

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HIGHLY SPECIALISED TECHNOLOGIES EVALUATION PROGRAMME

Equality impact assessment – Guidance development

HST Afamelanotide for treating erythropoietic protoporphyrria

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?

During scoping it was noted that children and people aged over 70 years were excluded from the marketing authorisation for afamelanotide. However it was agreed that this was not a potential equality issue that could be addressed by the committee because NICE cannot normally make recommendations outside of the terms of the marketing authorisation of the technology being evaluated.

2. Have any other potential equality issues been raised in the submissions, expert statements or independent academic report, and, if so, how has the Committee addressed these?

One professional group submission noted that the marketing authorisation for afamelanotide does not include its use in children. Again it was agreed that this was not a potential equality issue that could be addressed by the committee because NICE cannot normally make recommendations outside of the terms of the marketing authorisation of the technology being evaluated.

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?

Not applicable

7. Have the Committee's considerations of equality issues been described in the evaluation consultation document, and, if so, where?

No, because there were no potential equality issues raised which could be considered by the committee.

Approved by Associate Director (name): ...Sheela Upadhyaya...

Date: 07/12/2017

Final Evaluation Determination

1. Have the potential equality issues identified during the consultation process been addressed by the Committee, and, if so, how?

No equality issues have been identified during the consultation.

2. Have any other potential equality issues been raised in the submissions, expert statements or independent academic report, and, if so, how has the Committee addressed these?

No potential equality issues have been raised in the submissions, expert statements or academic report.

3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

No potential equality issues have been identified by the Committee.

4. Do the 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 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?
Not applicable.

7. Have the Committee's considerations of equality issues been described in the final evaluation determination, and, if so, where?
No.

Approved by Programme Director (name): Sheela Upadhyaya

Date: 12/03/2018

Post appeal

1. Have the potential equality issues identified during the appeal been addressed by the Committee, and, if so, how?
<p>The appeal panel found that the committee failed to adequately consider its duties under Equality Act; it considered that erythropoietic protoporphyria (EPP) meets the definition of disability under the Act. Although it accepted that the HST process is itself a reasonable adjustment for the benefit of people with rare diseases, it considered there was no evidence of adequate consideration of NICE's duties under the Act with respect to the use of afamelanotide for EPP specifically.</p> <p>The committee recognised that EPP is a disability as defined in the Equality Act, and understood its duties under the Act. It considered which features of the disability associated with EPP might cause people to be disadvantaged within an HST evaluation, and considered how it would be reasonable to adjust its approach to avoid discrimination and promote equality. The committee concluded that it would take into account the nature of EPP as a disability throughout its decision making, and</p>

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considered how it would be appropriate to adjust its approach in the context of this disability. For example, the committee considered the quality of life evidence submitted by stakeholder groups at the fourth evaluation committee meeting, and took into account the cost-effectiveness results of using this data in the economic model as part of a reasonable adjustment given the nature of the condition.

2. Have any other potential equality issues been raised in the post appeal submissions, expert statements or independent academic report, and, if so, how has the Committee addressed these?

Stakeholders suggested that, because of the nature of and challenges associated with EPP (which is a disability), ICERs should not be considered. The committee was mindful of its remit, the importance of considering value for money in a fair and consistent way, the fact that the methods for establishing ICERs in this population were not so uncertain as to be unreasonable, and that the ICERs were not the sole basis for its assessment of value for money. It concluded that it was appropriate to consider the ICERs for afamelanotide as part of its consideration of value for money.

3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

The committee was mindful of the particular challenges associated with EPP in measuring and quantifying the effect of the condition and the benefits of treatment. It took these challenges into account in its decision making and considered that it would be reasonable to consider alternative methods to capture the treatment benefits alongside its decision. For example, the committee took into account cost-effectiveness analyses which used data provided by stakeholders, despite the extremely high levels of uncertainty in these analyses.

Given the challenges associated with EPP, the committee concluded that it was important to take into account patient testimonies and other qualitative evidence as part of its decision making. It was also considered appropriate in this evaluation to take into account the alternative results

using stakeholder provided quality of life data as part of a reasonable adjustment given the nature of this condition.

4. Do the 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 recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

The committee considered the nature of EPP as a disability throughout and understood its duties under the Equality Act. See previous sections.

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?

Not applicable

7. Have the Committee's considerations of equality issues been described in the evaluation consultation document, and, if so, where?

Yes; the committee considered EPP as a disability and its duties under the Equality Act throughout and its considerations are documented throughout the ECD accordingly. See in particular sections 4.8, 4.22, 4.44, 4.45, 4.52 and 4.56.

Approved by Associate Director (name): Sheela Upadhyaya

Date: 25 February 2020

Consultation

1. Have the potential equality issues identified during the consultation process been addressed by the Committee, and, if so, how?

The committee recognised that EPP is a disability as defined in the Equality Act, and understood its duties under the Act. It considered which features of the disability associated with EPP might cause people to be disadvantaged within an HST evaluation, and considered how it would be reasonable to adjust its approach to avoid discrimination and promote equality. The committee concluded that it would take into account the nature of EPP as a disability throughout its decision making, and considered how it would be appropriate to adjust its approach in the context of this disability. For example, the committee considered the quality of life evidence submitted by stakeholder groups at the fourth evaluation committee meeting, and took into account the cost-effectiveness results of using this data in the economic model as part of a reasonable adjustment given the nature of the condition.

2. Have any other potential equality issues been raised in the submissions, expert statements or independent academic report, and, if so, how has the Committee addressed these?

Stakeholders suggested that, because of the nature of and challenges associated with EPP (which is a disability), ICERs should not be considered. The committee was mindful of its remit, the importance of considering value for money in a fair and consistent way, the fact that the methods for establishing ICERs in this population were not so uncertain as to be unreasonable, and that the ICERs were not the sole basis for its assessment of value for money. It concluded that it was appropriate to consider the ICERs for afamelanotide as part of its consideration of value for money.

Some stakeholders stated that they felt NICE still had not fully addressed the upheld appeal point in relation to consideration of its duties under Equality Act. The Committee considered it had addressed the upheld appeal point by further outlining the challenges of decision-making due to the characteristics of EPP and took these into account in its decision-making. This was done through consideration of a wide range of evidence, including that beyond the clinical trials, and by taking into account data provided by stakeholders within the economic model

3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

The committee was mindful of the particular challenges associated with EPP in measuring and quantifying the effect of the condition and the benefits of treatment. It took these challenges into account in its decision making and considered that it would be reasonable to consider alternative methods to capture the treatment benefits alongside its decision.

Given the challenges associated with EPP, the committee concluded that it was important to take into account patient testimonies and other qualitative evidence as part of its decision making.

4. Do the 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 recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

The committee considered the nature of EPP as a disability throughout and understood its duties under the Equality Act. See previous sections.

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?

Not applicable.

7. Have the Committee's considerations of equality issues been described in the evaluation consultation document, and, if so, where?

Yes; the committee considered EPP as a disability and its duties under the Equality Act throughout and its considerations are documented throughout the ECD accordingly. See in particular sections 4.8, 4.22, 4.44, 4.45, 4.52 and 4.56.

Approved by Associate Director (name): Richard Diaz

Date: 27 September 2022

Final evaluation determination

(when an ACD issued)

8. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

Some stakeholders stated that in their opinion, a treatment that is accepted to make such a difference to the patients' lives should be made available to them, as this would promote equality of opportunity by enabling a normal life, eliminate unlawful discrimination and fosterer good relations between people with particular protected characteristics and others.

Stakeholders stated that there are still aspects of the specific disability that cause difficulty in assessing the impact of EPP and its treatment, and there are still aspects that need particular consideration to ensure there is no discrimination of this patient group on the grounds of their disability.

The committee considered the nature of EPP as a disability throughout and understood its duties under the Equality Act. See previous sections.

9. 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

10. 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

11. 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

12. Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?

Yes, documented throughout the FED. See in particular sections 4.8, 4.22, 4.45, 4.47, 4.49 and 4.59

Approved by Associate Director (name): ...Richard Diaz.....

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afamelanotide for treating erythropoietic protoporphyria

Date: 23 Feb 2023