

Quick reference guide

Trastuzumab for the adjuvant treatment of early-stage HER2-positive breast cancer

1 Guidance

1.1 Trastuzumab, given at 3-week intervals for 1 year or until disease recurrence (whichever is the shorter period), is recommended as a treatment option for women with early-stage HER2-positive breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).

1.2 Cardiac function should be assessed prior to the commencement of therapy and trastuzumab treatment should not be offered to women who have a left ventricular ejection fraction (LVEF) of 55% or less, or who have any of the following:

- a history of documented congestive heart failure
- high-risk uncontrolled arrhythmias
- angina pectoris requiring medication
- clinically significant valvular disease
- evidence of transmural infarction on electrocardiograph (ECG)
- poorly controlled hypertension.

1.3 Cardiac functional assessments should be repeated every 3 months during trastuzumab treatment. If the LVEF drops by 10 percentage (ejection) points or more from baseline and to below 50% then trastuzumab treatment should be suspended. A decision to resume trastuzumab therapy should be based on a further cardiac assessment and a fully informed discussion of the risks and benefits between the individual patient and their clinician.

2 Implementation

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA107).

- Costing report and costing template to estimate the savings and costs associated with implementation.
- Audit criteria to monitor local practice.

NICE technology appraisal guidance 107

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Further information

Quick reference guide

This has been distributed to healthcare professionals working in the NHS in England and Wales (see www.nice.org.uk/TA107distributionlist). It is available from www.nice.org.uk/TA107quickrefguide

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1111).

Full guidance

This contains the following sections:

- 1 Guidance
- 2 The technology
- 3 The manufacturer's submission
- 4 Consideration of the evidence
- 5 Implementation
- 6 Recommendations for further research
- 7 Related guidance
- 8 Review of guidance.

The full guidance also gives details of the Appraisal Committee and the sources of evidence considered. It is available from www.nice.org.uk/TA107guidance

'Understanding NICE guidance'

Information for women with breast cancer and their carers is available from www.nice.org.uk/TA107publicinfo

For printed copies, phone the NHS Response Line on 0870 1555 455 (quote reference number N1112).

Related guidance

For information about NICE guidance that has been issued or is in development, see the website (www.nice.org.uk).

- Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care. *NICE clinical guideline* no. 14 (May 2004). Available from: www.nice.org.uk/CG014
- Guidance on the use of taxanes for the treatment of breast cancer (review). *NICE technology appraisal guidance* no. 30 (September 2001). Available from: www.nice.org.uk/TA030

NICE is in the process of developing the following guidance (details available from www.nice.org.uk).

- Docetaxel for the adjuvant treatment of early node-positive breast cancer. *NICE technology appraisal guidance* (publication expected September 2006).
- Paclitaxel for the adjuvant treatment of early node-positive breast cancer. *NICE technology appraisal guidance* (publication expected September 2006).
- Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care (partial update of CG14). *NICE clinical guideline* (publication expected October 2006).
- Hormonal therapies for early breast cancer. *NICE technology appraisal guidance* (publication expected November 2006).
- Breast cancer: diagnosis and treatment. *NICE clinical guideline* (publication expected July 2008).