Tactile breast imaging

Clinical Policy ID: CCP.1353

Recent review date: 1/2025

Next review date: 5/2026

Policy contains: Breast cancer screening; clinical breast exam; iBreastExam; mechanical or stress imaging; palpation; SureTouch.

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Coverage policy

Tactile breast imaging with either of the following devices is investigational/not clinically proven and, therefore, not medically necessary:

- SureTouch™ Digital Breast Exam (Sure Inc., Los Angeles, California).
- iBreastExam™ (UE LifeSciences, Philadelphia, Pennsylvania).

Limitations

All other uses of tactile breast imaging are not medically necessary.

Alternative covered services

- Mammography.
- Ultrasonography.
- Magnetic resonance imaging.

Background

Regular screening is the most reliable method for detecting breast cancer early when treatment is the most effective. Screening recommendations vary according to breast cancer risk, and several tools are available to approximate breast cancer risk based on various combinations of risk factors. Current methods of breast screening and diagnosis include breast self-examination, clinical breast exam, ultrasonography, mammography, and magnetic resonance imaging (Sarvazyan, 2012).

The clinical breast exam often represents the first line of screening defense for monitoring breast health. A clinical breast exam includes visual inspection to identify physical signs of breast cancer (e.g., breast asymmetry and differences in skin color, texture, temperature, and venous patterns) and palpation of the breasts and lymph nodes (Henderson, 2023). There are limitations to a manual clinical breast exam that can influence the ease or difficulty of breast cancer detection:

- Variation in palpation technique.
- Lack of standardized reporting.
- Tumor size, firmness, and location.
- Patient characteristics — density, nodularity, and durity (compressibility) of breast tissue; menopausal status; body weight; hormone use; age; and race.
- Examiner training and proficiency.

To overcome these limitations, tactile breast imaging was developed in the 1990s as a diagnostic modality based on digital 3-D reconstruction of the structure and elastic properties of breast tissue using mechanical sensors that mimic the human fingertips during a clinical breast exam (Sarvazyan, 2012). Tactile imaging is a branch of elasticity imaging that captures stress data at different levels of compression, rather than dynamic or static strain data employed with ultrasonic and magnetic resonance technologies.

During the breast examination, a handheld mechanical sensor is applied to the breast to record and store data in a digital format file. Tactile breast imaging quantifies and records the presence (or absence), size, shape, hardness, and location of breast lesions. It is also called “mechanical imaging,” “palpation imaging,” “computerized palpation,” or “stress imaging.” The duration of a typical lesion scan is approximately one to two minutes (Sarvazyan, 2012).

The U.S. Food and Drug Administration defines such a device as a “breast lesion documentation system… for use in producing a surface map of the breast as an aid to document palpable breast lesions detected during a clinical breast exam” (21CFR884.2990). They issued 510(k) approval as Class II medical devices with special controls (product code NKA) to the following devices that employ proprietary elastography technology:

- SureTouch through a Section 513(f)(2) de novo process under the name BreastView® Visual Mapping System (Assurance Medical, Washington, D.C.) in 2003 (U.S. Food and Drug Administration, 2019a).
- iBreastExam as a substantially equivalent device in 2015 (U.S. Food and Drug Administration, 2019b).

Findings

We identified two single-arm studies and one meta-analysis of nine studies presented as a meeting abstract for this policy. One study evaluated the diagnostic performance of the iBreastExam (Broach, 2016), and the other study and meta-analysis focused on SureTouch (Kaufman, 2014; Tasoulis, 2014). The current evidence consists of very low-quality, uncontrolled studies of the diagnostic efficacy for either tactile breast imaging device. The impact of these devices on patient outcomes has not been determined.

There is significant potential for bias in these studies that could result in hyper-inflated estimates of diagnostic accuracy of tactile breast imaging relative to other screening modalities. Limitations to the research include insufficient reporting of the referral process and work-up prior to tactile breast imaging, lack of randomization, unclear blinding, and inconsistent application of the gold standard (either radiology or histopathology).

It is unclear where tactile breast imaging would fit into current screening algorithms, as a reliable comparison to mammography or clinical breast exam has not been made. The majority of patients enrolled in these studies were described as symptomatic based on prior work-up or physical complaints, but the extent of the work-up was not defined.

Adjunctive clinical breast exam can detect approximately 2% to 6% more breast cancers than screening mammography alone, but its impact on extending survival or reducing breast cancer mortality is unclear (Oeffinger, 2015). As a result, guidelines disagree on recommendations for a clinical breast exam in asymptomatic women at average risk[1] for breast cancer (American Cancer Society, 2023; American College of Obstetricians and Gynecologists, 2021; National Comprehensive Cancer Network, 20244; U.S. Preventive Services Task Force, 2024).

The quality of the evidence for tactile breast imaging would need to dramatically improve before its value in breast cancer screening can be determined. A phase II study is comparing the accuracy of the iBreastExam for the detection of clinically relevant findings in the breast to current mammography (Clinicaltrials.gov identifier NCT02762565). A phase 4 single site, nonrandomized, prospective study is comparing the clinical utility (accuracy) of the iBreastExam for the detection of breast lesions or lumps to the results of a current mammography and/or ultrasound (Clinicaltrials.gov identifier NCT02597452).

In 2019, we added no new evidence or guidelines that would materially change the policy findings. The policy ID was changed from CP# 05.01.07 to CCP.1353.

In 2020, we updated one guideline (National Comprehensive Cancer Network, 2019) with no changes to the policy.

In 2021, we updated the references with no changes to the policy.

In 2022, we updated the references for the American College of Obstetricians and Gynecologists (2021), American Cancer Society (2021), and National Comprehensive Cancer Network (2021), and added the results of two recently completed studies (Clanahan, 2020; Clinicaltrials.gov identifier NCT02762565). A phase II study (Clinicaltrials.gov identifier NCT02762565; n = 78 participants) compared the sensitivity of the iBreastExam to mammography in a mixed symptomatic and screening population and posted the results on clinicaltrials.gov. The results of each participant were presented as four quadrants per breast. Of the 77 quadrants iBreastExam labeled as positive, 66 (86%) were confirmed positive by mammography or ultrasound.

A phase 4 study (Clinicaltrials.gov identifier NCT02597452; n = 486 participants) compared the specificity of the iBreastExam and clinical breast exam to mammography and/or ultrasound for the detection of breast lesions in an asymptomatic screening population in Pennsylvania (Clanahan, 2020). iBreastExam and clinical breast exam demonstrated moderate agreement on categorization (κ = 0.53) but negligible agreement with mammography (κ = 0.08), likely attributed to the different characteristics among methods used to screen the breast. Compared to

[1] A woman at average risk for breast cancer is one without a personal history of breast cancer; a strong family history of breast cancer; a genetic mutation known to increase risk of breast cancer (e.g., a breast cancer gene); and no chest radiation therapy before age 30 (American Cancer Society, 2023).

mammography, the specificity and negative predictive value of iBreastExam was 80.3% and 94.0%, respectively, and the specificity and negative predictive value of clinical breast exam was 88% and 94.5%, respectively. The authors suggest the potential of iBreastExam to reduce the population in need of additional diagnostic workup by 80%, and from that, its likely clinical utility may be as an additional triage mechanism for at-risk populations in resource-limited settings. However, more studies are needed to confirm these findings.

The new evidence is insufficient to support a clinical role for tactile breast imaging, and no guideline currently includes the modality in any clinical algorithm. No policy changes are warranted.

In 2023, we updated the references for the American Cancer Society (2022) and the National Comprehensive Cancer Network (2022). No newly relevant studies have been published. No policy changes are warranted.

In 2024, we updated references for the National Comprehensive Cancer Network (2023). No new relevant studies have been published. No policy changes are warranted.

In 2025, we found a systematic review evaluating the clinical utility of tactile breast imaging devices, including the iBreastExam. It identified 11 relevant prospective, nonrandomized studies encompassing a total of (n = 8,026) participants. Within these studies, diagnostic accuracy varied widely, with sensitivity values ranging from 34.3 % to 86 %, specificity values commonly exceeding 80 %, and lesion detection extending to masses smaller than one centimeter. Five studies were conducted in low- and middle-income countries, and several investigations involved both screening and diagnostic settings. Although findings demonstrated promising potential for handheld devices to improve early detection and triage in resource-limited environments, high false-positive rates and limited data on overall impact on patient mortality warrant cautious interpretation of these results (Bhimani, 2023). We also we updated references for the National Comprehensive Cancer Network (2024) and the American Cancer Society (2023). No policy changes were warranted.

References

On December 6, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “elasticity imaging techniques” (MeSH), “breast” (MeSH), “Ultrasonography, Mammary/methods” (MAJR), and free text terms “shear wave elastography,” “tactile breast imaging,” “digital breast exam,” “palpation imaging,” and “mechanical imaging.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/2017: initial review date and clinical policy effective date: 2/2018

1/2019: Policy references updated and policy ID changed.

1/2020: Policy references updated.

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.

1/2024: Policy references updated.

1/2025: Policy references updated.