BREAST BRACHYTHERAPY
RAD605.017
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COVERAGE:

Brachytherapy is considered medically necessary for patients undergoing initial treatment for stage I or II breast cancer when used as local boost irradiation in patients who are also treated with:

• breast-conserving surgery, AND
• whole breast external beam radiotherapy.

Accelerated partial breast irradiation using brachytherapy is considered investigational or experimental when used:

• alone without surgical excision,
• in patients with stage I or II disease as the sole form of radiotherapy after breast conserving surgery, or
• for local boost irradiation when combined with whole breast radiotherapy but without surgical excision.

DESCRIPTION:

Breast conservation therapy (BCT) is a multi-modality alternative to mastectomy for treatment of early stage II or I breast cancer. In current practice, most conventional BCT includes breast-conserving surgical excision of the tumor and whole breast radiotherapy (WBRT), delivered using external beam radiation (EBR). In addition, "boost" radiotherapy more narrowly directed to the tumor bed is often performed. WBRT and boost radiation therapy are thought to reduce local breast recurrence by eliminating residual cancer at the surgical site as well as by treating potentially multicentric disease.

Breast brachytherapy, as an alternative to EBR therapy, has been researched in 2 general clinical settings.

1. As an alternative to external beam "boost" radiation therapy, in conjunction with WBRT and breast-conserving surgery.

2. As the sole form of radiation therapy after breast conserving surgery.

This more recent application of brachytherapy is based in part on the observation that the majority of ipsilateral breast recurrences after breast-conserving surgery and radiation therapy occur at or near the tumor bed, with only a small proportion of recurrences located in the remote breast. In trials of breast-conserving surgery without associated radiation therapy, the vast majority of recurrences also occurred at or near the tumor bed, suggesting that multicentric disease is not a common cause of recurrence. Together these findings suggest that the major benefit of EBR therapy is related to radiation...
of the tumor bed. EBR therapy is typically delivered in fractionated
doses over a course of 5-7 weeks. This extended treatment course may
not be feasible for some patients, for example those living in remote
locations, the elderly or disabled. Brachytherapy can be delivered
over a course of a week; this shortened treatment course may make
breast-conserving surgery an option for increased numbers of patients.

A variety of brachytherapy techniques have been developed, differing
in:
• the timing of implantation relative to other components of breast-
  conserving therapy,
• the dose rate,
• the loading technique, and
• the radioisotopes used.

Most older studies of local boost brachytherapy described temporary
implantation of the needles, wires, or seeds after recovery from
surgery and completion of whole breast radiation therapy. More
recently, investigators have used perioperative implantation of the
hollow needles and catheters that guide placement of the radioactive
material. This can be done during the initial lumpectomy if the
decision to use brachytherapy has already been made, or at the time of
a re-excision if the lumpectomy specimen has positive surgical
margins. Intraoperative implantation avoids the need for a separate
surgical procedure with anesthesia for brachytherapy. Both low-dose
rate and high-dose rate techniques have been used, with high-dose rate
techniques increasing in popularity. In the low-dose rate technique,
temporarily implanted radioactive seeds deliver radiation therapy
continuously over a course of 4 days and then are removed. This
treatment is generally given as an inpatient. In the
high-dose rate technique, a computer controlled device pushes a highly
radioactive isotope into a catheter that has been placed into the
tumor bed. The patient is exposed to the radiation therapy for a brief
period - 5 to 15 minutes - and then the radioactive source is
withdrawn. High-dose rate brachytherapy is typically administered on
an outpatient basis in 8 fractions given twice daily over 4 days.

RATIONALE:

Part of this policy is based in part on a 1996 BCBSA TEC Assessment
that offered the following observations and conclusions:

**Brachytherapy as "boost" therapy following WBRT:**

• While there are no randomized studies comparing brachytherapy to
  external beam radiation therapy as a local boost, analysis of 7
  nonrandomized retrospective studies that included 2,022 patients
permit scientific conclusions.

- Net health outcomes after brachytherapy for local boost are equivalent to those after EBR therapy for local boost in women given breast-conserving surgery and WBRT as initial treatment for stage I or stage II breast cancer.

Specifically, the rate of local control at 5 years after treatment was 88%-98% for those given brachytherapy for local boost compared to 91%-99% for those given EBR therapy.

**Brachytherapy as the sole form of radiation therapy in patients given breast-conserving surgery for stage I or stage II breast cancer:**

- Data were insufficient to determine if brachytherapy improves net health outcomes.

The literature published since this 1996 BCBSA TEC Assessment does not change the above conclusions regarding brachytherapy as the sole form of radiation therapy. There has been growing research interest, both as a technique to shorten the treatment time compared to WBRT and as a technique to improve cosmesis. For example, Vicini and colleagues reported on a series of 174 patients with stage I or II breast cancer who were treated with breast conserving surgery followed by brachytherapy alone to the tumor bed. To perform a matched pair analysis, each brachytherapy patient was matched for age, tumor size, nodal status, estrogen receptor status, and use of adjuvant modalities with a patient treated with EBR therapy. After a median follow-up of 3 years, there was no significant difference in ipsilateral treatment failure or local treatment failure between the 2 groups. Smaller studies have reported similar results with the authors reporting the importance of detailed patient selection criteria to select patients at low risk of multicentric disease. Studies that have reported conflicting results may have used less rigid patient selection criteria. For example, in the Guy's London trial 27 patients received an iridium implant to the primary tumor bed as sole radiation treatment. After a 6-year median follow-up the recurrence rate was 32%. However, 37% of the patients had positive tumor margins, which may have contributed to the high recurrence rate.

While there are some promising results regarding brachytherapy as the sole form of radiation therapy, larger studies with longer follow-up will be needed to determine if radiation to the whole breast can be safely withheld. In February 2001, recommendations issued by the American Brachytherapy Society stated that "... the use of brachytherapy as a sole [radiation] modality should be considered investigational..."
and should be performed in the context of a controlled clinical trial."

Part of this policy is based on a December 2002 TEC Assessment that offered the following conclusions:

The MammoSite™ RTS was cleared for marketing via 510 (k) in May 2002 as substantially equivalent to other commercially available brachytherapy applicators used with sealed radiation sources. The U.S. Food and Drug Administration (FDA) Office of Device Evaluation judged it reasonably likely that the device will be used in ways outside those specified in the proposed labeling, and that such use could cause harm. Therefore, the FDA required inclusion of the following statement in the “Warnings” section of the device’s labeling. “The safety and effectiveness of the MammoSite RTS as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.”

The available evidence is insufficient to permit conclusions, and it cannot be determined whether accelerated partial breast irradiation (APBI) using brachytherapy improves net health outcomes of women given breast-conserving surgery for early stage breast cancer.

The available evidence is insufficient to permit conclusions and it cannot be determined whether ACBI using brachytherapy is as beneficial as WB-EBRT after breast conserving surgery for early stage breast cancer.

PRICING:

None

REFERENCES:

- BCBSA TEC Assessment Program, Volume 11 #7 (July 1996) “Brachytherapy in Breast-Conserving Initial Treatment of Stage I or II Breast Cancer.”
- Perera F, Engel J, Holliday R et al. “Local resection and brachytherapy confined to the lumpectomy site for early breast
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