MEDICAL POLICY

POLICY TITLE	HANDHELD RADIOFREQUENCY SPECTROSCOPY FOR INTRAOPERATIVE ASSESSMENT OF SURGICAL MARGINS DURING BREAST-CONSERVING SURGERY
POLICY NUMBER	MP 5.055

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	**6/1/2026**

POLICY

Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

DESCRIPTION/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 inaccurate, 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. However, disadvantages of this device include cost (of the console and the disposable probes) and the lack of evidence.

Regulatory Status

In December 2012, MarginProbe® (Dilon Medical Technologies, formerly 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.

In September 2025, the next-generation MarginProbe® 2.0 was approved by the FDA through a premarket approval supplement (P110014/S013). The company announced the forthcoming U.S. commercial launch on December 15, 2025. The updated system uses a multiple array technology with multiple sensors to boost sensitivity.

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 (e.g., 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. No evaluable data for MarginProbe 2.0 were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

DEFINITIONS

N/A

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®								
0546T								

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. *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*

3. *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*
4. *U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): MarginProbe System. 2012*
5. *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*
6. *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*
7. *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*
8. *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*
9. *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*
10. *Thill M, Dittmer C, Baumann K, et al. MarginProbe(R)--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*
11. *Thill M, Roder 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*
12. *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*
13. *Blohmer JU, Tanko J, Kueper J, et al. MarginProbe(C) reduces the rate of re-excision following breast conserving surgery for breast cancer. Arch Gynecol Obstet. Aug 2016; 294(2): 361-7. PMID 26796680*
14. *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*
15. *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*
16. *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*
17. *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*

18. *National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version.1.2026*
19. *American Society of Breast Surgeons. Performance and Practice Guidelines for Breast-Conserving Surgery/Partial Mastectomy. 2024*
20. *Chagpar, AB. Techniques to reduce positive margins in breast-conserving surgery. UpToDate. Updated Jun 12, 2024. Literature review through Jan 2026.*
21. *Wang J, Zhang L, Pan Z. Evaluating the impact of radiofrequency spectroscopy on reducing reoperations after breast conserving surgery: A meta-analysis. Thorac Cancer. 2023;14(16):1413-1419 PMID: 37073138*
22. *Morrow M, Van Zee KJ, Solin LJ, et al. Society of Surgical Oncology-American Society for Radiation Oncology-American Society of Clinical Oncology Consensus Guideline on Margins for Breast-Conserving Surgery With Whole-Breast Irradiation in Ductal Carcinoma In Situ. J Clin Oncol. 2016;34(33):4040-4046. PMID: 27528719*
23. *Moran MS, Schnitt SJ, Giuliano AE, et al. Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer. J Clin Oncol. 2014;32(14):1507-1515 PMID: 24516019*

POLICY HISTORY

MP 5.055	**11/26/2013 New policy**. BCBSA adopted. Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational. Policy coded.
	11/25/2014 Consensus Review. References and rationale updated. No changes to the policy statements. FEP variation added to refer to the FEP medical policy manual.
	11/24/2015 Consensus Review. No change to policy statements. References and rationale updated. Coding reviewed.
	09/27/2016 Consensus Review. No change to policy statements. References and rationale updated. Variation reformatted. Coding reviewed.
	11/28/2017 Consensus Review. No change to the policy statement. References and rationale updated. Coding reviewed.
	07/19/2018 Consensus Review. No change to the policy statement. References updated. Rationale revised.
	05/21/2019 Consensus Review. No changes to policy statement. Referenced updated. Added new code 0546T effective 07/01/2019. Removed unlisted code since specific code now available.
	05/22/2020 Consensus Review. No changes to policy statement. Referenced updated.
	03/11/2021 Consensus Review. No changes to policy statement. Updated Background/Description. No coding changes

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	03/17/2022 Consensus Review. No change to policy statement. References reviewed and updated. Product Variations updated.
	03/17/2023 Consensus Review. No changes to policy statement. NCCN statement added. Updated background, new reference.
	02/08/2024 Consensus Review. No changes to policy statement. Updated references.
	11/20/2024 Administrative Update. Removed NCCN statement.
	02/14/2025 Consensus review. No change to policy statement.
	02/06/2026 Consensus Review. No change to policy intent.