
Medical Policy



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***Current Policy Effective Date: 5/1/26**
(See policy history boxes for previous effective dates)

Title: Tactile Breast Imaging

Description

Tactile breast imaging (TBI), otherwise known as breast lesion documentation systems, are devices that produce a surface pressure map of the breast as an aid to document palpable breast lesions that are identified during clinical exams.

Medical Policy Statement

Tactile breast imaging by computer-aided tactile sensors is considered experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in 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:

NA

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

0422T

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

Tactile breast imaging uses state-of-the-art elastography technology. A hand held sensor is moved across the breast and underarm area (no compression or radiation is needed). Multi-dimensional color images populate on a computer screen in real-time, allowing the practitioner to view the size, shape, hardness and location of suspicious masses. Tactile breast imaging maps lesion information from raw tactile images by using advanced proprietary image algorithms. Digital images are stored for future reference and comparison.

Although the U.S. Food and Drug Administration approved the device as an aid for documenting palpable breast lesions detected during a clinical breast exam, it is unclear where tactile breast imaging would fit into current screening practices. A reliable comparison to mammography or clinical breast exam has not been determined.

Summary of Evidence:

The clinical evidence was assessed to determine whether the use of tactile breast imaging improves the net health outcome. Currently, it is unclear where, if at all, tactile breast imaging would fit into current screening practices for breast cancer. One study indicated that tactile breast imaging may be a valuable screening tool in resource-limited settings while cautioning about low-sensitivity and high false positive rates. Another source indicated that TBI is useful in recording and tracking palpable masses for future reference. At this time there is a lack of literature with head-to-head comparisons to other standard treatments. Published studies either lack control groups or have serious methodologic problems that prevent the drawing of treatment-guiding conclusions from their results. TBI has not demonstrated improved clinical outcomes in screening individuals for breast cancer. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Rationale

Kearney et al (2004) evaluated the sensitivity of tactile imaging with breast examinations. Ten breast phantoms in various sizes containing a total of 36 solid nodules were constructed out of a specially designed silicon compound with elasticity moduli typical for breast tissues. The nodules varied in size from 6 to 30 mm. The depth of placement varied from 10 to 50 mm. Eight of the phantoms contained 4 to 5 nodules. Two phantoms contained no nodules. The breast phantoms were manually examined for nodules. Then the examiner repeated the examination with the device after about 30 minutes training with the TBI. Examiners included skilled medical professionals (3 surgical oncologist, 3 advanced practice nurses) and unskilled

lay persons (3 secretaries and 4 engineers). The 4 engineers were additionally trained in 4 additional sessions and repeated the phantom exams. The ability to detect the nodules with and without the TBI by skilled and unskilled examiners was compared. The effect of repeat training was also evaluated. Authors concluded that the use of the tactile breast imager increases the sensitivity of breast palpation when used by lay persons in breast models. The sensitivity increases to the level exceeding that of a trained medical professional, particularly with training. The TBI has the potential to increase the detection of palpable breast models if the phantom findings can be duplicated in vivo.

Tasoulis et al (2014) assessed tactile imaging's diagnostic performance and compared it to clinical breast examination (CBE) in a prospective, blinded, comparative study of 276 consecutive subjects. All subjects underwent conventional imaging and tissue sampling if either a radiological or a palpable abnormality was present. Sensitivity, specificity and positive and negative predictive values for CBE and tactile imaging were calculated. Radiological findings and final diagnosis based on histology and/or cytology were used as reference standards. Receiver operator characteristic (ROC) curve analysis was also performed for each method. Sensitivity and specificity of tactile imaging in detecting radiologically proven abnormalities were 85.5% and 35%, respectively. CBE's sensitivity was 80.3 % and specificity 76%. In detecting a histopathological entity according to histology/cytology, sensitivity was 88.2% for tactile imaging and 81.6% for CBE. Specificity was 38.5% and 85.7% for tactile imaging and CBE, respectively. These results suggest a trend towards higher sensitivity of tactile imaging compared to CBE but significantly lower specificity. Subgroup analysis revealed superior sensitivity of tactile imaging in detecting a histological entity in pre-menopausal women. However, CBE's overall performance was superior compared to tactile imaging's according to ROC curve analysis. Authors determined that although further research is necessary, the use of tactile imaging by the primary care physician as a selection tool for referring subjects to a breast specialist should be considered especially in pre-menopausal women.

Bhimani et al (2023) performed a systematic review to evaluate iBreastExam's (iBEs) performance, determine the clinical utility and applicability of iBreastExam when compared with clinical breast examinations, ultrasound, and mammography and discuss its strengths and weaknesses when performing breast-cancer screening. Eleven studies with a total sample size of 16,052 breast were reviewed. The mean age ranged from 42 to 58 years. The sensitivity and specificity of the iBE ranged from 34.3% to 86% and 59% to 94%, respectively. For malignant lesions, iBE demonstrated a moderate to higher diagnostic capacity ranging from 57% to 93% and could identify tumor sizes spanning from 0.5 cm to 9 cm. Findings indicated that the device had low-sensitivity and high false positive rates. The authors cautioned that interpretation should be done with caution but determined that iBE for prescreening and triaging may be a useful tool in reducing the burden of diagnostic imaging in lower- and middle-income countries.

Supplemental Information

National Comprehensive Cancer Network

NCCN guidelines recommend the use of annual mammography with tomosynthesis to screen for breast cancer in individuals ≥ 40 . No mention is made for the use of tactile breast imaging.

U.S. Preventive Services Task Force

The USPSTF guidelines for breast cancer screening (2024) recommends biennial screening mammography for women aged 40 to 74 years (B grade). No mention is made for the use of tactile breast imaging.

No guidelines were found which address the use of tactile breast imaging during the screening process for breast cancer.

Regulatory Status

SureTouch Mobile Pressure Mapping System (Sure Inc.) received FDA 510(k) approval in 2019 (aka BEXA). The system is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast examination. The SureTouch Mobile Pressure Mapping System is intended for use by a qualified healthcare professional trained in its use and is not for home use.

iBreastExam Gen II (UE LifeSciences Inc.) received FDA 510(k) approval in 2019. The system is intended to produce a surface pressure map of the breast as an aid in documenting palpable breast lesions identified during a clinical breast examination. The iBreastExam Gen II device is intended for use by a qualified healthcare professional trained in its use and is not for home use.

Product code: NKA

Government Regulations

National:

No National determination was noted for the use of tactile breast imaging.

Local:

No Local determinations are noted for the use of tactile breast imaging.

(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

- Breast Elastography – Ultrasound or Magnetic Resonance
- Digital Breast Tomosynthesis (3D Mammography)
- Magnetic Resonance Imaging of the Breast
- Magnetic Resonance Imaging to Monitor Integrity of Silicone-Gel-Filled Breast Implants
- Scintimammography and Gamma Imaging of the Breast and Axilla
- Ultrasound for Breast Cancer Screening

References

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3. Kearney, T.J., Airapetian, S., Sarvazyan, A. "Tactile breast imaging to increase the sensitivity of breast examination." 2004. J of Clin Oncology. 22(14) <https://doi.org/10.1200/jco.2004.22.90140.1037>. Accessed January 14, 2026.
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6. Tasoulis MK, Zacharioudakis KE, Dimopoulos NG, Hadjiminis DJ. Diagnostic accuracy of tactile imaging in selecting patients with palpable breast abnormalities: a prospective comparative study. *Breast Cancer Res Treat*. 2014 Oct;147(3):589-98. doi: 10.1007/s10549-014-3123-3. Epub 2014 Sep 11. PMID: 25209004.
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9. U.S. Food & Drug Administration. SureTouch Mobile Pressure Mapping System. K181672. 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181672.pdf. Accessed January 14, 2026.
10. United States Preventive Services Taskforce. "Breast Cancer: Screening." 2024. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#bcei-recommendation-title-area>. Accessed January 14, 2026.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/14/26, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/25	2/25/25		Joint policy established (slp) Vendor Managed: N/A
5/1/26	2/17/26		Routine maintenance (slp) Vendor Managed: N/A Policy formatting updated MPS updated to current language

Next Review Date: 1st Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TACTILE BREAST IMAGING

I. Coverage Determination:

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

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.