

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HIGHLY SPECIALISED TECHNOLOGY EVALUATION PROGRAMME

Equality impact assessment – Guidance development

HST Volanesorsen for treating familial chylomicronaemia syndrome [ID1326]

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?

Stakeholders noted a couple of potential equality issues:

Pregnancy

- Familial chylomicronaemia syndrome (FCS) can have particularly severe effects on pregnant women and their foetuses because of increased levels of triglycerides and risk of gestational diabetes during pregnancy, leading to a potentially high mortality risk to the mother and unborn child. Stakeholders suggested that special considerations should be given to women who are or who are considering becoming pregnant because of the protected characteristics they share (sex, pregnancy and maternity).
- The committee recognised that people who are pregnant or wish to become pregnant are an important clinical group. However, while not contraindicated in pregnancy, the summary of product characteristics advises that during pregnancy the use of volanesorsen should be avoided. Therefore, the committee concluded that it would be inappropriate to consider people who are pregnant as a specific subgroup
- The committee also noted that it was not presented with data on the use of volanesorsen during pregnancy, nor how it could influence

the outcome of pregnancy (the drug does not cross the blood placenta barrier).

- The committee concluded that any recommendations would apply equally, regardless of pregnancy, so this does not in itself represent an equality issue.

Population

- Secondly, FCS is more prevalent in south eastern Asian communities.
- The committee recognised this, but concluded that its recommendations apply equally, regardless of ethnicity, so a difference in disease prevalence in different ethnic groups does not in itself represent an equality issue.

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?

The higher prevalence of FCS in some cultural and ethnic groups was raised as a potential equality issue by clinical experts in the submission. Please see question 1 regarding how this was considered by the committee.

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

None identified

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?

Please see "Other Factors" section (4.28 and 4.29) in the ECD.

Approved by Associate Director (name): Melinda Goodall.....

Date: 19/12/2019

Final evaluation determination

(when an ECD issued)

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

No additional potential equality issues have been raised.

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?

None identified.

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?

None identified.

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?

None identified.

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

Yes, please see "Other Factors" section (4.35 and 4.36) in the FED.

Approved by Associate Director (name): Nicole Elliott

Date: 07/09/2020