**Medical Policy Manual** Radiology, Policy No. 60

# *Opto-acoustic Imaging of the Breast*

**Effective**: November 1, 2024

**Next Review:** September 2025
**Last Review:** September 2024

## IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

## DESCRIPTION

Opto-acoustic imaging combines laser pulses with ultrasound imaging for evaluation of breast abnormalities. The imaging system include artificial intelligence to assist users in breast imaging reporting and data system classification.

## MEDICAL POLICY CRITERIA

Opto-acoustic imaging of the breast is considered **investigational.**

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## CROSS REFERENCES

1. Intensity Modulated Radiotherapy (IMRT) for Breast Cancer, Medicine, Policy No. 166
2. Cone Beam Computed Tomography of the Breast, Radiology, Policy No. 59

## BACKGROUND

Mammography is the current standard of care for breast cancer screening and diagnosis. Mammography is not without limitations. New technologies are being developed to address some of these limitations such as outcomes in dense tissue or identifying benign versus

malignant lesions. Opto-acoustic (also referred to as photoacoustic) imaging combines laser pulse wave, ultrasound and artificial intelligence technology for more precise screening and diagnostics.[1] The Imagio® Breast Imaging System is currently the only FDA approved opto-acoustic imaging system on the market.

### REGULATORY STATUS

The Imagio® Breast Imaging System received premarket approval on January 11, 2021 (Product code QNK; P200003).[1] The PMA indication is listed as:

> "This device is indicated for use by a trained and qualified healthcare provider for evaluation of palpable and non-palpable breast abnormalities in adult patients who are referred for a diagnostic imaging breast work-up, following clinical presentation or either screening or diagnostic mammography or other imaging examinations. The ultrasound mode should be initially used in a targeted fashion, to assess any focal area(s) of clinical or imaging concerns. In ultrasound mode, the device can be used to assign a BI-RADS category to either breast tissue or a mass that is causing clinical or imaging concerns. Masses that are classified as BI-RADS categories 3 through 5 can then be assessed using the Opto-Acoustic (OA) mode. In the OA mode, the Imagio Breast Imaging System provides information about the central nidus, boundary and peripheral zones, based on vascularity and blood oxygen saturation of the imaged tissues, to assist in the diagnosis of the benign or malignant mass(es) of interest. For ultrasound BI-RADS 3-5 masses, using the OA features of the mass allows for improved classification of the mass of interest as compared to ultrasound alone. The OA mode is not indicated for ultrasound BI- RADS 1 and 2 findings. The Imagio Breast Imaging System includes an artificial intelligence (AI) based software function to assist the users in assessing the BI-RADS Classifications. This device is not intended to be used as a replacement for mammographic screening or for definitive pathologic diagnosis."

## EVIDENCE SUMMARY

Validation of a new imaging technique involves the following steps:

1. Demonstration of its technical feasibility, including assessment of its reproducibility and precision. For comparison among studies, a common standardized protocol is necessary.
2. Establishment of normal and abnormal values as studied in different clinical situations. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to a gold standard must be known.
3. Assessment of the clinical utility of both positive and negative tests. The clinical utility of an imaging study is related to how the results of that study can be used to benefit patient management. Relevant outcomes of a negative test (i.e., suspected pathology is not present) may be avoidance of more invasive diagnostic tests or avoidance of ineffective therapy. Relevant outcomes of a positive test (i.e., suspected outcome is present) may also include avoidance of a more invasive test plus the institution of specific, effective therapy.

Studies evaluating sensitivity and specificity of opto-acoustic imaging and comparing this technology to existing standard imaging techniques are described below. There are no systematic reviews or randomized controlled trials for this indication.

### Nonrandomized Studies

Seiler (2023) completed a secondary retrospective analysis to assess sensitivity of the Opto-acoustic imaging used in the PIONEER-1 study described below.[2] This Reader-2 study included 480 patients (mean age, 49.9 years) with 480 breast masses (180 malignant, 300 benign) that had been classified as BI-RADS category 3-5 on the basis of conventional gray-scale ultrasound findings. Fifteen readers independently reviewed the previously acquired images after training in optoacoustic imaging interpretation. Averaged across all readers, specificity at fixed sensitivity of 98% was significantly higher for fused ultrasound and optoacoustic imaging (OA) with machine learning-based decision support tool (DST) assistance than for ultrasound alone (47.2% vs 38.2%; p = .03). Across all readers, partial AUC (pAUC) was higher (p < .001) for fused ultrasound and optoacoustic imaging with DST assistance (0.024 [95% CI, 0.023-0.026]) than for ultrasound alone (0.021 [95% CI, 0.019-0.022]). Better performance using fused ultrasound and optoacoustic imaging with DST assistance than using ultrasound alone was observed for 14 of 15 readers for specificity at fixed sensitivity and for 15 of 15 readers for pAUC.

Neuschler (2018) published the results of the pivotal study comparing opto-acoustic imaging (OA) to diagnose benign and malignant breast masses (PIONEER-1 study).[3] This is a prospective, controlled, multicenter observational study. The purpose was to compare diagnostic specificity of OA to ultrasound (US) alone, utilizing the US system of the OA device. Of 1690 subjects with 1757 masses (1079 [61.4%] benign and 678 [38.6%] malignant masses), OA downgraded 40.8% (3078/7535) of benign mass reads, with a specificity of 43.0% (3242/7538, 99% confidence interval [CI]: 40.4%, 45.7%) for OA versus 28.1% (2120/7543, 99% CI: 25.8%, 30.5%) US only. OA exceeded US in specificity by 14.9% (P < .0001; 99% CI: 12.9, 16.9%). Sensitivity for biopsied malignant masses was 96.0% (4553/4745, 99% CI: 94.5%, 97.0%) for OA and 98.6% (4680/4746, 99% CI: 97.8%, 99.1%) for US (P < .0001). The negative likelihood ratio of 0.094 for OA/US indicates a negative examination can reduce a maximum US-assigned pretest probability of 17.8% (low BI-RADS 4B) to a posttest probability of 2% (BI-RADS 3). This study was supported by Seno Medical Instruments.

## PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of opto-acoustic imaging of the breast.

## SUMMARY

There is not enough research to show that opto-acoustic imaging of the breast improves health outcomes. No clinical guidelines based on research recommend the use of opto-acoustic imaging of the breast. Therefore, opto-acoustic imaging of the breast is considered investigational for all indications.

## REFERENCES

1. (FDA) FDA. FDA Approval Order: Imagio Breast Imaging System P200003. [cited 09/18/2024]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200003A.pdf.

2. Seiler SJ, Neuschler EI, Butler RS, et al. Optoacoustic Imaging With Decision Support for Differentiation of Benign and Malignant Breast Masses: A 15-Reader Retrospective Study. *AJR Am J Roentgenol.* 2023;220(5):646-58. PMID: 36475811
3. Neuschler EI, Butler R, Young CA, et al. A Pivotal Study of Optoacoustic Imaging to Diagnose Benign and Malignant Breast Masses: A New Evaluation Tool for Radiologists. *Radiology.* 2018;287(2):398-412. PMID: 29178816

## CODES

| Codes | Number | Description |
|---|---|---|
| CPT | 0857T | Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure) |
| HCPCS | None ~~C9788~~ | ~~Opto-acoustic imaging, breast (including axilla when performed), unilateral, with image documentation, analysis and report, obtained with ultrasound examination.~~ (Deleted 01/01/2024) |

***Date of Origin:*** *September 2023*