Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

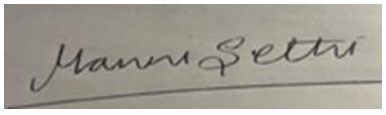
Plan: Keystone First	Submission Date: 2/1/2026
Policy Number: CCP. 1353	Effective Date: 2/1/2018 Revision Date: 1/1/2026
Policy Name: Tactile breast imaging	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Tactile breast imaging

Clinical Policy ID: CCP.1353

Recent review date: 1/2026

Next review date: 5/2027

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

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

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

- SureTouch™ Mobile Pressure Mapping System (Medical Tactile Inc., Los Angeles, CaliforniaiBreastExam™ (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 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). The U.S. Food and Drug Administration classifies these devices as breast lesion documentation systems (21 CFR 884.2990; product code NKA). Devices in this category have received marketing authorization through FDA’s de novo classification and 510(k) clearance pathways:

- SureTouch Mobile Pressure Mapping System (510(k) K181672)under the name BreastView® Visual Mapping System (Assurance Medical, Washington, D.C.) in 2003 (U.S. Food and Drug Administration, 2019a).
- iBreastExam Gen II (510(k) K190575)as a substantially equivalent device in 2015 (U.S. Food and Drug Administration, 2019b).

Findings

The evidence base for tactile breast imaging consists primarily of nonrandomized diagnostic accuracy and feasibility studies. These studies are characterized by heterogeneous populations, variable referral pathways, and inconsistent application of reference standards. Test performance estimates vary widely, and available evidence has not demonstrated improvements in patient-important outcomes such as stage at diagnosis or breast cancer–specific mortality.

Key methodological limitations include selection and verification bias, limited blinding, and incomplete characterization of downstream work-up. These limitations raise concern that reported diagnostic accuracy may be inflated relative to standard imaging-based screening and diagnostic evaluation.Guidelines

Current breast cancer screening recommendations emphasize mammography-based screening, with risk-stratified use of established imaging modalities. Contemporary guidelines do not incorporate tactile breast

imaging devices into screening or diagnostic algorithms and do not define clinical decision pathways in which tactile breast imaging substitutes for, or routinely augments, mammography, ultrasonography, or magnetic resonance imaging (US Preventive Services Task Force, 2024; American Cancer Society, 2023; American College of Obstetricians and Gynecologists, 2024; National Comprehensive Cancer Network (NCCN), 2025; Women's Preventive Services Initiative, 2025).

Guideline treatment of clinician-performed breast examination further limits the interpretability of device-augmented palpation approaches for screening. The American Cancer Society states that clinical breast examination is not recommended for breast cancer screening among average-risk women[1] at any age (American Cancer Society, 2023). In contrast, the NCCN Breast Cancer Screening and Diagnosis guideline incorporates clinical encounters that generally include a clinical breast examination when feasible, including in asymptomatic individuals (NCCN, 2025). In this context, evidence supporting tactile breast imaging as a screening test, a population-level triage tool, or a replacement for imaging-based screening would require robust comparative studies demonstrating clinically meaningful benefit beyond standard screening pathways.

Systematic reviews

Bhimani (2023) systematically reviewed prospective nonrandomized studies of tactile breast imaging devices, including iBreastExam, across screening and diagnostic settings in high-, middle-, and low-income countries. Study populations and designs were heterogeneous, diagnostic accuracy estimates varied widely, and data on downstream testing and clinical outcomes were limited.

Other study types

The earlier evidence base includes small to moderate-sized feasibility and validation studies, including work evaluating iBreastExam performance in low-resource environments (Broach, 2016). These studies are relevant to feasibility and device performance under selected conditions but do not address whether use of tactile breast imaging changes clinical outcomes, reduces diagnostic delay, or improves the effectiveness of established screening programs.

Comparative diagnostic studies of tactile imaging have also been published, including a prospective comparative study of tactile imaging in patients with palpable breast abnormalities (Tasoulis, 2014). These studies often enroll symptomatic or pre-selected populations and therefore have limited generalizability to population screening contexts. In addition, the predominance of nonrandomized designs and variable reference standards limits inference regarding comparative effectiveness versus standard imaging-based evaluation.

A prospective study compared iBreastExam and clinical breast examination to mammography and/or ultrasound in an asymptomatic screening population and reported moderate agreement between iBreastExam and clinical breast examination but negligible agreement with mammography-based findings, consistent with these approaches capturing different lesion characteristics and raising uncertainty about clinical placement (Clanahan, 2020). Registry-reported evaluations include a phase II study comparing iBreastExam sensitivity to mammography in a mixed population and a phase 4 prospective study comparing iBreastExam and clinical breast examination to mammography and/or ultrasound for lesion detection in an asymptomatic screening population (ClinicalTrials.gov identifier NCT02762565; ClinicalTrials.gov identifier NCT02597452). These studies do not establish improved health outcomes and do not define a guideline-supported role for tactile breast imaging in screening or diagnostic pathways.

Newer evidence adds a large community outreach study (n = 10,004) comparing iBreastExam with clinical breast examination for early detection (Joshi, 2025). While the sample size strengthens the descriptive evidence base, the design and comparator framework do not establish equivalence or incremental value relative to mammography-based screening, and the study does not address downstream outcomes such as

stage shift or mortality (Joshi, 2025). Overall, the body of evidence remains insufficient to support a clinical role for tactile breast imaging devices, and no major guideline includes these devices in a clinical algorithm (American Cancer Society, 2023; US Preventive Services Task Force, 2024; American College of Obstetricians and Gynecologists, 2024).

In 2026, we updated the evidence and guideline references to include a peer-reviewed comparative study of iBreastExam and updated major screening guidance (Joshi, 2025; US Preventive Services Task Force, 2024; American College of Obstetricians and Gynecologists, 2024; Women's Preventive Services Initiative, 2025).

References

On December 9, 2025, 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.

American Cancer Society. Recommendations for the early detection of breast cancer. https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html. Updated December 19, 2023.

American College of Obstetricians and Gynecologists. ACOG updates recommendation on when to begin breast cancer screening mammography. Published October 10, 2024. https://www.acog.org/news/news-releases/2024/10/acog-updates-recommendation-when-to-begin-breast-cancer-screening-mammography.

Bhimani F, Zhang J, Shah L, et al. Can the clinical utility of ibreastexam, a novel device, aid in optimizing breast cancer diagnosis? A systematic review. *JCO Glob Oncol*. 2023;9:e2300149. Doi: 10.1200/GO.23.00149.

Broach RB, Geha R, Englander BS, et al. A cost-effective handheld breast scanner for use in low-resource environments: A validation study. *World Jour Surg Onc*. 2016;14:277. Doi: 10.1186/s12957-016-1022-2.

Clanahan JM, Reddy S, Broach RB, et al. Clinical utility of a hand-held scanner for breast cancer early detection and patient triage. *JCO Glob Oncol.* 2020;6:27-34. Doi: 10.1200/JGO.19.00205.

ClinicalTrials.gov. Clinical utility of a low-cost hand-held breast scanner. Clinicaltrials.gov identifier NCT02762565. https://www.clinicaltrials.gov/ct2/show/NCT02762565?term=NCT02762565&draw=2&rank=1. Last updated August 16, 2021.

ClinicalTrials.gov. Clinical utility of a low-cost hand-held breast scanner for breast cancer early detection and patient triage. ClinicalTrials.gov identifier NCT02597452. https://www.clinicaltrials.gov/study/NCT02597452. Last updated April 6, 2020.

Henderson JA, Duffee D, Ferguson T. Breast Examination Techniques. [Updated 2023 Jan 16]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. Available from: https://www.ncbi.nlm.nih.gov/books/NBK459179/. Published January 2022.

Joshi SN, Dharpawar TS, Kulkarni SR, et al. Comparison of iBreastExam with clinical breast examination for early detection of breast cancer in community outreach clinics in Pune, India. Int J Cancer. Published online September 6, 2025. doi:10.1002/ijc.70137.

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Tasoulis MK, Zacharioudakis KE, Dimopoulos NG, Hadjiminas DJ. Diagnostic accuracy of tactile imaging in selecting patients with palpable breast abnormalities: A prospective comparative study. *Breast Cancer Res Treat*. 2014;147(3):589-598. Doi: 10.1007/s10549-014-3123-3.

U.S. Food and Drug Administration. SureTouch Mobile Pressure Mapping System. 510(k) premarket approval letter [K181672]. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181672.pdf. Published June 28, 2019.(a)

U.S. Food and Drug Administration. iBreastExam Gen II. 510(k) premarket approval letter [K190575/S001]. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190575.pdf. Published July 16, 2019.(b)

U.S. Preventive Services Task Force. Final update summary: Breast cancer: Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening. Published January 2016. Updated April 30, 2024.

Women's Preventive Services Initiative. Breast cancer screening for women at average risk. https://www.womenspreventivehealth.org/recommendations/breast-cancer/.

Electronic Code of Federal Regulations. 21 CFR § 884.2990 Breast lesion documentation system. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-884/subpart-C/section-884.2990.US Food and Drug Administration. Breast lesion documentation system class II special controls guidance document for industry and FDA. Published July 2, 2018. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/breast-lesion-documentation-system-class-ii-special-controls-guidance-document-industry-and-fda.

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.
1/2026: Policy references updated.

Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1353. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral