POLICY TITLE	THERMOGRAPHY
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I. POLICY

The use of all forms of thermography is considered **investigational,** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual MP-6.01.12 Thermography. The FEP Medical Policy manual can be found at: *https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies*.

III. DESCRIPTION/BACKGROUND

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Thermography is a noninvasive imaging technique that measures 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.

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.

Infrared radiation from the skin or organ tissue reveals temperature variations by producing brightly colored patterns on a liquid crystal display. 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.

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. Food and Drug Administration product codes: LHQ, FXN. Devices with product code LHQ may only be marketed for adjunct use. Devices with product code FXN do not provide a diagnosis or therapy. 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.
Infrared Sciences Breastscan IR System	Infrared Sciences	Feb-04	K032350
Telethermographic Camera, Series A, E, S, and P	FLIR Systems	Mar-04	K033967
Notouch Breastscan	UE Lifesciences	Feb-12	K113259
WoundVision Scout	WoundVision	Dec-13	K131596
AlfaSight 9000 Thermographic System	Alfa Thermodiagnostics	Apr-15	K150457
FirstSense Breast Exam®	First Sense Medical	Jun-16	K160573
Sentinel BreastScan II System	First Sense Medical	Jan-17	K162767
InTouchThermal Camera	InTouch Technologies	Feb-19	K181716

IV. RATIONALE

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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 (eg, 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 1 or 2 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.

V. DEFINITIONS Top

N/A

VI. BENEFIT VARIATIONS Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER Top

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of

benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational therefore not covered when used for Thermography

CPT Codes®								
93740	93799							

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IX. REFERENCES

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X. POLICY HISTORY

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MP 5.017	**CAC 5/27/03**
	CAC 4/26/05
	CAC 10/25/05
	CAC 10/31/06
	CAC 11/27/07
	CAC 11/25/08
	CAC 11/24/09 Consensus review. Policy statement unchanged. References updated.
	CAC 5/25/10 Adopted BCBSA Criteria.
	CAC 4/26/11 Consensus review.
	CAC 6/26/12 Consensus review. BCBSA Background /Description adopted. References updated. No change to policy statement. Changed FEP variation from standard to reference FEP Medical Policy Manual MP-6.01.12 Thermography
	7/26/13 Administrative update. Coding review completed
	CAC 9/24/13 Consensus review. No change to policy statements. Added Rationale Section. References reviewed and updated.
	CAC 9/30/14 Consensus review. No change to policy statements. Rationale and Reference sections updated. LCD number changed to L34711.
	11/17/14 Administrative update. Code review.
	CAC 9/29/15 Consensus review. No change to the policy statement. Reference and rationale update. Coding Reviewed
	CAC 11/29/16 Consensus review. No change to the policy statement. Reference and rationale update. Code 93740 added. Variation reformatting.

	12/19/17 Consensus review. No change to the policy statement. Background, references, and rationale updated**.** Coding Reviewed**.** Admin coding review 2/28/18: No changes.
	11/2/18 Consensus review. No change to the policy statement. Background and references updated, rationale condensed.
	8/6/19 Consensus review. No change to policy statements. Tables reformatted and references updated.
	8/11/20 Consensus review. No change to policy statements. References updated, coding reviewed. Updated FDA table.

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