Clinical Review Criteria
Infrared Thermography

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc., provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.

Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Thermography (220.11)</td>
</tr>
<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
</tr>
<tr>
<td>Local Coverage Article</td>
<td>None</td>
</tr>
</tbody>
</table>

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Infrared thermography is a non-invasive imaging procedure. It produces representations of variation in temperature on the surface of the human skin. Distribution of skin temperature depends on complex relationships between the skin tissue, inner tissue, local vasculature and metabolic and hormonal activity. Use of thermography as a diagnostic tool is based on the premise that the abnormal issue, such as a tumor, would raise the temperature on the skin surface due to increased metabolic activity. In the 1950s and 60s, researchers found that local skin temperatures over a breast tumor were about 2-3 degrees higher than normal skin temperature.

Although, over the past several decades, there has been experimentation with protocols for obtaining and interpreting thermograms, to date there no established procedures for using thermography to enhance diagnosis of breast cancer or other abnormalities (Mital & Scott, 2007; Ohashi & Uchida, 2000). Among the conditions for which thermography has been proposed are Raynaud’s phenomenon, gastric cancer, headaches, deep vein thrombosis, and impaired spermatogenesis in infertile men.

Several thermography devices have been approved by the FDA, including the Mark I Thermal Imager (IX-DR; Howell, MI) in 2002 and EMD Thermography System in 2006. The EMD Thermography system includes an infrared sensor that is placed in contact with the skin to measure temperature. In addition, special software is used to analyze and display the temperature measurements.

Both recently approved devices were considered to be substantially equivalent to predicate devices. Approval was based on the technology's ability to measure skin temperature, rather than their proven ability to improve diagnosis of any disease. According to FDA documents, thermography is indicated for use as an adjunctive medical imaging modality in situations where a physician chooses to use it.

Medical Technology Assessment Committee (MTAC)

Infrared Thermography
06/04/2008: MTAC REVIEW
Evidence Conclusion: There is no empirical evidence that adjunctive infrared thermography improves the diagnosis of any disease or abnormality.

Articles: No technology assessments conducted by other organizations were identified. The Medline search did not yield any empirical studies that evaluated the diagnostic accuracy of thermography as an adjunctive diagnostic modality for any indication. Several articles were identified that proposed methods for analyzing thermograms, or discussed technical aspects of using thermography.

The use of infrared thermography does not meet the Kaiser Permanente Medical Technology Assessment Criteria.