Thermography is a noninvasive imaging technique that measures temperature distribution in organs and tissues. The visual display of this temperature information is known as a thermogram. Thermography has been proposed as a diagnostic tool for treatment planning and for evaluation of treatment effects for a variety of conditions.

Interpretation of the color patterns is thought to assist in the diagnosis of many disorders such as complex regional pain syndrome (previously known as reflex sympathetic dystrophy), breast cancer, Raynaud phenomenon, digital artery vasospasm in hand-arm vibration syndrome, peripheral nerve damage following trauma, impaired spermatogenesis in infertile men, degree of burns, deep vein thrombosis, gastric cancer, tear-film layer stability in dry-eye syndrome, Frey syndrome, headaches, lower back pain, and vertebral subluxation.

Infrared radiation from the skin or organ tissue reveals temperature variations by producing brightly colored patterns on a liquid crystal display. Thermography involves the use of an infrared scanning device and can include various types of telethermographic infrared detector images and heat-sensitive cholesteric liquid crystal systems.
OBJECTIVE

The objective of this evidence review is to determine whether thermography improves the net health outcome for a variety of indications including but not limited to the diagnosis of breast cancer, musculoskeletal injuries, and temporomandibular joint disorder.

POLICY STATEMENT

The use of all forms of thermography is considered investigational.

POLICY GUIDELINES

There is no specific code for skin surface infrared thermography.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A number of thermographic devices have been cleared for marketing by the Food and Drug Administration through the 510(k) process. Food and Drug Administration product codes: LHQ, FXN. Devices with product code LHQ may only be marketed for adjunct use. Devices with product code FXN do not provide a diagnosis or therapy. Examples of these devices are shown in Table 1.

Table 1. Thermography Devices Cleared by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
<th>510(K) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrared Sciences Breastscan IR System</td>
<td>Infrared Sciences</td>
<td>Feb 2004</td>
<td>K032350</td>
</tr>
<tr>
<td>Telethermographic Camera, Series A, E, S, and P</td>
<td>FLIR Systems</td>
<td>Mar 2004</td>
<td>K033967</td>
</tr>
<tr>
<td>Notouch Breastscan</td>
<td>UE Lifesciences</td>
<td>Feb 2012</td>
<td>K113259</td>
</tr>
<tr>
<td>WoundVision Scout</td>
<td>WoundVision</td>
<td>Dec 2013</td>
<td>K131596</td>
</tr>
<tr>
<td>AlfaSight 9000 Thermographic System</td>
<td>Alfa Thermodiagnosics</td>
<td>Apr 2015</td>
<td>K150457</td>
</tr>
<tr>
<td>FirstSense Breast Exam</td>
<td>First Sense Medical</td>
<td>Jun 2016</td>
<td>K160573</td>
</tr>
<tr>
<td>Sentinel BreastScan II System</td>
<td>First Sense Medical</td>
<td>Jan 2017</td>
<td>K162767</td>
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</tbody>
</table>

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RATIONALE

Summary of Evidence

For individuals who have an indication for breast cancer screening or diagnosis who receive thermography, the evidence includes diagnostic accuracy studies and systematic reviews. The relevant outcomes are overall survival, disease-specific survival, and test validity. Using histopathologic findings as the reference standard, a series of systematic reviews of studies have evaluated the accuracy of thermography to screen and/or diagnose breast cancer and reported wide ranges of sensitivities and specificities. To date, no study has demonstrated whether thermography is sufficiently accurate to replace or supplement mammography for breast cancer diagnosis. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with breast cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have musculoskeletal injuries who receive thermography, the evidence includes diagnostic accuracy studies, a longitudinal prospective study, and a systematic review. The relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries found moderate levels of accuracy compared with other diagnostic imaging tests. There is a lack of a consistent reference standard. This evidence does not permit conclusions as to whether thermography is sufficiently accurate to replace or supplement standard testing. Moreover, there are no high-quality or randomized studies on the impact of thermography on patient management or health outcomes for patients with musculoskeletal injuries. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have temporomandibular joint (TMJ) disorder who receive thermography, the evidence includes a systematic review. The relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing TMJ disorder found a wide variation in accuracy compared to other diagnostics. There is a lack of a consistent reference standard. The evidence does not permit conclusions as to whether thermography is sufficiently accurate to replace or supplement standard testing. Moreover, there are no studies on the impact of thermography on patient management or health outcomes for patients with TMJ disorder. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have miscellaneous conditions (eg, herpes zoster, pressure ulcers, diabetic foot) who receive thermography, the evidence includes diagnostic accuracy studies. The relevant outcomes are test validity, symptoms, and functional outcomes. There are one or two preliminary studies on each of these potential indications for thermography. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Due to the small number of studies for each indication, diagnostic accuracy could not adequately be evaluated. The clinical utility of thermography for any of these miscellaneous conditions has not been investigated in studies considered. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

European Society of Breast Imaging

A position paper by the European Society of Breast Imaging (2017) and 30 other national breast radiology bodies on screening for breast cancer stated that "screening with thermography or other optical tools as alternatives to mammography is discouraged." 35.

American College of Physicians

The American College of Physicians (2019) issued a guidance statement for breast cancer screening in average-risk women that reviews existing screening guidelines. While the use of thermography was not mentioned in this statement, the authors conclude that
evidence is insufficient to understand the benefits and harms of primary or adjunctive screening strategies in women who are found to have dense breasts on screening mammography.  

**American College of Radiology**

The American College of Radiology guidelines for breast cancer screening (revised 2017) do not mention the use of thermography for breast cancer screening.  

**National Comprehensive Cancer Network**

National Comprehensive Cancer Network guidelines on breast cancer screening and diagnosis (v.1.2019) states that: "Current evidence does not support the routine use of thermography or ductal lavage as screening procedures."  

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force (2016) recommendations on breast cancer screening do not mention thermography. Additionally, there is insufficient evidence for the use of adjunctive screening methods for breast cancer (ultrasonography, magnetic resonance imaging, digital breast tomosynthesis, or other methods) in women identified to have dense breasts on a negative screening mammogram.  

**Medicare National Coverage**

Medicare does not cover thermography. Current Medicare coverage policy states: "Thermography for any indication (including breast lesions which were excluded from Medicare coverage ...) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective..."  

**REFERENCES**


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35. Sardanelli F, Aase HS, Alvarez M, et al. Position paper on screening for breast cancer by the European Society of Breast Imaging (EUSOBI) and 30 national breast radiology bodies from Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Israel, Lithuania, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland and Turkey. Eur Radiol. Jul 2017;27(7):2737-2743. PMID 28076999


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>FEP 6.01.12 Thermography</td>
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<th>Date</th>
<th>Action</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>Replace policy</td>
<td>Policy statement changed to read not medically necessary.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature search through April 2, 2013. References added; other references renumbered/removed. No change in policy statement.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature search, adding references 5, 4, 13. No changes to policy statement.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 21, 2016; references 13-14, 17, and 19 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 21, 2017; references 3, 9, and 17-18 added. Policy statement unchanged but “not medically necessary” corrected to “investigational”.</td>
</tr>
<tr>
<td>December 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 9, 2018; references 15-19 and 24 added. Policy statement unchanged.</td>
</tr>
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