

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA pirfenidone 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?

During the scoping process, consultees suggested that restricting treatment based on percent predicted forced vital capacity (FVC) (in line with the recommendations in previous NICE technology appraisal guidance for treating idiopathic pulmonary fibrosis) could discriminate against:

- minority ethnic people, particularly people of south Asian family origin
- disabled people who have difficulty standing straight, because FVC is expressed as a percentage of the predicted normal value for a person of the same height
- older people, because the reference tables are derived from populations under the age of 70 years, whereas the average age of people with idiopathic pulmonary fibrosis is 72 years.

The committee discussed these issues with the clinical experts during its first meeting, noting that:

- The Global Lung Initiative has introduced equations to predict FVC values in minority ethnic groups and, when these equations were used, FVC values for minority ethnic people were comparable to the FVC values of people in clinical trials (most of whom were white). Thus, when using the newer equations, people would not be denied treatment because of their ethnicity.
- For people who cannot stand straight, their armspan (which

approximates their height) can be used to calculate percent predicted FVC. Thus, when using this measure people would not be denied treatment because of their disability.

- According to clinical experts, it is difficult to compare the predicted FVC values of older people with the FVC values of people in clinical trials because older people show a wide range of predicted FVC.

The committee recognised the limitations of FVC but understood that, in clinical practice, the wider patient characteristics would be taken into account in interpreting percent predicted FVC.

Consultees also suggested that using FVC alone to assess disease severity is discriminatory because some people with idiopathic pulmonary fibrosis die when their percent predicted FVC remains above 80. The consultees stated that people with percent predicted FVC above 80% have clinically significant fibrosis and should be considered for treatment. The committee considered this group (FVC above 80% predicted) by reviewing the company's evidence of clinical and cost effectiveness for the 'mild' subgroup.

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 submissions repeated some of the potential equality issues raised during scoping (see above).

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, or difficulties with, access for the specific group?

The committee concluded that its recommendations did not discriminate

against any groups of people protected by the Equality Act. In the appraisal consultation document, NICE invited comments on the consideration of equality issues in this appraisal.

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 - for people who cannot stand straight, their armspan (which approximates their height) can be used to calculate percent predicted FVC. Thus, when using this measure people would not be denied treatment because of their 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 obligations to promote equality?

The committee noted that, in clinical practice, the wider patient characteristics would be taken into account in interpreting percent predicted FVC (see sections 4.5 and 4.20).

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

Yes, in paragraph 4.20 of the appraisal consultation document.

Approved by Associate Director (name): ...Melinda Goodall.....

Date: [26/05/2016]

Final appraisal determination (issued after appeal)

(when an ACD issued)

Technology appraisals: Guidance development

Equality impact assessment for the single technology appraisal of pirfenidone for treating idiopathic pulmonary fibrosis

Issue date: January 2018

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

No.

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 recommendation was not substantially 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 recommendation was not substantially 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 recommendation was not substantially 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 4.21 of the final appraisal determination.

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

Date: 16/01/2018