Comments on the ACD Received from the Public Through the NICE Website

Name	[redacted]
Role	NHS Professional
Other role	«otherrole»
Location	England
Conflict	no
Notes	[redacted]
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	NHS Bradford and Airedale strongly support the ACD recommendation that Lapatinib or trastuzumab in combination with an aromatase inhibitor are not recommended as options for the first-line treatment of metastatic hormone-receptor-positive breast cancer that overexpresses human epidermal growth factor receptor 2 (HER2). Â The evidence available shows that these treatments are not affordable or cost-effective, do not increase overall survival or quality of life and are associated with substantial increases in adverse events in patients. Based on the prevalence and cost information provided by NICE, approximately 20 patients per year would be eligible for such treatment were they approved. Â The increased lifetime costs (just for drug acquisition) if all eligible patients were treated this way would be in excess of Â£500,000. Â This spend would need to be found from within the existing budget for breast cancer (approx Â£4 million in 2008/09) and would therefore result in a loss of existing services.
Section 2 (clinical need and practice)	«Section_2»
Section 3 (The technologies)	The potential additional lifetime cost of approximately Â£26,000 per patient (for mean of 55.2 weeks' treatment) for drugs cost alone, would be result in an equivalent reduction elsewhere in breast cancer services to fund them if approved. In the event that these treatments were approved we would be extremely concerned about the substantial increase in adverse events and serious adverse events observed in both of the trials of lapatinib and trastuzumab added to compared to the use of an aromatase inhibitor alone. Â Given that both lapatinib and trastuzumab are associated with cardiotoxicity, additional cardiac monitoring before and after treatment would be required at further increased cost. Â Similarly it is noted that liver function monitoring before and after treatment is recommended for lapatinib which again would have resource implications.Section_3»
Section 4 (Evidence and interpretation)	Although the two RCTs are of high quality the overall evidence base is limited as there is only one relatively small trial for each drug combination. Â Also, given the substantially different populations recruited we do not feel that the indirect comparisons conducted by the manufacturers were appropriate. The evidence does not demonstrate any increase in overall survival through adding lapatinib and trastuzumab to an aromatase inhibitor. Â Although modest improvements in PFS were found for both drugs, where quality of life data was reported (only for lapatinib) there was not found to be any improvement compared to the use of an aromatase inhibitor alone. Neither laptinib and trastuzumab were found to be cost-effective. Â The estimated ICERs (Â£74,000 to Â£1,000,000, and Â£54,300 to Â£73,100 per QALY respectively) were substantially in excess of the recognised thresholds for cost-effectiveness.
Section 5 (implementation)	Based on the prevalence and cost information provided by NICE, approximately 20 patients per year would be eligible for such treatment were they approved. Â The increased lifetime costs (just for drug acquisition) if all eligible patients were treated this way would be in excess of Â£500,000. Â This spend would need to be found from within the existing budget for breast cancer (approx Â£4 million in 2008/09) and would therefore result in a loss of existing services.
Section 7 (related NICE guidance)	«Section_7»
Section 8 (proposed date of review of guidance)	«Section_8»
Date	19/01/2011 @ 10:01

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Conflict	no
Notes	
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Agree with the recommendation
Section 2 (clinical need and practice)	«Section_2»
Section 3 (The technologies)	«Section_3»
Section 4 (Evidence and interpretation)	These technologies do not reflect a cost effective use of NHS Resources with ICER for lapatinib plus leptosome compared with letrozole alone was likely to be between Â£74,400 and Â£1,000,000 per QALY gained, and for trastuzumab plus anastrozole compared with anastrozole alone was likely to be between Â£54,300 and Â£73,100 per QALY gained. Overall survival is not improved, and the combination results in a significant rise in ADRs. The populations in these trials were substantially different therefore the indirect comparisons carried out by the manufacturers should be interpreted with caution.
Section 5 (implementation)	«Section_5»
Section 7 (related NICE guidance)	«Section_7»
Section 8 (proposed date of review of guidance)	«Section_8»
Date	14/01/2011 @ 19:01ate»

Name	[redacted]
Role	NHS Professional«role»
Other role	
Location	England
Conflict	«conflict»
Notes	«notes»
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	Agree
Section 2 (clinical need and practice)	«Section_2»
Section 3 (The technologies)	Costs of Trastzumab need revising to reflect actual costs. For hospital administration VAT should be added. No discounts are available currently for herceptin. Echo costs need inclusion. For Homecare costs, extra costs of compounding, dispensing, delivery and nurse time are added.
Section 4 (Evidence and interpretation)	Overall survival was not increased. Yet harms increased. Toxicity (cardio and hepatic) needs to be measured for the effect on quality of life. The QALYs are high above the cost effective threshold and the NHS needs to be equitable. Other breast cancer treatments are available. NHS money will need to be taken from other services to meet the costs of these drugs e.g from patients with other end of life conditions who need support other than drugs e.g. heart failure, COPD.
Section 5 (implementation)	«Section_5»
Section 7 (related NICE guidance)	«Section_7»
Section 8 (proposed date of review of guidance)	«Section_8»
Date	«date»

Name	[redacted]
Role	«role»
Other role	«otherrole»
Location	England
Conflict	no
Notes	«notes
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	I support the view base on the evidence summary presented. Â the cost of therapy, considering the impact on survival, would seem unsustainable
Section 2 (clinical need and practice)	We are not aware of a specific need to further augment clinical practice beyond current recommendations
Section 3 (The technologies)	Adding lapatinib or trastuzumab to aromatase inhibitor treatment is estimated to increase lifetime costs by around Â£26,000 per patient, without an extension to life.
Section 4 (Evidence and interpretation)	In this indication these technologies are not a cost effective use of NHS resources Adding lapatinib or trastuzumab to an aromatase inhibitor improves median progression free survival (PFS), but not overall survival Adding lapatinib or trastuzumab to an aromatase inhibitor increases adverse events There were limitations to the quality of the research: Although the RCTs were of good quality, each combination (lapatinib plus letrozole or trastuzumab plus anastrozole) was only assessed in a single RCT with about 200 women with HER2+ and hormone receptor positive metastatic breast cancer.
Section 5 (implementation)	The exact number of people who would be eligible to receive trastuzumab or lapatinib plus an aromatase inhibitor (if approved) in preference to alternatives is unknown. Â Current expectations would be that an average PCO would treat around 11 patients, giveing an incremental cost in excess of Â£250k with no substantial survival benefits
Section 7 (related NICE guidance)	We agree with the proposed review date
Section 8 (proposed date of review of guidance)	
Date	12/01/2011 @ 17:01