**DIAGNOSTICS ASSESSMENT PROGRAMME**

**Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer**

**Diagnostics Consultation Document – Comments**

**Date: 31 January 2018**

**Name: UK Breast Cancer Group (UKBCG)**

**Organisation: UK Breast Cancer Group (UKBCG)**

| Comment number | Section number | Comment |
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| 1 | 5.1 | There is a strong drive internationally to de-escalate breast cancer treatment in a safe manner. Since the introduction of these tests the proportion of patients receiving chemotherapy for node negative disease has fallen. The NHS audit in 2016 showed quite clearly that since use of Oncotype DX there has been a reduction of approximately 25% in the use of adjuvant chemo in the eligible population. Genomic tests have been shown robustly to identify a sub-group of node negative patients with low risk of recurrence with endocrine therapy so this de-escalation in chemotherapy and hence reduction in excess toxicity has been done in a safe manner. It is reasonable to assume that breast cancer mortality has not been compromised and that acute chemotherapy-related mortality of approx. 0.25%, acute chemotherapy-related admissions affecting approximately 35% of breast cancer patients have been reduced and that long-term morbidity and late excess mortality from chemotherapy will fall. The MINDACT study also demonstrated safety in de-escalating low risk patients in a randomised trial setting. We have had access to prognostic tools for many years, namely ‘Adjuvant! Online’ in the past and currently ‘PREDICT’. However, prior to genomic tests clinicians clearly struggled to recommend no chemotherapy in ‘intermediate’ risk patients. |
| 2 | 5.1 | If we revert to an era of more chemotherapy-giving, we will encounter capacity issues in already stretched chemotherapy units. This has not been factored in. |
| 3 | 5.1 | Most major guideline producing groups now recommend these assays in the node-negative population, including NCCN, St Gallen, ASCO, ESMO. The decision will result in a return to NHS patients self-paying for the test creating a two-tier system. |
| 4 | 4.47  5.8 | The modelling used the TransATAC data which is a small data set. Based on this study, it assumes a 15% recurrence at 10yrs for all risk categories. This seems flawed. |
| 5 | 4.52 | Long term toxicities other than AML have not been factored into the economic model. Infertility, early menopause, peripheral neuropathy and occasional permanent hair loss are all commonly encountered in clinical practice. Chronic fatigue has been reported in up to 25% of patients. Cardiac toxicity (heart failure) arising from anthracycline use is a particular concern with reported excess mortality of 0.5-1.5%. |
|  |  | In a survey\* to breast Oncologists undertaken by UKBCG open over just 48 hours, of 75 responses, 100% reported using Oncotype regularly in their NHS practice and 100% supported its continuing use in node negative disease. This is an indication of the strength of feeling amongst Breast Oncologists in the UK towards securing continued access to these assays in the setting of node positive disease.  \*The survey was distributed by email to 200 members of UKBCG (breast oncologists) with a 37.5% response rate in 48 hours. |

**Please add further rows as required**