

# 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.

#### Consultation

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

Yes, stakeholders identified the following potential equality issues and requested that NICE:

- Consider that moderate and severe haemophilia B is rare in women and that the clinical trial did not include women
- Consider that AAV vectors can lead to liver toxicity and consideration should be given on use in people with cirrhosis or extensive fibrosis
- Ensure recommendations do not discriminate against people with HIV or historical hepatitis B or C
- Consider that dosing of etranacogene dezaparovec is based on weight and that there is some suggestion that high doses of AAV vectors may be associated with higher risks.

The committee discussed these issues and noted that issues related to differences in prevalence or incidence of a disease cannot normally be addressed in a technology appraisal recommendation. It was aware of clinical advice received by the EAG that the few women who experience severe and moderately severe haemophilia B would be affected similarly as men. The committee considered that any recommendation made would not need to differentiate between men and women. It was also aware of the exclusion criteria in the clinical trials and the weight-based dosing of etranacogene dezaparovec but noted that these are clinical factors that

should be considered if prescribing etranacogene dezaparvovec and not equality issues.

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 following potential equality issues were raised in the patient organisation and clinical expert submissions :

- If the treatment is to be delivered in a small number of specialist centres, consideration should be given to ensure equitable access to treatment for those who are more distant from those centres
- consideration required for people for whom English not first language, learning disabilities and for those with speech, sight or hearing impairment. Consideration also required for people with impaired mobility or who do not have the resources to attend the hospital regularly.

The committee was aware of the need for equitable access to etranacogene dezaparvovec should it be recommended but noted that access to treatments is an implementation issue that cannot be addressed in a technology appraisal recommendation.

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

The committee noted that the SmPC states that “for 12 months after administration of etranacogene dezaparvovec treated patients of reproductive potential and their female partners of childbearing potential must prevent or postpone pregnancy using barrier contraception”. It was aware that there are no data regarding etranacogene dezaparvovec use in women and that this should be considered if prescribing etranacogene dezaparvovec in women who are pregnant or breast feeding or planning to become pregnant.

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, please see section 3.16

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

**Date:** 25 July 2023