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

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)	We are in agreement with the present NICE recommendation and are in line with our present policy agreed at our Medicines and Technology Board. This decision was made on the grounds that this treatment was no more effective than the other treatment options recommended within NICE guidance for this indication. It must be noted that two local cancer networks have recommended its use (one at third treatment option in both post and pre-menopausal women and the second one in post menopausal and ER+ve, with advanced/ metastatic breast cancer patients and who have the following: - have relapsed on aromatase inhibitor therapy in advanced disease. - patients with severe joint pains exacerbated by aromatase inhibitor therapy. - patients with compliance issues (swallowing problems). - Patients in whom certainty of administration is an advantage. And there is agreement by local Breast MDY that initiation of Fulvestrant is the best treatment option available to the patient. Clearly there is a need to a single recommendation that we can commission for all out patient population.
Section 2 (The technology)	No further comments.
Section 3 (The manufacturer's submission)	It is clear that this appraisal will not reflect current clinical practice as already confirmed within this document that it is generally used 3rd or 4th line. This is confirmed in this our area where a cancer network is recommending it 3rd line. It was noted that the Finder trial only included Japanese patients and questioned whether these results would be representative to patients within the UK. It is noted that there are no published RCTs that have compared high dose fulvestrant against aromatase inhibitors for postmenopausal women with oestrogen receptor positive advanced breast cancer (locally advanced or metastatic) which has progressed or relapsed during or after other anti-oestrogen treatment. So only indirect comparisons can be made between the two groups which should be interpreted with caution. It would be worthwhile to consider whether there is a place in therapy specifically in patients unable to swallow oral medication or unable to tolerate aromatase inhibitors. The expectation that this treatment would be initiated within secondary care and then transferred out to primary care. Consideration needs to take into account the extra cost relating to this.
Section 4 (Consideration of the evidence)	The evidence provided there is a lot of uncertainty to whether or not fulvestrant at the higher dose (500mg) will provide significant improved outcomes (Progression free survival and overall survival)compared to aromatase inhibitors and as there

	is a significant increased cost it is difficult to justify including it within he present NICE clinical pathway. It should also be noted that it is likely if patients are given the option of either taking an oral tablet or having two injections administered every month, I suspect that the majority of patients would choose an oral tablet, especially as there is no strong evidence to show that there will any greater benefit. Within the subgroups would it be worth considering patients unable to swallow oral tablets and patients who were unable to tolerate aromatase inhibitors due to side effects.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	9/13/2011 3:41:00 PM

Name	[redacted]
Role	NHS Professional
Other role	
Location	England
Notes	no
Conflict	nothing else to declare
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We support NICE in this decision. Fulvestrant is not a cost effective use of NHS resources.
Section 2 (The technology)	This technology is not a cost effective use of NHS resources. The committee concluded that the ICER for fulvestrant in its licensed dose was likely to be at least Â£35,000 per QALY gained compared with the aromatase inhibitor anastrozole. However, considerable uncertainty remained regarding this estimate. Unit costs of fulvestrant are significantly higher than current standard treatment. The cost of fulvestrant is currently Â£1,044.82 for the first month, and Â£522.41 in subsequent months (excluding VAT). This is based on BNF 61 prices for a 250mg prefilled syringe. The manufacturer reports that this pack size will no longer be available after 2012 due to the licensed dose now being 500mg monthly. This may affect costs. This compares to a cost for anastrozole 1mg daily of Â£74.48 per month.
Section 3 (The manufacturer's submission)	The relative clinical effectiveness of fulvestrant compared to aromatase inhibitors is uncertain. There are no RCTs directly comparing the licensed dose of fulvestrant (500mg) against aromatase inhibitors (AIs). A network meta-analysis conducted by the manufacturer to allow these comparisons to be made indirectly suggested no significant differences in overall survival between fulvestrant and the AIs anastrozole and letrozole. Fulvestrant 500mg may offer a longer time to progression (TTP) compared to anastrozole however, there was heterogeneity between the studies included and limitations to the statistical methods used which meant that there was a high degree of uncertainty about the reliability of these results. Evidence submitted by the manufacturer does not reflect current UK clinical practice. In the UK, fulvestrant is considered as a third or fourth line treatment after aromatase inhibitor treatment. This use is outside the current marketing authorisation and therefore outside the remit of this technology appraisal. Â It is therefore unclear where fulvestrant would fit in the care pathway. no head to head RCT against other aromatase inhibs
Section 4 (Consideration of the evidence)	The exact number of patients who would be eligible for fulvestrant in its licensed indication is uncertain, but is likely to be small. The manufacturer estimates that 2,200 women would be eligible under the existing license. Â Clinical advice offered to NICE suggested that most postmenopausal women now receive an aromatase inhibitor as adjuvant hormone therapy for early breast cancer or as first-line treatment if presenting with advanced breast cancer. Â This limits the use of fulvestrant under its current license. Â

	4) There were limitations to the quality of the evidence: There were no RCTs comparing the licensed dose of fulvestrant against aromatase inhibitors. A network meta-analysis was conducted by the manufacturer to allow these comparisons to be made indirectly, but there were limitations to the methods used, including possible bias from the selection of the trials, heterogeneity between the trials included, and problems with the statistical methods used. These limitations reduce the reliability of the results of these analyses. 4) Fulvestrant does not offer any improvement in overall survival, nor does it meet the criteria for end of life considerations-no extended survivl
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	9/7/2011 5:03:00 PM

Name	[redacted]
Role	NHS Professional
Other role	Medical Director
Location	Wales
Notes	no
Conflict	I have in the past been on advisory boards for faslodex.
Comments on individual sections of the ACD:	
Section 1 (Appraisal Committee's preliminary recommendations)	We need to remember that patients with ER positive metastatic breast cancer will live longer than other groups of patients. They will run out of options for anti-hormonal therapy and herefore if wanting and requiring further therapy at this point will recieve chemotherapy. So without the availability of faslodex these patients will be offered chemotherapy with attendant costs and side-effects.
Section 2 (The technology)	
Section 3 (The manufacturer's submission)	
Section 4 (Consideration of the evidence)	What about patients already taking faslodex?
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Section 8 (Proposed date of review of guidance)	
Date	8/23/2011 5:48:00 PM

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)	
Section 2 (The technology)	This technology is not a cost effective use of NHS resources. The committee concluded that the ICER for fulvestrant in its licensed dose was likely to be at least Â£35,000 per QALY gained compared with the aromatase inhibitor anastrozole. However, considerable uncertainty remained regarding this estimate. Unit costs of fulvestrant are significantly higher than current standard treatment. The cost of fulvestrant is currently Â£1,044.82 for the first month, and Â£522.41 in subsequent months (excluding VAT). This is based on BNF 61 prices for a 250mg prefilled syringe. The manufacturer reports that this pack size will no longer be available after 2012 due to the licensed dose now being 500mg monthly. This may affect costs. This compares to a cost for anastrozole 1mg daily of Â£74.48 per month.
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	under its current license. Â There were limitations to the quality of the evidence: There were no RCTs comparing the licensed dose of fulvestrant against aromatase inhibitors. A network meta-analysis was conducted by the manufacturer to allow these comparisons to be made indirectly, but there were limitations to the methods used, including possible bias from the selection of the trials, heterogeneity between the trials included, and problems with the statistical methods used. These limitations reduce the reliability of the results of these analyses. Fulvestrant does not offer any improvement in overall survival, nor does it meet the criteria for end of life considerations.
Section 5 (Implementation)	
Section 6 (Proposed recommendations for further research)	
Section 7 (Related NICE guidance)	
Date	9/13/2011 1:36:00 PM