Medical Coverage Policy | Handheld Radiofrequency Spectroscopy for Intraoperative Assessment of Surgical Margins during Breast-Conserving Surgery

EFFECTIVE DATE: 07|01|2023
POLICY LAST REVIEWED: 04|03|2024

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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. Failure to achieve clear margins will often require additional surgery to re-excise breast tissue. Currently, histologic examination of excised tissues after completion of surgery is the only method to determine definitively whether clear margins were achieved. Intraoperative methods of assessing surgical margins, such as specimen imaging, frozen section pathology, and touch print cytology, are either not highly accurate, not commonly available, or require considerable time and resources.

A device to detect positive margins should have a high sensitivity, indicating the ability to accurately detect any tumor found in the margins, ideally above 95%. While specificity is less important, excess false-positive margin detection would lead to additional unnecessary tissue removal. A new device should have a specificity at least matching current standard best practices, estimated at 85%.

The MarginProbe is an intraoperative device which uses radiofrequency spectroscopy to measure the dielectric properties of tissue into which it comes in contact. Cancer cells and normal breast tissues produce different signals. A handheld probe is applied to a small area of the lumpectomy specimen and analyzes

whether the tissue is likely malignant or benign. The device gives a positive or negative reading for each touch. If any touch on a particular margin gives a positive reading, the margin is considered to be positive and more tissue should be re-excised if possible. The device can only be used on the main lumpectomy specimen; it cannot be used on shavings or in the lumpectomy cavity of the patient's breast. Use of MarginProbe is intended to increase the probability that the surgeon will achieve clear margins in the initial surgery, thus avoiding the need for a second procedure to excise more breast tissue.

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.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0546T Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2024
Provider Update, May 2023

REFERENCES:

Schnitt SJ, Moran MS, Giuliano AE. Lumpectomy Margins for Invasive Breast Cancer and Ductal Carcinoma in Situ: Current Guideline Recommendations, Their Implications, and Impact. J Clin Oncol. Jul 10 2020; 38(20): 2240-2245. PMID 32442067

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

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.

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

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

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 December 18, 2023.
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
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
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
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
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
Rossou C, Alampritis G, Patel B. Reducing re-excision rates in breast conserving surgery with Margin Probe: systematic review. Br J Surg. Jan 03 2024; 111(1). PMID 37991190
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
Thill M, Röder 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
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
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
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
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
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
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
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
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
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 December 18, 2023.
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 December 19, 2023.
National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 5.2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 18, 2023.

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