

Effective Date: November, 2005; Revised [5/08]

Subject: Thermography

Overview: Thermography is often referred to as digital infrared imaging or computerized thermal imaging. Thermography is a way of measuring and mapping the heat from tissue site such as a breast with the use of a special camera. A computer looks for “hot spots” or differences in heat. It then analyzes the images. The proposed theory is if an area of increased heat is found, it may indicate an increase in blood vessel formation due to cancer or any inflammation.

Policy and Coverage Criteria:

Thermography is **NOT** covered. It is considered experimental and unproven.

Exclusions: N/A

Supporting Information:

1. *Technology Assessment:*

Hayes, Inc.: Thermography in general, and infrared imaging (IRI) in particular, have been developed as a safe, noninvasive addition to, rather than a replacement for, mammography to improve early breast cancer detection and avoid unnecessary biopsy. Thermographic devices measure infrared or heat energy emanating from the surface of the skin and display heat or temperature in the form of a colored pattern. Warmer regions of skin may indicate the presence of precancerous tissue or tumors but any diagnosis of breast cancer must be confirmed with a biopsy. IRI, also referred to as telethermography, uses an infrared camera to collect the images that will be analyzed. Depending on the device used, the patient sits in a chair in front of the infrared camera or lies prone with breasts suspended through openings in the imaging bed. IRI may be static (steady-state), or dynamic. Dynamic infrared imaging (DIRI) allows an assessment of the manner and rate at which the temperature of the skin reheats after the breasts are cooled with chilled air. This approach relies on the theory that new blood vessels formed in cancerous tissue should fail to constrict in response to a “cold challenge” because they lack a layer of muscle. Unlike mammography, IRI and DIRI do not require breast compression or radiation exposure; therefore, thermography does not cause discomfort or pose a risk to safety. The BreastScan system requires an operator who sits at the workstation and activates the device with a computer mouse. Images from the scans are then interpreted by physicians trained in radiology.

The literature search identified four studies that assessed the usefulness of IRI or DIRI for breast cancer detection; however, only two studies are published in peer-reviewed journals. The study results suggest that DIRI has high sensitivity and poor to moderate specificity for detection of breast cancer. In the largest studies, DIRI had 97% to 98% sensitivity, indicating that it detected almost all of the breast cancers. However, the specificity was 14% in the largest study and 55% in a second study, which suggests that, like mammography, DIRI incorrectly identifies many benign masses as being malignant. Only one study evaluated the diagnostic efficacy of IRI, finding that it had 83% sensitivity and 81% specificity. Although this study found that IRI combined with mammography and clinical breast examination had 98% sensitivity, the investigators did not report whether this outcome was statistically significant. Moreover, the specificity of this combination of tests was not reported. Finally, none of the available studies determined whether the sensitivity and/or specificity of diagnosis improved when DIRI was combined with mammography, or whether breast thermography improves health outcomes.

2. *Literature Review:* There is limited evidence in medical literature supporting the use of thermography as a primary diagnostic tool for breast cancer. Ng and Kee concluded thermography, along with the use of artificial neural networks and bio-statistical methods, including regression and receiver operating characteristics, may be a useful tool along with mammography in breast cancer diagnosis. Breast thermography is not currently recommended by the American Medical Association or the American Cancer Society due to lack of evidence supporting its efficacy in detecting cancer.

3. *Benchmarks:*

Blue Cross Blue Shield of Mass.: **We do not cover thermography**, because it has not been shown to improve the health outcome of patients. **The use of all forms of thermography is considered *investigational***, including but not limited to its use in the diagnosis of breast cancer, and does not meet the BCBSMA Medical Technology Assessment Guidelines.

https://www.bluecrossma.com/common/en_US/medical_policies/342%20Thermography%20for%20diagnosis%20of%20various%20conditions%20prn.pdf

Aetna: **Aetna considers thermography (temperature gradient studies) experimental and investigational** because available medical literature indicates thermography to be an ineffective diagnostic technique.

http://www.aetna.com/cpb/cpb_alpha.html#T

Cigna: **CIGNA HealthCare does not cover thermography/temperature gradient studies for any indication, because it is considered experimental, investigational or unproven.**

http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0065_coveragepositioncriteria_thermography.pdf

4. Governmental/Regulatory Agencies and Professional Associations:

- *FDA:* Thermography devices are labeled by the U.S. Food and Drug Administration (FDA) as Class I medical devices under the 510(k) process. Under that process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the device prior to marketing it. According to FDA labeling, thermal imaging is a noninvasive diagnostic technique that allows a practitioner to quantify and visualize skin surface temperature changes. FDA revised its policy and approved the Liquid crystal thermographic system and the Telethermographic system in 2005.

CMS: 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.

<http://www.cms.hhs.gov/Transmittals/Downloads/R10NCD.pdf>

American Medical Association: 1) In view of the lack of sufficient proof of effectiveness, it is the policy of the AMA that the use of thermography for diagnostic purposes cannot be recommended at this time. It should be noted that research protocols using thermography are continuing and data derived from these studies will require careful evaluation. (2) The AMA will continue to monitor the published literature on thermography, with periodic reports as appropriate. (3) The AMA affirms the principle that proponents of a test, procedure, or treatment should bear the burden of proving that it is safe and effective for the proposed purpose through well-designed and well-controlled clinical trials. The results of these trials should be critically reviewed, preferably through reports submitted to peer-reviewed journals.

http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-175.988.HTM

Codes:

CPT Codes:

93740: Temperature gradient studies

93760: Thermogram, cephalic

93762: Thermogram, peripheral

References:

1. Hayes Inc. Health Technology Brief. Digital Infrared Imaging (Thermography) for Detection of Breast Cancer. Hayes Inc: Lansdale, PA. July 7, 2006.
2. Ng EY, Kee EC. Advanced integrated technique in breast cancer thermography. J Med Eng Tenchology. 2007 Aug 17;1-12.
3. American Medical Association. H-175.988 Thermography Update.
http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-175.988.HTM
4. American Cancer Society. Mammograms and Other Breast Imaging Procedures. Revised March 29, 2007.
http://www.cancer.org/docroot/PED/content/PED_2_3X_Mammography_and_Other_Breast_Imaging_Procedu
[res.asp?sitearea=PED](http://www.cancer.org/docroot/PED/content/PED_2_3X_Mammography_and_Other_Breast_Imaging_Procedu)
5. U.S. Food and Drug Administration (FDA). Centers for Devices and Radiologic Health.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=CFR&id=884.2982>
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=CFR&id=884.2980>