

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation

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?

The final scope for this technology appraisal guidance notes that, 'consideration should be given to the advantage of dabigatran in terms of its lower requirement for therapeutic monitoring.' Consultees during scoping considered that dabigatran could improve access to treatment for people for whom therapeutic monitoring is difficult. The Committee discussed this issue and agreed that dabigatran could offer advantages to those people in whom monitoring is difficult. However this was not thought to be an equalities issue in that the Committee's recommendation in relation to dabigatran etexilate would not disadvantage any specific protected group compared with other people.

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 marketing authorisation contains an age restriction meaning that the higher 150 mg twice daily dose is only available to people under 80 years of age. The Committee discussed this issue and was aware that although this was for reasons of safety, the age cut off is arbitrary. However, the Committee acknowledged that it has to appraise this technology within its licensed indication.

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

No.

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 access for the specific group?

No.

5. Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to access identified in question 4, or otherwise fulfil NICE's obligations to promote equality?

Not applicable.

6. Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?

Yes. Equality issues are discussed in the 'Summary of Appraisal Committee's key conclusions' table.

Approved by Associate Director (name): Janet Robertson

Date: 10 August 2011

Final appraisal determination

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

Consultees highlighted that by not considering dabigatran as an alternative treatment to warfarin for people with atrial fibrillation and in particular, those who cannot tolerate warfarin and therefore are left unprotected from the heightened risk of stroke could be deemed to be unfair to those patients. In addition, consultees also stated that in current practice there may be reduced access to anticoagulation monitoring and treatment for people with limited mobility.

The Committee discussed the limitations of warfarin therapy in section 4.2 of the Final Appraisal Determination.

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 access for the specific group?

No

3. If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to access identified in question 2, or otherwise fulfil NICE's obligations to promote equality?

No

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

Yes. In section 4.2 and 4.22.

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

Date: 11th October 2011