

Interim Clinical Policy:

Puberty suppressing hormones (PSH) for the purpose of puberty suppression for children and adolescents who have gender incongruence/dysphoria [1927]

Commissioning position

The proposal is: Puberty suppressing hormones (PSH) are not recommended to be available as a routine commissioning treatment option for treatment of children and adolescents who have gender incongruence/dysphoria within the criteria set out in this document.

This is an interim clinical policy which will be kept under review in light of any further emerging evidence and recommendations from the independent Cass Review and its research programme.

Background

Gender incongruence/dysphoria is a condition where a person experiences discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves¹ regarding their gender) and that person's natal sex (and the associated gender role, and/or primary and secondary sex characteristics). Diagnostic approaches have been described with reference to Diagnostic and Statistical Manual of Mental Disorders, version 5 published in 2013 (gender dysphoria) and International Statistical Classification of Diseases and Related Health Problems version 11 effective 2022 (gender incongruence).

The reason why some people experience gender incongruence/dysphoria is not fully understood and it is likely that the development of gender identity is multifactorial and influenced by both biological and social factors. Gender variant behaviours may start between ages 3 and 5 years, the same age at which most typically developing children begin showing gendered behaviours and interests (Fast et al, 2018). Gender atypical behaviour is common among young children and may be part of normal development (Young et al, 2019). Children who meet the criteria for gender incongruence/dysphoria may or may not continue to experience the conflict between their physical gender and the one with which they identify into adolescence and adulthood (Ristori et al, 2016).

¹ "Gender refers to the roles, behaviours, activities, attributes and opportunities that any society considers appropriate for girls and boys, and women and men." [source: WHO website Health Topics: Gender, at https://www.who.int/health-topics/gender]

Gender incongruence/dysphoria can become more distressing in adolescence due to the pubertal development of secondary sex characteristics and increasing social divisions between genders. Some studies have found that young people with gender incongruence/dysphoria may present to gender identity development services with a range of associated difficulties e.g., bullying, low mood / depression and self-harm and suicidality.

PSH competitively block puberty hormone receptors to prevent the spontaneous release of two puberty inducing hormones, Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland. This arrests the progress of puberty, delaying the development of secondary sexual characteristics. In England, the puberty suppressor triptorelin (a synthetic decapeptide analogue of a natural puberty hormone, which has marketing authorisations for the treatment of prostate cancer, endometriosis and precocious puberty) is one of the puberty suppressing hormones used for this purpose. The use of triptorelin for children and adolescents with gender incongruence/dysphoria is off-label.

In January 2020, a policy working group (PWG) was established by NHS England to undertake a review of the published evidence on the use of PSH. As part of this NHS England-led process, the National Institute for Health and Care Excellence (NICE) was commissioned to review the published evidence. Nine observational studies were included in the evidence review (NICE 2020). Overall, there was no statistically significant difference in gender dysphoria, mental health, body image and psychosocial functioning in children and adolescents treated with PSH (2020). The quality of evidence for all these outcomes was assessed as very low certainty using modified GRADE. There remains limited short-term and long-term safety data for PSH. PSH may reduce the expected increase in lumbar or femoral bone density during puberty. A re-run of the search was undertaken in April 2023 to capture literature published after the NICE evidence review in 2020. Nine further studies were identified.

Current treatments

Treatment of individuals with gender incongruence/dysphoria is recommended to be tailored to the specific needs of individual patients and aims to ameliorate the potentially negative impact of gender incongruence/dysphoria on general developmental processes, to support young people and their families in managing the uncertainties inherent in gender identity development and to provide ongoing opportunities for exploration of gender identity (Ristori et al, 2016).

The primary intervention will focus on psychosocial and psychological support; for some individuals, the use of PSH in adolescence to suppress puberty may be considered; this may be followed later with gender-affirming hormones of the desired sex (NHS England, 2013). If individuals fulfil additional criteria, they may have various types of gender affirming surgery from the age of 18 years through adult gender identity clinics (NHS England, 2013).

What we have decided

NHS England has carefully considered the evidence review conducted by NICE (2020) to treat children and young people who have gender dysphoria with PSH and has identified and reviewed any further published evidence available to date.

We have concluded that there is not enough evidence to support the safety or clinical effectiveness of PSH to make the treatment routinely available at this time. NHS England recommends that access to PSH for children and young people with gender incongruence/dysphoria should only be available as part of research.

On an exceptional, case by case basis any clinical recommendation to prescribe PSH for the purpose of puberty suppression outside of research and in contradiction to the routine commissioning position set out in this policy must be considered and approved by a national multidisciplinary team.

For children and young people who, at the point the proposed clinical commissioning policy takes effect, have been referred into an endocrine clinic but have not yet been assessed by a consultant endocrinologist for suitability of PSH, or who are already administering PSH through an NHS prescription, there is an expectation of consideration for treatment that would need to be clinically managed. In these cases it would be for the consultant endocrinologist to consider with the child or young person and their family whether to continue with off- label prescribing within the current clinical pathway.

The use of PSH as a precursor to a moving onto gender affirming hormones is covered by a separate clinical policy.

Links and updates to other policies

NHS England has no other policies relating to the sole use of PSH for the treatment of children and adolescents who have gender incongruence/dysphoria.

This document relates to the specialised service for Children and Young People with Gender Incongruence:

Gender identity development service for children and adolescent service specification

This document is linked to the revised policy for gender affirming hormones.

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.

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 is where a person experiences discomfort or distress because there is a mismatch between their experienced gender as compared with their assigned sex and its associated physical primary and secondary sex characteristics.
Puberty suppressing hormones	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/dysphoria.
Gender affirming hormones	Gender affirming hormones (also known as feminising/masculinising hormones and previously referred to as cross sex hormones) are hormones prescribed for an individual that are consistent with the experienced gender as compared to the assigned gender.
Diagnostic and Statistical Manual of Mental Disorders	The American diagnostic manual used to diagnose mental health disorders, and commonly used in UK practice.
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.

References

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