

## MEDICAL POLICY

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| <b>POLICY TITLE</b>  | <b>HANDHELD RADIOFREQUENCY SPECTROSCOPY FOR INTRAOPERATIVE ASSESSMENT OF SURGICAL MARGINS DURING BREAST-CONSERVING SURGERY</b> |
| <b>POLICY NUMBER</b> | <b>MP 5.055</b>  |

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| <b>CLINICAL BENEFIT</b> | <input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN.<br><input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br><input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE.<br><input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br><input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br><input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| <b>Effective Date:</b>  | <b>2/1/2024</b>  |

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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 general conclusion concerning the health outcomes or benefits associated with this procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

### II. PRODUCT VARIATIONS

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

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

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### 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 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 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 (e.g., MarginProbe), the evidence includes a randomized trial, several historical control studies, and a systematic review. Relevant outcomes are change in disease

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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.

**V. DEFINITIONS**

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N/A

**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 Blue Cross for benefit information.

**VII. DISCLAIMER**

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*Capital Blue Cross 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 Blue Cross 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.

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### Investigational therefore not covered:

| CPT Codes® |  |  |  |  |  |  |  |
|------------|--|--|--|--|--|--|--|
| 0546T      |  |  |  |  |  |  |  |

### IX. REFERENCES

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**X. POLICY HISTORY**

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| <b>MP 5.055</b> | <b>CAC 11/26/2013 New policy.</b> BCBSA adopted. Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational. Policy coded. |
|                 | <b>CAC 11/25/2014 Consensus review.</b> References and rationale updated. No changes to the policy statements. FEP variation added to refer to the FEP medical policy manual.   |
|                 | <b>CAC 11/24/2015 Consensus review.</b> No change to policy statements. References and rationale updated. Coding reviewed.  |
|                 | <b>CAC 09/27/2016 Consensus review.</b> No change to policy statements. References and rationale updated. Variation reformatted. Coding reviewed.   |
|                 | <b>CAC 11/28/2017 Consensus review.</b> No change to the policy statement. References and rationale updated. Coding reviewed.   |
|                 | <b>07/19/2018 Consensus review.</b> No change to the policy statement. References updated. Rationale revised.   |

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|  | <b>05/21/2019 Consensus review.</b> No changes to policy statement. Referenced updated. Added new code 0546T effective 7/1/19. Removed unlisted code since specific code now available. |
|  | <b>05/22/2020 Consensus review.</b> No changes to policy statement. Referenced updated.   |
|  | <b>03/11/2021 Consensus review.</b> No changes to policy statement. Updated Background/Description. No coding changes   |
|  | <b>03/17/2022 Consensus review.</b> No change to policy statement. References reviewed and updated. Product Variations updated.   |
|  | <b>03/17/2023 Consensus review.</b> No changes to policy statement. NCCN statement added. Updated background, new reference.  |

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