Advanced breast cancer (standing committee update)

Consultation on draft addendum - Stakeholder comments table
11 May 2017 to 09 June 2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

ID	Type	Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
1.	SH	AbbVie	Appendix E	56	3	The flow chart specifies that 24 studies were excluded based on full-text review. However, Appendix F reports that details of only 20 studies rather than the 24 excluded	Thank you for your comment. We have checked the excluded studies and updated the list. There are 20 excluded studies and 59 included, we have updated the addendum accordingly.
2.	SH	Association of Breast Surgery	Full	General	General	The Association of Breast Surgery considers this to be reasonable and in line with current practice	Thank you for your comment.
3.	SH	UK Breast Cancer Group	Full	General	General	Randomised controlled trials are needed to assess whether patients who have had adjuvant trastuzumab should be offered further biological response modifiers. Trial design should incorporate collection of data required for prospective cost-effectiveness analysis. Patients in this category were included in Cleopatra trial. The HR for benefit was the same as for the overall population	Thank you for your comment. We will ensure this information is passed to our surveillance team.
4.	SH	UK Breast Cancer Group	Full	General	General	The use of continued trastuzumab in patients with progressive metastatic disease should be investigated as part of a randomised controlled trial. Trial design should incorporate collection of data required for prospective cost-effectiveness analysis. This should be the use of trastuzumab beyond Trastuzumab-Emtansine (TDM-1, Kadcyla) should be investigated in RCT	Thank you for your comment. We will ensure this information is passed to our surveillance team.

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5.	SH	AbbVie	Full	26	31 - 32	Please import the correct reference	Thank you for your comment. This was a reference to Figures 1 and 2 that became corrupted during the transfer of the document to .pdf format. We have corrected this.
6.	SH	AbbVie	Full	27	5 - 6	Please import the correct reference	Thank you for your comment. This was a reference to Figure 3 that became corrupted during the transfer of the document to .pdf format. We have corrected this.
7.	SH	AbbVie	Full	28	8	Please import the correct reference	Thank you for your comment. This was a reference to Table 2 that became corrupted during the transfer of the document to .pdf format. We have corrected this.
8.	SH	AbbVie	Full	29	3	Please import the correct reference	Thank you for your comment. This was a reference to Table 3 that became corrupted during the transfer of the document to .pdf format. We have corrected this.
9.	SH	AbbVie	Full	29	14	Please report that the cost of biopsy of distant metastases is an average cost of percutaneous biopsy of lesion of pleura, percutaneous biopsy of lesion of, lung or mediastinum, percutaneous transvascular biopsy of lesion of liver, percutaneous punch biopsy of lesion of liver, 19 years and over and image guided biopsy of lesion of bone, as per economic model	Thank you for your comment. This is explained in the main body of the text. For clarity, the information has now been added as a footnote to Table 3 as well.
10.	SH	AbbVie	Full	29	19, 26	Please import the correct reference	Thank you for your comment. This reference became corrupted during

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							the transfer of the document to .pdf format. We have corrected this.
11.	SH	Breast Cancer Now	Full	41	2 - 4	We support the inclusion of this new recommendation to ensure that patients whose hormone receptor status has changed between their primary and secondary diagnosis receive the appropriate treatment management.	Thank you for your comment.
12.	SH	Breast Cancer Care	Short	5	2 - 4	Breast Cancer Care supports the inclusion of this new recommendation in the Advanced Breast Cancer Guideline. Reassessment of oestrogen receptor (ER) and human epidermal growth factor 2 receptor (HER2) status at the point of recurrence is now more commonplace, and is widely viewed as good practice. This update brings the guideline in line with the NICE Breast Cancer Quality Standard, which includes the statement (statement 4): *'People with newly diagnosed invasive breast cancer and those with recurrent breast cancer (if clinically appropriate) have the oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status of the tumour assessed'* It is also consistent with the ABC 3 International Consensus Guidelines for Advanced Breast Cancer*: • *'A biopsy (preferably providing histology) of a metastatic lesion should be performed, if easily accessible, to confirm diagnosis particularly when metastasis is diagnosed for the first time.'* • *'Biological markers (especially HR and HER-2) should be reassessed at least once in the metastatic setting, if clinically*	Thank you for your comment.

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						feasible. Depending on the metastatic site (e.g. bone tissue), technical considerations need to be discussed with the pathologist' • *'If the results of tumour biology in the metastatic lesion differ from the primary tumor, it is currently unknown which result should be used for treatment-decision making. Since a clinical trial addressing this issue is difficult to undertake, we recommend considering the use of targeted therapy (ET and/or anti-HER-2 therapy) when receptors are positive in at least one biopsy, regardless of timing'* --- **Cardoso, F. et al (2016) 3rd ESO–ESMO international consensus guidelines for Advanced Breast Cancer (ABC 3), The Breast, Volume 31 , 244 – 259, available at:* http://dx.doi.org/10.1016/j.breast.2016.10.001 [Accessed 05/06/2017]	
13.	SH	Pfizer	Short	5	1	It is agreed that consideration should be given to re-testing for HR and HER2 status on recurrence considering the evidence presented in the full version of the consultation document that a change in receptor status could result in a change in management as more tailored approaches to pharmaceutical management based on receptor status are now available. Whilst the literature assessment in the full consultation document focussed on the potential benefits of conversion to HER2+ status, it is noteworthy that a resurgence of innovation in the HR+ space further highlights the importance of accurately knowing receptor status to make the right treatment decision. Indeed, the CDK4/6 inhibitors are an example of this with data showing that progression-free survival is significantly prolonged in combination with endocrine therapy vs endocrine therapy alone.	Thank you for your comment.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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Suggested responses to SH comments that raise implementation issues

- When general implementation issues are raised and cannot be addressed by the GDC – 'Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned'. We emphasise that the developers use their own tailored response when the implementation issues raised can be addressed through the guideline development process – e.g. by redrafting a recommendation etc.

- Examples of good practice received – send to christopher.bird@nice.org.uk and give the following standard response: 'Thank you for your response. We will pass this information to our local practice collection team. More information on local practice can be found here (enter hyperlink to shared learning or put in URL'.

- Examples of resources – send to Rebecca.tushingham@nice.org.uk and give the following standard response: 'Thank you for your response. We will pass this information to our resource endorsement team. More information on endorsement can be found here (enter hyperlink to endorsement scheme or put in URL'.

- When asked to produce tools/apps to support guideline – 'NICE routinely produce baseline assessment and resource impact tools. To encourage the development of other practical support tools, we run an endorsement scheme aimed at encouraging our partners to develop these in alignment with NICE recommendations. Eligible tools are assessed and if successful, will be endorsed by NICE and featured on the NICE website alongside the relevant guideline.'

Reminder to CfG – delete before goes to developer

- When issues are raised by GDCs we suggest that the guideline centre lead contacts Julie Royce (Julie.Royce@nice.org.uk) or Jo Farrington (Jo.Farrington@nice.org.uk) to agree a response. Sometimes these are straightforward issues that we can deal with ourselves. Other times we may need to allocate an adviser and ask for more information to understand the key issues before we could consider any proposals coming from GDCs for implementation activity. This information could either be submitted via our proposal template or by sending round the following questions to the committee:

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- What is the challenge that you think needs to be addressed and why is this challenging? (Please give a reference to the related NICE recs/quality standards). If you have highlighted more than one challenge please indicate which you think is the most significant and why.
- What do you think NICE could do to help?
- Are you aware of any interest or initiatives being taken by other national partners with whom NICE could work to tackle the problem?
- If NICE were able to carry out some support work to help overcome this challenge, which stakeholders should we ensure we work with?

- Guideline centre leads need to contact Stephen Brookfield (Stephen.Brookfield@nice.org.uk) the Associate Director for Resource Impact Assessment for the paragraph about implementation in the GE report as the support team no longer produce this.