**Thermography**

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 01/01/00</th>
<th>Next Review Date: 05/18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 05/07, 07/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17</td>
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*This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.*

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Individuals: • With an indication for breast cancer screening or diagnosis</td>
<td>Interventions of interest are: • Thermography</td>
<td>Comparators of interest are: • Mammography</td>
<td>Relevant outcomes include: • Overall survival • Disease-specific survival • Test accuracy • Test validity</td>
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<tr>
<td>Individuals: • With musculoskeletal injuries</td>
<td>Interventions of interest are: • Thermography</td>
<td>Comparators of interest are: • Radiography • Magnetic resonance imaging • Standard care without imaging</td>
<td>Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes</td>
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<tr>
<td>Individuals: • With miscellaneous condition (e.g., herpes zoster, pressure ulcers, temporomandibular joint disorder)</td>
<td>Interventions of interest are: • Thermography</td>
<td>Comparators of interest are: • Radiography • Magnetic resonance imaging • Standard care without imaging</td>
<td>Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes</td>
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</tbody>
</table>

**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.

**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. Systematic reviews of studies evaluating the accuracy of
thermography to screen and/or to diagnose breast cancer found wide ranges of sensitivities and specificities. Studies to date have not demonstrated that 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 have found moderate levels of accuracy compared with other diagnostic imaging tests. This evidence does not permit conclusions 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 (e.g., 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 one or two preliminary studies each from outside of the United States on various miscellaneous 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.

Policy

The use of all forms of thermography is considered investigational.

Background

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. Infrared radiation from the skin or organ tissue reveals temperature variations by producing brightly colored patterns on a liquid crystal display. 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, low back pain, and vertebral subluxation.

Thermography may also assist in treatment planning and procedure guidance by identifying restricted areas of perfusion in coronary artery bypass grafting, identifying unstable atherosclerotic plaque, assessing response to methylprednisone in rheumatoid arthritis, and locating high undescended testicles.

Regulatory Status

In 2002, the Dorex Spectrum 9000MB Thermography System (Dorex Inc., Orange, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in quantifying and visualizing skin temperature changes. Its indicated use is as an aid in diagnosis and follow-up therapy in areas such as orthopedics, pain management,
neurology, and diabetic foot care. This type of device is also known as a telethermographic system. FDA product code: LHQ.

In 2003, several telethermographic cameras (series A, E, P, S) by Flir Systems (McCordsville, IN) were cleared for marketing by FDA through the 510(k) process. Their intended use is as an adjunct to other clinical diagnostic procedures when there is a need for quantifying differences in skin surface temperature. Between 2006 and 2009, three new or updated thermography devices received 510(k) marketing clearance from FDA based on demonstrating substantial equivalence to existing products. FDA product code: LHQ.

Related Protocol
Scintimammography and Gamma Imaging of the Breast and Axilla

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


