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)
Laser Interstitial Thermal Therapy

INSTRUCTIONS FOR USE

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Overview

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

Coverage Policy

The following ablative treatments for malignant breast tumors are considered not medically necessary:

- Cryoablation
- Percutaneous laser ablation
- Microwave ablation
- Radiofrequency ablation

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
0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral

General Background

Breast cancer is the most common malignancy among females in the United States and a leading cause of cancer-related mortality. Management is highly individualized, depending on cancer type

and stage, patient age, comorbidities, and a careful assessment of risks and benefits for each treatment option. Surgical intervention is the standard of care for most patients, with options including breast-conserving surgery and total mastectomy, selected based on tumor characteristics, patient preference, and other clinical factors. Surgery is frequently combined with other treatment modalities, including radiation therapy, systemic therapies, targeted therapies, and immunotherapy to optimize outcomes and reduce recurrence risk. The selection and sequencing of these therapies are guided by tumor biology, disease stage, and patient-specific factors. Multidisciplinary evaluation and shared decision-making are emphasized to ensure individualized care (NCCN, 2025).

Ablative treatments for malignant breast cancer, including cryoablation, percutaneous laser ablation, microwave ablation, and radiofrequency ablation (RFA), are emerging as promising alternatives to traditional surgery, particularly for early-stage disease. These minimally invasive treatments may help lower rates of infection and bleeding, shorten recovery time, allow for earlier initiation of adjuvant therapies, decrease pain, and provide improved cosmetic results. However, despite these potential advantages, ablative treatments are not currently considered a standard of care for malignant breast cancer. Technological advancement and more robust prospective studies with longer follow-up are needed to confirm the safety, efficacy, and role of ablative treatments compared to surgery (Carriero, et al., 2024).

Cryoablation

Cryoablation is an emerging and minimally invasive surgical technique for the treatment of malignant breast tumors. During the procedure, one or more cryoprobes are inserted percutaneously, often under ultrasound (US) guidance, at the center of a malignant breast tumor. The probes deliver alternating cycles of freezing and thawing using liquid nitrogen or argon gas. Cryoablation is intended to cause localized tumor destruction through dehydration, swelling, and rupture of cancerous cells (Carriero, et al., 2024).

U.S. Food and Drug Administration (FDA) – Cryoablation

On October 3, 2025, the ProSense Cryoablation System (IceCure Medical) received FDA De Novo authorization (DEN220077). This system is classified by the FDA as a cryoablation device for local treatment of low-risk breast cancer (Class: II) (Product Code: QXW). The FDA noted the following indications for use:

- "ProSense cryoablation system is indicated for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy, including patients not suitable for surgery for breast cancer treatment."
- "Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5 cm, [estrogen receptor–positive] ER-positive, [progesterone receptor] PR-positive, [human epidermal growth factor receptor 2] HER2-negative, Ki-67<15% and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma [IDC] (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0)."

The FDA (2025) also noted the following limitations for the ProSense Cryoablation System:

- "ProSense's safety and effectiveness for breast cancer treatment were evaluated in a single-arm trial with 5 years follow up. Breast cancer treatment outcomes following cryotherapy have not been studied in direct comparison to surgical excision (e.g., lumpectomy)."

- "Breast cancer treatment outcomes including recurrence rates, disease-free survival [DFS], and overall survival after use of this device are unknown beyond 5 years."
- "Unlike surgical removal of the tumor (e.g., lumpectomy) where there is a specimen for pathology to confirm whether the tumor was completely removed, cryoablation relies on imaging to determine if the tumor was destroyed. However, the exact boundaries may not
- be visible on imaging which can result in incomplete destruction of the tumor."
- "The recurrence rate is being further evaluated in a larger patient population through an ongoing post-market study."
- "ProSense cryoablation system is not intended as a treatment for recurrent breast cancer."
- "ProSense cryoablation system is not intended for patients in whom neo-adjuvant chemotherapy and/or biological therapy or other targeted neo-therapies apart from endocrine therapy are indicated."
- "ProSense cryoablation system is not intended as a treatment for breast cancers with inflammatory features."
- "Only patients with adequate breast size can undergo safe breast cancer treatment with ProSense cryoablation system."
- "Practices of cryoablation for women with breast implants have not been established. For patients with breast implants, you must document that adequate distance exists between the lesion and the implant to ensure that the ablated lesion will not contact or jeopardize the implant, and there is enough space to create the required margins."

Device or Product	Identifier	Manufacturer	Decision Date
ProSense Cryoablation System	DEN220077	IceCure Medical	10/3/2025

*FDA product codes: QXW

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review - Cryoablation

Currently, there is insufficient high-quality evidence in the published, peer-reviewed, scientific literature to support the safety, efficacy, and clinical utility of cryoablation for the treatment of malignant breast tumors (Galati, at al., 2024; Kawamoto, et al., 2024; Roca Navarro, et al., 2024; Fine, et al., 2024; Fine, et al., 2021; Simmons, et al., 2016). Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions (Tan, et al., 2024; Pusceddu, et al., 2019; Mauri, et al., 2017; Lanza, et al., 2015). These limitations include small sample sizes, limited number of studies, heterogeneity in study design and patient selection, short and variable follow-up durations, lack of randomized controlled trials and comparative data, inconsistent outcome assessment and reporting, and technical and procedural variability.

Tan et al. (2024) conducted a systematic review and meta-analysis to evaluate local recurrence and residual tumor rates in small early-stage breast cancers following cryoablation. The systematic review included seven studies involving 530 female individuals (531 breast tumors) who received cryoablation only, and five studies involving 220 female individuals (222 breast tumors) who received cryoablation followed by surgery. Nine studies were prospective single-arm, two studies were retrospective single-arm, and one study was retrospective and compared cryoablation to RFA. Interventions included US-guided cryoablation either as definitive treatment or as a preoperative procedure prior to lumpectomy or mastectomy. No studies directly compared cryoablation with breast-conserving surgery. Studies meeting the following criteria were included

in the systematic review: tumors ≤ 20 mm, early-stage breast cancer per National Cancer Institute definition, treatment with cryoablation, and reporting of local recurrence (no surgery) or residual tumor in surgical specimens (surgery). Studies of tumors > 20 mm, lobular histology, locally advanced or metastatic disease, or recurrent tumors were excluded. The primary outcomes were pooled local recurrence (cryoablation-only) and pooled residual tumor (cryoablation followed by surgery), each estimated using mixed-effects models. Follow-up duration across studies ranged from 1 to 104 months. Attrition or subjects lost to follow-up were not reported. The study results revealed that for the cryoablation-only studies, the pooled local recurrence was 1.1% (95% CI 0.42 to 3.03%) with low heterogeneity (I^2=0%; p=0.95). For cryoablation followed by surgery, the pooled residual tumor rate was 12.0% (95% CI 3.85 to 31.64%). However, substantial heterogeneity between studies was noted (I^2=76.1%; 95% CI 41.7 to 90.2%; p<0.01). A sensitivity analysis excluding one outlier yielded 8.2% (I^2=0%; 95% CI 3.84 to 16.68%; p=0.64). Across cohorts, no major procedure-related adverse events were reported. Overall, the authors concluded that the cryoablation outcomes were encouraging. Local recurrence rates after breast-conserving treatment, and residual tumor rates for cryoablation followed by surgery appeared comparable to re-excision rates following breast-conserving surgery. However, definitive conclusions await comparative studies. Limitations of the systematic review noted by the authors include the absence of comparative trials against breast-conserving surgery, the analysis had to be split between studies with and without surgical excision, the small number of studies precluded subgroup or meta-regression analyses, and the short follow-up duration in the cryoablation-only cohort. Additionally, blinding was limited for both imaging and pathology review, many studies were rated as low quality, one study was abstract only, and no randomized controlled trials or direct comparative studies were included.

Galati at al. (2024) conducted a prospective pilot case-control study to evaluate US-guided cryoablation for early-stage invasive breast cancer in adults scheduled for definitive surgery. The study included 20 participants: 10 with a cryo-feasible tumor location who underwent cryoablation prior to surgery and 10 that underwent surgery alone (control group). Eligibility required age ≥18 years, a single biopsy-proven T1 N0 invasive tumor ≤20 mm, US visibility, minimum distances from skin and nipple, and not eligible for neoadjuvant therapy. A histological diagnosis of pure ductal carcinoma in situ (DCIS), lesions where microcalcifications were the only mammographic evidence of breast cancer, any previous history of breast cancer in either breast, the presence of breast implants, contraindications to contrast media, inability to undergo cryoablation, pregnancy, breastfeeding, or recent childbirth were all reasons for exclusion. Primary outcomes included technical efficacy (histologic necrosis and complete ablation rate), safety (complications), and patient satisfaction. A secondary endpoint assessed prediction of ablation efficacy using magnetic resonance imaging (MRI) or contrast-enhanced mammography (CEM). All participants underwent surgery within 21 days of study enrollment. Satisfaction was assessed within 10 days after surgery. Pathology showed steatonecrosis in all 10 cryoablation cases with complete ablation in nine of 10. No serious complications were observed. Two post-ablative hematomas resolved within one week. Post-procedural MRI/CEM correctly predicted the presence or absence of residual disease in nine participants and demonstrated a negative predictive value of 8/8 (100%). Participants were observed to have responded positively to satisfaction questionnaires. The authors concluded that US-guided cryoablation of early-stage breast cancer was well accepted by participants, effective, and safe. Additionally, MRI and CEM were able to predict technical efficacy. Limitations of the study include the single-center design, small sample size, and lack of long-term follow-up.

Kawamoto et al. (2024) conducted a prospective follow-up study to evaluate the efficacy, safety, patient satisfaction, quality of life (QOL), and cosmetic outcomes of percutaneous US-guided cryoablation for early-stage primary breast cancer in Japan. The study was a continuation of a smaller pilot study previously reported by Kawamoto et al. (2021). The current study included 18 female participants (mean age: 59 years) who underwent US-guided percutaneous cryoablation,

followed by radiation and endocrine therapy. Inclusion criteria included adult women aged 20 to 85 years with a diagnosis of unifocal IDC, Eastern Cooperative Oncology Group Performance Status 0 or 1, HER2 negative, K-67 positivity < 20%, unifocal primary lesion detectable by mammography, US, or MRI, lesion size < 15 mm, negative sentinel lymph node biopsy results, and amenable to radiation therapy. Participants with invasive lobular carcinoma (ILC), invasive micropapillary carcinoma, intraductal lesions, and lesions within 5 mm of the skin or pectoralis major muscle were excluded. Outcomes were measured using imaging modalities (mammography, US, or MRI) at multiple timepoints up to 60 months, as well as patient-reported satisfaction and health-related QOL using standardized and validated questionnaires, and Moré topography. The mean follow-up was 44.3 months. The study results revealed no local recurrence or distant metastasis. Cosmetic outcomes, participant satisfaction, and QOL scores improved post-procedure. No serious adverse events were reported. Minor adverse events included transient skin redness and asymptomatic pectoralis muscle burns that were resolved spontaneously. The authors concluded that cryoablation for early-stage primary breast cancer was an effective and safe procedure with positive cosmetic and QOL outcomes. Limitations of the study include the single-center design, small sample size, and lack of a comparator.

Roca Navarro et al. (2024) conducted a prospective single-center study to determine the success of US-guided cryoablation in achieving the absence of residual invasive cancer (RIC) for participants with ER-positive/HER2-negative IDC ≤ 2cm and sonographically negative axillary nodes. The study included 59 female participants (mean age: 63 ± 8 years) and 60 IDCs. All participants underwent US-guided cryoablation as an initial intervention, followed by a scheduled lumpectomy. Inclusion criteria required patients to be aged 18 years or older, suitable for breast-conserving surgery, with no need for primary systemic therapy, and radiologically confirmed negative axillary status. Exclusion criteria included extensive intraductal tumor components, HER2-positive luminal tumors, or axillary involvement. The primary outcome was the absence of RIC in post-cryoablation lumpectomy specimens, with secondary outcomes including adverse events and statistical correlation between RIC and study variables. All tumors were tagged with ferromagnetic seeds and treated using a triple-phase Argon-based cryoablation protocol. The average interval between ablation and lumpectomy was 22 days. Pathological analysis revealed RIC in only one of 38 pure IDC cases and in four of 22 mixed IDC/DCIS cases. Clear surgical margins were observed for all treated tumors. Mild adverse events were reported in 7% of cases, including mild discomfort, moderate to severe pain requiring oral analgesia and anti-inflammatory medication, and one skin vesicle. No significant procedural complications were reported. The authors concluded that cryoablation was effective in eradicating 97% of pure infiltrating ER-positive/HER2-negative tumors ≤ 2cm and demonstrated potential as a surgical alternative in select patients. Limitations of the study include single-center design, small sample size, absence of a comparator, and lack of long-term follow-up.

Fine et al. (2021) conducted a prospective, multi-center, single-arm, non-randomized trial to evaluate the safety and efficacy of cryoablation on unifocal IDC. 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 aged 60 years or older and had a low-risk cancer profile (i.e., ER-positive and/or PR-positive, HER2-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 interim trial results. At 36 months, the IBTR rate was 0.52% (1/194 participants), 27 participants underwent adjuvant whole-breast radiation, one received chemotherapy, and 148 participants were prescribed endocrine therapy. Fifteen participants 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 pruritus. 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 the 5-year trial results. At a mean follow-up of 54.16 ± 13.07 months, the overall IBTR rate was 3.61% (7/194 patients). Based on a 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, two participants had distant metastasis (one also had ipsilateral recurrence), and four participants had second primary breast cancer, with no regional recurrence. The 5-year DFS rate was 92.8%, based on the survival analysis. The breast cancer survival rate was 96.7%, where two participants died due to distant metastasis from breast cancer and three for unknown reasons. The overall survival rate was 88.6% (82.9 to 92.5%), where all remaining participants died from comorbidities not related to breast cancer. Of the 194 participants included in the study, 153 received adjuvant treatment, among whom 2.61% had a recurrence (4/153). Of 194 participants, 32 were lost to follow-up or withdrew and were censored in the Kaplan-Meier estimates from their last clinical visit and 16 participants died of reasons unrelated to breast cancer. The authors concluded that cryoablation may be considered as an alternative to lumpectomy for patients with low-risk, early-stage breast cancer, if followed by appropriate adjuvant treatment. However, additional high-quality trials or registries are needed to confirm these findings.

Mauri et al. (2017) conducted a systematic review and meta-analysis of 45 studies, including 1,156 patients with breast cancer 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 for breast cancer have a high rate of technical success, while technique efficacy remains suboptimal and complication rates are relatively low (6 to 8%).

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 or 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 invasive breast cancer and/or DCIS in 21 (24.1 %) cancers. The authors concluded that the study supported the potential use of office-based, US-guided cryoablation in this population. However, additional high-quality studies are warranted to optimize cryoablation as a non-surgical alternative for breast cancer treatment. Limitations of the study include lack of control or comparator group, limited follow-up duration, and adverse events not reported.

Percutaneous Laser Ablation

Percutaneous laser ablation is a minimally invasive surgical technique, currently under clinical investigation for the treatment of malignant breast tumors. During the procedure, a cooled laser fiber is inserted percutaneously and guided to the malignant breast tumor using mammography, US, or MRI. Laser electromagnetic radiation is then delivered, intending to cause irreversible

thermal damage and destruction of tumor cells, while minimizing these effects on the surrounding healthy tissue. (Carriero, et al., 2024)

U.S. Food and Drug Administration (FDA) - Percutaneous Laser Ablation

There are currently no percutaneous laser ablation devices specifically approved by the FDA with an indication for the treatment of malignant breast tumors.

Literature Review - Percutaneous Laser Ablation

Currently, there is insufficient high-quality evidence in the published, peer-reviewed, scientific literature to support the safety, efficacy, and clinical utility of percutaneous laser ablation for the treatment of malignant breast tumors. Existing systematic reviews are constrained by the limitations of the available studies, which substantially weaken the strength of the conclusions Matsumoto and Facina, 2025).

Matsumoto and Facina (2025) conducted a systematic review of the existing literature evaluating percutaneous laser ablation for treatment of early breast cancer. The review assessed methodologies, patient selection criteria, and effectiveness compared to surgical treatments. Seventeen original studies (n=308) were included in the analysis. Reviews, editorials, and animal/in vitro studies were excluded. The complete ablation rate was approximately 74.4% in studies that reported this outcome. MRI was determined to be the best modality for evaluating results, with a negative predictive value of 92 to 100%. The most common complication was skin burns (6%). Less frequent complications included hematoma, pain, nodulation, erythema, seroma, and fat necrosis. The following recommendations for patient selection for futures studies were suggested: tumors less than 2 cm, 0.5 cm from skin/chest wall, pure IDC, absence of associated DCIS or ILC. The authors concluded that the use of percutaneous laser ablation remains restricted to cases with specific indications, or within the context of research protocols, and future studies aimed at standardizing this procedure as a standalone local treatment option in selected patients are needed. Limitations of the systematic review include the absence of standardized protocols across the included studies, inconsistent reporting of adverse events, and limited availability of long-term follow-up data.

Microwave Ablation

Microwave ablation, also known as microwave thermotherapy, is an emerging surgical technique, currently under clinical investigation for the treatment of malignant breast tumors. The technique uses electromagnetic radiation to agitate water molecules within a malignant breast tumor, generating heat and intending to result in coagulative necrosis (cancer cell destruction). Healthy cells surrounding the tumor, such as breast adipose tissue, may be spared from destruction due to their lower water content. In studies of breast cancer, microwave ablation has been performed using external applicators that compress the breast between two phased array waveguides and minimally invasive percutaneous methods (Carriero, et al., 2024; Sabel, 2014).

U.S. Food and Drug Administration (FDA) - Microwave Ablation

There are currently no microwave ablation devices specifically approved by the FDA with an indication for the treatment of malignant breast tumors.

Literature Review - Microwave Ablation

Currently, there is insufficient high-quality evidence in the published, peer-reviewed, scientific literature to support the safety, efficacy, and clinical utility of microwave ablation for the

treatment of malignant breast tumors. Some preliminary studies have demonstrated technical feasibility, but are limited by small sample sizes, lack of control groups, and absence of long-term follow-up. (Ji, et al. (2024; Zhou, et al., 2014; Dooley, et al., 2010; Vargas, et al., 2004; Gardner, et al., 2002).

Ji et al. (2024) conducted a prospective, non-randomized study to evaluate the technical success and safety of magnetic resonance-guided percutaneous microwave coagulation (MR-guided PMC) for breast malignancies. The study included 26 female participants (age: 52.0 ± 12.2; range: 31 to 75) with core-needle biopsy-proven unifocal breast cancer by US; with unifocal, lump-like appearing tumors, less than 2.0 cm in diameter confirmed by MRI; with at least 1 cm between the tumor, skin surface, and pectoralis muscle; and with no enlarged lymph nodes or distant metastases in ultrasonic axillary examination and computed tomography staging. Participants were excluded for pregnancy or lactation; presence of more than one breast lesion; or preference to undergo breast-conserving surgery. The primary endpoint was treatment efficacy, assessed by histopathological examination following prescheduled mastectomy. Using a local anesthetic, microwave generator, and internal water-cooled shaft antenna, all participants underwent MR-guided PMC. The study results revealed that all participants achieved complete response with no residual carcinoma on histopathological examination. During the procedure, 14 participants required an extended ablation time because real-time MRI showed that the safety margins were insufficient. Additionally, one patient required repositioning of the antenna during the procedure to ensure that the ablation zone completely encompassed a large, irregularly shaped breast tumor. Three participants reported pain during ablation and were treated intraoperatively with lidocaine. One participant was treated with ibuprofen for pain within 2 days post-procedure. Induration around the ablation area due to swelling and fibrosis occurred in 16 participants. However, this was not considered an adverse event by the authors as the affected participants reported this occurrence as psychologically acceptable. The authors reported that all of the participants were satisfied with the post-procedure cosmetic outcomes. The authors concluded that MR-guided PMC was a feasible, safe, and accurate minimally invasive treatment for small breast tumors. However, additional research is needed to broaden applicability and address long-term outcomes. Limitations of the study include the single-center design, small sample size, lack of a comparator, and absence of long-term follow-up.

Radiofrequency Ablation (RFA)

Radiofrequency ablation (RFA) is a widely used and minimally invasive surgical technique that has also been investigated as a treatment for malignant breast tumors. During RFA, one or more electrodes are positioned percutaneously to the malignant breast tumor using image guidance. Radiofrequency waves are then delivered, generating thermal energy that is intended to cause a highly targeted area of coagulative necrosis and destruction of cancer cells, while minimizing damage to surrounding healthy tissue (Carriero, et al., 2024).

U.S. Food and Drug Administration (FDA) - RFA

There are currently no RFA devices specifically approved by the FDA with an indication for the treatment of malignant breast tumors.

Literature Review - RFA

There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of RFA for the treatment of malignant breast tumors (Garcia-Tejedor, et al., 2018). 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 treatments. 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 RFA for the treatment of breast cancer < 2 cm. There were 17 studies with 399 individuals and 401 lesions included in the systematic review. The mean follow-up time for evaluation of local recurrence ranged from 9 to 88 months. Technical success rates ranged from 86.67% to 100%. There were seven incomplete ablations attributed to incorrect probe placement, poor US imaging, uncooperative individuals, and intolerable pain. The majority of individuals underwent surgical tumor excision after RFA (65.74%) and of these, 45.21% received immediate excision. Of those individuals who underwent surgical tumor excision after ablation, 92.34% underwent tumor resection, with the remainder undergoing total mastectomy. Of the 136 individuals who did not undergo resection, 133 received postoperative adjuvant radiotherapy. The complete ablation rate ranged from 66.7% to 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 systematic review, 27 developed complications (6.8%). The author noted limitations of the systematic review include 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 IDC of the breast and tumors measuring 20 mm or smaller. Of the 40 participants, 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=0.02). 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®): NCCN (2025) guidelines for breast cancer, which include the clinical management of patients with carcinoma in situ, invasive breast cancer, Paget disease, Phyllodes tumor, inflammatory breast cancer, male breast cancer, and breast cancer during pregnancy, do not include cryoablation, percutaneous laser ablation, microwave ablation, or RFA.

National Cancer Institute (NCI): In a comprehensive summary of peer-reviewed, evidence-based information regarding the treatment of adult breast cancer, NCI (2025) does not address cryoablation, percutaneous laser ablation, microwave thermotherapy, or RFA.

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.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• No clinical policy statement changes.	3/15/2026
Focused Review	• Added percutaneous ablation to policy and added new code: 0971T	10/15/2025
Annual Review	• No clinical policy statement changes.	4/15/2025
Annual Review	• No clinical policy statement changes.	3/15/2024