NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Guidance development

Tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer (update of DG10)

Consultation

1.	Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
During scoping it was noted that breast cancer is less common in men than women, and is underdiagnosed and often undertreated in men. The committee noted that all the clinical and economic evidence had been based on trials with women, but that the general subtypes are identical in men and women, and in clinical practice men would be treated in the same way as women. The committee concluded that the recommendations in the guidance should also apply to men.	

2.	Have any other potential equality issues been raised in the diagnostics assessment report, and, if so, how has the Committee addressed these?
The committee noted that the model for EndoPredict, IHC4+C, Oncotype DX and Prosigna related only to a postmenopausal population. The committee heard from a clinical expert that the biology of a cancer, for example the hormone receptor status and HER2 status, is more influential in determining the risk of distant recurrence than menopausal status. The committee concluded that the results of the model apply equally to premenopausal and postmenopausal subgroups.	

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

No other potential equality issues were identified by the committee.

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?
Prosigna is only indicated for use in postmenopausal people. However, EndoPredict and Oncotype DX are indicated for use in both pre- and postmenopausal people. Premenopausal people therefore have the option of 2 out of the 3 recommended tests.	

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 diagnostics consultation document, and, if so, where?
The consideration on men is described in section 5.21 of the second diagnostics consultation document and the consideration on menopausal status is described in section 5.20.	

Approved by Associate Director (name): Mark Campbell

Date: 9 April 2018

Diagnostics guidance document

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 either the first or second 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?
The recommendations were changed after the first consultation. Prosigna is only indicated for use in postmenopausal people. However, EndoPredict and Oncotype DX are indicated for use in both pre- and postmenopausal people. Premenopausal people therefore have the option of 2 out of the 3 recommended tests. The recommendations did not change following the second consultation.	

3.	If the recommendations have changed after consultation, 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?
The recommendations were changed after the first consultation. No potential adverse impact of the updated recommendations on people with disabilities has been identified. The recommendations did not change after the second 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?
The recommendations were changed after the first consultation. Prosigna is only indicated for use in postmenopausal people. However, EndoPredict and Oncotype DX are indicated for use in both pre- and postmenopausal people. Premenopausal people therefore have the option of 2 out of the 3 recommended tests. The recommendations did not change after the second consultation.	

5.	Have the Committee's considerations of equality issues been described in the diagnostics guidance document, and, if so, where?
The consideration on men is described in section 5.25 of the diagnostics guidance and the consideration on menopausal status is described in section 5.24. Section 5.24 of the diagnostics guidance notes that Prosigna is not indicated for use in postmenopausal people.	

Approved by Acting Programme Director (name): Mark Campbell

Date: 17 August 2018