BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

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

Effective Policy Date: July 1, 2023

Original Policy Date: December 2013

Related Policies:

None

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

Description

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 **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

In December 2012, MarginProbe (Dune Medical Devices, Caesarea, Israel) was approved by the U.S. Food and Drug Administration (FDA) 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 (P110014). 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. FDA product code: OEE.

RATIONALE

Summary of Evidence

For individuals who have localized breast cancer or ductal carcinoma in situ (DCIS) undergoing breast-conserving surgery (lumpectomy) who are evaluated with 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 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Breast Surgeons

In 2015, the most current version of the American Society of Breast Surgeons performance and practice guidelines for breast-conserving surgery mention that specimens should be submitted for margin assessment either intraoperatively or post-surgically, depending on each institution's protocol. A recommendation for a specific margin assessment method over another was not made.[21,]

In 2017, the American Society of Breast Surgeons issued a consensus guideline for breast cancer lumpectomy margins, providing an algorithm for re-excision surgery after lumpectomy or breast conservation for invasive or in-situ breast cancer. Margin definitions and treatment recommendations are based on inked specimen edges and do not include recommendations for the intraoperative assessment of surgical margins via radiofrequency spectroscopy.[22,]

National Comprehensive Cancer Network

Current (v. 4.2022) National Comprehensive Cancer Network guidelines for breast cancer do not include recommendations for intraoperative assessment of surgical margins using radiofrequency spectroscopy for ductal carcinoma in situ or invasive breast cancer.[23,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

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

1. Maloney BW, McClatchy DM, Pogue BW, et al. Review of methods for intraoperative margin detection for breast conserving surgery. J Biomed Opt. Oct 2018; 23(10): 1-19. PMID 30369108
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Handheld radiofrequency spectroscopy for intraoperative margin assessment during breast-conserving surgery. TEC Assessments. 2013;Volume 28:Tab 4.
3. Schnabel F, Boolbol SK, Gittleman M, et al. A randomized prospective study of lumpectomy margin assessment with use of MarginProbe in patients with nonpalpable breast malignancies. Ann Surg Oncol. May 2014; 21(5): 1589-95. PMID 24595800
4. Rivera RJ, Holmes DR, Tafra L. Analysis of the Impact of Intraoperative Margin Assessment with Adjunctive Use of MarginProbe versus Standard of Care on Tissue Volume Removed. Int J Surg Oncol. 2012; 2012: 868623. PMID 23326653
5. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): MarginProbe System. 2012; https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110014B.pdf. Accessed January 3, 2023.
6. Allweis TM, Kaufman Z, Lelcuk S, et al. A prospective, randomized, controlled, multicenter study of a real-time, intraoperative probe for positive margin detection in breast-conserving surgery. Am J Surg. Oct 2008; 196(4): 483-9. PMID 18809049
7. Geha RC, Taback B, Cadena L, et al. A Single institution's randomized double-armed prospective study of lumpectomy margins with adjunctive use of the MarginProbe in nonpalpable breast cancers. Breast J. Nov 2020; 26(11): 2157-2162. PMID 32772474
8. Butler-Henderson K, Lee AH, Price RI, et al. Intraoperative assessment of margins in breast conserving therapy: a systematic review. Breast. Apr 2014; 23(2): 112-9. PMID 24468464
9. St John ER, Al-Khudairi R, Ashrafian H, et al. Diagnostic Accuracy of Intraoperative Techniques for Margin Assessment in Breast Cancer Surgery: A Meta-analysis. Ann Surg. Feb 2017; 265(2): 300-310. PMID 27429028
10. Gray RJ, Pockaj BA, Garvey E, et al. Intraoperative Margin Management in Breast-Conserving Surgery: A Systematic Review of the Literature. Ann Surg Oncol. Jan 2018; 25(1): 18-27. PMID 28058560
11. Thill M, Dittmer C, Baumann K, et al. MarginProbe--final results of the German post-market study in breast conserving surgery of ductal carcinoma in situ. Breast. Feb 2014; 23(1): 94-6. PMID 24291375
12. Thill M, Rder K, Diedrich K, et al. Intraoperative assessment of surgical margins during breast conserving surgery of ductal carcinoma in situ by use of radiofrequency spectroscopy. Breast. Dec 2011; 20(6): 579-80. PMID 21885281
13. Sebastian M, Akbari S, Anglin B, et al. The impact of use of an intraoperative margin assessment device on re-excision rates. Springerplus. 2015; 4: 198. PMID 26020017
14. Blohmer JU, Tanko J, Kueper J, et al. MarginProbe reduces the rate of re-excision following breast conserving surgery for breast cancer. Arch Gynecol Obstet. Aug 2016; 294(2): 361-7. PMID 26796680

15. Coble J, Reid V. Achieving clear margins. Directed shaving using MarginProbe, as compared to a full cavity shave approach. Am J Surg. Apr 2017; 213(4): 627-630. PMID 28049561
16. Kupstas A, Ibrar W, Hayward RD, et al. A novel modality for intraoperative margin assessment and its impact on re-excision rates in breast conserving surgery. Am J Surg. Mar 2018; 215(3): 400-403. PMID 29191356
17. Gooch JC, Yoon E, Chun J, et al. The Relationship of Breast Density and Positive Lumpectomy Margins. Ann Surg Oncol. Jun 2019; 26(6): 1729-1736. PMID 30888516
18. LeeVan E, Ho BT, Seto S, et al. Use of MarginProbe as an adjunct to standard operating procedure does not significantly reduce re-excision rates in breast conserving surgery. Breast Cancer Res Treat. Aug 2020; 183(1): 145-151. PMID 32607640
19. Cen C, Chun J, Kaplowitz E, et al. Margin Assessment and Re-excision Rates for Patients Who Have Neoadjuvant Chemotherapy and Breast-Conserving Surgery. Ann Surg Oncol. Sep 2021; 28(9): 5142-5148. PMID 33635409
20. Hoffman A, Ashkenazi I. The efficiency of MarginProbe in detecting positive resection margins in epithelial breast cancer following breast conserving surgery. Eur J Surg Oncol. Jul 2022; 48(7): 1498-1502. PMID 35219544
21. American Society of Breast Surgeons. Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy. 2015; https://www.breastsurgeons.org/statements/guidelines/PerformancePracticeGuidelines_Breast-ConservingSurgery-PartialMastectomy.pdf. Accessed January 3, 2023.
22. American Society of Breast Surgeons. Consensus Guideline on Breast Cancer Lumpectomy Margins. 2017; https://www.breastsurgeons.org/docs/statements/Consensus-Guideline-on-Breast-Cancer-Lumpectomy-Margins.pdf. Accessed January 3, 2023.
23. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version.4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 3, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2013	New policy	
December 2014	Replace policy	Policy updated with literature review; references 2-3 and 6-9 added; reference 4 updated. No changes in policy statement.
December 2015	Replace policy	Policy updated with literature review through July 12, 2015; reference 9 added. Policy statement unchanged.
December 2016	Replace policy	Policy updated with literature review; no references added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through December 11, 2017; references 7 and 13 added; reference 14 updated. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through January 8, 2019; several references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through November 26, 2019; reference added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through November 17, 2020; references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 7, 2022; reference added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 3, 2023; references added. Policy statement unchanged.