Description

Thermography is a noninvasive imaging technique that is 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 to use with a variety of conditions as a diagnostic tool, for treatment planning, and to evaluate the effects of treatment.

Summary of Evidence

There is insufficient evidence to support the use of thermography. Sufficient data are lacking that thermography can accurately diagnose any condition or improve the accuracy of another diagnostic tool. Moreover, there are no published studies evaluating the impact of thermography on patient management or health outcomes. Thus, thermography is considered investigational.

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 such as 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 9000 MD Thermography System (Dorex Inc.; Orange, CA) was cleared for marketing by 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.


