



**Clinical Commissioning
Policy Statement:
Intra-Operative Radiotherapy
for the Treatment of Early
Breast Cancer**

**Reference: NHS England
B01/PS/b**

NHS England

Clinical Commissioning policy Statement: Intra- Operative Radiotherapy in the Treatment of Selected Patients with Early Breast Cancer

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POLICY STATEMENT:

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Intra-Operative Radiotherapy in the Treatment of Selected Patients with Early Breast Cancer

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Background:

From April 2013, NHS England is responsible for the commissioning of all forms of Radiotherapy. NHS England and the Radiotherapy CRG in collaboration with Cancer Research UK (CRUK) have published a vision for innovation in radiotherapy over the next ten years.

Breast cancer is the most common cancer in women in the UK and the incidence is increasing. Treatment for women diagnosed with breast cancer varies depending on the stage of the disease at presentation, but can include a combination of surgery, chemotherapy, radiotherapy and endocrine therapy.

The National Institute for Clinical Excellence (NICE) advises the use of adjuvant whole breast radiotherapy for all patients who undergo breast conserving surgery (BCS) due to the reduction in rates of local recurrence as compared to BCS alone. This form of treatment is thus considered the 'gold standard' for breast conserving therapy.

It has been established through examination of patterns of recurrence by experts in the field that it may only be necessary to treat the tumour bed with a margin in selected patients, as 85% of local recurrences occur at the site of the original tumour. This has led to research into the use of partial breast irradiation (PBI); treating the tumour site plus the adjacent breast tissue. This can be delivered using a variety of methods including external beam radiotherapy, brachytherapy and intra-operative radiotherapy.

The current clinical commissioning policies do not consider the use of Intra-operative radiotherapy in the treatment of

	early breast cancer.
Commissioning position:	NHS England does not routinely commission Intra-operative radiotherapy in the treatment of early breast cancer.
Effective from:	April 2014
Evidence summary:	<p>Intra-operative radiotherapy (IORT) is the application of therapeutic levels of radiation to a target area, such as a tumour, while the area is exposed during surgery. The treatment can be applied using low energy (0kv) x-rays, or with electrons (IOERT). These techniques are most commonly used in the treatment of breast cancer, but can be used for other tumours, e.g. cancer of the cervix.</p> <p>The clinical commissioning policy statement is confined to the use of IORT for the treatment of early breast cancer whilst further work is undertaken to scope and define other cancer types treated and technologies used.</p> <p>Intra-operative radiotherapy is emerging as a potential alternative to whole breast irradiation after breast conserving surgery. To date it has been undertaken in a small number of centres in England as part of a clinical trial.</p> <p>The National Institute for Clinical Excellence advises the use of adjuvant whole breast radiotherapy for all patients who undergo breast conserving surgery (BCS) due to the reduction in rates of local recurrence as compared to BCS alone. This form of treatment is thus considered the 'gold standard' for breast conserving therapy.</p> <p>TARGIT is an international, randomised controlled trial that aims to establish the non-inferiority of a single dose of radiotherapy delivered directly to the tumour bed at the time of surgery, in comparison with post-operative radiotherapy to the whole breast. 3451 patients were randomised and, with a mean follow up of 2.5 years, the 5 year ipsi-lateral breast recurrence (IBR) rates was 3.3% for the IORT arm and 1.3% for the EBRT arm representing an absolute difference in IBR of 2%.</p> <p>A small number of radiotherapy centres (predominantly in London) have provided intra-operative radiotherapy as part of an international randomised controlled trial (TARGIT A) which opened in 2000.</p> <p>Internationally, 3451 patients have been randomised within the TARGIT A trial - 1721 to the intra-operative arm (IORT)</p>

	<p>and 1730 patients to the EBRT arm. 15.2% of patients randomised to IORT required supplemental EBRT based on risk factors identified on final pathology. Approximately 440 of these patients were treated in hospitals in England</p> <p>The Radiotherapy Clinical Reference Group (CRG) had previously identified the need for a commissioning policy for this treatment modality whilst the publication of the TARGIT A data on the entire cohort was awaited. Essentially, it is important that the results demonstrate that intra-operative radiotherapy offers an equivalent tumour control rate as that of whole breast irradiation and does not increase the risk of mastectomy of the treated breast at a later date. The results of the TARGIT A trial with a mean follow up of 2.5 years have subsequently been published. The evidence is considered immature as a minimum 5 year follow up data is required in order to fully evaluate whether this form of treatment offers similar tumour control rates.</p> <p>Clarification of NHS England's commissioning position is required until the mature results (minimum five year follow up) TARGIT A trial data becomes available.</p>
Equality impact:	Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.
Responsible CRG:	Radiotherapy
Mechanism for Funding:	There is no expected change in service provision or numbers of patients treated anticipated as a result of adoption of this policy as the interim clinical commissioning policy recommends that IORT should not be routinely commissioned for patients with early breast cancer.
Date Approved	July 2014
Policy review date:	This clinical commissioning policy statement will be reviewed in October 2014 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

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