**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Proposed Health Technology Appraisal**

# INTRABEAM Photon Radiosurgery System for the adjuvant treatment of early or locally advanced breast cancer

**Draft scope (Pre-referral)**

## Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of the INTRABEAM Photon Radiosurgery System for the adjuvant treatment of early or locally advanced breast cancer during surgical removal of the tumour.

## Background

Breast cancer is the most common cancer in the UK accounting for about 1 in 3 of all cancers in women. In 2009, there were 43,183 diagnoses of breast cancer in England and Wales with approximately 95% of these being for early disease. When the cancer spreads outside the lining of the ducts, this is considered to be invasive early breast cancer and classified as stage I and II (or operable breast cancer). Breast cancer incidence rates generally increase with age; with 81% of new diagnoses in women aged over 50 years.

Treatment for early disease can be divided into primary treatment, which is surgical (removal of the tumour), and adjuvant treatment, which involves radiotherapy, hormone therapy, or chemotherapy after removal of the primary cancer by surgery. NICE clinical guideline no. 80 for early and locally advanced breast cancer recommends adjuvant chemotherapy or radiotherapy for people with early breast cancer following successful breast conserving surgery (that is, removal of tumour with clear margins) to prevent loco-regional recurrences. Adjuvant radiotherapy is currently delivered in UK clinical practice by external beam radiotherapy using a linear accelerator and an external beam tumour bed boost is used in people with high risk of local recurrence. NICE interventional procedures guidance no. 268 'Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision' only recommends brachytherapy as an adjuvant treatment in the context of research.

## The technology

INTRABEAM Photon Radiosurgery System (Carl Zeiss) is a mobile irradiation system designed to deliver a single dose of targeted low energy x-ray radiation directly to the tumour bed while limiting healthy tissue exposure to radiation.

INTRABEAM Photon Radiosurgery System has a CE marking for use in radiosurgery treatment and may be used as an alternative to whole breast radiation or as a boost before whole breast radiation is provided. It has been studied in a clinical trial as an intraoperative treatment in people undergoing

breast conserving surgery compared with conventional whole breast external beam radiotherapy provided after surgery. It has also been studied in people who underwent breast conserving surgery but had a high risk of local recurrence and received INTRABEAM as a boost during surgery followed by conventional whole breast external beam radiotherapy after surgery.

| | |
|---|---|
| **Intervention(s)** | INTRABEAM Photon Radiosurgery System with or without external beam radiotherapy |
| **Population(s)** | People with early or locally advanced operable breast cancer. |
| **Comparators** | • External beam radiotherapy delivered by linear accelerator |
| **Outcomes** | The outcome measures to be considered include:<br>• overall survival<br>• progression-free survival<br>• rate of recurrence<br>• adverse effects of treatment<br>• health-related quality of life. |
| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.<br>Costs will be considered from an NHS and Personal Social Services perspective. |
| **Other considerations** | Guidance will only be issued in accordance with the CE marking. |
| **Related NICE recommendations** | Related Technology Appraisals:<br>Technology Appraisal No. 112, November 2006, 'Hormonal therapies for the adjuvant treatment of early oestrogen-receptor positive breast cancer'. Transferred to static guidance list in October 2009.<br>Related Guidelines:<br>Clinical Guideline No. 80, February 2009, 'Breast cancer (early & locally advanced): diagnosis and |

| | |
|---|---|
| | treatment', Review proposal date: 2015.<br>Related Interventional Procedures:<br>Interventional Procedure No. 268, July 2008, 'Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision'. |

**Questions for consultation**

Has the most appropriate comparator for the INTRABEAM Photon Radiosurgery System for the adjuvant intraoperative treatment of early or locally advanced breast cancer been included in the scope? Are there any other comparators that should be included?

Aside from breast cancer, would the INTRABEAM Photon Radiosurgery System be used in other types of cancers in UK clinical practice?

Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which the INTRABEAM Photon Radiosurgery System has a CE marking;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Multiple Technology Appraisal (MTA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)