



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 \(eviCore-Cigna cobranded Radiation Oncology Guidelines\)](#)
[Laser Interstitial Thermal Therapy](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 not medically necessary:

- cryoablation
- microwave ablation
- radiofrequency ablation

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

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 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. Ablative techniques used in breast cancer may include cryoablation, radiofrequency ablation, microwave ablation, high-intensity focused ultrasound (US), and laser ablation. 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; however, none are approved for the indication of malignant tumors of the breast (ASBS, 2018).

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: Fine et al. (2021) conducted a prospective, multi-center, single-arm, non-randomized trial to evaluate the safety and efficacy of cryoablation on unifocal invasive ductal carcinoma. There were 194 participants included in the study with a mean age of 75 years. Participants with a tumor size of ≤ 1.5 cm were included in the trial if they were age 60 years or older and had a low-risk cancer profile (i.e., estrogen receptor positive and/or progesterone

receptor positive, human epidermal growth factor receptor 2 negative, low to intermediate histology grade, and lymph node negative). Participants were excluded if they had an extensive intraductal component, had multifocal and/or multicentric disease, had multifocal calcifications on mammogram, had prior surgical biopsy for diagnosis or treatment of the index lesion, had known coagulopathy or thrombocytopenia, or if they were receiving neoadjuvant therapy in any form. The primary outcome was ipsilateral breast tumor recurrence (IBTR) at five years.

- Fine et al. (2021) reported the interim results at three years. At 36 months, the IBTR rate was 0.52% (1/194 patients), 27 patients underwent adjuvant whole-breast radiation, one received chemotherapy, and 148 patients were prescribed endocrine therapy. Fifteen patients underwent post-cryoablation sentinel node biopsy and two were found to be positive. Adverse events were reported as mild or moderate and included: bruising, localized edema, skin freeze burn, rash, mild bleeding, local hematoma, skin induration, pain, and pruritis.

Author noted limitations of the study included the inability to generalize these results to a heterogeneous patient population and the fact that the study was industry-sponsored, single-arm, and non-randomized. Additional limitations of the study include the short-term follow-up and small patient population.

- Fine et al. (2024) reported 5-year results. At a mean follow-up period of 54.16 ± 13.07 months, the overall IBTR rate was 3.61% (7/194 patients). Based on the Kaplan–Meier estimate, the IBTR rate was 4.3% at 60 months, 1.7% at 48 months, and 0.6% at 36 months.

In addition to the seven reported ipsilateral recurrence cases, 2 patients had distant metastasis (one also had ipsilateral recurrence) and 4 patients had second primary breast cancer, with no regional recurrence, with a 5-year DFS rate of 92.8%, based on the survival analysis. The breast cancer survival rate was 96.7%, where 2 patients died due to distant metastasis from breast cancer and three for unknown reasons. The overall survival rate was 88.6% (82.9–92.5%), where all remaining patients died from comorbidities not related to breast cancer.

Of the 194 patients included in the study, 153 received adjuvant treatment, among whom 2.61% had a recurrence (4/153).

Of 194 patients, 32 patients were lost to follow-up or withdrew and were censored in the Kaplan–Meier estimates from their last clinical visit and 16 patients died of reasons unrelated to breast cancer.

The authors propose cryoablation may be considered as an alternative to lumpectomy for patients with low-risk, early-stage breast cancer, if followed by appropriate adjuvant treatment. Additional high-quality studies are needed to evaluate the safety and efficacy of cryoablation for the treatment of invasive ductal carcinoma of the breast.

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 pathologic 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).

Jean et al. (2025) reported a retrospective review that included 60 patients with primary breast cancer who were poor surgical candidates or who refused surgery and were treated with

cryoablation at a single academic cancer center. Of the 60, 45 had invasive ductal carcinoma (IDC), 6 patients had invasive lobular carcinoma, 2 patients had multicentric ductal carcinoma in situ (DCIS), and 7 patients had other histology. With a median follow up of 9.8 months (mean follow up of 21 months), there was a recurrence rate of 10% (6/60 patients). Patients in the recurrence group had more poorly differentiated disease than those in the non-recurrence group (66.7% vs. 22.2%, $p = 0.038$). Tumor size did not differ between non-recurrence and recurrence groups (no recurrence group mean 2.7 ± 2.6 cm, recurrence group mean 2.5 ± 1.0 cm, $p = 0.506$). Patients with recurrence had a longer follow up than those without recurrence (not significant). Patients with poorly differentiated disease had a higher risk of recurrence.

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): 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 (Xia, et al., 2021; Ito, et al., 2018; Klimberg, et al., 2014; Manenti, et al., 2013; Noguchi, et al., 2012; Palussière, et al., 2012; Ohtani, et al., 2011;

Xia et al. (2021) conducted a systematic review and meta-analysis of retrospective, non-comparative studies to evaluate the safety and efficacy of radiofrequency ablation (RFA) for the treatment of breast cancer < 2 cm. There were 17 studies with 399 participants and 401 lesions included in the review. The mean follow-up time for evaluation of local recurrence ranged from 9–88 months. Technical success rates ranged from 86.67%–100%. There were seven incomplete ablations attributed to incorrect probe placement, poor ultrasound imaging, uncooperative patients, and intolerable pain. The majority of patients underwent surgical tumor excision after RFA (65.74%) and of these patients, 45.21% received immediate excision. Of those patients who underwent surgical tumor excision after ablation, 92.34% underwent tumor resection with the remainder undergoing total mastectomy.

Of the 136 patients who did not undergo resection, 133 received postoperative adjuvant radiotherapy. The complete ablation rate ranged from 66.7%–100%. There were no reports of local recurrence reported in those studies ($n=10$ studies) that included this outcome ($n=232$ participants) at a median follow-up of 27.29 months regardless of whether or not the participant underwent surgical resection following RFA. Of the 401 lesions included in the study, 27 developed complications (6.8%). The authors noted limitations of the review included small sample sizes and short-term follow-up for local recurrence rates. Additional high-quality, prospective studies are needed to evaluate the safety and efficacy of RFA for the treatment of breast cancer.

In a small, randomized trial, Garcia-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.

Professional Societies/Organizations

National Comprehensive Cancer Network® (NCCN®): The NCCN Breast Cancer guideline (Version 1.2025 — January 31, 2025) does not address cryoablation, microwave thermotherapy, or radiofrequency ablation.

National Cancer Institute (NCI): NCI Breast Cancer Treatment (PDQ®) Health Professional Version (updated December 6, 2024) does not mention cryoablation, microwave thermotherapy, or radiofrequency ablation.

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.

Medicare Coverage Determinations

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

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary:

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®) ©2024 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<ul style="list-style-type: none"> No clinical policy statement changes. 	4/15/2025
Annual Review	<ul style="list-style-type: none"> No clinical policy statement changes. 	3/15/2024

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