

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Etranacogene dezaparovec for treating moderately severe or severe haemophilia B

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

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?

At consultation stakeholders commented that HOPE-B excluded people with HIV and hepatitis. The summary of product characteristics for etranacogene dezaparovec does not exclude people with HIV and historical hepatitis B and C. The committee did not exclude these groups from their recommendation.

The company also clarified that its summary of product characteristics states that etranacogene dezaparovec is not recommended in women of childbearing potential and should not be used during pregnancy or during breastfeeding.

The committee concluded that any recommendation would not exclude people with HIV or hepatitis and would not need to differentiate between men and women.

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?
No.

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 In section 3.17 of the Final Draft Guidance

Approved by Technical Adviser (name): Vicky Kelly

Date: 19/06/2024