

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Lumacaftor–ivacaftor for treating cystic fibrosis homozygous for the F508del mutation

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

Consultation

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| 1. Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how? |
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No equality issues were raised during the scoping process.
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| 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? |
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<p>The remit of this NICE technology appraisal was to appraise the clinical and cost effectiveness of lumacaftor in combination with ivacaftor within its marketing authorisation for treating cystic fibrosis in people who are homozygous for the F508del mutation. The committee concluded that, even without including all of its preferred assumptions, the estimated ICERs were considerably higher than what is normally considered a cost-effective use of NHS resources, and therefore it could not recommend the use of lumacaftor–ivacaftor in the NHS.</p>
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<p>The company considered that there was potential for inequality of access for people with cystic fibrosis based on their subtype if lumacaftor-ivacaftor was not recommended for treating cystic fibrosis in people who are homozygous for the F508del mutation. People aged 6 or more with 1 of 9 mutations (G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, and G1349D) have routine access to ivacaftor monotherapy through an NHS England clinical commissioning policy. Ivacaftor monotherapy does not have a</p>

marketing authorisation for people homozygous for the F508del mutation and this population was not covered by NHS England's clinical commissioning policy.

The committee was aware that NHS England commissioning policy decisions should not be taken as setting precedent for future policy decisions. The committee considered that the issue raised by the company did not constitute an equalities issue for any group protected by the equalities legislation and that its recommendation was in line with NICE's [guide to the processes of technology appraisal](#) (2014) and [guide to the methods of technology appraisal](#) (2013). The committee concluded that its recommendation was fair and did not discriminate against any protected groups, and therefore no changes were required to its draft recommendation.

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?

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?
N/A

7. Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
Please see section 4.25 of the ACD and the 'Summary of Appraisal Committee's key conclusions' table in the appraisal consultation document.

Approved by Associate Director (name): Helen Knight

Date: 16/03/2016

Final appraisal determination

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

No additional potential equality issues were raised during the consultation.

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?

N/A

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?

N/A

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?

N/A

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

Please see section 4.25 of the final appraisal determination (FAD) and the

'Summary of Appraisal Committee's key conclusions' table in the FAD.

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

Date: 09/06/2016