Medical Policy Manual

**Topic:** Microwave Thermotherapy for Primary Breast Cancer

**Date of Origin:** March 2, 2004

**Section:** Medicine

**Last Reviewed Date:** May 2014

**Policy No:** 111

**Effective Date:** August 1, 2014

**IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

**DESCRIPTION**

Focused microwave phase array thermotherapy is a technique for exposing tissues to high temperatures to damage or destroy cancer cells or to make cancer cells more sensitive to radiation therapy or certain anticancer drugs. In microwave heating, the higher the water content in tissues, the higher the temperature that may be achieved. Since breast cancer cells have a higher water content than the surrounding healthy breast tissues, the cancer cells can be exposed to high temperatures without harming the surrounding normal tissues.

Microwave technology has been investigated in the treatment of breast cancer in the following circumstances:

- In conjunction with lumpectomy in patients with early stage breast cancer
- In conjunction with preoperative chemotherapy to reduce the size of the tumor in patients with advanced breast cancer

**Regulatory Status**

Currently, no microwave thermotherapy device that is indicated for the treatment of breast cancer has received approval for marketing from the U.S. Food and Drug Administration (FDA). The Microfocus™ APA 1000 System (Celsion, Columbia, MD) is a device that is currently undergoing clinical trials.
through the FDA investigational device exemption process (IDE).

**MEDICAL POLICY CRITERIA**

Focused microwave phase array thermotherapy is considered *investigational* as a treatment of breast cancer.

**SCIENTIFIC EVIDENCE**

The principal health outcomes associated with treatment of breast malignancies are typically measured in units of survival past treatment: disease-free survival (DFS), a period of time following treatment where the disease is undetectable; progression-free survival (PFS), the duration of time after treatment before the advancement or progression of disease; and overall survival (OS), the period of time the patient remains alive following treatment. In order to understand the impact of microwave thermotherapy on these outcomes, well-designed randomized controlled trials (RCTs) that compare the addition of this therapy to standard medical and/or surgical treatment alone (lumpectomy or conventional pre-operative chemotherapy) are needed.

**Literature Appraisal**

Clinical trial data is limited to small case series and two small randomized trials, summarized below.

### Randomized Controlled Trials

- Vargas and colleagues randomized patients with invasive (T2, T3) breast cancer to receive either preoperative focused-microwave thermotherapy in combination with neoadjuvant anthracycline-based chemotherapy (n=15) or a control group that received anthracycline-based regimen alone (n=13).\(^1\) There was greater tumor volume reduction in the experimental group compared with the control group (88% vs. 59%, respectively). However, the specific impact of microwave thermotherapy on these outcomes was not reported.

- Dooley and colleagues randomized early breast cancer patients to either a control group who received surgery only (n=41), or an experimental group who received thermotherapy prior to surgery (n=34).\(^2\) Although there were fewer positive margins in the experimental group than in the control group [0% (0 of 34) and 10%, respectively], the difference did not reach statistical significance (p=0.13), indicating that the impact of adjunctive treatment with microwave thermotherapy is still uncertain.

### Nonrandomized Trials

Three small case series on the use of microwave thermotherapy in the treatment of breast cancer have been reported.\(^3\)\(^-\)\(^5\) However, interpretation of results from these small case series is difficult due to the lack of a control group. Without an adequate control group it is not possible to account for the many types of bias that can affect study outcomes.
To be able to come to conclusions about the use of microwave thermotherapy, sufficiently large randomized controlled trials, with longer follow-up of clinical outcomes are needed.

**Clinical Practice Guidelines**

A search of the literature failed to identify any evidence-based clinical practice guidelines which address the use of microwave thermotherapy. National Comprehensive Cancer Network (NCCN) clinical practice guidelines from 2014 are silent on the use microwave thermotherapy in the treatment of breast cancer.\(^6\)

**Summary**

Current available literature is not sufficient to determine whether treatment with microwave thermotherapy improves survival rates or decreases or delays breast cancer recurrence. None of the medical devices under study in the medical literature have received clearance from the U.S. Food and Drug Administration (FDA) for either of these indications. Therefore, use of this procedure is considered investigational.

**REFERENCES**

2. Dooley, WC, Vargas, HI, Fenn, AJ. Randomized study of preoperative focused microwave phased array thermotherapy for early-stage invasive breast cancer. *Cancer Therapy*. 2008;6(2):395-408. PMID: No PMID Entry

**CROSS REFERENCES**

None

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