Interim Clinical Policy:

Puberty suppressing hormones (PSH) for children and adolescents who have gender incongruence or dysphoria

Public Consultation Guide

Publication reference:

Introduction and background

NHS England is committed to working with a wide range of patients, patient groups and other stakeholders in developing the services it commissions.

A public consultation is an opportunity to check whether proposals are right, well evidenced and supported, the public understand their impact, and identify any alternatives before decisions are made.

NHS England commissions gender incongruence / dysphoria services, and the purpose of this consultation is to seek views on a proposed interim clinical policy on puberty suppressing hormones (sometimes referred to as 'puberty blockers' or 'hormone blockers') for children and adolescents who have gender incongruence/dysphoria.

This consultation follows two weeks of targeted stakeholder testing which brought comments from 23 individuals and organisations. The views shared during stakeholder testing have been taken into account in this further round of consultation. Please read the engagement report to see how we have considered this early feedback.

This public consultation will run for 90 days from 3 August to 1 November 2023.

At the end of the consultation period, all feedback will be considered before the interim clinical policy is published.

We recommend that you read this consultation guide alongside the other documents published as part of the consultation. While this consultation guide has been produced to summarise the proposals, the other documents provide additional detail.

Policy proposition

The policy proposition is that puberty suppressing hormones (PSH) are not recommended to be available as a routine commissioning option for treatment of children and adolescents who have gender incongruence or dysphoria.

The current arrangements for puberty suppressing hormones (PSH)

PSH are currently prescribed through the NHS for children and young people with a diagnosis of persistent gender dysphoria after a certain stage of pubertal development, alongside psychosocial and psychological support, though no formal clinical commissioning policy is in place.

Before a referral for a child (under 16 years) can be made by a clinician, NHS England's Multi-Professional Review Group (MPRG) reviews whether appropriate processes have been followed by the clinician. This includes assurance that child safeguarding and child protection issues have been fully considered, and to ensure all necessary steps have been taken, and all relevant information has been provided to, and understood by the young person and their parents/carers.

The evidence on PSH

NHS England only commissions treatments based on evidence of both clinical and cost effectiveness and with appropriate assurances around safety.

In January 2020, a policy working group 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. Overall, there was no statistically significant difference in gender incongruence, mental health, body image and psychosocial functioning in children and adolescents treated with PSH.

The quality of evidence for all these outcomes was assessed as very low certainty. There remains limited short-term and long-term safety data for PSH, however, PSH may reduce the expected increase in lumbar or femoral bone density during puberty.

NHS England has carefully considered the evidence review conducted by NICE, any subsequent evidence found in the follow up literature surveillance, further evidence suggested during stakeholder testing as well as the interim recommendations of the Cass Review and has concluded that there is not enough evidence to support the safety, clinical effectiveness and cost effectiveness of PSH to make the treatment routinely available at this time.

NHS England recommends that PSH for children and young people with gender incongruence should only be accessed through research.

How will these changes impact the services/patients?

PSH are currently prescribed through the NHS for children and young people with a diagnosis of persistent gender dysphoria, alongside psychosocial and psychological support, though no formal clinical commissioning policy is in place. The policy proposition, if adopted, means that these arrangements will cease. Those already accessing PSH at the time the policy is implemented would need to reach a decision with their consultant endocrinologist about whether to continue this treatment.

Some children and young people may be eligible for enrolment in clinical research that would provide access to PSH. Outside of this research setting, NHS clinicians would no longer prescribe PSH for children and young people as a treatment for gender incongruence or dysphoria.

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.

Stakeholder engagement

NHS England sent a draft policy proposition out for targeted stakeholder testing for 2 weeks from 8th June 2023 to 25th June 2023. We received 23 responses during this engagement phase, including 13 responses from organisations, four from clinicians/academics and six from individuals or carers/family members.

Themes arising from responses to this early engagement included;

- the need for clarity regarding patients children and young people receiving PSH treatment
- lack of alignment with WPATH standards of care (version 8)
- the need to define 'exceptional circumstances' that may warrant prescribing PSH outside of formal research
- a request for clarification on the terms "early-onset" and "late-onset" gender dysphoria as used in the Equalities and Health Inequalities Impact Assessment
- concerns around ethics of ongoing research

NHS England has attempted to respond to and address these comments where possible in the updated version of the policy now being consulted on.

To clarify arrangements regarding those currently receiving (or imminently due to start) PSH, a paragraph has been included in the policy stating:

> "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… 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."

On alignment to WPATH standards; NHS England commissions treatment based on evidence of clinical effectiveness, cost effectiveness and safety. WPATH standards of care do not determine clinical commissioning decision for the NHS.

NHS England recognises the desire for clarification on what circumstances may be defined as "exceptional" when deciding whether PS may be prescribed outside of formal research. Exceptional circumstances will need to be determined on a case-by-case basis by a specially convened national multidisciplinary team who will have agreed terms of reference.

On clarification on the terms “early-onset” and “late-onset” gender dysphoria, NHS England has established a national Children and Young People’s Gender Dysphoria Research Oversight Board which has now approved the development of a study into the impact of puberty suppressing hormones (‘puberty blockers’) on gender dysphoria in children and young people with early-onset gender dysphoria. The Research Oversight Board will determine definitions of early- and late-onset gender dysphoria in due course.

The concerns voiced around the ethics of ongoing research presented a wide range of views, with some respondents saying it was unethical to provide access to PSH even in the content of research as it constituted medical experimentation on children, while others suggested that offering PSH *only* in the context of research could be construed as coercion to participate in research in order to access treatment. The Research Oversight Board membership includes the National Institute for Health and Care Research (NIHR), the Medical Research Council (MRC), the Royal College of Paediatrics and Child Health (RCPCH), Dr Hilary Cass and a range of other clinical and academic experts. The Oversight Board’s new study into the impact of puberty suppressing hormones (‘puberty blockers’) on gender dysphoria in children and young people with early-onset gender dysphoria will be taken forward through the National Research Collaboration Programme in place between NHS England and NIHR, and will be subject to the usual ethical and scientific approvals.

Some respondents suggested further evidence for consideration in the development of this policy which NHS England has reviewed. Please see the PSH Public Health Evidence Report for a detailed account of how this additional evidence was assessed.

How to respond to these proposals

In this 90-day public consultation, NHS England would like to hear what patients, parents and carers, clinicians, providers and other interested parties think about the proposed interim clinical policy; in particular:

- Has all of the relevant evidence been taken into account?
- Does the equality and health inequality impact assessment reflect the potential impact that might arise as a result of the proposed changes?
- Are there any changes or additions you think need to be made to this policy?

You can provide your views with NHS England by completing the online survey on the consultation hub.

Please respond by 29 October 2023.

Before responding to the survey, please familiarise yourself with the following documents published as part of the consultation:

- Interim Clinical Policy: Puberty suppressing hormones (PSH) for children and adolescents who have gender incongruence/dysphoria
- Evidence review GnRH for children and adolescents with gender dysphoria
- GnRH Literature surveillance
- PSH Public Health Evidence Report
- PSH Equality and Health Inequalities Impact Assessment (EHIA)

Next steps following consultation

The responses to the public consultation will be analysed and reported by an independent organisation. NHS England will consider all responses and publish a finalised interim policy alongside a full consultation report and detailed analysis.