

## Project scope: Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer

22/11/2022

### Research question

What is the clinical and cost effectiveness, and patient and clinical experience, of tumour profiling tests for guiding chemotherapy decisions for people with early stage breast cancer?

### Inclusion criteria

The selection of studies for inclusion in the literature review element of the project will be based on the following criteria:

<b>Population</b>	<p>People with ER-positive, HER2-negative, early stage breast cancer (stages I or II) with 0 to 3 positive lymph nodes.</p> <p>Subgroups: lymph node negative, pre/post-menopausal women, different ethnicities</p>
<b>Intervention</b>	Oncotype DX, MammaPrint, EndoPredict, Prosigna
<b>Comparator</b>	Current decision making (to assess risk) in Scotland i.e. PREDICT, the Nottingham Prognostic Index (NPI) and Adjuvant!
<b>Outcomes</b>	<p>Disease free survival</p> <p>Overall survival</p> <p>Distant recurrence</p> <p>QoL (health-related, disease-related morbidity and chemotherapy-related)</p> <p>Costs (test, medicines, healthcare utilisation, training etc.)</p> <p>Test accuracy / prognostic ability</p> <p>Impact on decision making</p> <p>Time to results</p> <p>Chemotherapy benefit prediction</p>
<b>Limits</b>	Secondary /tertiary care

## Planned activities

SHTG have agreed on the following activities to support the consideration of tumour profiling tests for guiding chemotherapy decisions for people with early stage breast cancer?

1. Establish if/when NICE plan to update DG34 (in progress)
2. Review the literature post NICE DG34 so that we have a new 'baseline' for the evidence
3. Gather evidence from patient organisations
4. Appraise the NICE economic model and provide guidance on direction of results based on updated clinical evidence and costs. If possible, replicate and update the NICE economic model.
5. Use consensus methodology to develop recommendations where it is not possible to reach evidence-based recommendations.

## End products

At the end of the project, SHTG will publish:

- [SHTG Recommendations](#) (incl. consensus recommendations where applicable)
- Plain language summary

## Timescales (approximate)

6 to 7 months