

Medical Coverage Policy



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Ablative Treatments for Malignant Breast Tumors

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Related Coverage Resources

[High Intensity Focused Ultrasound \(HIFU\) Hyperthermia \(eviCore-Cigna cobranded Radiation Therapy Clinical Guidelines\)](#)
[Laser Interstitial Thermal Therapy](#)

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Overview

This Coverage Policy addresses the following ablative treatments for malignant breast tumors: cryoablation, microwave thermotherapy, and radiofrequency ablation.

Coverage Policy

The following ablative treatments for malignant breast tumors are considered experimental, investigational or unproven:

- cryoablation
- microwave thermotherapy
- radiofrequency ablation

General Background

Treatment of breast cancer will depend upon 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 standard of care for most breast cancers. Surgical options include 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.

Less invasive breast cancer treatment modalities are currently being studied. Techniques being evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency. Ablation therapy uses heat or cold to destroy, or ablate, cancerous tumors without the need for more invasive surgery. Special probes are used to deliver ablative treatments directly to the tumor. The surgeon relies on imaging to guide the probes to the correct position and monitor the progress of the treatment. Ablation therapy has been proposed as a minimally invasive surgical alternative for the treatment of malignant breast tumors. It is also being studied for use in conjunction with breast-sparing surgery as well as for palliative use. This policy addresses three types of ablative treatments for malignant breast tumors:

- Cryoablation, also called cryosurgery or cryotherapy, is a procedure in which an extremely cold liquid or gas is used to freeze and destroy abnormal tissue. A cryoprobe is cooled with substances such as liquid nitrogen, liquid nitrous oxide, or compressed argon gas. The ablation process involves two phases: freezing and thawing, comprising of four mechanisms to destroy tumor cells: direct damage by intracellular ice formation and osmotic dehydration and indirect damage due to ischemia and immunologic response.
- Microwave thermotherapy or microwave therapy exposes the tumor to extremely high temperatures using electromagnetic waves to induce tumor destruction. It uses localized heating caused by water molecules which move within tissues, and externally applied focused microwaves to cause tissue necrosis. This technique can heat and damage high-water-content tumor cells, while tissues with lower-water-content such as adipose and breast glandular tissues remain unharmed.
- Radiofrequency ablation or RFA is a procedure that uses low frequency radio waves with a long wavelength to generate heat and cause coagulative necrosis. During RFA, a needle electrode is inserted to deliver an alternating current that generates ionic agitation, localized tissue heating and cell death. RFA differs from other techniques as the heat is not supplied by the probe itself, however this will lead to a limiting volume which can be ablated at a time and multiple probes are required for large lesions.

U.S. Food and Drug Administration (FDA)

There are numerous ablative devices approved by the FDA.

Literature Review

There is insufficient evidence to demonstrate that ablative treatments for malignant breast tumors, performed in lieu of or in conjunction with lumpectomy, is equivalent to current accepted treatment regimens that include lumpectomy or mastectomy in terms of survival, cancer recurrence or tissue response to adjuvant therapy. Studies are generally small prospective or retrospective case series with short-term follow-up, various tumor sizes, with variations in selection criteria and techniques, and primary end points that do not address long term survival.

Mauri et al. (2017) conducted a meta-analysis of 45 studies, including 1,156 breast cancer patients and 1,168 lesions. Radiofrequency (n=577; 50%), microwaves (n=78; 7%), laser (n=227; 19%), cryoablation (n=156; 13%) and high-intensity focused ultrasound (HIFU, n=129; 11%) were used. The rate of technical success was defined as the rate of patients in whom the operator was able to technically complete the ablation procedure; technical efficacy was defined as the rate of lesions completely ablated. The reference standard for complete ablation was histopathology of the excised specimen or imaging follow-up. Differences between techniques were not significant for technical success (p=0.449), major complications (p=0.181) or minor complications (p=0.762), but significant for technique efficacy (p=0.009). Pooled technique efficacy was 75% (radiofrequency=82%; cryoablation=75%; laser=59%; HIFU=49%). The authors concluded that imaging-guided percutaneous ablation techniques of breast cancer have a high rate of technical success, while technique efficacy remains suboptimal and complication rates are relatively low (6–8%).

Cryoablation: The American College of Surgeons Oncology Group Z1072 phase II trial explored the effectiveness of cryoablation in the treatment of breast cancers (Simmons, et al., 2016). The primary endpoint of Z1072 was the rate of complete tumor ablation, defined as no remaining invasive breast cancer (IBC) or ductal carcinoma in situ (DCIS) on pathological examination of the targeted lesion. All patients underwent surgical

resection following cryoablation. Of the 87 cancers treated with cryoablation and eligible for evaluation, central pathologic review revealed successful cryoablation in 66 (75.9 %) cancers and residual IBC and/or DCIS in 21 (24.1 %) cancers. Well-designed randomized trials are needed to better elucidate the role of cryoablation in multimodality treatment of breast cancer. Overall, the literature data are heterogeneous, as highlighted in a systematic review (Lanza, et al., 2015) who reported a variable local tumor control ranging from 19% to 95% (Pusceddu, et al., 2019).

Microwave Thermotherapy: There are few studies evaluating the use of microwave thermotherapy in the treatment of malignant breast tumors. Further investigation of the use of microwave thermotherapy, both as a preoperative heat-alone treatment to reduce positive margins for early-stage breast cancer and as a preoperative combination heat and chemotherapy treatment to reduce tumor volume for large breast cancer tumors to improve breast conservation, are needed (Zhou, et al., 2014; Dooley, et al., 2010; Vargas, et al., 2004; Gardner, et al., 2002).

Radiofrequency Ablation (RFA): In a small randomized trial, García-Tejedor et al. (2018) compared the safety and efficacy of RFA as a local treatment for breast cancer with that of lumpectomy in 40 women with invasive ductal carcinoma of the breast and tumor measuring 20 mm or smaller. Of the 40 patients, a study group of 20 underwent RFA and surgery and a control group of 20 underwent lumpectomy (without RFA). Results demonstrated the surgical margins were positive in 11 of the 20 participants in the lumpectomy group (55%) and four of the 20 in the RFA group (20%) ($p = .02$). Median follow-up was 25 months. The authors noted that the early termination of the study at the interim analyses meant that the target sample size for the main outcome was not reached.

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, various tumor sizes, varying RFA techniques, and do not compare RFA to established minimally invasive procedures. In many studies, viable tumor cells were present following ablation (Ito, et al., 2018; Klimberg, et al., 2014; Manenti, et al., 2013; Noguchi, et al., 2012; Palussière, et al., 2012; Ohtani, et al., 2011; Medina-Franco, et al., 2008; Garbay, et al., 2008; van der Ploeg, et al., 2007).

Professional Societies/Organizations

American Society of Breast Surgeons (ASBS): The ASBS Consensus Guideline on the Use of Transcutaneous and Percutaneous Methods for the Treatment of Benign and Malignant Tumors of the Breast (Revised October 16, 2018) includes the following recommendations:

Indications for percutaneous and/or transcutaneous ablative treatments of malignant tumors of the breast:

- ◆ Cryoablation is currently approved for treatment of benign and malignant soft tissue tumors by the FDA.
- ◆ Currently, there are no specific technologies that have FDA approval for breast tumors.
- ◆ Participation in registries and clinical trials evaluating the use of these technologies with and without surgical excision of a breast malignancy is advised as early data emerges on their efficacy.

Indications for percutaneous or transcutaneous ablative treatment of malignant tumors of the breast: At this time, there are no FDA approved percutaneous or transcutaneous ablative treatments for breast cancer. At the present time, cryoablation is approved for treatment of soft tissue malignancies. However, there is emerging data from clinical trials utilizing percutaneous ablative therapies for patients with early stage breast cancer without surgical excision. Techniques being evaluated include ablation by focused ultrasound, laser, cryotherapy, microwave, and radiofrequency. Percutaneous excision by vacuum-assistance is also being investigated.

National Comprehensive Cancer Network® (NCCN®): The NCCN Breast Cancer guideline (6.2020 — September 8, 2020) does not address cryoablation, microwave thermotherapy, or radiofrequency ablation.

National Cancer Institute (NCI): NCI Breast Cancer Treatment (PDQ®) Health Professional Version (updated September 2, 2020) does not mention cryoablation, microwave thermotherapy, or radiofrequency ablation.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative

No applicable information found.

Use Outside of the US

The 2019 European Society of Medical Oncology (ESMO) Clinical Practice Guidelines on Early Breast Cancer does not mention cryoablation, microwave thermotherapy, or radiofrequency ablation.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

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.

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
19499	Unlisted procedure, breast
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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