Clinical Policy Title: Tactile breast imaging

Clinical Policy Number: 05.01.07

Effective Date: February 1, 2018
Initial Review Date: November 16, 2017
Most Recent Review Date: January 11, 2018
Next Review Date: January 2019

Related policies:

CP# 170103  Breast cancer screening in women

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of tactile breast imaging with either of the following devices to be investigational and, therefore, not medically necessary:

- SureTouch™ Digital Breast Exam (Sure Inc., Los Angeles, California).

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of tactile breast imaging are not medically necessary.
**Alternative covered services:**

- Mammography.
- Ultrasonography.
- Magnetic resonance imaging (MRI).

**Background**

In 2017, an estimated 316,120 new cases of breast cancer will be diagnosed in women, including 63,410 new cases of the non-invasive, early-form carcinoma in situ (CIS) (American Cancer Society [ACS], 2017). 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 MRI (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 (McDonald, 2004). There are limitations to a manual clinical breast exam that can influence the ease or difficulty of breast cancer detection (McDonald, 2004):

- 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.

**Tactile breast imaging:**

To overcome these limitations, tactile breast imaging was developed in the 1990s as a diagnostic modality based on digital 3-D reconstruction of 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 (Sarvazyan, 2012). 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.

The U.S. Food and Drug Administration (FDA) 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 FDA has issued 510(k) approval as Class II medical devices with special controls (product code NKA) to the following devices that employ proprietary elastography technology:

- iBreastExam as a substantially equivalent device in 2015 (FDA, 2017b).

**Searches**

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 18, 2017. 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:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**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. The FDA approved the device as an aid for documenting palpable breast lesions detected during a clinical breast exam, but the value of a clinical breast exam has been questioned. Adjunctive clinical breast exam can detect approximately 2 percent to 6 percent 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 clinical breast exam in asymptomatic women at average risk\(^1\) for breast cancer (The American Congress of Obstetricians and Gynecologists [ACOG], 2017; ACS, 2017; National Comprehensive Cancer Network [NCCN], 2017; U.S. Preventive Services Task Force [USPSTF], 2016).

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 underway to compare the accuracy of the iBreastExam for the detection of clinically relevant findings in the breast to current mammography (clinical_trials.gov identifier NCT02762565), and a phase 4 study of the clinical utility (accuracy) of the iBreastExam for the detection of breast lesions or lumps compared to the results of a current mammogram and/or ultrasound (clinical_trials.gov identifier NCT02597452).

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Broach (2016)</td>
<td>Key points:</td>
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</table>

\(^1\) 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 BRCA gene); and no chest radiation therapy before age 30 (ACS, 2017).
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| A cost-effective handheld breast scanner for use in low-resource environments: a validation study | • Case series of 77 females and one male presenting to a breast imaging center for a diagnostic work-up; mean age = 42 years (range 21 years – 79 years).  
• Patients evaluated by ultrasound (77), diagnostic mammography (52), and biopsy (39).  
• Imaging and/or biopsy confirmed a mass (fibroadenoma, cyst, papilloma, myofibroblastoma, fat necrosis, ductal carcinoma in situ, or cancer) in 60 patients, of whom 12 patients had a cancer diagnosed.  
• In total, 77 of 342 quadrants scanned had lesions confirmed on imaging. iBreastExam identified 66 of 77 lesions: sensitivity = 86%; specificity = 89%. |
| clinicaltrials.gov identifier: NCT02814292 |                                                                                                    |
| iBreastExam                                                                                     |                                                                                                    |
| Kaufman (2014)                                                                                 | Key points:                                                                                       |
| Clinical studies of palpation imaging of the breast on more than 1,000 patients                 | • Meta-analysis of nine clinical studies involving 1,155 total symptomatic patients in the United States, China, and the United Kingdom comparing mammography, breast ultrasound, clinical breast exam, MRI, and tactile breast imaging to pathology.  
• For identifying the presence of an abnormality, sensitivity of tactile breast imaging and clinical breast exam was 89% and 83%, respectively.  
• For identifying the presence of breast cancer:                                                                                                                    |
| Meeting abstract                                                                                |                                                                                                    |
| SureTouch                                                                                       |                                                                                                    |
| Kaufman (2014)                                                                                 |                                                                                                    |
| Diagnostic accuracy of tactile imaging in selecting patients with palpable breast abnormalities: a prospective comparative study |                                                                                                    |
| SureTouch                                                                                       |                                                                                                    |
| Tasoulis (2014)                                                                                 | Key points:                                                                                       |
| SureTouch                                                                                       |                                                                                                    |
| References                                                                                      |                                                                                                    |
| Professional society guidelines/other:                                                           |                                                                                                    |


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

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

The American Medical Association has given it a Category III (043XTI) code, Tactile breast Imaging by computer-aided tactile sensors, unilateral or bilateral.

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<td>0422T</td>
<td>Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral</td>
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<td>N63.31-N63.32</td>
<td>Unspecified lump in axillary tail</td>
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<td>N63.41-N63.42</td>
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