

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Elafibranor for treating primary biliary cholangitis

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

Final draft guidance

(when no draft guidance was issued)

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

- primary biliary cholangitis disproportionately affects women compared to men, with a nearly tenfold higher incidence in women
- primary biliary cholangitis is a rare disease

The committee acknowledged that primary biliary cholangitis is a rare condition that can make evidence generation particularly difficult. It considered that because its recommendation does not restrict access to treatment for some people over others, these were not potential equality issues.

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| 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? |
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Submissions from the company, patient and professional organisations and experts identified potential equality issues for consideration. The issues identified were:

- approximately 90% of people with PBC globally are women and the incidence rate is 5 to 6 times higher in women than men
- people diagnosed with PBC under the age of 50 experience more severe and progressive PBC and poor treatment response compared with people over the age of 50 at diagnosis
- men are at greater risk of more advanced PBC at diagnosis and poor treatment response compared with women
- people with PBC are the most likely to die out of all people waiting for liver transplants because of priority given to others
- some evidence suggests smoking, nail polish, hair dyes, hormone replacement and toxic waste are linked to PBC.

The committee considered the issues raised in its deliberations. It noted that concerns about access to liver transplant were outside its remit. The committee concluded that because its recommendation does not restrict access to treatment for some people over others, these were not potential equality issues.

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

None

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 issues identified.

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 issues identified.

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?

No issues identified.

7. Have the committee's considerations of equality issues been described in the final draft guidance, and, if so, where?

Yes, in section 3.15 of the final draft guidance.

Approved by Associate Director (name): Ian Watson

Date: 14/10/2024