Protocol

Thermography

(60112)

Medical Benefit		**Effective Date**: 01/01/00	**Next Review Date**: 05/19
Preauthorization	No	**Review Dates**: 05/07, 07/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18	

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.

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

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. 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 (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 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.

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 accomplishing the following tasks: 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

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

Device Name	Manufacturer	Clearance Date	510(K) No.
Dorex Spectrum 9000MB Thermography System	Dorex	Nov 2002	K023434
Infrared Sciences Breastscan IR System	Infrared Sciences	Feb 2004	K032350
Notouch Breastscan	Lifesciences	Feb 2012	K113259
WoundVision Scout	WoundVision	Dec 2013	K131596
FirstSense Breast Exam®	First Sense Medical	Jun 2016	K160573

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.

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