Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 552
Latest Review Date: February 2023
Category: Surgery
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage*

Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat **handheld radiofrequency spectroscopy** for intraoperative assessment of surgical margins during breast-conserving surgery as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 (e.g., 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.

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.

The 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.

KEY POINTS:

This policy was created in 2013 based on a TEC Assessment and updated with literature search through January 3, 2023.

Summary of Evidence

For individuals who have localized breast cancer or ductal carcinoma in situ undergoing breast-conserving surgery (lumpectomy) who receive handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins (e.g., MarginProbe), the evidence includes 1 randomized trial, several historical control studies, and 1 systematic review. Relevant outcomes are change in disease status (relapse rates) and morbid events (re-excision rates). 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.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Current National Comprehensive Cancer Network guidelines for breast cancer (version 4.2022) do not include recommendations for intraoperative assessment of surgical margins using radiofrequency spectroscopy for ductal carcinoma in situ or invasive breast cancer.

American Society of Breast Surgeons

The most current version of the American Society of Breast Surgeons' performance and practice guidelines for breast-conserving surgery (2015) mention that specimens should be submitted for margin assessment either intraoperatively or post-surgery, depending on each institution's protocol. A recommendation for one margin assessment method over another was not made.

In 2017, the American Society of Breast Surgeons issued a consensus guideline for breast cancer lumpectomy margins, providing an algorithm for re-excision surgery after lumpectomy or breast conservation for invasive or in-situ breast cancer. Margin definitions and treatment

recommendations are based on inked specimen edges and do not include recommendations for the intraoperative assessment of surgical margins via radiofrequency spectroscopy.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Handheld radiofrequency spectroscopy, MarginProbe

APPROVED BY GOVERNING BODIES:
In January 2013, MarginProbe® received premarket approval (PMA) from FDA. The Dune MarginProbe®™ System is an adjunctive diagnostic tool for identification of cancerous tissue at the margins (≤1 mm) of the main ex-vivo lumpectomy specimen after primary excision and is indicated for intraoperative use in conjunction with standard methods (e.g., intraoperative imaging and palpation) for patients undergoing lumpectomy for previously diagnosed breast cancer.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:

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

PREVIOUS CODING:
CPT:
Prior to 07/01/19, there was no specific CPT code for Spectroscopy assessment. An unlisted code would have been used.

19499	Unlisted procedure, breast

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POLICY HISTORY:

Adopted for Blue Advantage, September 2014
Medical Policy Group, September 2014
Available for comment September 8 through October 22, 2014
Medical Policy Group, August 2015
Medical Policy Group, February 2016
Medical Policy Group, March 2017
Medical Policy Group, March 2018
Medical Policy Group, April 2019
Medical Policy Group, February 2020
Medical Policy Group, February 2021
Medical Policy Group, February 2022
Medical Policy Group, February 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.