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Clinical Commissioning Policy

Prescribing of Gender Affirming Hormones (masculinising or feminising hormones) as part of the Children and Young People's Gender Service

Summary

Gender Affirming Hormones (masculinising or feminising hormones) (GAH) are available as a routine commissioning treatment option for young people with continuing gender incongruence / gender dysphoria from around their 16th birthday subject to individuals meeting the eligibility and readiness criteria as set out in this document.

The policy is restricted to certain age groups as there is insufficient evidence to confirm safety in those age groups not included in the policy.

Committee discussion

Clinical Panel members considered that the need for a revision of terminology is important, as is careful consideration around policy implementation. The changes to the policy did not substantially change the access arrangements of the original policy 'Prescribing of Cross-Sex Hormones as part of the Gender Identity Development Service for Children and Adolescents' from August 2016.

What we have decided

NHS England will commission this intervention as part of the specialised service for Children and Young People with Gender Incongruence. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Links and updates to other policies

This policy has been informed by the following documents:

- Advice for Doctors Treating Transgender Patients, General Medical Council, 2016
- Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria; Royal College of Psychiatrists, 2013.
- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, Endocrine Society, 2018.

Plain language summary[1]

About gender incongruence

Gender incongruence / gender dysphoria is a condition where a person experiences discomfort or distress because there is a mismatch between their natal sex and the gender with which they identify.

Gender incongruence / gender dysphoria can be more distressing in adolescence due to the pubertal development of secondary sex characteristics and increasing social divisions between genders.

NHS England commissions a specialist multi-disciplinary gender incongruence service for children and young people up to their 18th birthday.

About current treatment

Treatment options for gender incongruence in adolescents, following an initial process of assessment and diagnosis, focus on psychosocial, psychological and psychoeducational support (NHS England Interim Service Specification for Children and Young People's Gender Services, 2023). GAH therapy may be considered for some individuals who have continuing gender incongruence and who may wish to proceed with gender reassignment in later life.

A move to irreversible sex reassignment surgery (gender affirmation surgery) may follow a few years later for some individuals, typically at an age greater than 18 years and is delivered by adult gender dysphoria services.

About gender affirming hormones

GAH are medicines that may be prescribed to a person with gender incongruence / gender dysphoria. The medicines are consistent with the individual's experienced gender as compared to the natal gender.

NHS England will commission GAH therapy for young people who meet the eligibility and readiness criteria described in this policy document from around their 16th birthday.

NHS England has explored whether it would be appropriate to prescribe GAH to young people with gender incongruence below 16 years of age. Given the very limited evidence (including from other countries) about the effects and harms of GAH to young people under 16 years, the policy stipulates that young people should be aged around 16 years to receive a prescription for these medicines.

Epidemiology and needs assessment

At current referral patterns 69% of referrals to the current commissioned service are of natal females and 31% are of natal males[2]. This data accords with figures published by the Cass Review in March 2022, which show a trend since 2011 in which the number of natal females is increasingly higher than the number of natal males being referred. That change

[1] NHS England acknowledges that language in this area is evolving and is different depending on the stakeholder's perspective.

[2] Source: Data return by Tavistock and Portman NHS Foundation Trust, February 2023

in the proportion of natal girls to boys is reflected in the statistics from the Netherlands (Brik et al. 2020).

The number of referrals into the Children and Young People's Gender Incongruence Service is currently likely to be around 1 per 2000 population per year. The current referral profile suggests that the majority of referrals will be of adolescents following the onset of puberty.

Inclusion criteria

Patients must meet **ALL** of the eligibility and readiness criteria listed in the table below which details each criterion and the associated rationale:

Eligibility and readiness criteria	**Reason for this criterion**
The individual has been assessed by the appropriate specialist multi-disciplinary team over a period of time* and fulfils the criteria for a diagnosis of Gender Incongruence (ICD-11). This includes those individuals who are non-binary or have evidence of continuing Gender Incongruence. *The duration of the assessment to be determined by the clinical team as relative to the needs of the individual.	To ensure that the individual is highly likely to continue to identify in the experienced gender, meaning that GAH therapy is an appropriate treatment in the long term.
There is evidence of presentation coherent with gender identity and intention to live in their preferred gender in the long term.	To ensure that the individual is aware that changing their body alone will not necessarily make it easier to make the transition to the gender with which they identify.
The individual is actively engaging with the appropriate specialist multi-disciplinary team and regularly attending appointments.	To ensure that the individual has ongoing opportunities to explore their options and manage any arising issues.
The individual is in good physical health, and preferably is not smoking.	To ensure that there are no health contraindications for GAH. To ensure that the individual understands that smoking can have a negative effect on the development of the secondary sex characteristics that GAH treatments are intended to affect.
The impact on the individual's fertility has been discussed with them; they understand that the treatment will affect their fertility, and that if required by the individual, a request is made to the GP to refer on to licensed NHS fertility experts for discussions on egg/sperm retrieval and storage.	To ensure that the individual is fully aware that GAH treatment may compromise their fertility; therefore, it may be preferable for them to talk to their GP about egg or sperm retrieval via a licensed NHS fertility service - if this has not already been undertaken prior to starting on GAH treatment.

That the individual is able to give informed consent and has cognitive and emotional maturity. That is, they must be given all of the information about what the treatment involves, including the benefits and risks, the strength / limitations of the evidence base, whether there are reasonable alternative treatments, and what will happen if treatment does / does not go ahead. Particular care will be taken to ensure these conditions are met with individuals who have a learning disability and those for whom English is a second language.	To ensure that the individual can comprehend as fully as possible what the physical treatment will offer, has sufficient autonomy and emotional resilience to participate in decision making and meets the Fraser guidelines.
That the individual is interacting with others and engaging socially (such as by attending school or college or is seeking employment, accepting that societal limitations may affect this).	To ensure that the individual is generally able to engage in the social aspects of daily living as this may help them to better manage their transition to the gender with which they identify.
Ideally there will be support for the individual for example, from one or both parents (the family)/carers, or social support if the individual is a 'Looked After Child', and the Local Authority has been consulted.	To ensure that the individual will receive support at home with both managing their physical transition and in coping with the side effects of treatment. It is recognised that some individuals approaching adulthood may not have this support – in these cases, the role of wider social networks will be taken into consideration.
Associated difficulties such as a psychotic episode, drug addiction or self-harming are not escalating.	To ensure that such difficulties are taken into account when considering the impact on an individual ability to manage the effects of GAH treatment; such difficulties will be reviewed on a case-by-case basis.
The CYP Gender Service National MDT, that includes clinicians not directly involved in the formation of the individual's care plan, agrees on the suitability of the individual receiving GAH based on the consideration of these eligibility and readiness criteria.	To ensure that the individual understands that there is limited clinical evidence on the effects and harms of prescribing GAH treatment below their 16th birthday; and also that GAH treatment is a significant decision with long term indications.

Exclusion criteria

Patients meeting ANY of the below exclusion criteria are not eligible for treatment:

- Abnormalities in status or timing of pubertal development or other physical contraindications that require further investigation.
- If there are any concerns about the individual's physical health such as low bone density.
- If the individual and their family/carers do not attend regular follow up appointments at the Paediatric Endocrine Liaison Clinic and/or the general clinics at the Gender Incongruence Service as agreed in their individualised care plan.

- If the individual is having a significant psychotic episode or has another significant mental health disorder that is not adequately controlled as this may reduce their ability to manage the emotional issues that may arise from the changes in hormone levels from the hormone treatments and may impact on their capacity to consent; in such cases, if the hormone treatments have begun, these may be paused whilst the young person is being supported by other services to better manage their condition.
- If the individual decides to cease treatment for any reason.
- Sourcing of endocrine interventions outside of NHS protocols where criteria are not met (Appendix A)

Patient pathway

A recommendation for GAH will form part of the individual's Individual Care Plan and must be agreed between the specialist multi-disciplinary team and the young person and their family/carers. Before any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken. The duration of this exploration may vary considerably depending on the complexity of the situation.

Individuals who are assessed as having continuing gender incongruence may be referred to the Paediatric Endocrine Liaison Team for assessment for suitability of the intervention.

For natal males, GAH via physiologic doses of oestrogen alone is insufficient to suppress testosterone levels into the normal range and addition of an anti-androgen alongside the GAH is necessary.

In some cases, the referral to the Paediatric Endocrine Liaison Team is made for the purpose of physical assessment to exclude a disorder of sex development or other endocrine conditions.

Collaboration between the young person's General Practitioner (GP) and the specialist multi-disciplinary team is essential in the best interests of the young person. Where shared care is agreed, the GP should receive timely and meaningful support from the specialist team including issues around shared care such as administration, prescribing, patient safety monitoring and basic physical examinations.

Governance arrangements

The provider must be compliant with the British Society for Paediatric Endocrinology and Diabetes', UK Standards for Paediatric Endocrinology (2010).

The provider will have relevant documented policies, including for safeguarding children and young people; clinical audit; clinical risk assessment; informed consent; complaints; and prescribing and administration of medicines.

The recommendation from the specialist multi-disciplinary team to prescribe GAH therapy must be made by a medically-qualified professional.

Mechanism for funding

The commissioning will be managed through the relevant local NHS England Specialised Commissioning Team. Integrated Care Boards fund the costs of GAH for each patient.

Audit requirements

NHS England acknowledges the strength of views for an alternative, criteria-based approach and recognises that in some administrations, in some circumstances, GAH therapy is prescribed to younger people. In response, NHS England requires standardised data collection, (inside and outside of a clinical trial), in order to continue to develop the evidence base in the context of an ethically approved study. This will include an exploration of the feasibility and appropriateness of a criteria-based approach rather than an age basis approach.

To facilitate this, providers will be required to regularly submit core data, as defined by a national data sub-group of the National Children and Young People's Gender Dysphoria Research Oversight group, to NHS England and to enter eligible patients into appropriate clinical trials.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net. NHS England will also consider the recommendations of the independent Cass Review in so far as those recommendations relate to this policy document.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Gender incongruence	Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/expressed gender and the natal sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of

	his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about two years. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.
Gonadotrophin Releasing Hormone analogues (GnRHa)	Synthetic (man-made) hormones that suppress the hormones naturally produced by the body and in doing so, suppress puberty, with the aim of reducing the level of puberty- related anxiety in an individual with gender incongruence.
Gender affirming hormones	Gender affirming hormones are masculinising or feminising hormones depending on the experienced gender as compared to the assigned gender. For example: • a trans man (female to male) or a non-binary person, natal female, may be prescribed testosterone, which is a masculinising hormone • a trans woman (male to female) or a non-binary person, natal male, may be prescribed oestrogen, which is a feminising hormone

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Appendix A

If a young person has already been started on masculinising / feminising hormones outside of NHS protocols, The Service will not consider a continuation of prescribing through NHS protocols as a harm reduction measure unless ALL of the following criteria are met:

- Evidence of a comprehensive documented assessment by a multidisciplinary 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; and
- Masculinising / feminising hormones were commenced not before approximately 16 years of age; and
- If puberty suppressing hormones were prescribed, they were not commenced before Tanner Stage 2; and
- Evidence that impact to fertility was discussed with the young person before initiation of the hormones