

MEDICAL POLICY

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

Original Issue Date (Created):	11/1/2013
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I. 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 conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-7.01.140 Handheld Radiofrequency Spectroscopy for Intraoperative Assessment of Surgical Margins during Breast-Conserving Surgery. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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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

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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. **Regulatory Status**

In January 2013, MarginProbe® received PMA approval from the Food and Drug Administration (FDA). The Dune MarginProbe®™ System is an adjunctive diagnostic tool for identification of cancerous tissue at the margins ($\leq 1\text{mm}$) of the main ex-vivo lumpectomy specimen following primary excision and is indicated for intraoperative use in conjunction with standard methods (such as intraoperative imaging and palpation) for patients undergoing lumpectomy for previously diagnosed breast cancer.

IV. RATIONALE

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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 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.

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V. DEFINITIONS
N/A

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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							

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IX. REFERENCES

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X. POLICY HISTORY

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MP 5.055	CAC 11/26/13 New policy. BCBSA adopted. Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational. Policy coded.
	CAC 11/25/14 Consensus review. References and rationale updated. No changes to the policy statements. FEP variation added to refer to the FEP medical policy manual.
	CAC 11/24/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	CAC 9/27/16 Consensus review. No change to policy statements. References and rationale updated. Variation reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. No change to the policy statement. References and rationale updated. Coding reviewed.

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	7/19/18 Consensus review. No change to the policy statement. References updated. Rationale revised.
	5/21/2019 Consensus review. No changes to policy statement. Referenced updated. Added new code 0546T effective 7/1/19. 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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