

National Institute for Health and Clinical Excellence

Guidance Executive

Lapatinib for women with previously treated advanced or metastatic breast cancer

- 1 The Guidance Executive received a paper, on 22 December 2009, seeking approval, subject to consideration of a number of issues, for the publication of a Final Appraisal Determination, on the use of lapatinib for women with previously treated advanced or metastatic breast cancer.
2. The paper reported that the Appraisal Committee had considered the comparison of lapatinib plus capecitabine, with trastuzumab post-progression and that its view is that although trastuzumab is not licensed for the indication for which lapatinib is being appraised, the evidence provided suggests that trastuzumab is being used in the NHS in England and Wales post progression and therefore could be considered to be a valid comparator. The paper further reported that the Committee had noted the Appeal Panel's acceptance of the approach it had used to the method of establishing the cost-effectiveness of lapatinib versus trastuzumab. This method being an incremental analysis, in which the data provided by the sponsor suggested that although lapatinib plus capecitabine compared with trastuzumab containing regimens was cost effective in the base case, this was based on a comparison of trastuzumab versus capecitabine which the Committee did not consider to be cost effective. Finally, the paper reported that the Appraisal Committee had noted that comments from consultees argued that lapatinib could be a cost-saving option, particularly when including the proposed patient access scheme, with the added benefit of oral administration, when compared with continued use of trastuzumab, post-progression.
3. The Guidance Executive was also advised that that Appraisal Committee had been made aware that the Institute's clinical guideline recommended two approaches to the use of trastuzumab when the disease progresses; specifically:
 - For patients who are receiving treatment with trastuzumab for advanced breast cancer, discontinue treatment with trastuzumab at the time of disease progression outside the central nervous system; and
 - Do not discontinue trastuzumab if disease progression is within the central nervous system alone.

4. Although it was clear that the Appraisal Committee had followed a logical course in its approach to selecting the comparator, the Guidance Executive was concerned that it might not be the appropriate one in this appraisal. The Guidance Executive's concern is based on the fact that evidence, from the sponsor, other consultees and in the view of the National Cancer Director, trastuzumab is being used extensively post-progression. If this is the case, the Appraisal Committee should be mindful of the Institute's responsibility to provide the NHS with guidance, which makes the most effective use of its resources. Whilst this will normally require NICE guidance to recommend practice which an advisory body knows to be cost effective, there may be circumstances in which an intervention might represent an improvement in the effectiveness with which NHS funds are being used, even though those NHS funds themselves may not necessarily represent the most cost effective use of resources.
- 5 The Appraisal Committee will be aware of the severe economic circumstances facing the NHS over the next 5 years. NICE must ensure that its guidance remains relevant and credible. The Guidance Executive is concerned that in circumstances where there is a prima facie case for considering that a new technology might help the NHS make better use of resources than current standard practice, the option should be explored and only rejected where the wider interests of the NHS and the patients who rely on it for their care would clearly be damaged.
- 6 The Guidance Executive is conscious that the authority of the Appeal Panel and the clinical guideline relevant to this appraisal should be respected. In asking the Appraisal Committee to reconsider its position on the use of trastuzumab as the comparator in this appraisal, it is using its authority, delegated from the Board of the Institute, to ensure that guidance issued by NICE is fully compliant with the Directions issued to NICE by the Secretary of State in promoting clinical excellence and the effective use of resources.

Andrew Dillon
Chief Executive

January 2010