

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Andexanet alfa for reversing anticoagulation ID1101

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

Consultation

- | |
|---|
| 1. Have any potential equality issues been identified during the scoping process (draft scope consultation and scoping workshop discussion), and, if so, what are they? |
|---|

No equality issues were identified during the scoping process.
--

- | |
|--|
| 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 other equality issues have been raised in the submissions.

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

The committee noted an equality concern raised at consultation of ACD1. Some people do not accept blood products, so would be unable to accept PCC.

The committee was aware that PCC is not an established treatment for reversing anticoagulation with apixaban or rivaroxaban. The committee was also aware that the company used data from people who had received PCC in the ORANGE study for its indirect treatment comparison because this group was thought to better represent the population who would receive

andexanet alfa rather than because of an expectation that all people with life-threatening or uncontrolled bleeds would receive PCC. The committee concluded that uncertainty about the effectiveness of andexanet applied equally to people who would not have PCC as part of their standard management and that there was no need to alter its recommendation.

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

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.

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 determination, and, if so,

where?

Yes, in paragraph 3.18 Equalities

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?

During the second consultation, stakeholders and clinical experts noted a further equality concern that there would be national variation in access to andexanet alfa if recommended only in research. However, because the recommendations for andexanet alfa are for all ICH bleeds in the anticipated marketing authorisation, the committee agreed that its recommendations do not have a different effect on people protected by the equality legislation than on the wider population.

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?

Recommendation has not changed after consultation.

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?

Recommendation has not changed after consultation.

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?

Recommendation has not changed after consultation.

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

Yes, in paragraph 3.19, Equalities.

Approved by Associate Director (name): Janet Robertson

Date: 25 March 2021