

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Azacitidine for treating acute myeloid leukaemia with more than 30% bone marrow blasts

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?

No equality issues were raised during consultation. The company requested to amend the proposed remit in line with anticipated wording of marketing authorisation which specified an age cut-off of '65 years or more'. In line with NICE TA processes, the final scope states that '*Guidance will only be issued in accordance with the marketing authorisation.*' which includes the age cut-off above. The clinical trials also included an age cut-off of '65 years or more'. However, as NICE has an obligation towards people protected by the equality legislation; it was decided that age restriction should not be specified in the remit or scope.

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 equality issues were identified in the submissions, expert statements or academic report

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

No equality issues were identified by the Committee

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 appraisal consultation document, and, if so, where?

Not applicable

Approved by Associate Director (name): ...Frances Sutcliffe.....

Date: 23 03 2016

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?

A potential equality issue was raised by a consultee suggested that an inequitable situation would be created by not recommending treatment for people with more than 30% bone marrow blasts due to existing positive guidance for people with 20-30% bone marrow blasts.

The committee was aware that severity of disease is not a protected characteristic as defined by the Equalities Act, and that it did not fall within NICE's obligations to avoid discrimination in the performance of its functions. The committee noted that azacitidine being considered separately for acute myeloid leukaemia with 20% to 30% and more than 30% bone marrow blasts was a result of the timing of the regulatory marketing authorisation approval process and as such was outside NICE's control, but agreed that it would have been preferable to develop a single piece of guidance for azacitidine in this indication.

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?

Not applicable – the recommendations have 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?

Not applicable – the recommendations have 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?

Not applicable – the recommendations have 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 section 4.20 and 4.21

Approved by Centre or Programme Director (name): ...Meindert Boysen ...

Date: 06/06/2016