Cigna Medical Coverage Policy

Subject: Radiofrequency Ablation for Breast Cancer

Table of Contents
Coverage Policy .................................................. 1
General Background ........................................... 1
Coding/Billing Information ................................... 3
References .......................................................... 3

Hyperlink to Related Coverage Policies
Cryoablation of Breast Lesions
Emerging Breast Localization/Biopsy Procedures
Microwave Thermotherapy for Breast Cancer
Prophylactic Mastectomy

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Coverage Policy

Cigna does not cover radiofrequency ablation for the treatment of breast cancer because it is considered experimental, investigational or unproven.

General Background

Breast cancer is the most common form of cancer among women. In situ breast cancer is confined within the ducts (i.e., ductal carcinoma in situ) or lobules (i.e., lobular carcinoma in situ). Invasive or infiltrating carcinomas start in the ducts or lobules and invade the surrounding fatty tissue.

Treatment of breast cancer depends on the type and stage of cancer, patient’s age and comorbidities, and the risks and benefits associated with the various treatment options. Surgical intervention is the primary treatment option for most breast cancers and includes breast-sparing surgery (e.g., lumpectomy, segmental mastectomy, partial mastectomy) and total mastectomy. Surgical treatment may be combined with other therapies, such as chemotherapy, radiation therapy, immunotherapy and/or monoclonal antibody therapy.

The goal of breast-conserving treatment is to remove the malignant tumor and surrounding margin of tissue in the least invasive manner. Radiofrequency ablation (RFA) has been proposed as a less invasive alternative to surgical excision for breast cancer. RFA is performed by positioning a probe in the tumor using ultrasound guidance or computerized tomography (CT). Prongs, or electrodes, are extruded from the end of the probe and a current is emitted from the tips. The heating destroys the surrounding tissue by thermal coagulation and protein denaturation. Ablation times may vary based on breast size, tumor location, and composition and vascularity of the tissue. With variation in the prong array, a section of three to five centimeters (cm) can be...
treated. In most studies, general anesthesia has been administered, but in some clinical trials RFA has been successfully performed in an outpatient setting using local anesthesia (Agnese and Burak, 2005; Huston and Simmons, 2005; Fornage, et al., 2004; Burak, 2003; Singletary, et al., 2002).

RFA is generally well tolerated and may provide a better post-procedure cosmetic result compared to more invasive procedures. It has also been associated with minimal reported complications (e.g., minor pain, bruising, low-grade fever and skin burns). The major disadvantage of RFA is the inability to determine if the surrounding margin of tissue is free of viable cancer cells. RFA is not an established treatment modality for breast cancer.

**U.S. Food and Drug Administration (FDA)**

Ablation systems are approved by the FDA under the 510(k) process as a Class II electrosurgical cutting and coagulation accessory device. An example of this device is the Cool-tip™ RF Ablation System (Valleylab, Boulder, CO). The Cool-tip device is approved for use in “percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions and osteoma tumors” (FDA, 2006).

**Literature Review**

There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of RFA for the treatment of breast cancer. Available studies are primarily in the form of case series or retrospective reviews with small, heterogeneous patient populations, short-term follow-up, various tumor sizes, variations in selection criteria and RFA techniques, and do not compare RFA to established minimally invasive procedures. In many studies, viable tumor cells were present following ablation (Klimberg, et al., 2014; Shah, et al., 2013; Noguchi, et al., 2012; Wilson, et al., 2012; Palussiere, et al., 2012; Mackey, et al., 2012; Santoro, et al., 2012; Ohtani, et al., 2011; Kinoshita, et al., 2011; Tsuda, et al., 2011; Yamamoto, et al., 2011; Garbay, et al., 2008; Medina-Franco, et al., 2008; Earashi, et al., 2007; Khati, et al., 2007; Oura, et al., 2007).

Earlier studies reporting on RFA for the treatment of breast cancers included various tumor sizes: 2.0 cm or less (n=21) (Fornage, et al., 2004), 0.8-1.6 cm (n=10) (Burak, et al., 2003), less than 3.0 cm (n=23) (Hayashi, et al., 2003) and 0.7-3.0 cm (n=26) (Izzo, et al., 2001). In all studies viable cancer cells were found in patients following RFA. One study reported that three tumors had incomplete ablation of the index tumor (Hayashi, et al., 2003). RFA long-term outcomes are unknown and patient selection criteria have not been established.

Zhao and Wu (2010) conducted a systematic review of the literature to evaluate minimally-invasive thermal ablation, including radiofrequency ablation, for the treatment of breast cancer. Twelve studies utilizing radiofrequency ablation met inclusion criteria. Nine studies (n=5-34) were feasibility studies and reported complete coagulation necrosis in 76%–100% of patients who then underwent surgical excision. Three pilot studies (n=3–52) with short-term follow-ups (n=15–29.4 months) reported no breast cancer recurrence following RFA. Some patients were also treated with hormone or radiation therapy following RFA. The authors noted that long-term follow-ups of tumor regression and survival rates are unknown.

In a systematic review, van der Ploeg et al. (2007) identified over 150 articles on RFA for breast cancer. Only six phase II studies with an equal level of evidence met inclusion criteria for analysis and comparison. The studies were comprised of small patient populations (n=5–26) and involved tumors less than or equal to 3.0 cm, with the exception of one study that included five patients with 4–7 cm tumors. Surgical excision was performed immediately after or between weeks one and three following RFA. H&E was used to assess tumor margins, and NADH-diaphorase staining was used to assess cell viability. Complete tumor ablation was reported in 80–100% of cases. The authors stated that the studies were difficult to compare because of variations in selection criteria, RFA technique, time interval between RFA and surgical excision of the tumor, heterogeneity of breast size, tumor location, and composition and vascularity of the breasts. They also explained that more research is “clearly needed” to determine target temperature and duration of RFA, as well as shape, size and design of electrodes. Due to technical limitations, only small breast lesions are candidates for RFA. Additional research is needed to establish effects on surrounding tissue, recurrence rates, optimal technique and long-term effects.

**Professional Societies/Organizations**


**Use Outside of the US**
The European Society of Medical Oncology practice guideline for primary breast cancer does not mention radiofrequency ablation as a treatment for breast cancer (Senkus, et al., 2013).

Summary
There is insufficient evidence in the published, peer-reviewed scientific literature to support radiofrequency ablation (RFA) for the treatment of breast cancer. Limitations of the studies include small, heterogeneous patient populations, short-term follow-ups, and lack of comparison of RFA to established breast-conserving therapies. There are limited and variable outcome data on loco-regional and distant recurrence rates, as well as disease-free survival rates. Well-designed, prospective, randomized clinical trials are needed to determine the long-term outcomes and the effectiveness of RFA for the treatment of breast cancer.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Experimental/Investigational/Unproven/Not Covered when used to report radiofrequency ablation for breast cancer:

<table>
<thead>
<tr>
<th>CPT* Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>19499</td>
<td>Unlisted procedure, breast</td>
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References


