

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal

INTRABEAM Radiotherapy System for the adjuvant treatment of early breast cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of the INTRABEAM Radiotherapy System for the adjuvant treatment of early 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 2010, there were 44,266 people diagnosed with 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). Over 10,000 people died in England and Wales as a result of breast cancer in 2010. Breast cancer incidence rates generally increase with age; with over 80% of new diagnoses in women aged over 50 years. It is estimated that 95% of women are expected to survive their disease for at least 1 year and 85% of women survive 5 years or more.

Treatment for early disease can be divided into primary treatment, which is surgical (removal of the tumour), and adjuvant treatment, which can include radiotherapy, hormone therapy, biological therapies, or chemotherapy after removal of the primary cancer by surgery. NICE clinical guideline 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 may be supplemented with an external beam tumour bed boost. NICE interventional procedures guidance 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 Radiotherapy 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 Radiotherapy System has a CE marking for use in radiotherapy 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 Radiotherapy System with or without external beam radiotherapy
Population(s)	People with early operable breast cancer.
Comparators	External beam radiotherapy delivered by linear accelerator
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • overall survival • progression-free survival • ipsilateral local recurrence • adverse effects of treatment • 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. 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. 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: 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. Related Guidelines: Clinical Guideline No. 80, February 2009, 'Breast cancer (early & locally advanced): diagnosis and

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