





# Primary care prescribing for people who access Gender Identity Services (GIS)

NHS England is the direct commissioner of specialised gender identity services for individuals with a diagnosis of gender dysphoria<sup>1,2</sup>, however a consistent theme amongst primary care professionals is that current arrangements are not optimal for patients or prescribers. This has led to publication of guidance from professional bodies to support prescribers, for example:

- British Medical Association guidance for GPs "Managing patients with gender dysphoria"<sup>3</sup>
- General Medical Council's Ethical hub on trans healthcare<sup>4</sup>

Both explain the role of GPs in managing patients with gender identity problems, including questions relating to patient records, confidentiality, bridging prescriptions and prescribing and monitoring responsibilities. This guidance aims to explain what should be provided in primary care and to highlight some of the underpinning ethical and legal considerations.

Although there is a lack of a national or locally agreed pathway from specialist to primary care for patients with gender dysphoria, there remains an expectation from GIS that GPs will prescribe and monitor hormones in line with their recommendations. Most recommended treatments are used "off label" and research evidence around the long-term impacts is still developing and remains limited. NHS Surrey Heartlands does not have a GIS within its footprint, as such there is no invitation to be engaged in the process to agree provider specific shared care arrangements to support good governance and safety.

This guidance has been developed to support prescribing in appropriate circumstances and covers:

- Children and young people (aged less than 17 years)
- Requests to prescribe
- Shared care
- Ongoing care
- Private providers
- Due diligence





# **Children and Young People**

In May 2024, the UK government introduced regulations to restrict the prescribing and supply of puberty supressing hormones from 3 June to 3 September 2024 New restrictions on puberty blockers - GOV.UK (www.gov.uk). In response, NHSE has issued more detailed guidance on prescribing of these which has been used to inform the Surrey Heartlands statements for primary care prescribing in CYP. See appendix 1 for advice to prescribers and dispensers in the pdf here:



The Southern hub for CYP gender services is provided through a partnership of Evelina Children's Hospital, Great Ormond Street Hospital and South London and Maudsley Mental Health Trust <a href="The NHS Children and Young People's Gender Service">The NHS Children and Young People's Gender Service</a> (London) | Great Ormond Street Hospital (gosh.nhs.uk).

With current services under review and future service transformation expected, prescribing in children and young people (CYP) should be in line with the Final Cass Report<sup>5</sup> and NHSE Clinical Commissiong policies which state that:

#### Puberty suppressing hormones (March 2024) <sup>6</sup>

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. The new NHS services will not prescribe PSH to new patients unless as part of a trial.

For those CYP already on PSH, advice has been issued in a letter from NHSE<sup>7</sup> which states that for patients already referred under the care of an endocrine team 'there is an expectation that GnRHa will continue to be administered / be initiated, if that is the informed choice of the young person / parents of a child under 16 years, subject to the outcome of usual clinical review of the individual's existing individual care plan jointly between the individual's Lead Clinician and the young person / parents of a child under 16 years'.

NHSE have provided assurance to the ICB that children that have been prescribed hormone blockers have remained under GIDS (whilst they have not had new referrals) and have been transferred over to the new service from 1.4.24 so should continue to have medical follow up and shared care etc. just under a new provider.

From the advice above it is likely that there are no current patients under NHS services being prescribed puberty supressing hormones in primary care, however because this is not a certainty it is advised that for patients who have started puberty blockers under the care of an NHS provider, prescribing may need to continue in primary care until the patient is next reviewed by the service Lead Clinician within the new provider. Any concerns should be referred to the new



service provider initially <u>The NHS Children and Young People's Gender Service</u> (London) | Great Ormond Street Hospital (gosh.nhs.uk)

**Private initiations:** For patients who started puberty blockers under the care of a private provider, prescribing may need to continue in primary care until the patient is next reviewed. Patients should be advised of the new NHS policy and recommendation made to return to the private provider for consideration of stopping.

Based on the clinical commissioning policies issued by NHSE, Surrey Heartlands Area Prescribing Committee have agreed the following arrangements for children and young people in primary care:

Puberty suppressing hormones for under 18s (Private & NHS), and anti-		
androgens		
New patients	Do not prescribe	
Current patients	Continue to in line with any agreed shared care protocols in place. Strongly advise the patient to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.  These medications can be stopped and do not need to be weaned off.	

### Gender affirming hormones (March 2024) 8

NHS England will commission this intervention as part of the specialised service for Children and Young People with Gender Incongruence in those aged around 16 years AND meeting their eligibility and readiness criteria.

Based on the clinical commissioning policies issued by NHSE, Surrey Heartlands Area Prescribing Committee have agreed the following arrangements for children and young people in primary care:

Gender affirming hormones (excluding anti-androgens)		
New patients	Consider any request for gender affirming hormones in line with	
	appropriate shared care protocols.	
	Requests from private provider should additionally be subject to	
	a due diligence check (appendix 1)	
Current patients	Continue to in line with any agreed shared care protocols in	
	place.	



# Requests to prescribe

NHS England recommends that all requests to prescribe should be considered on a case-by-case basis and GPs should approach shared care and collaboration with gender identity specialists in the same way as they would any other specialist<sup>9</sup>. Participating in a formal shared care agreement is voluntary, subject to a self-assessment of personal competence, and requires the agreement of all parties, including the patient. The advice should therefore be read in conjunction with the principles which underpin shared care as set out by the GMC in Good practice in prescribing and managing medicines and devices<sup>10</sup>.

- The clinician is responsible for the prescriptions they sign
- Drugs and other treatment should only be prescribed when a clinician has adequate knowledge of a patient's health and satisfied that the treatment serves the patient's needs
- 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 unsafe

#### **Shared care**

Due to the nature of the service commissioned by NHS England for GIS providers, primary care prescribers will, in the main, be asked to initiate treatment on written recommendation from a specialist via a shared care protocol. **Initiation by primary care** is supported by Surrey Heartlands if the prescriber is competent to exercise their share of clinical responsibility and is assured that the shared care protocol provides enough information for them to discharge their responsibilities safely (for example assurance that all the risks of treatment have been discussed with the patient and frequency of follow up is clearly indicated).

If the GP feels unable to accommodate the initial request to prescribe, it is suggested that contact is made with the requesting clinician to discuss further. Queries should be raised with the GIS provider in a timely manner for assurance and action that benefits the patient. Under shared care arrangements, the responsibility to prescribe would usually sit with the service initiating therapy and requesting shared care, however the NHS commissioned GIS providers are not funded to routinely prescribe but can do so if, after discussion between GP and Specialist, it is agreed that prescribing cannot be undertaken in primary care.

NHSE commission gender identity services for adults from several sites across the UK. London and SE provider of NHS adult gender identity services is **Tavistock** 



and Portman NHS Foundation Trust Gender Identity Clinic. Resources for healthcare professionals are available on their website here <u>Clinical information and guidance for hormone therapy - Gender Identity Clinic – GIC</u> and include:

- Shared care prescribing guidance
- Ongoing hormone monitoring and management information
- Post-discharge hormone management
- Patient information booklets

Other centres currently commissioned for adults are:

- Sheffield Health and Social Care NHS Foundation Trust <u>Information for</u> GPs | Sheffield Health and Social Care (shsc.nhs.uk)
- Leeds and York Partnership NHS Foundation Trust <u>Leeds and York</u> <u>Partnership NHS Foundation Trust -Gender Identity Service</u> (leedsandyorkpft.nhs.uk)
- Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust Information for professionals - Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (cntw.nhs.uk)
- Northamptonshire Healthcare NHS Foundation Trust Gender Identity Clinic | NHFT
- Nottinghamshire Healthcare NHS Foundation Trust <u>Treatments offered</u> | Transgender (ncth.nhs.uk)
- Devon Partnership NHS Trust For GPs and professionals | DPT

In the absence of a national shared care protocol, each site will have its own documentation that should be provided with each patient. Under the assumption that most Surrey Heartlands patients will be seen by The Tavistock & Portman site, it should be noted from their shared care that:

- The minimum frequency of follow up by the specialist service is not specified

   it is advisable to check that follow up has been arranged from the individual
   care plan or clinic letter. NHS England require a minimum of every 12
   months.
- Inclusion of ability to discharge a patient from the service this is allowed under the NHSE service specification but does not then strictly adhere to the understanding of what shared care is and may result in no specialist follow up at some point.
- On occasion a GP maybe asked to order a DEXA scan which are not routinely performed under GMS contracts – in the first instance it is suggested that contact is made with the Specialist to refer directly for DEXA
- Appears to minimise the risks associated with the drugs and the patient consent letter indicates that no discussion of risk with GP is wanted – risk of GP breaching GMC guidance. For patient friendly advice on risk see <u>Gender</u> <u>dysphoria - Treatment - NHS (www.nhs.uk)</u>

After consideration, if a GP concludes that they are unable to accept responsibility for prescribing and monitoring, and if concerned that declining involvement will pose



a significant clinical risk, consideration must be given as to how to enable the patient to receive appropriate support and treatment funded by the NHS. If the patient is distressed, or the GP believes them to be at risk from self-harm, the GP should offer them support and consider the need for referral to an NHS commissioned specialised Gender Identity Clinic or to local mental health services as appropriate.

# **On-going care**

It is imperative that clients who take the preparations under medical supervision are monitored as recommended. We recommend a documented annual review where the prescriber should:

- Review prescribing and results from monitoring
- Check that the person remains in touch with their specialist, in line with shared care recommendations. Prescribers may wish to return prescribing to the specialist if this contact is recommended but has ceased.
- Good quality data regarding long term clinical and psychological effects of "off label" prescribing of licensed medicines used for Gender Dysphoria is sparse.
   Discuss benefits vs risks of treatment regarding long term use, particularly with respect to psychological outcomes and clinical outcomes such as effects on fertility, cancer, endocrine or cardiovascular disease in the future.
- Highlight the importance of national screening/testing/advice linked to biological gender such as breast screening, measurement of PSA, cervical smears etc as appropriate. The annotation of records should be discussed as appropriate.

#### **Private GIS**

All private gender services accept self-referral. Due to the significant waiting times for NHS gender identity clinics, some patients choose to seek review from independent gender specialists, which may be located outside of the UK.

Patients should be 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.

It is highly recommended that the GP ask the service provider to demonstrate the necessary expertise before responding to the provider's request. In all cases, prescribers should not issue any prescriptions until satisfied that the criteria defined by NHS England is met in their service specifications for adults<sup>11</sup> and CYP<sup>2</sup>. Any request for shared should be in line with an NHS commissioned service and GPs



could ask the private provider to sign up to an NHS agreed document e.g. <u>Clinical information and guidance for hormone therapy - Gender Identity Clinic – GIC</u>.

Appendix 1 shows a standard letter that GPs can send to non-NHS providers to satisfy due diligence and to help set up appropriate shared care agreements. The letter lists the evidence which private providers should be expected to supply to support a GP's request. See Appendix 1: DRAFT LETTER FOR DUE DILLIGENCE OF PRIVATE PROVIDER

# References

- 1. NHS England » Service specification: Gender Identity Services for Adults (Non-Surgical Interventions) (2019)
- 2. NHS England » Interim service specification for specialist gender incongruence services for children and young people (updated March 2024)
- 3. Gender incongruence in primary care (bma.org.uk) (accessed July 2023)
- 4. Trans healthcare ethical topic GMC (gmc-uk.org) (accessed July 2023)
- 5. Final Report Cass Review (March 2024)
- 6. Puberty suppressing hormones (March 2024)
- 7. Puberty supressing hormones: Letter to ICBs (March 2024)
  Access via PAD page <u>Guidelines: Transgender Health Children & Young People (res-systems.net)</u>
- 8. Gender affirming hormones (March 2024)
- 9. NHS England: Primary Care Responsibilities in Prescribing & Monitoring
  Hormone Therapy for Transgender and Non-Binary Adults (updated) (April 2016)
- 10. Good practice in prescribing and managing medicines and devices (gmc-uk.org) (2021)
- 11. NHS England » Service specification: Gender Identity Services for Adults (Non-Surgical Interventions) (updated Nov 2022)



# Appendix 1: DRAFT LETTER FOR DUE DILLIGENCE OF PRIVATE PROVIDERS

Dear Colleague,

Many thanks for your correspondence. In line with NHS England directions, I will consider undertaking prescribing and monitoring of treatment for our patient, under your guidance, subject to the following conditions being met:

- 1. Your organisation provides evidence confirming the credentials of both your service and clinicians in the field of gender dysphoria (please see below)
- 2. You provide a signed shared care protocol in line with those provided by NHS-commissioned providers, example can be found here <u>Clinical information and</u> guidance for hormone therapy Gender Identity Clinic GIC and
- 3. For patients aged under 17 (before their 17<sup>th</sup> birthday), you provide a signed shared care agreement from a paediatric endocrinologist, in line with NHS England guidance. Please note that we do not accept requests for transgender hormones for individuals until around their 16th birthday, as outlined by NHS Commissioning Policy, and in addition such requests must align with all other commissioning requirements. We do not accept requests for puberty blockers in children and young people in line with the Cass report and interim NHSE England policy.

Please note that we will not issue any prescriptions until we have been satisfied of the above conditions.

To satisfy clause 1, NHS England advice states that GPs must ensure such requests comply with the following points for adults, children and young people:

- The request is from a reputable company that provides a safe and effective service
- The circumstances of the request for the particular individual meet the general principles of the
  - GMC's Good Practice in Prescribing and Managing Medical Devices
- The health professional making the request is an appropriate gender specialist. The GMC states 'an experienced 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 Gender Identity Clinic. Evidence provided should include the following:
  - o Formal links with NHS-commissioned specialised Gender Identity Clinics
  - Formal links with relevant professional associations
  - o Previous time spent working in NHS-commissioned specialised gender identity services
  - o Evidence of ongoing continuous professional development
  - Participating in credible research related to gender nonconformity and gender dysphoria
- The decision to recommend endocrine therapy should have the documented support of two gender specialists who are directly involved in the patient's care; at least one of whom must be medically qualified
- The provider has an effective multidisciplinary team of gender specialists that meets regularly (either in person or electronically)
- The impact on the individual's fertility has been discussed with them and informed consent has been given

In addition, specifically for children and young people:



- Evidence of a comprehensive documented assessment by a multi-disciplinary team that includes a medical practitioner with specialist expertise in gender incongruence in children and adolescents; and
- Evidence of continued psychological support through engagement with the MDT;

I look forward to hearing from you. Yours sincerely,