Medical Coverage Policy

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Coverage Policy Number..... 0540

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

General Background

According to the U.S. Cancer Statistics Working Group (2023), 1,248,749 women were diagnosed with breast cancer between 2016 and 2020. Of these women, 914,472 were white and 145,630 were Black. The five year, all races and all ethnicities relative survival is 90%. Similar disparities in survival were published in a 2016 report by the CDC (Richardson, et al., 2016) that utilized data from United States Cancer Statistics (USCS). The authors concluded that breast cancer mortality between 1999 and 2014 was 40% higher in Black women compared to white women and that there are increasing incidences of breast cancer diagnoses in Black women particularly between the ages of 60–79 years. The authors suggested that a possible explanation for the increase in breast cancer diagnosis could be attributed to an increased use of screening mammography and increasing rates of obesity among Black women. The authors also suggested that a lack of access to care could be contributing to the higher death rates among Black women. The data points to a need for additional research, education, and public health interventions to address these disparities.

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, 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. This publication reported the interim results at three years. Subjective reports of cosmetic results served as the secondary outcome. Follow up occurred a six, 12, 24, and 36 months. 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. Cosmetic satisfaction was reported by 95% of patients and 98% of treating physicians. 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. 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).

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; Medina-Franco, et al., 2008; Garbay, et al., 2008; van der Ploeg, et al., 2007).

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 < 2cm. There were 17 studies with 399 participants and 401 lesions included in the review. The number of participants in each study ranged from 3–52 and ages ranged from 33–99 years. Studies were included if they evaluated patients with a diagnosis of

breast cancer who underwent RFA regardless of whether there was surgical resection (i.e., immediate or delayed) after ablation and studies reporting on at least one outcome measure. Studies were excluded if they: were review articles, letters to the editor, comments, editorials or case reports; were lacking in clinical outcome data, or were studies in which tumors were larger than 2 cm. The intervention consisted of RFA on tumors < 2cm. There were no comparators. The primary outcomes measured included: technical success rate of the ablation (i.e., technologically complete and good cooperation from patients), complete ablation rate (i.e., ablation of all tumor tissues confirmed with imaging and pathological examination, or complete necrosis of tumor tissues), complications, and local recurrence (i.e., incomplete local treatment and recurrence in the breast distant from the ablation zone). Type of anesthesia, pain tolerance, mean ablation time, and surgical excision after ablation were secondary outcomes that were measured. 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 average ablation time was 15.8 minutes. The majority of patients received RFA under general anesthesia (83.88%) while the remainder received local anesthesia. One patient reported intolerable pain and could not complete the ablation. 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%) that included: skin burn, skin puckering, skin swelling, breast inflammation, infection, nipple retraction, pneumothorax, and chest muscle burn. Author 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, 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.

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 (5.2023—December 5, 2023) does not address cryoablation, microwave thermotherapy, or radiofrequency ablation.

National Cancer Institute (NCI): NCI Breast Cancer Treatment (PDQ®) Health Professional Version (updated November 13, 2023) does not mention cryoablation, microwave thermotherapy, or radiofrequency ablation.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	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.
(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®) ©2023 American Medical Association: Chicago, IL.**

References

1. American Cancer Society (ACS). Less invasive cancer surgery techniques. Last Revised: October 2, 2019. Accessed Jan 4, 2024. Available at URL address: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery/special-surgical-techniques.html

2. American Society of Breast Surgeons 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. Accessed Jan 4, 2024. Available at URL address: https://www.breastsurgeons.org/about/statements/

3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Jan 4, 2024. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcds-alphabetical-report.aspx?proposedStatus=A&sortBy=title

4. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Jan 4, 2024. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title

5. Clinicaltrials.gov. Accessed Jan 4, 2024. Available at URL address: https://clinicaltrials.gov/ct2/show/NCT01992250 and https://clinicaltrials.gov/ct2/show/NCT02200705

6. Dooley WC, Vargas HI, Fenn AJ, Tomaselli MB, Harness JK. Focused microwave thermotherapy for preoperative treatment of invasive breast cancer: a review of clinical studies. Ann Surg Oncol. 2010 Apr;17(4):1076-93.

7. Fine RE, Gilmore RC, Dietz JR, Boolbol SK, Berry MP, Han LK, Kenler AS, Sabel M, Tomkovich KR, VanderWalde NA, Chen M, Columbus KS, Curcio LD, Feldman SM, Gold L, Hernandez L, Manahan ER, Seedman SA, Vaidya RP, Sevrukov AB, Aoun HD, Hicks RD, Simmons RM. Cryoablation Without Excision for Low-Risk Early-Stage Breast Cancer: 3-Year Interim Analysis of Ipsilateral Breast Tumor Recurrence in the ICE3 Trial. Ann Surg Oncol. 2021 Oct;28(10):5525-5534.

8. Fleming MM, Holbrook AI, Newell MS. Update on Image-Guided Percutaneous Ablation of Breast Cancer. AJR Am J Roentgenol. 2017 Feb;208(2):267-274.

9. Garbay JR, Mathieu MC, Lamuraglia M, Lassau N, Balleyguier C, Rouzier R. Radiofrequency thermal ablation of breast cancer local recurrence: a phase II clinical trial. Ann Surg Oncol. 2008 Nov;15(11):3222-6.

10. García-Tejedor A, Guma A, Soler T, Valdivieso A, Petit A, Radiofrequency Ablation Followed by Surgical Excision versus Lumpectomy for Early Stage Breast Cancer: A Randomized Phase II Clinical Trial. Radiology. 2018 Nov;289(2):317-324.

11. Gardner RA, Vargas HI, Block JB, Vogel CL, Fenn AJ, Kuehl GV, Doval M. Focused microwave phased array thermotherapy for primary breast cancer. Ann Surg Oncol. 2002;9(4):326-32.

12. Huston TL, Simmons RM. Ablative therapies for the treatment of malignant diseases of the breast. Am J Surg. 2005 Jun;189(6):694-701.

13. Ito T, Oura S, Nagamine S, Takahashi M, Yamamoto N, et al. Radiofrequency Ablation of Breast Cancer: A Retrospective Study. Clin Breast Cancer. 2018 Aug;18(4):e495-e500.

14. Klimberg VS, Ochoa D, Henry-Tillman R, Hardee M, Boneti C, Adkins LL, et al. Long-term results of phase II ablation after breast lumpectomy added to extend intraoperative margins (ABLATE l) trial. J Am Coll Surg. 2014 Apr;218(4):741-9.

15. Lanza E, Palussiere J, Buy X, Grasso RF, Beomonte Zobel B, Poretti D, Pedicini V, Balzarini L, Cazzato RL. Percutaneous Image-Guided Cryoablation of Breast Cancer: A Systematic Review. J Vasc Interv Radiol. 2015 Nov;26(11):1652-7.e1.

16. Manenti G, Scarano AL, Pistolese CA, Perretta T, Bonanno E, et al. Subclinical Breast Cancer: Minimally Invasive Approaches. Our Experience with Percutaneous Radiofrequency Ablation vs. Cryotherapy. Breast Care (Basel). 2013 Oct;8(5):356-60.

17. Mauri G, Sconfienza LM, Pescatori LC, Fedeli MP, Alì M, et al. Technical success, technique efficacy and complications of minimally-invasive imaging-guided percutaneous ablation procedures of breast cancer: A systematic review and meta-analysis. Eur Radiol. 2017 Aug;27(8):3199-3210.

18. Medina-Franco H, Soto-Germes S, Ulloa-Gómez JL, Romero-Trejo C, Uribe N, Ramirez-Alvarado CA, Robles-Vidal C. Radiofrequency ablation of invasive breast carcinomas: a phase II trial. Ann Surg Oncol. 2008 Jun;15(6):1689-95.

19. National Cancer Institute (NCI). Breast Cancer Treatment (PDQ®). Health Professional Version. Updated Nov 13, 2023. Accessed Jan 4, 2024. Available at URL address: https://www.cancer.gov/types/breast/hp/breast-treatment-pdq#section/all

20. National Cancer Institute (NCI). NCI Dictionary of Cancer Terms. Accessed Jan 4, 2024. Available at URL address: https://www.cancer.gov/publications/dictionaries/cancer-terms

21. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. National Comprehensive Cancer Network, Inc. 2020, All Rights Reserved. Breast Cancer.
Version 5.2023—December 5, 2023. Accessed Jan 4, 2024. Available at URL address: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

22. Niu L, Mu F, Zhang C, et al. Cryotherapy protocols for metastatic breast cancer after failure of radical surgery. Cryobiology. Aug 2013;67(1):17-22. PMID 23619024.

23. Noguchi M, Motoyoshi A, Earashi M, Fujii H. Long-term outcome of breast cancer patients treated with radiofrequency ablation. Eur J Surg Oncol. 2012 Nov;38(11):1036-42.

24. Ohtani S, Kochi M, Ito M, Higaki K, Takada S, Matsuura H, et al. Radiofrequency ablation of early breast cancer followed by delayed surgical resection--a promising alternative to breast-conserving surgery. Breast. 2011 Oct;20(5):431-6.

25. Palussière J, Henriques C, Mauriac L, Asad-Syed M, Valentin F, Brouste V, et al. Radiofrequency ablation as a substitute for surgery in elderly patients with nonresected breast cancer: pilot study with long-term outcomes. Radiology. 2012 Aug;264(2):597-605.

26. Peek MCL, Douek M. Ablative techniques for the treatment of benign and malignant breast tumours. J Ther Ultrasound. 2017 Jul 3;5:18.

27. Pusceddu C, Paliogiannis P, Nigri G, Fancellu A. Cryoablation In The Management Of Breast Cancer: Evidence To Date. Breast Cancer (Dove Med Press). 2019 Oct 10;11:283-292.

28. Richardson LC, Henley SJ, Miller JW, Massetti G, Thomas CC. Patterns and trends in age-specific black-white differences in breast cancer incidence and mortality – United States, 1999–2014. MMWR Morb Mortal Wkly Rep 2016;65: 1093-1098.

29. Simmons RM, Ballman KV, Cox C, Carp N, Sabol J, ACOSOG investigators, et al. A Phase II Trial Exploring the Success of Cryoablation Therapy in the Treatment of Invasive Breast Carcinoma: Results from ACOSOG (Alliance) Z1072. Ann Surg Oncol. 2016 Aug;23(8):2438-45.

30. Tafra L, Fine R, Whitworth P, Berry M, Woods J, Ekbom G, et al. Prospective randomized study comparing cryo-assisted and needle-wire localization of ultrasound-visible breast tumors. Am J Surg. 2006 Oct;192(4):462-70

31. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Nov 2023. Accessed Jan 4, 2024. Available at URL address: https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/

32. van der Ploeg IM, van Esser S, van den Bosch MA, Mali WP, van Diest PJ, Borel Rinkes IH, van Hillegersberg R. Radiofrequency ablation for breast cancer: A review of the literature. Eur J Surg Oncol. 2007 Mar 16.

33. Vargas HI, Dooley WC, Gardner RA, Gonzalez KD, Venegas R, Heywang-Kobrunner SH, Fenn AJ. Focused microwave phased array thermotherapy for ablation of early-stage breast cancer: results of thermal dose escalation. Ann Surg Oncol. 2004;22(2):139-46.

34. Ward RC, Lourenco AP, Mainiero MB. Ultrasound-Guided Breast Cancer Cryoablation. AJR Am J Roentgenol. 2019 Sep;213(3):716-722.

35. Xia LY, Hu QL, Xu WY. Efficacy and Safety of Radiofrequency Ablation for Breast Cancer Smaller Than 2 cm: A Systematic Review and Meta-Analysis. Front Oncol. 2021 May 3;11:651646.

36. Zhau Z, Wu F. Minimally-invasive thermal ablation of early-stage breast cancer: a systemic review. Eur J Surg Oncol. 2010 Dec;36(12):1149-55.

37. Zhou W, Jiang Y, Chen L, Ling L, Liang M, Pan H, et al. Image and pathological changes after microwave ablation of breast cancer: a pilot study. Eur J Radiol. 2014 Oct;83(10):1771-7.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No clinical policy statement changes.	3/15/2024

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