Accelerated partial breast irradiation as sole radiotherapy after breast-conserving surgery for early stage breast cancer

BlueCross BlueShield Association

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

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Citation

Authors' objectives
"To evaluate whether evidence shows that for women with tumors smaller than 2.3 cm, clean margins, and no more than 3 positive nodes, APBI as sole radiation post breast-conserving surgery improves net health outcomes at least as much as WB-EBRT.” (from executive summary)

Authors' conclusions
Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether accelerated partial-breast irradiation (APBI) as sole radiotherapy meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria to decrease recurrence after breast-conserving surgery for early stage breast cancer.

1. The technology must have final approval from the appropriate governmental regulatory bodies. Iodine-125 seeds were marketed prior to enactment of the 1976 Medical Device Amendments. Thus, they were cleared for marketing on a “grandfathered” basis. Subsequent radioactive isotope implants, including iridium-192, were approved via 510(k) as substantially equivalent to the radioactive iodine seeds. A number of breast brachytherapy devices have received U.S. Food and Drug Administration’s (FDA) 510(k) marketing clearance. 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 FDA’s 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." In December 2005, the FDA cleared for marketing the Axxent Electronic Radiotherapy device (Xoft, Inc., Fremont, CA) via 510(k) as substantially equivalent to the MammoSite and other brachytherapy systems. The Axxent® device is a balloon brachytherapy system that uses a disposable, microminiature radiation source to deliver the radiation rather than radioisotopes. Three additional devices used for breast brachytherapy recently received 510(k) clearance from the FDA. First is a remote-controlled radionuclide applicator system by BioLucent, Inc. (Aliso Viejo, CA), called the Strat-Adjusted Volume Implant or SAVI, which was cleared on October 20, 2006. This device is described by the manufacturer as a hybrid approach, combining interstitial brachytherapy and balloon brachytherapy. Like balloon brachytherapy, the device is inserted in the tumor cavity through a small incision. A bundle of catheters is then spread out to form an ellipsoid shape inside the cavity. Second is the Adjustable Multi-Catheter Source Applicator or ClearPath from North American Scientific, Inc. (Chatsworth, CA), which was cleared on November 9, 2006. The third is the SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy from SenoRx, Inc. (Aliso Viejo, CA), which was cleared on May 18, 2007.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The
Assessment sought to compare outcomes of APBI, with those of WB-EBRT, after breast-conserving surgery. Follow-up of at least 8 years is needed to demonstrate their equivalence. The single randomized, controlled trial reported follow-up of only 30 months, far short of the minimum needed. Other studies reported on longer follow-up but were uncontrolled, did not report on recurrences, included patients who did not meet the eligibility criteria, or had other important flaws. All of the studies that met the study selection criteria for this Assessment focused on interstitial brachytherapy, a technique with a steep learning curve for practitioners. These findings cannot be extrapolated automatically to other types of APBI. Consequently, the evidence on APBI as sole radiotherapy for early stage breast cancer is insufficient to permit conclusions concerning its effect on health outcomes.

3. The technology must improve the net health outcome. Since available evidence is insufficient to permit conclusions, it cannot be determined whether APBI as sole radiotherapy improves net health outcomes of women undergoing breast-conserving surgery for early stage breast cancer.

4. The technology must be as beneficial as any established alternatives. Since available evidence is insufficient to permit conclusions, it cannot be determined whether APBI as sole radiotherapy is as beneficial as WB-EBRT after breast-conserving surgery for early stage breast cancer.

5. The improvement must be attainable outside the investigational settings. Whether APBI using as sole radiotherapy improves health outcomes after breast-conserving surgery for early stage breast cancer has not been demonstrated in the investigational setting.

Based on the above, accelerated partial breast irradiation as the sole radiation treatment after breast-conserving surgery for early stage breast cancer does not meet the TEC criteria.

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