

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Esketamine for treatment-resistant depression

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

Consultation 1

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

The company proposed adding people above >65 years as a subgroup because this group of people are likely to receive a different dose of the drug due to tolerability. The company highlighted that there was a lack of data for this subgroup, and considered that this could constitute an equalities issue. Subgroups based on age have not been included in the scope. Unless specified in the marketing authorisation, the committee cannot make recommendations based on age because it is a protected characteristic. Lack of data for this subgroup is therefore not a scoping equalities issue.

The company also highlighted that esketamine has post-administration restrictions to driving, and considered that this might be an equalities issue due to difference in geographic access. However, issues relating to geographic access cannot be addressed in a technology appraisal.

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?

The committee noted that the main trials only included people aged 18-64. However, it considered that any recommendation would extend to all adults. The committee considered additional evidence from a supporting trial which included adults aged 64+ as supplementary evidence.

The committee noted comments suggesting that there may be equity issues from variation in access to clinics within the UK. However, the committee's recommendation does not restrict access to treatment for this group over any other group and so the committee agreed that this does not represent a potential equality issue.

The committee noted comments suggesting that people in the criminal justice system may need access to esketamine. The committee considered that the recommendations do not prevent access to esketamine for the population in the criminal justice system over any other group. It understood that there were likely to be existing processes in place for managing controlled substances in the criminal justice system which would not prevent access to esketamine were it recommended for use in the NHS.

The committee noted comments suggesting that there may be equity issues for people with additional physical health conditions who may need additional support to access or administer treatment. However, the committee's recommendation does not restrict access to treatment for this group over any other group and so the committee agreed that this does not represent a potential equality issue.

The committee noted comments suggesting that some people may have cultural or religious objections to treatment with antidepressants. However, these objections would apply to both treatment arms; the committee agreed that this does not represent a potential equality issue.

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 appraisal consultation document, and, if so, where?
Yes, in section 3.20	

Approved by Associate Director (name): Jasdeep Hayre

Date: 20/01/2020

Consultation 2

1.	Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?
<p>The NHS commissioning expert raised concerns about equity of access for people in the criminal justice system. The committee considered that the recommendations do not prevent access to esketamine in the criminal justice system over any other setting. It understood that there were likely to be existing processes in place for managing controlled substances in the criminal justice system, which would not prevent access to esketamine were it recommended. The patient organisation raised that there may be cultural</p>	

or religious objections to treatment with esketamine. The committee was aware that these objections would also apply for other existing treatments for depression; however it agreed that this equality issue could not be addressed in a recommendation. The technical team also noted that the main clinical evidence only includes people aged 18 to 64. However, any recommendation would extend to all adults and additional evidence from a trial that included adults aged over 64 was considered from the supplementary evidence. So, the committee concluded that there were no equalities issues that could be addressed in the guidance.

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?

No

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 appraisal consultation document, and, if so, where?

Yes, in section 3.34 of the second ACD.

Approved by Associate Director (name): Jasdeep Hayre

Date: 20/08/2020

Final appraisal determination 1

(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 clinical expert noted that people who are under served are more likely, in the clinical expert's experience, to have severe depression. The committee considered that the recommendation does not restrict access to treatment for some people over others.

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?
Not applicable.

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?
Not applicable.

5. Have the committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?
Yes, in section 3.40 of the FAD.

Approved by Associate Director (name): ...Linda Landells.....

Date: 6 May 2022

Final appraisal determination 2

(following appeal)

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

The appeal panel suggested that the committee should explain how the uncertainties identified by the committee during the appraisal were related to the patient group's protected characteristics and to explain how it had to sought to adjust for these. The committee was mindful that its role is to appraise treatments and recommend those that are a clinically and cost-effective use of NHS resources. The committee carefully considered the uncertainties common in clinical trials in mental health and recognised the difficulties of collecting clinical data in the population of people with treatment-resistant depression. It noted that no specific adjustments to the considerations of evidence had been proposed. So it considered all the available evidence including a wide range of views from patient and clinical experts alongside clinical trial data. The committee concluded that it was still unable to recommend esketamine for routine use and that it had considered the available evidence.

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?

Not applicable.

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?

Not applicable.

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?

Not applicable.

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

Yes, in section 3.40 of the FAD.

Approved by Associate Director (name): Jasdeep Hayre

Date: 24 October 2022