

FEP 7.01.140 Handheld Radiofrequency Spectroscopy for Intraoperative Assessment of Surgical Margins During Breast-Conserving Surgery

Effective Date: July 15, 2018

Related Policies: None

Handheld Radiofrequency Spectroscopy for Intraoperative Assessment of Surgical Margins During Breast-Conserving Surgery

Description

As part of the treatment of localized breast cancer, breast-conserving surgery is optimally achieved by attaining tumor-free margins around the surgical resection site. Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins (eg, MarginProbe) is intended to increase the probability that the surgeon will achieve clear margins in the initial procedure, thus avoiding the need for a second surgery to excise more breast tissue.

FDA REGULATORY STATUS

In January 2013, MarginProbe® (Dune Medical Devices, Caesarea, Israel) was approved by the U.S. Food and Drug Administration through the premarket approval process as an adjunctive diagnostic tool for identification of cancerous tissue at the margins (≤ 1 mm) of the main ex vivo lumpectomy specimen after primary excision. It is indicated for intraoperative use in conjunction with standard methods (eg, intraoperative imaging and palpation) for patients undergoing lumpectomy for previously diagnosed breast cancer. Food and Drug Administration product code: OEE.

POLICY STATEMENT

Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered **not medically necessary**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have localized breast cancer or DCIS undergoing breast-conserving surgery (lumpectomy) who receive handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins (eg, MarginProbe), the evidence includes a randomized trial, several historical control studies, and a systematic review. Relevant outcomes are change in disease status and morbid events. In the randomized trial, histologic examination of surgical margins was not used in the control arm; the

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outcome measure (complete surgical resection) was not directly clinically relevant and was biased against the control arm; and patient follow-up was insufficient to assess local recurrence rates. The difference in re-excision rates between the 2 trial arms was not statistically significant. Diagnostic characteristics of the device showed only moderate sensitivity and poor specificity; thus, the device will miss some cancers and provide frequent false-positive results. Although several historical control studies have shown lower re-excision rates among patients in whom MarginProbe was used, the studies lacked adequate rigor to demonstrate whether the outcomes are attributable to MarginProbe. The studies did not report recurrence outcomes, which is important for assessing adequacy of resection. A randomized trial that assesses recurrence rates is required to evaluate whether the net health outcome improves with handheld radiofrequency spectroscopy compared with standard intraoperative surgical margin evaluation, including histologic techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Current National Comprehensive Cancer Network guidelines for breast cancer (v.3.2017) do not include recommendations for intraoperative assessment of surgical margins using radiofrequency spectroscopy for ductal carcinoma in situ or invasive breast cancer.¹⁴

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2013	New Policy	
December 2014	Update Policy	Policy updated with literature review; references 2-3 and 6-9 added; reference 4 updated. No changes in policy statement.
December 2015	Update Policy	Policy updated with literature review through July 12, 2015; reference 9 added. Policy statement unchanged.
December 2016	Update Policy	Policy updated with literature review; no references added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; references 7 and 13 added; reference 14 updated. Policy statement unchanged.

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