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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of intraoperative assessment of surgical margins using handheld radiofrequency spectroscopy improves the net health outcome in individuals undergoing breast-conserving surgery for localized breast cancer.

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).

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.

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 morbidity events. In the randomized trial, histologic examination of surgical margins was not used in the control arm; the 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

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines for breast cancer (v.3.2018) do not include recommendations for intraoperative assessment of surgical margins using radiofrequency spectroscopy for ductal carcinoma in situ or invasive breast cancer.16

American Society of Breast Surgeons

The most current version of the American Society of Breast Surgeons’ performance and practice guidelines for breast-conserving surgery (2015) mention that specimens should be submitted for margin assessment either intraoperatively or post-surgery, depending on each institution's protocol. A recommendation for one margin assessment method over another was not made.17

U.S. Preventive Services Task Force Recommendations

Not applicable.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Medicare National Coverage

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

REFERENCES


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