

POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

CLINICAL BENEFIT	☑ MINIMIZE SAFETY RISK OR CONCERN.
	☑ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.
	☐ ASSURE APPROPRIATE LEVEL OF CARE.
	☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.
	☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.
	☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	2/1/2024

POLICY
RATIONALEPRODUCT VARIATIONS
DEFINITIONSDESCRIPTION/BACKGROUND
BENEFIT VARIATIONSDISCLAIMER
POLICY HISTORYCODING INFORMATION
REFERENCES

I. POLICY

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

II. PRODUCT VARIATIONS

Top

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

FEP PPO - Refer to FEP Medical Policy Manual. 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

Top

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, peripheral arterial disease, 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



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

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 <u>Top</u>

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



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

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. No major organization making screening recommendations recommends thermography. Of those commenting on it, the American Cancer Society states, "No study has ever shown that it is an effective screening tool for finding breast cancer early", and the American College of Radiology specifically states it does not endorse thermography for detecting clinically occult 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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

VII. DISCLAIMER Top

Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

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

Procedu	re Codes				
93740	93799				

IX. REFERENCES Top

- 1. Vreugdenburg TD, Willis CD, Mundy L, et al. A systematic review of elastography, electrical impedance scanning, and digital infrared thermography for breast cancer screening and diagnosis. Breast Cancer Res Treat. Feb 2013; 137(3): 665-76. PMID 23288346
- 2. Fitzgerald A, Berentson-Shaw J. Thermography as a screening and diagnostic tool: a systematic review. N Z Med J. Mar 09 2012; 125(1351): 80-91. PMID 22426613
- 3. Morales-Cervantes A, Kolosovas-Machuca ES, Guevara E, et al. An automated method for the evaluation of breast cancer using infrared thermography.. 2018; 17: 989-998. PMID 30564079
- 4. Neal CH, Flynt KA, Jeffries DO, et al. Breast Imaging Outcomes following Abnormal Thermography. Acad Radiol. Mar 2018; 25(3): 273-278. PMID 29275941
- 5. Omranipour R, Kazemian A, Alipour S, et al. Comparison of the Accuracy of Thermography and Mammography in the Detection of Breast Cancer.. Aug 2016; 11(4): 260-264. PMID 27721713
- 6. Rassiwala M, Mathur P, Mathur R, et al. Evaluation of digital infra-red thermal imaging as an adjunctive screening method for breast carcinoma: a pilot study. Int J Surg. Dec 2014; 12(12): 1439-43. PMID 25448668
- 7. Sanchis-Sanchez E, Vergara-Hernandez C, Cibrian RM, et al. Infrared thermal imaging in the diagnosis of musculoskeletal injuries: a systematic review and meta-analysis. AJR Am J Roentgenol. Oct 2014; 203(4): 875-82. PMID 25247955



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

- 8. Corte AC, Pedrinelli A, Marttos A, et al. Infrared thermography study as a complementary method of screening and prevention of muscle injuries: pilot study.. 2019; 5(1): e000431. PMID 30687515
- 9. de Melo DP, Bento PM, Peixoto LR, et al. Is infrared thermography effective in the diagnosis of temporomandibular disorders? A systematic review. Oral Surg Oral Med Oral Pathol Oral Radiol. Feb 2019; 127(2): 185-192. PMID 30482738
- 10. Han SS, Jung CH, Lee SC, et al. Does skin temperature difference as measured by infrared thermography within 6 months of acute herpes zoster infection correlate with pain level? Skin Res Technol. May 2010; 16(2): 198-201. PMID 20456100
- Park J, Jang WS, Park KY, et al. Thermography as a predictor of postherpetic neuralgia in acute herpes zoster patients: a preliminary study. Skin Res Technol. Feb 2012; 18(1): 88-93. PMID 21605168
- 12. Romano CL, Logoluso N, Dell'Oro F, et al. Telethermographic findings after uncomplicated and septic total knee replacement. Knee. Jun 2012; 19(3): 193-7. PMID 21441031
- 13. Oliveira AL, Moore Z, O Connor T, et al. Accuracy of ultrasound, thermography and subepidermal moisture in predicting pressure ulcers: a systematic review. J Wound Care. May 02 2017; 26(5): 199-215. PMID 28475447
- 14. Nakagami G, Sanada H, lizaka S, et al. Predicting delayed pressure ulcer healing using thermography: a prospective cohort study. J Wound Care. Nov 2010; 19(11): 465-6, 468, 470 passim. PMID 21135794
- 15. Wu CL, Yu KL, Chuang HY, et al. The application of infrared thermography in the assessment of patients with coccygodynia before and after manual therapy combined with diathermy. J Manipulative Physiol Ther. May 2009; 32(4): 287-93. PMID 19447265
- 16. Hara Y, Shiraishi A, Yamaguchi M, et al. Evaluation of allergic conjunctivitis by thermography. Ophthalmic Res. 2014; 51(3): 161-6. PMID 24603108
- 17. Singer AJ, Relan P, Beto L, et al. Infrared Thermal Imaging Has the Potential to Reduce Unnecessary Surgery and Delays to Necessary Surgery in Burn Patients. J Burn Care Res. Nov/Dec 2016; 37(6): 350-355. PMID 26720102
- 18. Martinez-Jimenez MA, Ramirez-GarciaLuna JL, Kolosovas-Machuca ES, et al. Development and validation of an algorithm to predict the treatment modality of burn wounds using thermographic scans: Prospective cohort study. PLoS ONE. 2018; 13(11): e0206477. PMID 30427892
- 19. Dong F, Tao C, Wu J, et al. Detection of cervical lymph node metastasis from oral cavity cancer using a non-radiating, noninvasive digital infrared thermal imaging system. Sci Rep. May 08 2018; 8(1): 7219. PMID 29739969
- 20. Agazzi A, Fadanelli G, Vittadello F, et al. Reliability of LoSCAT score for activity and tissue damage assessment in a large cohort of patients with Juvenile Localized Scleroderma. Pediatr Rheumatol Online J. Jun 18 2018; 16(1): 37. PMID 29914516
- 21. Ranosz-Janicka I, Lis-Swiety A, Skrzypek-Salamon A, et al. Detecting and quantifying activity/inflammation in localized scleroderma with thermal imaging. Skin Res Technol. Mar 2019; 25(2): 118-123. PMID 30030915
- 22. Cruz-Segura A, Cruz-Dominguez MP, Jara LJ, et al. Early Detection of Vascular Obstruction in Microvascular Flaps Using a Thermographic Camera. J Reconstr Microsurg. Sep 2019; 35(7): 541-548. PMID 31067581



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

- 23. Unger M, Markfort M, Halama D, et al. Automatic detection of perforator vessels using infrared thermography in reconstructive surgery. Int J Comput Assist Radiol Surg. Mar 2019; 14(3): 501-507. PMID 30519870
- 24. Chen R, Huang ZQ, Chen WL, et al. Value of a smartphone-compatible thermal imaging camera in the detection of peroneal artery perforators: Comparative study with computed tomography angiography. Head Neck. May 2019; 41(5): 1450-1456. PMID 30636085
- 25. Li DG, Dewan AK, Xia FD, et al. The ALT-70 predictive model outperforms thermal imaging for the diagnosis of lower extremity cellulitis: A prospective evaluation. J Am Acad Dermatol. Dec 2018; 79(6): 1076-1080.e1. PMID 30003987
- 26. Al Shakarchi J, Inston N, Dabare D, et al. Pilot study on the use of infrared thermal imaging to predict infrainguinal bypass outcome in the immediate post-operative period. Vascular. Dec 2019; 27(6): 663-667. PMID 31067207
- 27. Magalhaes C, Vardasca R, Rebelo M, et al. Distinguishing melanocytic nevi from melanomas using static and dynamic infrared thermal imaging. J Eur Acad Dermatol Venereol. Sep 2019; 33(9): 1700-1705. PMID 30974494
- 28. Anzengruber F, Alotaibi F, Kaufmann LS, et al. Thermography: High sensitivity and specificity diagnosing contact dermatitis in patch testing. Allergol Int. Apr 2019; 68(2): 254-258. PMID 30598404
- 29. Umapathy S, Thulasi R, Gupta N, et al. Thermography and colour Doppler ultrasound: a potential complementary diagnostic tool in evaluation of rheumatoid arthritis in the knee region. Biomed Tech (Berl). May 26 2020; 65(3): 289-299. PMID 31821162
- 30. Jones B, Hassan I, Tsuyuki RT, et al. Hot joints: myth or reality? A thermographic joint assessment of inflammatory arthritis patients. Clin Rheumatol. Sep 2018; 37(9): 2567-2571. PMID 29679167
- 31. Gatt A, Falzon O, Cassar K, et al. The Application of Medical Thermography to Discriminate Neuroischemic Toe Ulceration in the Diabetic Foot. Int J Low Extrem Wounds. Jun 2018; 17(2): 102-105. PMID 29947290
- 32. Gatt A, Falzon O, Cassar K, et al. Establishing Differences in Thermographic Patterns between the Various Complications in Diabetic Foot Disease.. 2018; 2018: 9808295. PMID 29721019
- 33. Balbinot LF, Robinson CC, Achaval M, et al. Repeatability of infrared plantar thermography in diabetes patients: a pilot study. J Diabetes Sci Technol. Sep 01 2013; 7(5): 1130-7. PMID 24124938
- 34. van Doremalen RFM, van Netten JJ, van Baal JG, et al. Validation of low-cost smartphone-based thermal camera for diabetic foot assessment. Diabetes Res Clin Pract. Mar 2019; 149: 132-139. PMID 30738090
- 35. Sandi S, Yusuf S, Kaelan C, et al. Evaluation risk of diabetic foot ulcers (DFUs) using infrared thermography based on mobile phone as advanced risk assessment tool in the community setting: A multisite cross-sectional study. Enferm Clin. Mar 2020; 30 Suppl 2: 453-457. PMID 32204210
- 36. Hazenberg CE, van Netten JJ, van Baal SG, et al. Assessment of signs of foot infection in diabetes patients using photographic foot imaging and infrared thermography. Diabetes Technol Ther. Jun 2014; 16(6): 370-7. PMID 24690146
- 37. Petrova NL, Donaldson NK, Tang W, et al. Infrared thermography and ulcer prevention in the high-risk diabetic foot: data from a single-blind multicentre controlled clinical trial. Diabet Med. Jan 2020; 37(1): 95-104. PMID 31629373



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

- 38. Sardanelli F, Aase HS, Alvarez M, et al. Position paper on screening for breast cancer by the European Society of Breast Imaging (EUSOBI) and 30 national breast radiology bodies from Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Israel, Lithuania, Moldova, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Sweden, Switzerland and Turkey. Eur Radiol. Jul 2017; 27(7): 2737-2743. PMID 27807699
- 39. Qaseem A, Lin JS, Mustafa RA, et al. Screening for Breast Cancer in Average-Risk Women: A Guidance Statement From the American College of Physicians. Ann Intern Med. Apr 16 2019; 170(8): 547-560. PMID 30959525
- 40. Mainiero MB, Moy L, Baron P, et al. ACR Appropriateness Criteria (R) Breast Cancer Screening. J Am Coll Radiol. Nov 2017; 14(11S): S383-S390. PMID 29101979
- 41. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. Version 1.2022. 2022
- 42. U.S. Preventive Services Task Force. Breast Cancer: Screening. 2016
- 43. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination for Thermography (220.11). 1992
- 44. UpToDate Online Journal [serial online]. Elmore, Joann and Lee, Christopher. Screening for breast cancer: Evidence for effectiveness and harms. UpToDate; updated August 2, 2022
- 45. Wermelink B, Ma KF, Haalboom M, El Moumni M, de Vries JPM, Geelkerken RH. A Systematic Review and Critical Appraisal of Peri-Procedural Tissue Perfusion Techniques and their Clinical Value in Patients with Peripheral Arterial Disease. Eur J Vasc Endovasc Surg. 2021;62(6):896-908. doi:10.1016/j.ejvs.2021.08.017 PMID: 34674935.
- 46. Rakhunde MB, Gotarkar S, Choudhari SG. Thermography as a Breast Cancer Screening Technique: A Review Article. Cureus. 2022;14(11):e31251. Published 2022 Nov 8. doi:10.7759/cureus.31251 PMID 36505165
- 47. Wynn M, Stephens M, Pradeep S, Kennedy R. Risk factors for the development and evolution of deep tissue injuries: A systematic review [published correction appears in J Tissue Viability. 2023 May;32(2):321]. J Tissue Viability. 2022;31(3):416-423. doi:10.1016/j.jtv.2022.03.002 PMID: 35450822
- 48. Leñero-Bardallo JA, Serrano C, Acha B, Pérez-Carrasco JA, Bernabeu-Wittel J. Thermography for the differential diagnosis of vascular malformations. Clin Exp Dermatol. 2021;46(2):314-318. doi:10.1111/ced.14346 PMID 32572993
- 49. Blue Cross Blue Shield Association Medical Policy Reference Manual 6.01.12 Thermography. October 2023.

X. POLICY HISTORY

Top

MP 5.017

8/11/20 Consensus review. No change to policy statements. References updated, coding reviewed. Updated FDA table.

9/17/21 Consensus review. No change to policy statement. References updated.

11/23/2022, Consensus review. No change to policy stance. References updated.



POLICY TITLE	THERMOGRAPHY
POLICY NUMBER	MP 5.017

10/6/2023 Consensus review. No change to policy stance. Updated references.

Top

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.