NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer (DG34)

Published: December 2018

Summary

The diagnostic guidance is a full update of NICE guidance DG10 (published 2013) and replaces it.

DG10 recommended Oncotype DX as an option for guiding adjuvant chemotherapy decisions for people with oestrogen receptor positive (ER+), lymph node negative (LN−) and human epidermal growth factor receptor 2 negative (HER2−) early breast cancer subject to certain criteria.

The update recommends further options for tumour profiling tests EndoPredict and Prosigna as well as Oncotype DX Breast Recurrence Score.

Around 7,200 people with breast cancer are eligible for tumour profiling tests. Because there is uncertainty around future uptake of the recommended tumour profiling tests, we have created 3 scenarios for completion at a local level, in the resource impact template that supports this guidance:

- no change in uptake from current practice
- a limited change in uptake with EndoPredict and Prosigna
- uptake is divided equally between Oncotype DX, EndoPredict and Prosigna.

This report is supported by a local resource impact template, because the list prices of Oncotype DX, EndoPredict and Prosigna have discounts that are commercial in confidence and the current uptake data for tumour profiling testing are not available. The discounted prices can be put into the template and other variables may be amended.

Tumour profiling tests are commissioned by providers and reimbursed by NHS England. Chemotherapy and radiotherapy for breast cancer is commissioned by NHS England, other care for breast cancer is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

1 Tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer

1.1 NICE has recommended EndoPredict (EPclin score), Oncotype DX Breast Recurrence Score and Prosigna as options for guiding adjuvant chemotherapy decisions for people with oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative and lymph node (LN)-negative early breast cancer, only if:

- they have an intermediate risk of distant recurrence using a validated tool such as PREDICT or the Nottingham Prognostic Index
- information provided by the test would help them choose, with their clinician, whether or not to have adjuvant chemotherapy taking into account their preference
- the companies provide the tests to the NHS with the discounts agreed in the access proposals and
- clinicians and companies make timely, complete and linkable record-level test data available to the National Cancer Registration and Analysis Service as described in the data collection arrangements agreed with NICE (see section 5.29).

1.2 NICE has not recommended MammaPrint because it is not cost effective. NICE has not recommended IHC4+C because the analytical validity of the test is uncertain.

1.3 Tumour profiling tests are designed to provide information on the activity of genes within tumour samples from people with early breast cancer. The results of the tests provide a risk profile of an individual's breast cancer which can be combined with other clinical risk factors that are routinely assessed, such as nodal status and tumour size, to better predict the risk of disease recurrence in the

future. Chemotherapy can be used to reduce the risk of future disease recurrence. Oncotype DX may also predict the benefit a patient may receive from chemotherapy.

1.4 Organisations should assess the impact of the different tumour profiling tests based on local practice. We have assumed that there will be similar levels of chemotherapy use and therefore costs with each of the tests due to the uncertainty around chemotherapy decision making.

1.5 This resource impact report accompanies the NICE guidance on tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer and should be read with it.

2 Resource impact of the guidance

2.1 We estimate that around 7,200 people with breast cancer are eligible for tumour profiling tests to guide adjuvant chemotherapy decisions each year.

2.2 EndoPredict and Prosigna represent further options for testing in addition to Oncotype DX. Providers will need to decide locally which test to use and amend the resource impact template supporting this guidance to reflect local plans.

2.3 Data are not available in respect of current uptake of tumour profiling tests. Therefore organisations need to input data locally. In order to support this, we have we have created 3 scenarios for completion at a local level in the resource impact template.

Scenario 1 – no change in uptake from current practice.

Scenario 2 – a limited change in uptake where overall uptake of testing remains the same but there are small increases in use of EndoPredict and Prosigna.

Scenario 3 – uptake of testing remains the same but is divided equally between Oncotype DX, EndoPredict and Prosigna.

2.4 This report is supported by a local resource impact template. The manufacturers of Oncotype DX, EndoPredict and Prosigna provide simple discounts to the list prices, with the discounts applied at the point of purchase or invoice. The level of the discounts are commercial in confidence. The discounted prices of the tests can be put into the template and other variables may be amended.

2.5 For enquiries about the patient access schemes:

- Oncotype DX SOgram@genomichealth.com or call +44 20 3031 8087.
- EndoPredict NHS_EndoPredict@myriad.com or call +44 2038976620.
- Prosigna prosigna_uk@nanostring.com or call +44 1494 590430.

3 Implications for commissioners

3.1 Tumour profiling tests are commissioned by providers and reimbursed by NHS England. Chemotherapy and radiotherapy for breast cancer is commissioned by NHS England, other care for breast cancer is commissioned by clinical commissioning groups. Providers are NHS hospital trusts.

3.2 The committee noted that although clinical and patient experts thought that the main benefit of the tests was in avoiding unnecessary chemotherapy, some tests were estimated to increase chemotherapy use at least in some subgroups (see guidance section 5.11). The committee concluded that there was uncertainty around chemotherapy decision making and how the tumour profiling tests may impact upon this. It noted that there was more uncertainty for the 2-level tests (that is, EndoPredict) and that model inputs for Prosigna were subject to uncertainty because they

used evidence from Oncotype DX. This evidence on Oncotype DX may no longer be applicable to UK practice because of the publication of TAILORx (Sparano et al. 2018). Therefore there is uncertainty around chemotherapy decision making for all 3 tests and we have assumed the impact on chemotherapy of the different tests to be broadly similar

3.3 Evidence suggests that the tumour profiling tests, EndoPredict (EPclin score), Oncotype DX Breast Recurrence Score and Prosigna, have the ability to predict the risk of distant recurrence in people who have ER-positive, HER2-negative, early breast cancer. This evidence is strongest in LN-negative disease. In addition, Oncotype DX Breast Recurrence Score may be able to predict which patients will respond to chemotherapy, however evidence for this is uncertain.

3.4 Tumour profiling tests to guide adjuvant chemotherapy decisions in people with breast cancer falls within the programme budgeting category 02F Cancer, Breast.

4 How we estimated the resource impact

The population

4.1 The relevant population for tumour profile testing are the incident population who have early stage invasive breast cancer, who have an intermediate risk of distant recurrence using a validated tool such as PREDICT or the Nottingham Prognostic Index, and who are oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative and lymph-node negative.

4.2 The recommendations primarily relate to people with lymph-node negative disease. The committee considered that tumour profiling tests should be available as an option for people fulfilling the recommendation requirements and who have micro metastatic

disease. Discussion within the multidisciplinary team may be particularly helpful for this group.

4.3 In clinical practice, men (who make a small proportion of people with breast cancer), would have treatment in the same way as women, as the general subtypes are identical in men and women. The incident population includes women and men.

4.4 The population assumptions are included in table 1.

Table 1 Number of people eligible for tumour profiling tests to guide adjuvant chemotherapy for people with breast cancer in England

Population	Proportion of previous row (%)	Number of people
Adult population		43,482,790
Incidence of breast cancer[1]	0.11	46,000
People with invasive breast cancer [2]	90	41,500
People with early and locally advanced disease[2]	95	39,400
People with invasive breast cancer who have an intermediate risk of distant recurrence based on a validated tool[3]	28	11,000
Oestrogen receptor positive[4]	91	10,000
Human epidermal growth factor receptor 2 negative[4]	90	9,000
Lymph node negative[4]	80	7,200
Total number of people eligible for tumour profiling tests	**100**	**7,200**

[1] Source: Office for National Statistics cancer registrations data 2016

[2] Source: NICE TA495 Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer

[3]Source: Analysis of TransATAC in Table 122 Diagnostic assessment report for NICE Tumour profiling (DG34)

[4]Source: NHS breast screening programme and Association of Breast Surgery An audit of screen detected breast cancers for the year of screening April 2016 to March 2017

Assumptions

4.5 The proportion of people likely to have adjuvant chemotherapy is uncertain, indications are that it could range from between 27% and 44% of people having tumour profiling tests (section 4.65 Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer (DG34)).

4.6 It is estimated that the distant recurrence of breast cancer for people who have had tumour profiling tests is between 12% and 16%, and 21% of people who have not had tumour profiling tests (Diagnostic assessment report for Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer (DG34)).

About this resource impact report

This resource impact report accompanies the NICE guidance on tumour profiling tests to guide adjuvant chemotherapy decisions in people with early breast cancer and should be read with it.