
Medical Policy



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. When Centers for Medicare and Medicaid (CMS) coverage rules are not fully developed, this medical policy may be used by BCBSM or BCN Medicare Advantage plans 42 CFR § 422.101 (b)(6). Please refer to the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Optical Coherence Tomography of the Breast and/or Axillary Lymph Nodes

Description

Optical Coherence Tomography (OCT) of the breast and axillary lymph nodes is a high-resolution, non-invasive imaging modality that uses infrared light to produce real-time, microscopic, cross-sectional images of tissues. It is used for assessment of lymph nodes or tumor margins for breast conserving surgery.

Medical Policy Statement

Optical coherence tomography of the breast and/or axillary lymph nodes is experimental/investigational. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0351T

0352T

0353T

0354T

Background

Breast conserving surgery (BCS) is a preferable and viable option for some women with early-stage breast cancer. Unlike mastectomy, BCS removes only the tumor and a small area of normal tissue around it, and can potentially provide good cosmetic, functional and survival outcomes. According to the American Cancer Society, for most women with early-stage breast cancer, BCS plus radiation therapy is as effective as mastectomy. With BCS, the margins around the tumor need to be adequately excised in an attempt to minimize the risk of leaving malignant tissue in the surgical field and potentially increasing the risk of cancer recurrence. Addressing the risk of recurrence may be handled with postoperative radiation therapy.

Optical coherence tomography (OCT) is a high-resolution, near-infrared (IR) light imaging modality capable of visualizing microscopic features within tissue and is comparable to ultrasound except reflections of near-IR light are detected rather than sound. OCT creates a real-time image of the microstructural detail of tissue in situ and has been proposed for the assessment of surgical margins in individuals undergoing breast-conserving surgery. Optical coherence tomography can perform cellular-level imaging but does so at the expense of imaging depth. The use of intra-operative OCT may shift the microscopic assessment of tissue from post-operative laboratory assessment in the pathology lab to real-time, point-of-care assessment in the operating room, with improved comprehensive sampling of the surgical margin. However, the effectiveness of this approach has not been definitively established.

Summary of Evidence

Further studies with even higher resolution, comprehensive volumetric imaging, and automated tissue-type classification are expected to reveal additional unique features that can be used to further improve the identification of positive and negative margins intraoperatively with OCT. Intraoperative identification of positive margins will decrease the need for additional surgical procedures and the rate of local recurrence in breast cancer patients. At this time, the effectiveness of the use of optical coherence tomography for the evaluation of breast and axillary lymph nodes in breast cancer patients has not been firmly established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Rationale

Evidence reviews assess clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Review of Evidence

Noting that inadequate margins continue to occur frequently in patients who undergo surgical resection of a tumor, suggesting that current intra-operative methods are not sufficiently reliable in determining the margin status, Heidkamp and associates (2021) conducted a systematic review.¹ The studies provided an overview of novel imaging techniques for intra-operative margin assessment in surgical oncology, and reported on their technical properties, feasibility in clinical practice and diagnostic accuracy. This systematic review identified 134 studies that examined and developed 16 groups of techniques for intra-operative margin assessment: fluorescence, advanced microscopy, US, specimen radiography, OCT, magnetic resonance imaging (MRI), elastic scattering spectroscopy, bio-impedance, X-ray CT, mass spectrometry, Raman spectroscopy, nuclear medicine imaging, terahertz imaging, photo-acoustic imaging, hyper-spectral imaging and pH measurement. Studies were noted to be in early developmental stages and none of the above techniques were clearly superior in demonstrating high diagnostic accuracy or high feasibility. The authors concluded that the field of imaging techniques for intra-operative margin assessment is highly evolving. Although the techniques may be helpful, the current evidence mostly originates from studies in early developmental stages and thus does not support the recommendation of any specific technique to clinical practice.

Gubarkova et al (2023) stated that intra-operative differentiation of tumorous from non-tumorous tissue could help in the assessment of resection margins and therapy responses. The aim is to reduce the incidence of breast tumor recurrence.² These researchers carried out the calculation of the attenuation coefficient and its color-coded 2D distribution for different breast cancer subtypes using spectral-domain cross-polarization (CP) OCT. It has been shown that color-coded attenuation coefficient maps may be used to detect inter- and intra-tumor heterogeneity of various breast cancer subtypes as well as to assess the effectiveness of therapy. A total of 68 freshly excised human breast specimens containing tumorous and surrounding non-tumorous tissues after BCS was studied. The authors concluded that this study provided a new diagnostic approach to the differentiation of breast cancer tissue types based on the assessment of the attenuation coefficient from real-time CP OCT data and has the potential to be used for further rapid and accurate intra-operative evaluation of the resection margins during BCS. Moreover, these researchers stated that current efforts are underway for the construction and implementation of a hand-held CP OCT probe for in-vivo imaging during BCS and real-time resection margins assessment.

OCT imaging has been used to image a broad spectrum of malignancies, including those arising in the breast, brain, bladder, gastrointestinal, respiratory, and reproductive tracts, the skin, and oral cavity, among others.³ Over the past decade, regarding the field of oncology, the application of optical coherence tomography (OCT) has been prospering. OCT imaging has initially been applied for guiding biopsies. It has been used for intraoperatively evaluating tumor margins and lymph nodes, and for the early detection of small lesions that would often not be visible on gross examination, tasks that align well with the clinical emphasis on early detection and intervention. Recently, OCT imaging has been explored for imaging tumor cells and their dynamics, and for the monitoring of tumor responses to treatments. This review explores the evolution of OCT technologies for the clinical application of OCT in surgical and noninvasive interventional oncology procedures and concludes with a discussion of the future directions.

In an article published in 2014, Butler-Henderson et al noted that approximately 25 % of patients undergoing breast conserving therapy for breast cancer will require a 2nd operation to achieve adequate clearance of the margins.⁴ A number of techniques for assessing margins intra-operatively have been reported. This systematic review examined current intra-operative methods for assessing margin status. The final pathology status, statistical measures including accuracy of tumor margin assessment, average time impact on the procedure and 2nd operation rate, were used as criteria for comparison between studies. Although pathological methods, such as frozen section and imprint cytology performed well, they added on average 20 to 30 minutes to operation times. An ultrasound probe allows accurate examination of the margins and delivers results in a timely manner, yet it has a limited role with ductal carcinoma in-situ where calcification is present and in multi-focal cancer. In addition, the authors stated that further research is needed in other intra-operative margin assessment techniques, such as mammography, radiofrequency spectroscopy and OCT.

In 2016, Nolan et al stated that evaluation of lymph node (LN) status is an important factor for detecting metastasis and thereby staging breast cancer.¹⁴ Currently utilized clinical techniques involve the surgical disruption and resection of lymphatic structure for histological examination. While reasonably effective at detection of macro-metastasis, the majority of the resected lymph nodes are histologically negative. Improvements are needed to better detect micro-metastasis, provide immediate and accurate intra-operative feedback for in-vivo cancer staging to better guide surgery. These researchers cited in this evaluated the use of OCT for the intra-operative assessment of human LNs for metastatic disease in 37 patients with breast cancer. They assessed the sensitivity and specificity of double-blind trained readers who analyzed intra-operative OCT LN images for presence of metastatic disease, using co-registered post-operative histopathology as the gold standard. The results suggested that intra-operative OCT examination of LNs is an appropriate real-time, label-free, non-destructive alternative to frozen-section analysis, potentially offering faster interpretation and results to empower superior intra-operative decision-making. The authors concluded that intra-operative OCT has strong potential to supplement current post-operative histopathology with real-time in-situ assessment of LNs to preserve both non-cancerous nodes and their lymphatic vessels and thus reduce the associated risks and complications from surgical disruption of lymphoid structures following biopsy.

Schmidt et al (2020) examined wide-field optical coherence tomography (WF-OCT) for tissue visualization of margins.¹⁵ This IRB-approved pilot study included women with invasive or in situ carcinoma scheduled for primary BCS. Lumpectomy specimens and any final/revised

margins were imaged by optical coherence tomography immediately prior to standard histological processing. The optical coherence tomography used provided two-dimensional, cross-sectional, real-time depth visualization of the margin widths around excised specimens. A volume of images was captured for 10 × 10 cm tissue surface at high resolution (sub-30 µm) to a depth of 2 mm. Integrated interpretation was performed incorporating final pathology linked with the optical image data for correlation. Wide-field optical coherence tomography was performed on 185 tissue samples (50 lumpectomy specimens and 135 additional margin shaves) in 50 subjects. Initial diagnosis was invasive ductal carcinoma (IDC) in 10, ductal carcinoma in situ (DCIS) in 14, IDC/DCIS in 22, invasive lobular carcinoma (ILC) in 2, ILC/DCIS in 1, and sarcoma in 1. Optical coherence tomography was concordant with final pathology in 178/185 tissue samples for overall accuracy of 86% and 96.2% (main specimen alone and main specimen + shave margins). Of seven samples that were discordant, 57% (4/7) were considered close (DCIS < 2 mm from margin) per final pathology. Although the WF-OCT demonstrated some concordance with histology at tissue margins, further studies are needed for comprehensive evaluation in the intraoperative setting.

Yemul et al (2019) studied methods for the interpretation of breast OCT images to possibly develop guidelines for the identification of breast tissue features in OCT images.¹⁶ Mastectomy and breast-conserving surgery specimens from 26 women were imaged with a handheld OCT probe. During standard pathology specimen dissection, representative 1-cm × 1-cm tissue regions were grossly identified, assessed with OCT, inked for orientation and image-matching purposes, and processed. Histological slides corresponding to the OCT image region were digitally photographed. OCT and histology images from the same region were paired by selecting the best structural matches. In total, 2880 OCT images were acquired from 26 breast specimens (from 26 patients) and 48 matching OCT-histology image pairs were identified. These matched image pairs illustrate tissue types including adipose tissue, dense fibrosis, fibroadipose tissue, blood vessels, regular and hyperplastic ducts and lobules, cysts, cyst, fibroadenoma, invasive ductal carcinoma, invasive lobular carcinoma, ductal carcinoma in situ, calcifications, and biopsy cavities. Differentiation between pathologies was achieved by considering feature boundaries, interior appearance, posterior shadowing or enhancement, and overall morphologic patterns. The results indicate that OCT might be used to identify and distinguish between benign and malignant features in human tissue tissues.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they are issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network (NCCN)⁸

The National Comprehensive Cancer Network's (NCCN) clinical practice guideline on "Breast cancer" (Version 1.2026) does not mention the use of OCT as a management tool. This lack of mention indicates that use of OCT to determine status of surgical biopsy margins is not the current standard of medical practice at this time. Further evidence in the form of larger, well-conducted trials is warranted to demonstrate whether OCT devices provide net health outcomes for women undergoing BCS.

American Society of Clinical Oncology (ASCO)⁹

ASCO in their 2018 guidelines "Integrative Therapies During and After Breast Cancer Treatment" do not mention the use of OCT as a management or therapeutic tool.

Regulatory Status

At this time, no OCT devices have been approved or cleared by the FDA for marketing in the U.S., but several are currently under investigation, including the Margin Assessment Machine (MAM) (Perimeter Medical, Toronto, Canada) and the Foresee Imaging System (Diagnostic Photonics, Inc, Chicago, IL). Both of these devices involve the use of a handheld probe attached to a computer. The probe is applied to a small area of the resected surgical specimen in the operating room. The Foresee device may also be used to evaluate tissue inside the surgical cavity. This use of OCT may also be referred to as "computed optical margin assessment."

Government Regulations

National/Local:

There are no national or local coverage determinations on this topic.

L35490, Category III Codes, effective on or after 01/01/2026. Codes 0351T-0354T are not listed as approved codes.

There are no fees assigned to the codes 0351T-0354T.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Heidkamp J, Scholte M, Rosman C, et al. Novel imaging techniques for intraoperative margin assessment in surgical oncology: A systematic review. *Int J Cancer*. Aug 2021; 149(3): 635-645.
2. Gubarkova E, Kiseleva E, Moiseev A, et al. Intraoperative assessment of breast cancer tissues after breast conserving surgery based on mapping the attenuation coefficients in 3D cross-polarization optical coherence tomography. *Cancers*. May 2023; 15(9): 2663.
3. Wang J, Xu Y, Boppart SA. Review of optical coherence tomography in oncology. *J Biomed Opt*. Dec 2017; 22(12): 1-23.
4. Butler-Henderson K, Lee AH, Price RI, Waring K. Intraoperative assessment of margins in breast conserving therapy: A systematic review. *Breast*. 2014;23(2):112-119.

5. Assayag O, Antoine M, Sigal-Zafrani B, Riben M, Harms F, Burcheri A et al. Large Field, High Resolution Full-Field Optical Coherence Tomography: A Pre-clinical Study of Human Breast Tissue and Cancer Assessment. *Technol Cancer Res Treat*. 2014 Oct;13(5):455-68.
6. Liu YZ, Shemonski ND, Adie SG, Ahmad A, Bower AJ, Carney PS, Boppart ST. Computed optical interferometric tomography for high-speed volumetric cellular imaging. *Biomed Outpatient Express*. 2014 Sep 1; 6(9): 2988-3000.
7. McLaughlin RA, Scolaro L, Robbins P, et al. Imaging of human lymph nodes using optical coherence tomography: Potential for staging cancer. *Cancer Res*. 2010;70(7):2579-2584.
8. National Comprehensive Cancer Network. Clinical practice guideline: Breast cancer. Version 1.2026. NCCN: Fort Washington, PA. Available at http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf (March 2026)
9. Society of Surgical Oncology. SSO-ASTRO consensus guideline margins for breast-conserving surgery with whole breast irradiation in stage I and II invasive breast cancer. February 2014. Available at: [sso-astro-asco-consensus-guideline-on-margins-for-breast-conserving-surgery-with-whole-breast-irradiation-in-dcis-sfvrn2.pdf](http://www.sso-astro-asco-consensus-guideline-on-margins-for-breast-conserving-surgery-with-whole-breast-irradiation-in-dcis-sfvrn2.pdf). Accessed March 2026.
10. Nguyen FT, Zysk AM, Chaney EJ, et al. Optical coherence tomography: The intraoperative assessment of lymph nodes in breast cancer. *IEEE Eng Med Biol Mag*. 2010;29(2):63-70.
11. Patel R, Khan A, Quinlan R, Yaroslavsky AN. Polarization-sensitive multimodal imaging for detecting breast cancer. *Cancer Res*. 2014 Sep 1;74(17):4685-93.
12. Savastru D, Chang EW, Miclos S, Pitman MB, Patel A, Iftimia N. Detection of breast surgical margins with optical coherence tomography imaging: a concept evaluation study. *J Biomed Opt*. 2014 May;19(5):056001.
13. Zysk AM and Nguyen FT. Optical coherence tomography: a review of clinical development from bench to bedside. *Journal of Biomedical Optics* 12(5): 051403. September/October 2007.
14. Nolan RM, Adie SG, Marjanovic M, et al. Intraoperative optical coherence tomography for assessing human lymph nodes for metastatic cancer. *BMC Cancer*. 2016; 16:144.
15. Schmidt H, Connolly C, Jaffer S, et al. Evaluation of surgically excised breast tissue microstructure using wide-field optical coherence tomography. *Breast J*. Oct 2020; [Epub ahead of print].
16. Yemul KS, Zysk AM, Richardon AL, et al. Interpretation of optical coherence tomography images for breast tissue assessment. *Surg Innov*. 2019;26(1):50-56.
17. HAYES Technology Brief, "MarginProbe System (Dune Medical Devices) for Intraoperative Assessment of Surgical Margins in Patients with Breast Cancer," Lansdale, PA: HAYES, Inc., May 2018. Archived April 2019.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/15	4/21/15	5/8/15	Joint policy established
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance. Additional reference added. No change in policy status.
7/1/18	4/17/18	4/17/18	Updated rationale, added reference # 20. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance. No change in policy status.
7/1/20	4/14/20		Routine policy maintenance added reference #21. No change in policy status.
7/1/21	4/20/21		Routine policy maintenance added reference #22 added. No change in policy status.
7/1/22	4/19/22		Routine policy maintenance, no change in policy status.
7/1/23	4/18/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A. (ds)
7/1/24	4/16/24		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
7/1/25	4/15/25		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
7/1/26	4/21/26		Rationale updated, 3 references added, several references deleted, no change in policy status. Vendor managed: N/A (ds, lk)

Next Review Date: 2nd Qtr. 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OPTICAL COHERENCE TOMOGRAPHY OF THE BREAST AND/OR AXILLARY
LYMPH NODES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A