

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

STA Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations [ID1342]

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.

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?
Stakeholders noted potential equality issues: Prevalence of BRCA mutation: <ul style="list-style-type: none">BRCA mutations are more common in certain ethnicities and population groups, for example, young women;The committee was aware that some people with HER2-negative advanced cancer with BRCA mutations may be younger and from Black family backgrounds. But it noted that the higher prevalence of the condition in some population groups cannot be addressed by a technology appraisal. If recommended, the recommendation would be applied to all ages and family backgrounds. Population and subgroups, given the unmet need:

- The company stated that it wishes to avoid inequity in access to talazoparib by subgrouping the population, given the unmet need and clinical benefit in progression-free survival and quality of life demonstrated in EMBRACA;
- Unmet need is not a protected characteristic under the Equality Act 2010, but the committee was aware that HER2-negative advanced cancer with BRCA mutations is a condition with high unmet need and this was noted in the draft guidance.
- Subgroups by hormone receptor status and by previous line of treatments (0, 1, or 2 and above) were pre-planned in the company's pivotal trial EMBRACA. The committee noted that the subgroup analyses are difficult to interpret. There are also other uncertainties in the evidence base regarding talazoparib's treatment effect on the overall survival. So, the committee concluded that additional evidence and further analysis would help provide further insight to its decision making.

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

The committee was also aware that triple negative breast cancer is more common in some ethnicities and patient groups.

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?

Not applicable

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?

Not applicable

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?

Yes, see section 3.2, section 3.9 to 3.11 and section 3.29 in draft guidance.

Approved by Associate Director (name): Ian Watson

Date: 20/07/23

Final Draft Guidance

(when draft guidance issued)

1. (Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?)
Stakeholders noted potential equality issues: Prevalence of BRCA mutation: <ul style="list-style-type: none">BRCA mutations are more common in people of Ashkenazi Jewish ethnicity, andalthough breast cancer is rare in men, it is more common in men with a BRCA mutations than other men. The committee noted these equality issues, and agreed that its recommendations do not have a different impact on people protected by the equality legislation than on the wider population.

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?
The recommendation has changed. The technology is recommended. The recommendations do not make it more difficult for specific groups to access the technology compared with other groups.

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?
No.

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?

Yes, in section 3.30 of the Final Draft Guidance.

Approved by Associate Director (name): Ian Watson

Date: 10/01/2024