Microwave thermotherapy for breast cancer

Clinical Policy ID: CCP.1397

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: breast cancer, focused microwave phase array thermotherapy, microwave thermotherapy.

AmeriHealth Caritas VIP Care has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas VIP Care's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas VIP Care, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas VIP Care's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas VIP Care will update its clinical policies as necessary. AmeriHealth Caritas VIP Care's clinical policies are not guarantees of payment.

Coverage policy

Microwave thermotherapy for breast cancer is investigational/not clinically proven, and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Chemotherapy.
- Hormone therapy.
- Lumpectomy.
- Mastectomy.
- Radiation therapy.
- Stem cell transplant.
- Targeted therapy.

Background

Breast cancer is the most commonly diagnosed cancer in the United States. Trends in the U.S. population reveal an increased incidence of lower-risk breast cancers and ductal carcinoma in situ attributed to screening mammography, and lower mortality rates attributed to screening and improved treatment. The National Cancer Institute estimated that, in 2025, 316,950 new cases of invasive disease and 59,080 cases of breast ductal carcinoma in situ would be diagnosed, and 42,170 deaths would occur among American women. The rates of locoregional recurrence have decreased over time and were estimated at less than 3% in patients treated with breast-conserving surgery and radiation therapy (National Cancer Institute, 2025).

A variety of treatment options are being sought to improve on these trends. Thermotherapy works on the principle that heat applied to the organ in question (in this case, the breast) generates antitumor activity. Typically, thermotherapy raises the temperature of the breast to 42° to 45° Celsius. The heating treatment works by producing cytotoxic effects that yield the denaturation of cytoplasmic/membrane tumor proteins, by decreasing blood flow which impairs the oxygen and nutrient supply to the tumor, and by activating heat shock proteins that help destroy breast tumors. Thermotherapy is not used as monotherapy, as it is unable to effectively treat breast cancer by itself. Instead, it may be combined with other commonly used treatments such as surgery, chemotherapy, radiation therapy, and cryotherapy (Alphandery, 2014).

Microwave thermotherapy, also known as focused microwave phase array thermotherapy, is proposed for breast cancer in addition to some other cancers. During treatment, the breast is compressed between two microwave applicators with fans that help cool the skin's surface. Five sensors are attached to the skin to monitor skin temperature during treatment. Two additional sensors are inserted in the breast — one to monitor breast temperature, and the other to direct microwave energy into the cancerous tissue. The tumor temperature is typically raised to 46° to 50° Celsius during 60 seconds of treatment of treatment (Alphandery, 2014).

As of this writing, the U.S. Food and Drug Administration (2025) has not approved any microwave thermotherapy systems for breast cancer treatment.

Findings

Guidelines

The National Comprehensive Cancer Network (2025) guideline for breast cancer treatment does not address the use of focused microwave thermotherapy as a treatment option. The American Society of Breast Surgeons issued a consensus guideline in 2017 on transcutaneous and percutaneous methods of treating breast cancer and updated it in 2018. The Society stated that while thermotherapies are being investigated, they are not approved by the U.S. Food and Drug Administration, and should not be performed, except in clinical trials (American Society of Breast Surgeons, 2018).

Evidence review

Minimally invasive thermal ablation, of which microwave thermotherapy is one type, has been studied in patients with breast cancer. The advantages of these techniques are less morbidity, lower cost, less scarring and pain, and improved cosmesis. Only a small number of systematic reviews of microwave thermotherapy for breast cancer exist, and these articles are summarized below. A major limitation of these studies is that virtually none of the randomized controlled trials (other than the early clinical trials) are included, making judgment on effectiveness and safety of microwave thermotherapy elusive compared to other breast cancer treatments.

A systematic review of 34 nonrandomized and single-arm studies (n = 2,100) divided participants with locally recurrent breast cancer into single- and double-arm groups. Hyperthermia was delivered mostly by either microwaves or radiofrequency at 8 to 2450 Mhz. In the eight two-arm studies, a complete response was achieved

in 60.2% of patients with radiation therapy and thermotherapy, compared to just 38.1% of those with radiation therapy only ($P < .0001$). The 63.4% complete response for single-arm studies was comparable to that for two-arm studies. Authors concluded that treatment is more effective when thermotherapy is added to radiation therapy for breast cancer patients, but they cited the need for randomized trials to refine the patient selection criteria, the optimal radiation therapy dose and fractionation schedules, and ideal hyperthermia treatment parameters (Datta, 2016).

Microwave thermotherapy has been compared with other techniques for minimally invasive ablation for breast cancer. One review of 45 studies (n = 1,156) included radiofrequency (n = 577), microwaves (n = 78), laser (n = 277), cryoablation (n = 156), and high-intensity focused ultrasound (n = 129). Differences between techniques were not significant for technical success ($P = .449$), major complications ($P = .181$), or minor complications ($P = .762$) — but were significant for technique efficacy ($P = .009$). Results indicate that microwave thermotherapies are technically successful, but their efficacy remains suboptimal (Mauri, 2017).

A systematic review of 23 articles (n = 2,330) evaluated the efficacy of hyperthermia therapy for recurrent breast cancer while radiotherapy is being administered. The majority of participants underwent microwave hyperthermia therapy (n = 2,155). Thirty-two hyperthermia therapy parameters were tested. In reporting studies, a significant positive outcome included complete response (10/15 studies); duration of local control (10/13); overall survival (2/2); and thermal toxicity (7/11). Patients who received a high thermal dose had on average 34% more complete responses than those who received a low thermal dose (Bakker, 2019).

In an overview of studies of microwave ablation for early-stage breast cancer, one of the studies (n = 64) compared microwave ablation with nipple-sparing mastectomy for treating specific invasive ductal carcinoma cases; findings indicated tumor control was comparable, and microwave ablation offered better cosmetic results. A second study focused on a multicenter clinical study (n = 35) for microwave ablation and a smaller group (n = 13) for surgery to assess microwave ablation's local effect and antitumor immune response in early-stage breast cancer. The results, after 36 months, confirmed successful complete ablation in 91.4% of those treated with microwave ablation. Additionally, microwave ablation demonstrated some potential for enhancing antitumor immunity, though the long-term implications remain unexplored (Carriero, 2023).

In 2022, we updated the references, removed older references, and added no new relevant literature to the policy. The coverage statement was modified to focus the policy solely on breast cancer.

In 2023, we updated the references, removed older references, and added no newly relevant literature to the policy.

In 2024, we updated references and found no new relevant literature was found and no policy changes were warranted.

In 2025, we updated the references and found no newly published relevant literature to add to the policy. No policy changes are warranted.

References

On September 16, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “hyperthermia, induced (MeSH),” “microwave (MeSH),” “breast neoplasms (MeSH),” “minimally invasive thermal ablation,” and “microwave thermotherapy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Alphandery, E. Perspectives of breast cancer thermotherapies. *J Cancer*. 2014;5(6):472-479. Doi: 10.7150/jca.8693.

American Society of Breast Surgeons. Use of transcutaneous and percutaneous methods for the treatment of benign and malignant tumors of the breast. Consensus guidelines. https://www.breastsurgeons.org/docs/statements/Consensus-Guideline-on-the-Use-of-Transcutaneous-and-Percutaneous-Methods-for-the-Treatment-of-Benign-and-Malignant-Tumors-of-the-Breast.pdf. Last approved October 16, 2018.

Bakker A, van der Zee J, van Tienhoven G, Kok HP, Rasch CRN, Crezee H. Temperature and thermal dose during radiotherapy and hyperthermia for recurrent breast cancer are related to clinical outcome and thermal toxicity: A systematic review. *Int J Hyperthermia*. 2019;36(1):1024-1039. Doi: 10.1080/02656736.2019.1665718.

Carriero S, Lanza C, Pellegrino G, et al. Ablative therapies for breast cancer: State of art. *Technol Cancer Res Treat*. 2023;22:15330338231157193. Doi: 10.1177/15330338231157193.

Datta NR, Puric E, Klingbiel D, Gomez S, Bodis S. Hyperthermia and radiation therapy in locoregional recurrent breast cancers: A systematic review and meta-analysis. *Int J Radiat Oncol Biol Phys*. 2016;94(5):1073-1087. Doi: 10.1016/j.ijrobp.2015.12.361.

Mauri G, Sconfienza LM, Pescatori LC, 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;27(8):3199-3210. Doi: 10.1007/s00330-016-4668-9.

National Cancer Institute. Breast cancer treatment (Adult) (PDQ®)–Health Professional Version https://www.cancer.gov/types/breast/hp/breast-treatment-pdq. Updated April 25, 2025.

National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Breast cancer. Version 4.2025. https://www.nccn.org. Published April 17, 2025.

U.S. Food and Drug Administration. Premarket approval (PMA) database searched using the term "microwave." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Page last updated September 15, 2025.

Policy updates

7/2018: initial review date and clinical policy effective date: 8/2018

11/2019: Policy references updated. Policy ID changed to CCP.1397.

11/2020: Policy references updated.

11/2021: Policy references updated.

11/2022: Policy references updated. Coverage modified.

11/2023: Policy references updated.

11/2024: Policy references updated.

11/2025: Policy references updated.