FEP 6.01.12 Thermography

Effective Date: January 15, 2018

Related Policies:
6.01.18 Scintimammography and Gamma Imaging of the Breast and Axilla

Thermography

Description
Thermography is a noninvasive imaging technique intended to measure 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.

FDA REGULATORY STATUS
A number of thermographic devices have been cleared for marketing by the Food and Drug Administration through the 510(k) process. 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>Dorex Spectrum 9000MB Thermography System</td>
<td>Dorex</td>
<td>Nov 2002</td>
<td>K023434</td>
</tr>
<tr>
<td>Infrared Sciences Breastscan IR System</td>
<td>Infrared Sciences</td>
<td>Feb 2004</td>
<td>K032350</td>
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<tr>
<td>Notouch Breastscan</td>
<td>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>FirstSense Breast Exam®</td>
<td>First Sense Medical</td>
<td>Jun 2016</td>
<td>K160573</td>
</tr>
</tbody>
</table>

POLICY STATEMENT
The use of all forms of thermography is considered investigational.

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

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. Relevant outcomes are overall survival, disease-specific survival, test accuracy, 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 been able to demonstrate 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 and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries has 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 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 miscellaneous conditions (eg, herpes zoster, pressure ulcers, temporomandibular joint disorder) who receive thermography, the evidence includes diagnostic accuracy studies and a systematic review. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. There are 1 or 2 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. Studies have not adequately evaluated the diagnostic accuracy or clinical utility of thermography for any of these conditions. 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 et al
A 2017 position paper by the European Society of Breast Imaging and 30 national breast radiology bodies on screening for breast cancer stated, “screening with thermography or other optical tools as alternatives to mammography is discouraged.”17

American College of Radiology
A 2013 American College of Radiology statement (republished 2016) concluded that there is insufficient evidence to support the use of thermography for breast cancer screening.18

U.S. Preventive Services Task Force Recommendations
The 2016 U.S. Preventive Services Task Force recommendations on breast cancer screening do not mention thermography.19

Medicare National Coverage
Medicare does not consider thermography to be eligible for coverage. The Medicare coverage policy, current as of August 2017 states: “Thermography for any indication (including breast lesions which were excluded from Medicare coverage on July 20, 1984) 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. This exclusion was published as a CMS Final Notice in the Federal Register on November 20, 1992.”20

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.


17. 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

<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></td>
</tr>
<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Policy statement changed to read not medically necessary.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search through April 2, 2013.</td>
</tr>
</tbody>
</table>

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