NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 17 May 2023

Intervention: Gonadotrophin releasing hormone analogues

Indication: treatment of children and adolescents who have gender incongruence

URN: 1927

Gateway: 2, Round 1

Programme: Gender

CRG: Gender Dysphoria Services

Information provided to the Panel

Rapid Policy Statement Proposition

Evidence Review completed by NICE

Literature Surveillance

Equalities and Health Inequalities (EHIA) Assessment

This interim Policy Statement Proposition recommends that this treatment is not routinely commissioned for children and young people CYP) with gender incongruence and should only be accessed through a research setting. Panel members were informed about the independent Cass Review that has been commissioned by NHS England to make recommendations on how to improve services for CYP experiencing gender incongruence. There is a research programme as part of this review where healthcare data is being collected, and a systematic review is being undertaken as part of the Cass Review and will inform the Review's recommendations. The final Cass Review recommendations are anticipated later in 2023.

NICE previously completed an evidence review on this subject in 2020 which included nine observational studies. The quality of evidence for the identified critical outcomes for decision making – gender dysphoria, mental health – was assessed at the time as very low certainty. There was no statistically significant difference in measurements compared with baseline. No evidence was found for quality of life. The quality of evidence reported for important outcomes was also assessed as very low certainty. Surveillance of published literature, using the original PICO and bibliographic search strategies, has been undertaken to identify any relevant studies published since the NICE 2020 review. This assessment was presented to Panel members.

Clinical Panel considered the interim proposition and supporting evidence.

Panel members considered the issue where a child may have transitioned at a very early age, and the distress being caused should puberty progress rapidly during the wait for any research findings to be available. Panel members considered a requirement for consideration for 'exceptional' circumstances for access to puberty suppressants and possible options around this. Three possible options were considered:

1. Continuation of a policy working group to consider scenarios and make recommendations to Clinical Panel for policy revision

2. Formation of a national prior approval multi-disciplinary team to make assessments
3. Access enabled using the planned criteria for the clinical trial up to the point of it opening

Members debated each and it was proposed a 4th option could be included which was a combination of options 2 and 3. Members voted, and the outcome was: Option 2 received 4 votes in favour and Option 4 received 6 votes in favour.

EHIA – no amendments requested.

Recommendation

Clinical Panel agreed with the interim proposition and recommends this proceeds as a not for routine commissioning proposition.

Why the panel made these recommendations

Clinical Panel members considered the very low certainty quality of evidence and the work currently underway through the independent Cass Review. Any future position would need to be informed by final recommendations of that review.

Documentation amendments required

- Inclusion of 'exceptional' circumstances for access to puberty suppressants in the interim with option 4 as the recommended option for operationalising

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Declarations of Interest of Panel Members: One declaration of interest received.

Panel Chair: Anthony Kessel, Clinical Director, Clinical Policy Team, Specialised Services

Post Panel note:

Following the Clinical Panel meeting the title of the Interim Policy Statement Proposition has been changed to *Puberty suppressing hormones (PSH) for the purpose of puberty suppression of children and adolescents who have gender incongruence.*

Clinical Panel discussion – 19th July 2023

Following agreement to proceed at the May Clinical Panel meeting, the Interim Policy Statement Proposition was published for two weeks of stakeholder testing. In response, 8 stakeholders highlighted that there were 19 identifiable and unique study references that may not have been previously considered in the evidence review or recent literature surveillance report. Full text copies of all 19 were obtained and reviewed for relevance as outlined in the Public Health report presented to Clinical Panel. An explanation of the process undertaken to assess these 19 papers was shared with Panel members. Of the 19 studies, one study was highlighted to have been identified but excluded from the original evidence review. Panel members heard that this study did meet the PICO details and search methodology. Although the study's positive but very low certainty findings add information for an important (not critical) outcome for which evidence was not previously available, on assessment, the findings were not considered to materially impact on the conclusion of the review or the interim policy proposition.

Outcome: Panel members agreed that an appropriate process had been followed. The one identified paper was appropriately reviewed, and Panel agreed that it did not affect the recommended commissioning position.

Clinical Panel discussion – January 2024

The Interim Policy Statement Proposition was recently published for public consultation, which concluded 1st November 2023. 251 unique references for evidence were suggested during public consultation. A Public Health Report was presented to Clinical Panel members and the process followed for the consideration of each reference was explained. Duplicate articles were identified and excluded. 246 unique references were checked for relevance against the search strategy and PICO used for the original evidence review completed by NICE and literature surveillance report, and against the references detailed in the evidence review, the literature surveillance report and the stakeholder testing Public Health Evidence Report. Most references did not meet the PICO criteria. Some evidence had previously been considered. 22 full text articles were reviewed in depth. Three met the PICO and were identified as not being included in any previous evidence reviews. These were carefully reviewed and It was determined that these didn't materially affect the proposition as written.

It was highlighted to Panel members that three unique references were links to websites pages from which specific information could not be determined but were not peer reviewed and published articles, so didn't impact on the position.

Outcome: All Panel members present agreed with the position as presented and that there was no impact on the proposition as currently stated.