

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE**1 Guideline title**

Advanced breast cancer: diagnosis and treatment

1.1 Short title

Advanced breast cancer

2 Background

- (a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Cancer to develop a clinical guideline on the diagnosis and treatment of breast cancer for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see appendix A).
Recommendations on early and advanced breast cancer will be developed in parallel. This document is the scope for the recommendations on advanced breast cancer. The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.
- (b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.
- (c) This guideline will support current national initiatives outlined in the 'NHS Cancer Plan', the 'Calman-Hine Report', the 'Cameron Report', the 'Manual of Cancer Service Standards for England' and the 'Wales Cancer Standards'. The guidelines will also refer to the

NICE service guidance 'Improving outcomes in breast cancer' and 'Improving supportive and palliative care for adults with cancer' and the clinical guideline 'Referral guidelines for suspected cancer'.

- (d) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

Breast cancer is the most common cancer for women in England and Wales, with about 37,000 new cases diagnosed^{1,2} and 11,000 deaths³ recorded in England and Wales each year. In men breast cancer is rare, with about 270 cases diagnosed^{1,2} and 70 deaths³ in England and Wales each year. Of these new cases in women and men, around 10% are diagnosed in the advanced stages, when the tumour has spread significantly within the breast or to other organs of the body. In addition, there is a significant number of women who have been previously treated with curative intent who subsequently develop either a local recurrence or metastases. Over recent years there have been important developments in the investigation and management of these patients including new chemotherapy, and biological and hormonal agents. There is some evidence of practice variation across the country and of patchy availability of certain treatments and procedures. A clinical guideline will help to address these issues and offer guidance on best practice.

4 The guideline

- a) The guideline development process is described in detail in two publications which are available from the NICE website (see 'Further information'). 'The guideline development process: an overview for

¹ Office for National Statistics (2005) *Cancer statistics registrations: registrations of cancer diagnosed in 2002, England*. Series MB1 number 33. London: National Statistics.

² Welsh Cancer Intelligence and Surveillance Unit (2005) *Cancer incidence in Wales 1992–2002*. Cardiff: Welsh Cancer Intelligence and Surveillance Unit.

³ Office for National Statistics (2003) *Mortality statistics: cause. England and Wales 2003*. London: The Stationery Office.

stakeholders, the public and the NHS' describes how organisations can become involved in the development of a guideline. 'Guideline development methods: information for national collaborating centres and guideline developers' provides advice on the technical aspects of guideline development.

- b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see appendix A).
- c) The scope forms the basis on which the work of a guideline development group (GDG) is planned and should be very clear about which patient groups are included and which areas of clinical care will be considered (sections 4.1–4.3).
- d) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

- a) Women and men with invasive adenocarcinoma of the breast of clinical stage 4 (i.e. with known metastatic disease).

4.1.2 Groups that will not be covered

- a) Women and men with invasive adenocarcinoma of the breast of clinical stages 1, 2 and 3 (this will be covered by the NICE guideline on 'Early breast cancer: diagnosis and treatment').
- b) Women and men with metastases to the breast from other primary tumours.
- c) Women and men with rare breast tumours (for example, angiosarcoma, lymphoma)

- d) Women and men with benign breast tumours (for example, fibroadenoma, benign phyllodes tumours).

4.2 Healthcare setting

- a) Primary care – excluding population-based and opportunistic screening.
- b) Secondary care.
- c) Tertiary care by specialist breast cancer teams.
- d) Palliative care services

4.3 Clinical management

- a) Investigation.
- b) Surgery.
- c) Radiotherapy.
- d) Hormonal therapy.
- e) Chemotherapy.
- f) Biological agents and other targeted therapies.
- g) Bisphosphonates.
- h) Management of lymphoedema.
- i) Patient information and communication.
- j) Supportive and palliative care.

4.4 Status

4.4.1 Scope

This is the final version of the scope.

4.4.2 Guideline

The development of the guideline recommendations will begin in June 2006.

5 Further information

5.1 Related NICE guidance

5.1.1 Published guidance

The following guidance will be cross referred to in the advanced breast cancer guideline as appropriate:

- Referral guidelines for suspected cancer. *NICE clinical guideline* no. 27 (2005). Available from: www.nice.org.uk/CG027
- 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 (2004). Available from: www.nice.org.uk/CG014
- Improving supportive and palliative care for adults with cancer. *Cancer service guidance* (2004). Available from: www.nice.org.uk/csgsp
- Improving outcomes in breast cancer – manual update. *Cancer service guidance* (2002). Available from: www.nice.org.uk/csgbc
- Bisphosphonates (alendronate, etidronate, risedronate), selective oestrogen receptor modulators (raloxifene) and parathyroid hormone (teriparatide) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. *NICE technology appraisal* no. 87 (2005). Available from: www.nice.org.uk/TA087
- Guidance on the use of trastuzumab for the treatment of advanced breast cancer. *NICE technology appraisal* no. 34 (2002). Available from: www.nice.org.uk/TA034

5.1.2 Guidance to be updated

The following NICE technology appraisals will be updated within this guideline and withdrawn when the guideline is published:

- Guidance on the use of capecitabine for the treatment of locally advanced or metastatic breast cancer. *NICE technology appraisal* no. 62 (2003). Available from: www.nice.org.uk/TA062
- Guidance on the use of vinorelbine for the treatment of advanced breast cancer. *NICE technology appraisal* no. 54 (2002). Available from: www.nice.org.uk/TA054
- Guidance on the use of taxanes for the treatment of breast cancer. *NICE technology appraisal* no. 30 (2001). Available from: www.nice.org.uk/TA030

5.1.3 Guidance in development

NICE is in the process of developing the following technology appraisal (details available from www.nice.org.uk). Recommendations from this technology appraisal will be incorporated in the advanced breast cancer guideline:

- Gemcitabine for the treatment of locally advanced or metastatic breast cancer. *NICE single technology appraisal*. (Publication expected October 2006.)

NICE is also in the process of developing the following guidance (details available from www.nice.org.uk) and these will be cross referred to in the advanced breast cancer guideline as appropriate:

- Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk. *NICE clinical guideline*. (Publication date to be confirmed.)
- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. *NICE technology appraisal*. (Publication expected April 2006.)
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women. *NICE technology appraisal*. (Publication expected April 2006.)

5.2 Guideline development process

Information on the guideline development process is provided in:

- 'The guideline development process: an overview for stakeholders, the public and the NHS'
- 'Guideline development methods: information for National Collaborating Centres and guideline developers'.

These booklets are available as PDF files from the NICE website (www.nice.org.uk/guidelinesprocess). Information on the progress of the guideline will also be available from the website.

Appendix A – Referral from the Department of Health

The Department of Health and Welsh Assembly Government asked the Institute:

‘To prepare a guideline for the NHS in England and Wales on the clinical management of breast cancer, to supplement existing service guidance. The guideline should cover:

- the key diagnostic and staging procedures
- the main treatment modalities including hormonal treatments
- the role of tumour-specific bisphosphonates.’