NATIONAL INSTITUTE FOR HEALTH AND CARE **EXCELLENCE**

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA of nintedanib for treating idiopathic pulmonary **fibrosis**

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?

A consultee raised a potential equality issue during the scoping stage: a potential to disadvantage patients under the age of 40 years because these were excluded from the relevant clinical trials. The Committee did not address this issue because guidance will only be issued in line with marketing authorisation, which is not restricted to people over 40 years of age and therefore this issue was not considered relevant for this appraisal

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?

Evidence submissions from patient experts suggested the following as potential equality issues:

- 1. They noted that current NICE guidance for idiopathic pulmonary fibrosis restricts the use of pirfenidone to people with forced vital capacity (FVC) of 50–80% of their predicted value, and suggested that the drug is clinically effective in a broader population than this subgroup.
- 2. They suggested that NICE guidance should clearly define poor response to treatment.

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The Committee did not consider these as equality issues because:

- 1. NICE makes recommendations based on both the clinical effectiveness and cost effectiveness of a technology. Clinical and cost-effectiveness evidence for subgroups was considered as part of the appraisal and reflected in the Committee's recommendations.
- 2. NICE will define treatment response, based on what the Committee hears at the appraisal meeting, if it is relevant to the final guidance recommendations.
- 3. Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?

No potential equality issues have been raised.

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, the preliminary recommendations do not make it more difficult in practice for a specific group to access the technology compared with other groups.

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, there is no potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability.

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

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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): Melinda Goodall.....

Date: 05/11/2015

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 consultee raised a potential equality issue during consultation, suggesting that the recommendation that "people whose treatment with nintedanib ... was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop" creates inequity because it allows people with a percent predicted FVC above 80%, who were prescribed nintedanib before NICE guidance was published, to continue treatment while barring access to people diagnosed with idiopathic pulmonary fibrosis in the future.

NICE recognises that before the marketing authorisation is granted, people may have access to treatments through other schemes, which may not involve a formal cost-effectiveness analysis. It is unethical and potentially detrimental to a person's health to withdraw a treatment from someone already receiving it and benefitting from it, and therefore NICE make allowances for people who have accessed new treatments before its formal guidance is released.

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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.

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.

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.

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

Not applicable.

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

Date: 17/11/2015

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Issue date: November 2015