

Corporate Medical Policy

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

File Name: handheld_radiofrequency_spectroscopy_for_intraoperative_assessment_of_surgical_margins
Origination: 9/2013
Last Review: 11/2024

Description of Procedure or Service

Breast-conserving surgery as part of the treatment of localized breast cancer is optimally achieved by attaining margins around the surgical resection that are free from tumor cells. 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 of definitively determining whether clear margins were achieved. Intra-operative 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.

MarginProbe® is an intraoperative device based on the principles of radiofrequency spectroscopy that measures 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 resected surgical specimen and analyzes the tissue as to whether it is likely malignant or benign. During the operation, the surgeon touches the MarginProbe device to each surface of the biopsy specimen. The device gives a reading of positive or negative for each touch. If any one of the touches on a particular margin gives a positive reading, the margin is considered to be positive and should be re-excised if possible. The device can only be used on the main lumpectomy specimen, and cannot be used on shavings or in the lumpectomy cavity in the patient's breast. Use of the MarginProbe® device is intended to increase the probability that the surgeon will achieve clear margins in the initial operation, thus avoiding the need for a second surgery to excise more breast tissue.

Regulatory Status

In December 2012, MarginProbe® received premarket approval (Dune Medical Devices, Caesarea, Isreal) 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 1mm) 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. FDA product code: OEE

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When it is covered

Not applicable.

When it is not covered

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Policy Guidelines

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 (e.g., MarginProbe), the evidence includes one randomized trial, several historical control studies, and systematic reviews. Relevant outcomes are change in disease status and morbid events. In the randomized trial, histologic examination of surgical margins was not employed 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 two 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 have 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 net health outcome is improved 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0546T

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 8/8/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 8/14/2014

Specialty Matched Consultant Advisory Panel – 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 8/13/2015

Specialty Matched Consultant Advisory Panel – 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/11/2016

Specialty Matched Consultant Advisory Panel – 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/9/2017

Specialty Matched Consultant Advisory Panel – 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/8/2018

Specialty Matched Consultant Advisory Panel – 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/14/2019

Specialty Matched Consultant Advisory Panel – 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/13/2020

Specialty Matched Consultant Advisory Panel – 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.140, 2/11/2021

Specialty Matched Consultant Advisory Panel – 11/2021

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version.2.2022.

https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

Specialty Matched Consultant Advisory Panel – 11/2022

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.

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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>.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version.4.2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

Specialty Matched Consultant Advisory Panel - 11/2023

Medical Director Review- 11/2023

Specialty Matched Consultant Advisory Panel 11/2024

Medical Director Review 11/2024

Policy Implementation/Update Information

- 10/29/13 New policy developed. Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery is considered investigational. Medical Director review 9/2013. Notification given 10/29/13 for policy effective date 12/31/13. (sk)
- 10/28/14 Reference added. (sk)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/14. No change to Policy statement. (sk)
- 10/1/15 Reference added. Policy Guidelines updated. No change to Policy statement. (sk)
- 12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
- 4/1/16 Reference added. (sk)
- 12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
- 3/31/17 Reference added. Policy Guidelines updated. (sk)
- 1/12/18 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
- 3/29/18 Reference added. (sk)
- 12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)
- 5/14/19 Reference added. (sk)
- 7/1/19 New code 0546T added to Billing/Coding section. (sk)
- 12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
- 8/25/20 Reference added. (sk)

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- 12/8/20 Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)
- 11/30/21 Reference added. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)
- 5/2/23 Policy review. References added. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)
- 12/5/23 References added. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director Review 11/2023. (rp)
- 12/31/24 References added. Specialty Matched Consultant Advisory Panel review 11/2024. Medical Director review 11/2024. (rp)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.