Policy Number	**RAD601.053**
Policy Effective Date	**03/15/2025**
Policy End Date	**12/31/2025**

Optical Coherence Tomography of the Breast

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Optical coherence tomography (OCT) of the breast **is considered experimental, investigational and/or unproven** as a pre-surgical, an intraoperative, or a post-surgical assessment of breast tissue cells from a lumpectomy, mastectomy, lymph-node dissection, and/or the surgical cavity or surrounding tissues (e.g., adipose tissue) examination.

Policy Guidelines

None.

Description

Optical coherence tomography (OCT) is a rapidly emerging technology recently being researched to be used in clinical medicine and human biology to improve disease prevention, diagnoses, and treatment. 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. Advances in optical imaging techniques enable observation of tissue microstructure at high resolution and in real time. This use of OCT may also be referred to as "computed optical margin assessment."

Background

OCT is the optical analogue to ultrasound, in which reflected light is detected rather than sound. Light reflects off the tissue and is captured by a detector. Image analysis software combines the signals from the reflected light to form an image, such as the breast. These images allow tissue observation at high resolution and in real time, thus reducing patient risk. (1, 2) Optical imaging can be used to perform optical biopsies, generating images that resemble histological sections but without removal and staining of the tissue. (3)

OCT of the breast has the potential to reduce patient risk by the accurate and rapid assessment of tumor margins during breast cancer resection, such as during mastectomy, lumpectomy, and lymph node dissection. The National Institutes of Health (NIH) listed the advantages of OCT over existing radiological techniques (4):

- Optical imaging significantly reduces patient exposure to harmful radiation by using non-ionizing radiation, which includes visible, ultraviolet, and infrared light.
- Optical imaging is particularly useful for visualizing soft tissues. Soft tissues can be easily distinguished from one another due to the wide variety of ways different tissues absorb and scatter light.
- Because it can obtain images of structures across a wide range of sizes and types, optical imaging can be combined with other imaging techniques, such as magnetic resonance imaging (MRI) or x-rays, to provide enhanced information for doctors monitoring complex diseases or researchers working on intricate experiments.
- Optical imaging takes advantage of the various colors of light in order to see and measure many different properties of an organ or tissue at the same time. Other imaging techniques are limited to just one or two measurements.

Traditional resection procedures resulted in tissue samples sent to the laboratory for pathological assessment of suspicious areas, carefully slicing thin sections, staining and viewing under high-resolution microscopes to confirm the presence of tumor cells and determination if any are located along the surgical margin, looking for healthy cell and surgical margins. These techniques are time-consuming and tend to significantly under-sample tissue, leaving many areas microscopically uninspected. (3) If done during the resection procedure, the surgery times are extended, an additional 20-30 minutes. If done post-resection, the patient undergoes repeat surgical procedure(s). (5) Utilizing intraoperative OCT of the breast improves the accuracy of surgical biopsies and assessing margin status. Tiny-fiber optic probes study cells of the surgical site without inflicting damage.

Regulatory Status
Only 2 OCT devices have been approved for marketing by the U.S. Food and Drug Administration (FDA). On May 13, 2016, the Perimeter Optical Tissue Imaging System (OTIS™) 1.0 Optical Coherence Tomography System (Perimeter Medical Imaging, Inc., Toronto, Canada) received FDA 510(k) premarket approval (K160240). Earlier in 2014, the Foresee (4C) Imaging System (Diagnostic Photonics, Inc., Chicago, Illinois) received FDA 510(k) premarket approval (K133209). Both devices are indicated for the use as an imaging tool in the evaluation of excised human tissue microstructure by providing 2-dimensional, cross-section, real-time depth visualization.

FDA Product Code: NQQ.

Rationale

Medical policies assess the 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 (QoL), and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Optical coherence tomography (OCT) of the breast is intended as an alternative to visual macroscopic and microscopic assessment to differentiate between normal and tumor tissue during a surgical procedure. The most relevant type of studies evaluating the utility of OCT of the breast includes a head-to-head comparison between OCT and histologic assessment of breast tissue, currently considered the gold standard. (6) Yemul et al. (2018) evaluated 2880 breast OCT images from 26 breast specimens from 26 patients and 48 matching OCT-histology image pairs identified, to systematically catalog the features of breast OCT images. (7) The matched pairs demonstrated numerous tissue types, which included tissue feature boundaries, interior appearances, posterior shadowing or enhancements, and overall morphologic patterns

that will serve as a reference guide to distinguish benign and malignant features in human breast tissue.

Clinical Trials

Nguyen et al. (2009) studied 37 patients split between training and study groups. (8) OCT of the breast images were used and histologically correlated from 1 cm^2 regions of lumpectomy surgical margin specimens. A 17-patient training set was used to establish standard imaging protocols and breast OCT evaluation criteria. The remaining 20 patients were enrolled in a feasibility study. Of the 20 patients, 11 were identified with a positive or close surgical margin and 9 were identified with a negative surgical margin using OCT of the breast. When based on histology examination, 9 true positives, 9 true negatives, 2 false positives, and zero false negatives. This yielded a sensitivity of 100% and specificity of 82%. The researchers concluded breast OCT has the potential as a real-time method for assessment of surgical margins in breast surgeries.

A year later in 2010, Nguyen et al. reported the intraoperative examination of lymph nodes of the 17 patients (normal – 13, reactive – 1, and metastatic – 3) with breast cancer used as the training set from the 2009 study. (9) Scattering changes were identified in the specimens, which were used to differentiate normal from the reactive and metastatic nodes. These scattering changes correlate with the inflammatory and immunological changes observed in follicles and germinal centers of cells inspected. The authors concluded intraoperative OCT of the breast has the potential to assess in real-time node status without having to resect and histologically process tissue samples to visualize microscopic features. Thus, utilizing breast OCT reduced the number of samples taken from resecting the high number of lymph nodes when a small percentage of them were found to be metastatic, which is a fact to be weighed against potential complications, such as lymphedema.

In 2015, Erickson-Bhatt et al. published the results of a translational study evaluating the results derived from an OCT of the breast device to those from standard postoperative histopathological assessment in 35 subjects undergoing wide local excision surgery for breast cancer. (10) The authors reported that the ex-vivo images from the breast OCT device yielded a sensitivity of 91.7% (95% confidence interval [CI], 62.5%-100%) and specificity of 92.1% (95% CI, 78.4%-98%). Study limitations include ex-vivo breast OCT analysis and a small sample size.

Singla et al. (2018) released an evaluation of breast cancers involving the microscopic testing of a hematoxylin and eosin-stained tissue biopsy. (11) The authors noted that repeat surgery is required in 20% to 30% of cases because of incomplete excision of malignant tissue. For this study, when assessing healthy and malignant breast tissue using OCT of the breast, the breast OCT attained the sensitivity, specificity, and accuracy of 90.2%, 91.7% and 90%, respectively, from tissues collected from 48 patients (22 normal fibro-adipose tissue and 26 invasive ductal carcinoma cancerous tissues). The histological imaging correlated with the testing samples. The authors concluded that utilizing the proposed method of OCT of the breast may be used to perform automatic intraoperative identification of breast cancer margins in real-time and to guide core needle biopsies.

In 2015, Zysk et al. published the results of a multicenter, prospective, blinded feasibility study assessing the final surgical margins during breast-conserving surgery and potential impact on patient outcomes. (12) Forty-six patients with a total of 2191 images from 229 shaved margins were collected and studied. Of the 8 patients (17%) with positive margins, the device identified positive margins in 5 (63%). Among patients with pathologically negative margins, an estimated mean additional tissue volume of 10.7 milliliters (»1% of overall breast volume) would have been unnecessarily removed due to false positives.

Systematic Reviews

A systematic review of the intraoperative methods for assessing margin status in breast conserving therapy was completed in 2014 by Butler-Henderson et al. (5) The criteria used to review the techniques included were the final pathology status, statistical measures including accuracy of tumor margin assessment, average time impact on the procedure and second operation rate. The researchers concluded that pathological methods (such as frozen section and imprint cytology) performed well but added surgical time. The ultrasound probe allowed for timely accurate readings of the margins but was limited in ductal carcinoma in situ (DCIS) samples due to the presence of calcification and in multifocal cancer. Additional research will be needed for intraoperative mammography, radiofrequency spectroscopy, and breast OCT.

van Manen et al. (2018) published a systematic review assessing image guidance during oncological interventions for the following cancer types: skin, oral, lung, breast, hepatobiliary, gastrointestinal, urological, and gynecological. (13) Of the 785 articles found in the authors' searches, 136 articles were available for analysis. They found that the technology is used preoperatively and intraoperatively. The reviewers determined that OCT showed promising results in tumor detection on a microscopic level, especially using higher resolution imaging techniques, i.e., high-definition OCT and full-field OCT.

Pilot Study

Schmidt et al. (2019) conducted an International Review Board approved pilot study to evaluate wide-field optical coherence tomography (WF-OCT) to evaluate visualization of tissue margins. (14) A total of 50 participants were enrolled with 185 tissue samples evaluated by WF-OCT. The initial diagnosis for 32 participants was invasive ductal carcinoma (IDC) with or without ductal carcinoma in situ (DCIS), pure DCIS for 14, invasive lobular carcinoma (ILC) with or without DCIS for 3, and sarcoma in 1 individual. Final histopathology diagnosis was <2 mm in 17 specimens, and WF-OCT was consistent with final pathology results of the main lump and all shave samples in 178/185 (96.2% accuracy). However, for the main lump only, the accuracy was 86.0% (43/50). A total of 7/185 (3.8%) samples were inconsistent with final histopathology; WF-OCT had 1 false positive, and 6 false negatives. Margin re-excision was necessary for 7 participants, and 3 of these participants had additional disease identified by WF-OCT and confirmed by histopathology. Additional studies with a larger multi-institutional approach to further investigate the sensitivity and specificity of this technique are needed.

Summary of Evidence

For individuals who are undergoing optical coherence tomography (OCT) of the breast for breast cancer treatment, the evidence includes retrospective and prospective reviews with small sample sizes, in addition to 2 systematic reviews and an International Review Board approved pilot study. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. While breast OCT is promising, the lack of large randomized clinical trials has not established consistent specificity in determining normal cells from tumor cells when utilized during or post-breast surgical procedures. As a result, the evidence is not sufficient to determine that the technology results in a meaningful improvement in the net health outcome. Therefore, OCT of the breast is considered experimental, investigational and/or unproven as a pre-surgical, an intraoperative, or a post-surgical assessment of tissue cells from the breast from a lumpectomy, mastectomy, lymph-node dissection, and/or the surgical cavity or surrounding tissues (e.g., adipose tissue).

Practice Guidelines and Position Statements

There are no professional guidelines and position statements that would likely influence this medical policy.

Ongoing and Unpublished Clinical Trials

A currently ongoing and unpublished trial that might influence this policy is listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT03791853	Light-CT in the Diagnosis of Breast Tumor and Lymph Node	150	12/31/2023 (last known status was Recruiting 12/2021)

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0351T, 0352T, 0353T, 0354T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/31/2025	Document became inactive.
03/15/2025	Document updated with literature review. Coverage unchanged. Reference 14 added; others updated.
03/15/2024	Reviewed. No changes.
03/15/2023	Document updated with literature review. Coverage unchanged. No references added; one deleted.
07/01/2022	Reviewed. No changes.
04/01/2021	Document updated with literature review. Coverage unchanged. No references added.
10/15/2020	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage unchanged. References 8, 12, 14 added; none removed.
10/15/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
05/15/2015	Reviewed. No changes.
07/01/2014	New medical document. Optical coherence tomography of the breast is considered experimental, investigational and/or unproven as a presurgical, an intraoperative, or a post-surgical assessment of breast tissue cells from a lumpectomy, mastectomy, lymph-node dissection, and/or the surgical cavity or surrounding tissues (e.g., adipose tissue) examination.