHS England; and new NHS Children and Young People's Gender Services began to be operational from 1 April 2024, working to a new clinical model.
- The new clinical model, as defined by NHS England clinical commissioning policy, prohibits the routine prescribing of GnRH analogues (commonly known as Puberty Blockers or Puberty Suppressing Hormones).
- The Cass Review recommended a clinical trial to determine the effectiveness of puberty suppression and the safety of prolonged treatment. The National Institute for Health and Care Research is working closely with NHS England to begin a clinical trial.
- Exogenous hormones (also known as Cross Sex Hormones, Gender Affirming Hormones, or masculinising / feminising hormones) may be prescribed through the specialist NHS service to young people from age 16 where the prescribing recommendation has been endorsed by a national MDT, and where the prescriber can demonstrate that 'extreme caution' has been applied in clinical decision making, to include a clear clinical rationale for not waiting until the 18th

birthday; NHS England is currently reviewing the evidence for exogenous hormones as a treatment option for gender incongruence / gender dysphoria with the intention of consulting on the evidence base in 2025/26 as part of the process for clinical commissioning policy formation.

- The Cass Review concluded that it “*understands and shares the concerns about the use of unregulated medications and of providers that are not regulated within the UK. Any clinician who ascertains that a young person is being given drugs from an unregulated source should make the young person and their family aware of the risks of such treatment*”. The Review recommended that the Department of Health and Social Care should define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing.
- In December 2024, following advice from the Commission on Human Medicines, the Government made permanent legislation⁹ that restricts the sale and supply of GnRH analogues through private prescription to young people under 18 years; these restrictions prevent, subject to certain narrow exceptions, a UK pharmacist from dispensing a private prescription for GnRH analogues and a GP from prescribing GnRH analogues outside of the NHS service where the purpose of the prescription is puberty suppression in relation to gender incongruence and/or gender dysphoria. The legislation does not extend to exogenous hormones.

⁹ The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Restrictions on Private Sales and Supplies) Order 2024