NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY EVALUATION PROGRAMME

Equality impact assessment – Guidance development

HST Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome

The impact on equality has been assessed during this evaluation according to the principles of the NICE equality scheme.

Consultation

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?
Equality issues identified at scoping included: 1. That the means of delivery – daily sub-cutaneous injection – may exclude some from accessing treatment, for example those living independently with visual impairment would not be able to safely self-administer a sub-cutaneous injection. The committee discussed this in the meeting. However, clinical experts highlighted that the burden of administration would reduce significantly with the new weekly formulation in a pre-filled injector. 2. That the STA route (originally proposed) would compromise ability of the small number of patients with these rare conditions (with range of severe disabilities and significant burden on families and caregivers) to access this new technology. This topic was routed as a HST so this potential issue is not applicable. 3. That the condition is an autosomal recessive condition and likely to be more common in communities where there is consanguinity (i.e. having blood relations). The committee considered that, because setmelanotide is not recommended in the full licenced population, its recommendation did not made it more difficult for a particular group to access treatment.

2.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the committee addressed these?
One stakeholder highlighted that 20% of people with BBS do not have identifiable pathogenic variants on testing and are identified clinically. The committee noted that genetic confirmation was a requirement in the marketing authorisation for setmelanotide. So, some people with the condition would not be able to access the treatment. The committee considered that its recommendation applies to the full licenced population, and it could not make a recommendation outside of this.	

3.	Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?
No	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No	

6.	Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with,

	access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
N/A	

7.	Have the committee's considerations of equality issues been described in the draft guidance, and, if so, where?
Yes, see section 3.28 of the draft guidance	

Approved by Associate Director (name): Jasdeep Hayre

Date: 25 July 2023

Draft guidance 2

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?
At consultation, the company highlighted additional ethnic groups that may be disproportionately affected by BBS. It stated that, as a recessive disorder, BBS disproportionately affects people from ethnic background where consanguineous marriage is more commonly practiced. Also, that people from Black, Asian and minority ethnic family backgrounds have an increased cardiometabolic health risk at lower BMI thresholds. The committee considered these issues but concluded that its recommendation applies equally, regardless of ethnicity, so a difference in disease prevalence does not in itself represent an equality issue.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
Setmelanotide is only recommended for routine commissioning to treat obesity and hyperphagia only in people with BBS who start treatment aged between 6 and 17 years (with continuation into adulthood if clinically indicated).	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified

in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
No, setmelanotide is above the thresholds normally considered an acceptable use of NHS resources in a highly specialised technology when applying a QALY weighting in analyses that include people who start treatment as adults and in the population when both adults and children and young people are pooled together.

5. Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?
Yes, in DG section 3.29

Approved by Associate Director (name): Jasdeep Hayre

Date: 15/02/2024

Final appraisal determination

(when an ACD issued)

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?
The committee noted that 40% of the BBS population are adults. The adults would not be able to access treatment with setmelanotide in its recommendation. It recalled that the cost-effectiveness estimates in the populations including adults were substantially higher than the threshold normally considered cost effective for highly specialised technologies. So, a negative recommendation in people starting treatment as adults would be proportionate to NICE's legitimate aim to recommend clinical- and cost-effective technologies.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
N/A – recommendation unchanged	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
N/A – recommendation unchanged	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

N/A – recommendation unchanged

5. Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
Yes: FDG section 3.29

Approved by Associate Director (name): Jasdeep Hayre

Date: 11 April 2024