06.01.16 Thermography and Temperature Gradient Studies

Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

Original Effective Date: November 1996

Review Date: November 2025

Revised: November 2023

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Summary

Description

Thermography (i.e., thermal imaging and temperature gradient studies) 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.

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, and test validity. Using histopathologic findings compared to 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 demonstrated that 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 that the technology results in an improvement in the net health outcome.

For individuals who have musculoskeletal injuries who receive thermography, the evidence includes diagnostic accuracy studies, a longitudinal prospective study, and a systematic review. Relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing musculoskeletal injuries found moderate levels of accuracy compared with other diagnostic imaging tests. There is no 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 high-quality or randomized studies on the impact of thermography on patient management or health outcomes for patients with musculoskeletal injuries. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have temporomandibular joint (TMJ) disorder who receive thermography, the evidence includes a systematic review. Relevant outcomes are test validity, symptoms, and functional outcomes. A systematic review of studies on thermography for diagnosing TMJ disorder found a wide variation in accuracy compared to other diagnostics. There is no consistent reference standard. The 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 the TMJ disorder. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have miscellaneous conditions (e.g., herpes zoster, pressure ulcers, diabetic foot) who receive thermography, the evidence primarily includes diagnostic accuracy studies. Outcomes in these studies are test validity, symptoms, and functional outcomes. Most studies assessed temperature gradients or the association between temperature differences and the clinical condition. Due to the small number of studies for each indication, diagnostic accuracy could not adequately be evaluated. The clinical utility of thermography has only been considered in a single study of diabetic foot ulcers. For other miscellaneous conditions, the clinical utility of thermography has not been investigated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether thermography improves the net health outcomes for a variety of indications including but not limited to the diagnosis of breast cancer, musculoskeletal injuries, and temporomandibular joint disorder.

PRIOR APPROVAL

Not applicable.

POLICY

The use of all forms of thermography (i.e., thermal imaging and temperature gradient studies) is considered **investigational** for all indications because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

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.

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, lower 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 plaques, 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 U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA 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 which is not intended to be an all-inclusive list.

Table 1. Thermography Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Clearance	510(K) No.
AlfaSight 9000 Thermographic System™	Alfa Thermodiagnostics	2015	K150457
FirstSense Breast Exam®	First Sense Medical	2016	K160573
Infrared Sciences Breastscan IR System	Infrared Sciences	2004	K032350
InTouchThermal Camera	InTouch Technologies	2019	K181716
Notouch Breastscan	UE Lifesciences	2012	K113259
Sentinel BreastScan II System	First Sense Medical	2017	K162767
Smile-100 System	Niramai Health Analytix Private Limited	Mar 2022	K212965

Device Name	Manufacturer	Clearance	510(K) No.
Telethermographic Camera, Series A, E, S, and P	FLIR Systems	2004	K033967
ThermPix™ Thermovisual Camera	USA Therm	Apr 2022	K213650
WoundVision Scout™	WoundVision	2013	K131596

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.

RATIONALE

The evidence review was created in November 1996 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 2025 is in the policy.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Breast Cancer Screening or Diagnosis

Clinical Context and Test Purpose

The purpose of using thermography in individuals undergoing breast cancer screening or diagnosis is to inform decisions on diagnosis and treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are asymptomatic individuals being screened for breast cancer or individuals undergoing testing to diagnose breast cancer.

Interventions

The intervention of interest is thermography.

Comparators

The following test is currently being used to make decisions about breast cancer diagnosis: mammography.

Outcomes

The outcome of interest for diagnostic accuracy is test validity (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are overall survival and breast cancer-specific survival rates.

The potential beneficial outcomes of primary interest in the case of a true-negative would be the avoidance of unnecessary surgery and associated consequences (e.g., morbidity, mortality, resource utilization, patient anxiety). The potential harms from a false-positive could be inappropriate assessment and improper management of patients with breast malignancies, which could result in the following: inappropriate surgical decisions, high frequency of unnecessary further testing, and unnecessary patient anxiety. The potential harms from a false-negative could be a determination that the patient does not have malignancy, which would lead to a delay in surgery and tumor diagnosis.

The timing for routine screening can be guided by national guidelines on breast cancer screening. The timing for diagnosis would be after an initial screening test or clinical examination.

Study Selection Criteria

For the evaluation of clinical validity of thermography for breast cancer, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

Several systematic reviews of the published literature on the diagnostic accuracy of thermography were identified. A select few of the earlier systematic reviews are summarized in Tables 2 and 3 below. A systematic review by Vreugdenburg et al (2013) identified 8 studies on thermography for diagnosis of breast cancer that included a valid reference standard (e.g., biopsy with histopathologic confirmation). A previous systematic review by Fitzgerald and Berentson-Shaw (2012) identified 6 studies, 1 using thermography for breast cancer screening and the others using thermography to diagnose breast cancer among symptomatic women or those with a positive mammogram. A summary of the characteristics of clinical validity for these systematic reviews is provided in Table 2. A summary of the clinical validity results is provided in Table 3. Study findings were not pooled due to heterogeneity in data reporting and assessment methodology utilized.

More recently, Goñi-Arana et al (2024) published an updated systematic review and meta-analysis that evaluated the effectiveness of thermography for detecting breast cancer. Their search of PubMed and Scopus between 2001 and May 31, 2023 identified 22 studies for inclusion in their analysis, including the large study by Martín-Del-Campo-Mena et al (2023) that included 3337 participants. Although their meta-analysis found that sensitivities and specificities may have increased over time (88.5% and 71.8%, respectively), significant limitations remain, including high heterogeneity (I^2 value of 79.3% for sensitivity and 99.1% for specificity), which continues to preclude drawing strong conclusions about these findings.

Table 2. Systematic Reviews: Characteristics of Clinical Validity of Thermography in Breast Cancer Screening or Diagnosis

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Vreugdenburg et al (2013)	For screening studies: • asymptomatic women with unknown disease status For diagnostic studies: • women with suspicious symptoms, suspicious findings on clinical examination, or an abnormal mammogram	Diagnostic, cross-sectional studies: • Retrospective case-control; sample selection consecutive • Prospective cohort; sample selection NR • NR cohort; sample selection NR	Biopsy with histopathologic confirmation	Various	Reference Test Prior to Index Test: 1/8; Reference Test During Course of Study: 7/8	Studies blind to reference: • Blind: 4/8 • Not blind: 2/8 • Unclear: 2/8 Studies blind to comparator: • Blind: 2/8 • Not blind: 3/8 • Unclear: 2/8 • N/A: 1/8	All 8 studies utilized different measurement scales and cut-off scores. Poor reporting of index and reference test timing.
Fitzgerald et al (2012)	For screening studies: • asymptomatic women aged 40 to 65 For diagnostic studies: • symptomatic women	Screening studies: • Prospective cohort; sample selection NR Diagnostic studies: • NR case-control; sample selection NR	Screening studies: • mammography Diagnostic studies: • biopsy with histopathologic confirmation	Various	In screening studies, only patients with a positive index test received the reference test. In diagnostic studies,	In all studies, blinding was poorly reported.	Studies utilized various measurement scales and cut-off scores. Thermograms were scored by software, manually, or through a combination of methods. Screening

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
		• NR cohort; sample selection NR			timing of index and reference tests poorly reported.		study utilized more than one thermography device. Poor reporting of index and reference test timing.

N/A: not available; NR: not reported.

[a] Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective; sample selection random or consecutive.

[b] Note other characteristics that could bias or limit relevance such as use of historical data, evolution of technology, or practice setting.

Table 3. Systematic Reviews: Clinical Validity of Thermography in Breast Cancer Screening or Diagnosis

Study; Subgroup	Initial N (Range)	Final N (Range)	Excluded N	Prevalence of Condition	Clinical Validity			
					Sensitivity	***Specificity***	***PPV***	***NPV***
Vreugdenberg et al (2013); Diagnostic studies	NR	1709 (29 to 769)	565 (13 to 524)*	NR	25-97%	12-85%	24-81%	36-95%
Fitzgerald et al (2012); Diagnostic studies	1224 (63 to 769)	NR	NR	NR	25-97%	12-85%	24-83%	36-95%
Fitzgerald et al (2012); Screening studies, at initial screening	10,229 (NR)	NR	NR	NR	61%	74%	0.01%	1.00%

Study; Subgroup	Initial N (Range)	Final N (Range)	Excluded N	Prevalence of Condition	Clinical Validity			
Fitzgerald et al (2012); Screening studies, at 5-yr follow-up	10,229 (NR)	NR	NR	NR	28%	74%	0.01 %	0.99 %

NPV: negative predictive value; NR: not reported; PPV: positive predictive value.

*Only 3/8 studies reported the number of excluded patients in the indicated subgroup.

Diagnostic Studies

Tables 4 through 7 below, summarize some select examples of diagnostic accuracy studies. Morales-Cervantes et al (2018) compared the accuracy of automated or manual thermography screening in 206 women scheduled for mammography in Mexico. A retrospective study conducted in the U.S. by Neal et al (2018) assessed outcomes in 38 women referred for further breast imaging following abnormal thermography testing. Omranipour et al (2016) compared the accuracy of thermography and mammography in 132 patients in Iran who had breast lesions and were candidates for breast biopsy. Rassiwala et al (2014) in India reported on 1008 women being screened for breast cancer. Summaries of characteristics and results of clinical validity for these diagnostic studies are provided in Tables 4 and 5.

Table 4. Diagnostic Study Characteristics of Clinical Validity of Thermography in Breast Cancer Screening or Diagnosis

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Morales-Cervantes et al (2018)	For screening study: • women scheduled for consultation with clinical evidence of tumor suspicious for breast cancer and breast cancer risk factors	Prospective cohort, NR sample allocation	Biopsy with histopathologic confirmation	Automated Thermography (Thermal Score)[c] • + (Thermal Score ≥ 2.5) • - (Thermal Score < 2.5) Manual Thermography • NR Mammography (BI-RADS Rating): • NR	Reference testing performed for women with mammography BI-RADS score indicating suspicion for cancer. Mammography performed after thermography.	Blinding of mammography assessor with respect to thermography not described. Double-blinding indicated for manual assessment of thermograms by oncologist. Blinding of biopsy	Blinding and allocation poorly described. No data reported for mammography despite inclusion as comparator. Reported results may be biased

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
						assessor not described.	and inaccurate due to selective use of reference tests.
Neal et al (2018)	For diagnostic study: • women referred for conventional breast imaging (mammogram and/or ultrasound) for evaluation of abnormal thermography findings	Retrospective cohort, NR sample allocation	Biopsy with histopathologic confirmation or at least 1 year of clinical and/or imaging follow-up	Abnormal Thermography: • Any report of abnormal findings Mammography: (BI-RADS Rating): • + (B4-5) • - (B1-3) Ultrasound (mammography declined by patient) or Mammography: • NR	Thermography testing performed prior to mammography and/or ultrasound. Reference testing performed after index tests. Histopathological reference testing offered for women with BI-RADS score 4-5.	Blinding of assessors not described.	Blinding and allocation not described. Limited data reporting. Reference testing not uniform for all patients. Small study size with retrospective design. Long-term health outcomes not described.

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Omranipour et al (2016)	For diagnostic study: • women with breast lesions based on clinical, mammographic, or ultrasonographic finding in need of breast biopsy	Prospective cohort, NR sample selection	Core needle or surgical biopsy with histopathologic confirmation	Mammography (BI-RADS Rating): • + (B4-5) • - (B1-3) Thermography (Rating): • + (TH3-5) • - (TH1-2)	Reference testing performed after imaging index tests.	Mammography assessors blinded to thermography test results. Blinding of thermography and histopathology assessors not described.	Blinding and allocation poorly described. Concordance of risk classification cannot be assessed due to limited data reporting.
Rassiwala et al (2014)	For screening study: • women aged 20 to 60 years without a prior diagnosis of breast cancer	Prospective cohort, NR sample allocation	For women with normal thermograms: clinical examination only. For women with ΔT ≥ 2.5: clinical, radiologic, and histopathologic examination.	Positive (Potentially having breast cancer) • (ΔT ≥ 3) Abnormal • (ΔT > 2.5, < 3) Normal • (ΔT ≤ 2.5)	Reference test provided only to women with abnormal or elevated thermography index test results.	NR	Blinding and allocation not described. Reported results may be biased and inaccurate due to selective use of reference tests.

BI-RADS: breast imaging reporting and data system; NR: not reported; ΔT: temperature gradient.

[a] Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective; sample selection random or consecutive.

[b] Note other characteristics that could bias or limit relevance such as use of historical data, evolution of technology, or practice setting.

[c] Thermal score is defined as the sum of the surface temperature difference at the site of the lesion compared to that of the contralateral breast and the vascularity score, based on the following scale: 1) absence of vascular patterns; 2) symmetrical or moderate vascular patterns; 3) significant vascular asymmetry; 4) vascular asymmetry extended in at least one-third of breast area.

Table 5. Clinical Validity of Thermography in Breast Cancer Screening or Diagnosis

Study; Subgroup	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity			
					Sensitivity	***Specificity***	***PPV***	***NPV***
Morales-Cervantes et al (2018)								
Automated Thermography*	NR	206	NR	198 benign; 8 malignant	100%	68.68%	11.42%	100%
Manual Thermography*	NR	206	NR		87.50%	56.06%	7.44%	99.10 %
Mammography	NR	206	NR		NR	NR	NR	NR
Neal et al (2018)								
Abnormal Thermography	45	38	7	36 benign; 2 malignant	NA	NA	NR (2/38)	NA
Mammography following Abnormal Thermography	45	38	7		NR	NR	33.3%	100%
Omranipour et al (2016)								
Thermography	NR	132	NR	45 benign; 87 malignant	81.6%	57.8%	78.9%	61.9%
Mammography	NR	132	NR		80.5%	73.3%	85.4%	66.0%
Rassiwala et al (2014)								
Thermography**	NR	1,008	NR	41 malignant in 49 women with positive or abnormal thermograms	97.6%	99.17%	83.67 %	99.89 %

NA: not applicable; NPV: negative predictive value; NR: not reported; PPV: positive predictive value.
* Clinical validity results for this subgroup must be interpreted with caution as subjects with normal mammograms did not undergo histopathologic reference testing for diagnostic confirmation.
** Clinical validity results for this subgroup must be interpreted with caution as subjects with normal thermograms did not undergo radiologic and histopathologic reference testing for diagnostic confirmation, only clinical assessment.

The diagnostic accuracy of automated thermography in the study by Morales-Cervantes et al (2018) was 69.9%. The authors did not report on the diagnostic accuracy of manual thermography. While automated thermographic screening improved the sensitivity and specificity of the test compared to a manual, qualitative approach, reported values must be interpreted with caution as only patients with positive mammograms were subjected to diagnostic reference testing. Neal et al (2018) indicated that 95% of

patients referred for follow-up imaging evaluation following abnormal thermography testing did not have breast cancer, concluding that conventional breast imaging appears sufficient to manage patients. According to Omranipour et al (2016), the diagnostic accuracy of thermography (67.7%) was lower than for mammography (76.9%; p values not reported). The reported false-negative rate was not accurately calculated in Rassiwala et al (2014) because women who had normal thermograms only had a clinical examination and did not undergo radiologic and histopathologic reference tests for confirmation, highlighting a major limitation of this study. For patients with positive or abnormal thermograms, 8 results were considered false-positive. One false-negative was reported, but it is unclear which subgroup this patient belonged to or how this was determined, given that patients with normal thermograms were only assessed with a clinical examination. Tables 6 and 7 display further notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 6. Study Relevance Limitations: Breast Cancer Screening or Diagnosis

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Morales-Cervantes et al (2018)	1, 4. Intended use population unclear; study population not representative of intended use (screening study enriched with patients with clinical symptoms).	1, 2. Classification thresholds for manual thermographic assessment not described; BI-RADS version used unclear with no description of classification thresholds.	1, 2. BI-RADS classification thresholds for mammography not defined; normal mammograms not compared to credible reference standard.	1, 3, 5. Study does not directly assess a key health outcome; key clinical validity outcomes not reported; adverse events of the test not described.	
Neal et al (2018)		1. Classification thresholds for patients receiving ultrasounds after declining mammography not described; classification thresholds for thermography not evaluated.	1. Not compared to consistent reference standard.	1. Study does not report on key long-term health outcomes; key clinical validity outcomes not reported.	1. Follow-up duration not sufficient for patients not evaluated by biopsy.
Omranipour et al (2016)				1, 5. Study does not directly assess a key health outcome; adverse events of the test not described.	

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Rassiwala et al (2014)	4. Study population not representative of intended use (age for screening).		1, 2. Classification thresholds not defined; normal index tests not compared to credible reference standard.	1, 4, 5. Study does not directly assess a key health outcome; reclassification of diagnostic or risk categories not reported; adverse events of the test not described.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
BI-RADS: breast imaging reporting and data system.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.
[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.
[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

Table 7. Study Design and Conduct Limitations: Breast Cancer Screening or Diagnosis

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Morales-Cervantes et al (2018)	1. Selection not described.	1. Blinding to index and reference tests not fully described.	3, 4. Procedure for manual interpretation of thermograms and mammograms not described; expertise of all evaluators not described.	1-2. Not registered; evidence of selective reporting (mammography data not reported).	1. No description of indeterminate or missing samples.	1-2. Confidence intervals and/or p values not reported; comparison to mammography not reported.
Neal et al (2018)	1. Selection not described.	1. Blinding not described.	2-3. Timing of index and comparator tests not same; procedures for interpreting all tests not described	1. Not registered.	3. High loss to follow-up or missing data.	1-2. Confidence intervals and/or p values not reported; comparison to other tests not reported.

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Omranipour et al (2016)	1. Selection not described.	1. Blinding to index and reference tests not described.	1. Timing of delivery of index and reference tests not fully described.	1. Not registered.	1. No description of indeterminate or missing samples.	1. Confidence intervals and/or p values not reported.
Rassiwala et al(2014)	1. Selection not described.	1. Blinding not described.	1,3-4. Timing of delivery of index and reference tests not fully described; procedure for interpreting reference tests not described; expertise of evaluators not described.	1. Not registered.	1. Inadequate description of indeterminate or missing samples.	1. Confidence intervals and/or p values not reported.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (ie, convenience).
[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c]Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. Highbr loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with other tests not reported.

Clinical Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No studies have demonstrated how the results of thermography could be used to enhance the management of breast cancer patients in a manner that would improve their health outcomes.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

It is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence that the diagnostic accuracy of thermography is at least as high as mammographic techniques for breast cancer screening and diagnosis.

Section Summary: Breast Cancer Screening or Diagnosis

Systematic reviews of studies evaluating the accuracy of thermography for diagnosing breast cancer found wide ranges of sensitivities and specificities and, where data are available, relatively low diagnostic accuracy compared with mammography. To date, no study has demonstrated that 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.

Musculoskeletal Injuries

Clinical Context and Test Purpose

The purpose of using thermography in individuals who have a musculoskeletal injury is to inform a decision whether to proceed to appropriate treatment or not.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with musculoskeletal injuries.

Interventions

The intervention of interest is thermography.

Comparators

The following tests and practices are currently being used to make decisions about musculoskeletal injuries: standard care without imaging and other forms of imaging (e.g., with radiography, magnetic resonance imaging).

Outcomes

The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are a reduction in pain symptoms and improvement in functional ability. The timing would be following a musculoskeletal injury.

Study Selection Criteria

For the evaluation of clinical validity of thermography, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews: Musculoskeletal Injury

A systematic review by Sanchis-Sanchez et al (2014) evaluated the literature on thermography for diagnosing musculoskeletal injuries. Six studies met the eligibility criteria (N=416); 3 included patients with suspected stress fractures (n=119) and the remainder addressed other musculoskeletal injuries. Characteristics and results of clinical validity for stress fracture diagnostic studies were reported and summaries are provided in Tables 8 and 9. A systematic review by Vardasca et al (2019) evaluated the literature on musculoskeletal applications of thermography specific to the arm and forearm. However, the review mainly focused on correlations between skin surface temperatures and physical condition or health recovery monitoring. As diagnostic accuracy data were not extracted or pooled from included studies, this review was not assessed for evidence of clinical validity.

Table 8. Systematic Review: Characteristics of Clinical Validity of Thermography in Musculoskeletal Injury

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Sanchis-Sanchez (2014)	For diagnostic studies: • studies reporting on the diagnostic accuracy of infrared thermal imaging in the diagnosis of musculoskeletal injuries (eg, bone fractures, dislocations, sprains, muscle contractures, tendinopathy, contusions, or compartment syndrome) that utilized a recognized reference standard (eg, radiographs, CT, MRI, or ultrasound scanning)	• Prospective cohort; sample selection consecutive (4/6) • Prospective cohort; sample selection NR (1/6) • Prospective cohort; sample selection by convenience (1/6)	High-quality radiographic imaging (various)	NR; various methodologies utilized	Reported (1/6 studies) Unclear (4/6 studies, including all studies on stress fractures) NR (1/6 studies)	Reported (2/6 studies) Unclear (4/6 studies, including all studies on stress fractures)	High heterogeneity in thermography index test methodologies and diagnostic accuracy. QUADAS assessment by authors indicates moderate-to-high risk of bias in studies on stress fractures.

CT: computed tomography; MRI: magnetic resonance imaging; NR: not reported; QUADAS: Quality Assessment of Diagnostic Accuracy Studies.

[a] Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective; sample selection random or consecutive.
[b] Note other characteristics that could bias or limit relevance such as use of historical data, evolution of technology, or practice setting.

Table 9. Systematic Review: Clinical Validity of Thermography in Musculoskeletal Injury

Study; Sub group	Initial N (Range)	Final N (Range)	Excluded N	Prevalence of Condition	Clinical Validity (95% Confidence Interval)			
					Sensitivity	***Specificity***	***PPV***	***NPV***
Sanchis-Sanchez (2014) Stress Fractures	NR	119 (17 to 84)	NR	NR	NR Range: 45.3 to 82%	69% (49 to 85%) Range: 60 to 100% p-value:.17	NR Positive Likelihood Ratio: 2.31 (0.63 to 8.47) Range: 1.13 to 6.25 p-value:.12	NR Negative Likelihood Ratio: NR Range: 0.22 to 0.91

NPV: negative predictive value; NR: not reported; PPV: positive predictive value.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

Longitudinal Studies: Musculoskeletal Injury

Corte et al (2019) completed a longitudinal prospective study with 28 professional soccer players that composed a first division of Brazilian's soccer team between 2015 and 2016. In both seasons (2015 and 2016), muscle injuries were documented and classified in grade of severity, by ultrasound. During the following season (2016), infrared medical thermography was applied twice a week (48 hours after game) and if a difference of temperature was detected higher than 0.4°C, a prevention protocol was initiated. Muscle injuries in 2016 were documented. The results noted in 2015, the total number of muscle injuries was 11. In 2016, the total number of muscle injuries was 4 (p=0.04). It represents an incidence/player of 78% in 2015 and 28% in 2016, corresponding to a decrease of 64% in 2016. Seven players played in the first team in both seasons. Among these seven players, muscle injuries were reduced from 8 (in 2015) to 3 (in 2016)—a decrease of 63% in the season we used thermographic monitoring (p=0.06). In conclusion the pilot data provides a promising catalyst for a rigorous RCT that could examine whether thermography can contribute to a muscle injury prevention program.

Table 10: Study Relevance Limitations: Musculoskeletal Injury

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Côrte et al. (2019)	2. Clinical context is unclear (definition and reporting of muscle injuries are subjective).	2. Version used unclear (therapy utilized in prevention protocol was based on physician discretion and not standardized).	1, 2. Classification thresholds for ultrasound not defined; comparison to credible reference standard unclear.	3, 4, 5. Key clinical validity outcomes not reported; reclassification of diagnostic or risk categories not reported; adverse events of the test not described.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.
[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.
[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

Table 11: Study Design and Conduct Limitations: Musculoskeletal Injury

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]

Côrte et al. (2019)	1. Selection not random or consecutive.	1. Blinding to index and reference tests not described.	1-4. Timing of delivery of index or reference tests not described; timing of index and comparator tests not described; procedure for interpreting comparator and/or reference tests not described; expertise of evaluators not described.	1. Not registered.	1. No description of indeterminate or missing samples.	1, 2. Confidence intervals and/or p values not reported; diagnostic comparison to other tests not reported.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
b Blinding key: 1. Not blinded to results of reference or other comparator tests.
c Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
d Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
e Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
f Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with other tests not reported.

No high-quality or randomized studies have been published that evaluate health outcomes in patients with musculoskeletal injuries who were managed with and without thermography.

Chain of Evidence: Musculoskeletal Injuries

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. It is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence that the diagnostic accuracy of thermography is at least as high as standard techniques for diagnosing musculoskeletal injuries.

Section Summary: Musculoskeletal Injuries

A systematic review of studies on thermography for diagnosing musculoskeletal injuries found moderate levels of accuracy compared with other diagnostic imaging tests. There was 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 insufficient studies on the impact of thermography on patient management or health outcomes for patients with musculoskeletal injuries.

Temporomandibular Joint Disorder

Clinical Context and Test Purpose

The purpose of using thermography in individuals who have temporomandibular joint (TMJ) disorder is to inform a decision whether to proceed to appropriate treatment or not.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with TMJ disorder.

Interventions

The intervention of interest is thermography.

Comparators

The following tests and practices are currently being used to make decisions about TMJ disorder: standard clinical examination without imaging, diagnostic scales (e.g., Research Diagnostic Criteria for Temporomandibular Disorders [RDC/TMD], Fonseca Anamnestic Index, Anamnestic Index), and other forms of imaging (e.g., with radiography, arthrotomography, magnetic resonance imaging).

Outcomes

The outcomes of interest for diagnostic accuracy include test accuracy and test validity (i.e., sensitivity, specificity). The primary outcomes of interest for clinical utility are a reduction in pain symptoms and improvement in functional ability.

Study Selection Criteria

For the evaluation of clinical validity of thermography for TMJ disorder, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

A systematic review by de Melo et al (2019) evaluated the diagnostic accuracy of infrared thermography in TMJ disorder. Nine studies were identified utilizing a variety of comparators. The authors note that while no specific diagnostic tool is currently considered the gold standard for the diagnosis of TMJ disorder, the RDC/TMD diagnostic is commonly used with a reported sensitivity and specificity of 87% and 92%, respectively. Four out of 9 studies utilized RDC/TMD, whereas the remaining studies utilized clinical examination or other methods. Characteristics and results of clinical validity for TMJ disorder diagnostic accuracy in this systematic review are summarized in Tables 12 and 13.

Table 12: Systematic Review: Characteristics of Clinical Validity of Thermography in Temporomandibular Joint Disorder

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]

de Melo et al (2019)	For diagnostic studies: studies reporting on the diagnostic accuracy of infrared thermography versus other diagnostic tests and imaging methods in patients with temporomandibular disorder	NR; sample selection consecutive (1/9 studies) or by convenience (8/9 studies)	RDC/TMD diagnostic, clinical examination, or other imaging methods	NR	NR High-risk of bias based on flow and timing: 4/9 studies; Unclear risk of bias based on flow and timing: 5/9 studies.	NR	Thermography index test methodologies unclear. Heterogeneity in use of comparator and/or reference standard. Assessment by authors indicates high-risk of bias in all studies.

NR: not reported; RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders.
[a] Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective; sample selection random or consecutive.
[b] Note other characteristics that could bias or limit relevance such as use of historical data, evolution of technology, or practice setting.

Table 13: Systematic Review: Clinical Validity of Thermography in Temporomandibular Joint Disorder

Study	Initial N (Range)	Final N (Range)	Excluded N	Prevalence of Condition	Clinical Validity (95% Confidence Interval)			
					Sensitivity	***Specificity***	***PPV***	***NPV***
de Melo et al. (2019)	NR	548 (23 to 104)	NR	NR	NR; Range: 38.5 to 90%	NR; Range: 22.8 to 95.5%	NR	NR

NPV: negative predictive value; NR: not reported; PPV: positive predictive value.

Clinical Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No studies have been published that evaluate health outcomes in patients with TMJ disorder who were managed with and without thermography.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

It is not possible to construct a chain of evidence for clinical utility due to the lack of sufficient evidence that the diagnostic accuracy of thermography is at least as high as standard techniques for diagnosing TMJ disorder.

Section Summary: Temporomandibular Joint Disorder

A systematic review of studies on thermography for diagnosing TMJ disorder found a wide variation in accuracy compared with other diagnostics. There was 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 TMJ disorder.

Miscellaneous Conditions

A number of studies have assessed a range of potential thermography applications. To date, no randomized study has examined the impact of thermography on patient management decisions or health outcomes. Examples of other studies on thermography, mainly conducted outside of the U.S., include those evaluating the association between thermographic findings and post-herpetic neuralgia in patients with herpes zoster, surgical site healing in individuals who underwent knee replacements, predicting pressure ulcers and pressure ulcer healing, posttreatment pain in patients with coccygodynia, evaluation of allergic conjunctivitis, evaluation of burn depth, association between thermographic findings and burn treatment, detecting cervical lymph node metastasis from oral cavity cancer, monitoring lesions or inflammation in patients with scleroderma, detection of vascular obstruction[4] or perforator vessels during surgery, diagnosis of lower extremity cellulitis, prediction of infrainguinal bypass surgery, detection of melanoma, detection of contact dermatitis during allergy patch testing, diagnosis of acute appendicitis, and measuring disease activity in individuals with rheumatoid arthritis, osteoarthritis, or other rheumatic diseases.

Several studies evaluating the clinical validity of thermography to assess potential complications of the diabetic foot have been conducted. Thermographic images of nondiabetic feet, nonulcerated diabetic feet, and ulcerated diabetic feet have been compared. Another study used thermography to diagnose infections in patients admitted with diabetic foot complications. The only study to date to investigate the clinical utility of thermography compared with no thermography assessed diabetic foot ulcer incidence in 110 participants with a history of diabetic neuropathy and foot ulcers.[4] After 12 months follow-up, the study found no significant difference between use of monthly thermography versus no thermography and foot ulcer incidence (62% vs. 56%; adjusted odds ratio, 0.55, 95% confidence interval [CI], 0.21 to 1.40) or time to ulcer recurrence (adjusted hazard ratio, 0.67, 95% CI, 0.34 to 1.3).

Section Summary: Miscellaneous Conditions

For most of these potential indications, there are 1 or 2 preliminary studies on each of the indications. Several studies evaluated the clinical validity of thermography in assessing diabetic foot and related complications. For all indications, the studies described temperature gradients or the association between temperature differences and the clinical condition. Due to the small number of studies for each indication, the diagnostic accuracy could not adequately be evaluated. The clinical utility of thermography for these miscellaneous conditions was not investigated in any study.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Cancer Society (ACS)

The American Cancer Society published their Guidelines for the Early Detection of Cancer that last reviewed in November 2023 recommends mammograms as a method for detecting breast cancer it does not mention the use of thermography..

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists (ACOG) practice bulletin from 2017 for breast cancer risk assessment and screening in average-risk women do not mention the use of thermography for breast cancer screening.

American College of Physicians (ACP)

The American College of Physicians (2019) issued a guidance statement for breast cancer screening in average-risk women those reviews existing screening guidelines. While the use of thermography was not mentioned in this statement, the authors conclude that evidence is insufficient to understand the benefits and harms of primary or adjunctive screening strategies in women who are found to have dense breasts on screening mammography.

American College of Radiology (ACR)

The American College of Radiology guidelines updated 2023 for female breast cancer screening do not mention the use of thermography for breast cancer screening.

The American College of Radiology issued a statement on Imaging for Myelopathy in 2021 that does not mention the use of thermography as a screening recommendation for myelopathy.

European Society of Breast Imaging et al

A position paper by the European Society of Breast Imaging (2017) and 30 other national breast radiology bodies on screening for breast cancer stated that the “…screening with thermography or other optical tools as alternatives to mammography is discouraged.”

National Comprehensive Cancer Network (NCCN)

The National Comprehensive Cancer Network’s guideline on Breast Cancer Screening and Diagnosis (version 2.2025) states that: “Current evidence does not support the routine use of thermography as screening procedures.”

United States Preventive Services Task Force

The U.S. Preventive Services Task Force (2024) recommendations on breast cancer screening (currently undergoing an update) do not mention thermography. Additionally, there is insufficient evidence for the use of adjunctive screening methods for breast cancer (ultrasonography or magnetic resonance imaging) in women identified to have dense breasts on a negative screening mammogram.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. Lovett KM, Liang BA Risks of online advertisement of direct-to-consumer thermography for breast cancer screening. Nat Rev Cancer. 2011 Dec; 11(12):827-8.
2. Kontos M, Wilson R, Fentiman I. Digital infrared thermal imaging (DITI) of breast lesions: sensitivity and specificity of detection of primary breast cancers. Clin Radiol. 2011 Jun;66(6):536-9. Epub 2011 Mar 5.
3. Brennan M., Houssami N. Thermography in breast cancer diagnosis, screening, and risk assessment: systemic review. Breast Cancer Management 2013; 2(2) 163-172
4. Food and Drug Administration Safety Communication: Breast Cancer Screening Thermography is not an Alternative to Mammography. Date Issued June 2, 2011. Updated October 6, 2023. www.fda.gov Accessed October 16, 2025.
5. American Cancer Society (ACS), Mammograms and Other Breast Imaging Tests and Experimental and Other Breast Imaging Methods.
6. American Cancer Society (ACS). American Cancer Society Guidelines for the Early Detection of Cancer. Last updated November 1, 2023. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/912.00.pdf. Accessed October 16, 2025.
7. 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
8. 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
9. Morales-Cervantes A, Kolosovas-Machuca ES, Guevara E, et al. An automated method for the evaluation of breast cancer using infrared thermography. EXCLI J. 2018; 17: 989-998. PMID 30564079
10. Neal CH, Flynt KA, Jeffries DO, et al. Breast Imaging Outcomes following Abnormal Thermography. Acad Radiol. Mar 2018; 25(3): 273-278. PMID 29275941
11. Omranipour R, Kazemian A, Alipour S, et al. Comparison of the Accuracy of Thermography and Mammography in the Detection of Breast Cancer. Breast Care (Basel). Aug 2016; 11(4): 260-264. PMID 27721713
12. 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
13. Sanchis-Sánchez E, Vergara-Hernández C, Cibrián 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
14. Côrte AC, Pedrinelli A, Marttos A, et al. Infrared thermography study as a complementary method of screening and prevention of muscle injuries: pilot study. BMJ Open Sport Exerc Med. 2019; 5(1): e000431. PMID 30687515

15. 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
16. 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
17. 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
18. Romanò 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
19. 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
20. Nakagami G, Sanada H, Iizaka 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
21. Bilska A, Stangret A, Pyzlak M, et al. Skin surface infrared thermography in pressure ulcer outcome prognosis. J Wound Care. Dec 02 2020; 29(12): 707-718. PMID 33320753
22. 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
23. Hara Y, Shiraishi A, Yamaguchi M, et al. Evaluation of allergic conjunctivitis by thermography. Ophthalmic Res. 2014; 51(3): 161-6. PMID 24603108
24. 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. 2016; 37(6): 350-355. PMID 26720102
25. Dang J, Lin M, Tan C, et al. Use of Infrared Thermography for Assessment of Burn Depth and Healing Potential: A Systematic Review. J Burn Care Res. Jun 12 2021. PMID 34120173
26. Martínez-Jiménez 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
27. 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
28. 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
29. Ranosz-Janicka I, Lis-Święty 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
30. Cruz-Segura A, Cruz-Domínguez 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
31. 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

32. 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
33. 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
34. 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
35. 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
36. 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
37. Aydemir U, Sarıgoz T, Ertan T, et al. Role of digital infrared thermal imaging in diagnosis of acute appendicitis. Ulus Travma Acil Cerrahi Derg. Nov 2021; 27(6): 647-653. PMID 34710229
38. 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
39. 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
40. Schiavon G, Capone G, Frize M, et al. Infrared Thermography for the Evaluation of Inflammatory and Degenerative Joint Diseases: A Systematic Review. Cartilage. Dec 2021; 13(2_suppl): 1790S-1801S. PMID 34933442
41. Branco JHL, Branco RLL, Siqueira TC, et al. Clinical applicability of infrared thermography in rheumatic diseases: A systematic review. J Therm Biol. Feb 2022; 104: 103172. PMID 35180959
42. 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
43. Gatt A, Falzon O, Cassar K, et al. Establishing Differences in Thermographic Patterns between the Various Complications in Diabetic Foot Disease. Int J Endocrinol. 2018; 2018: 9808295. PMID 29721019
44. 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
45. 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
46. 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
47. 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

48. 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
49. Sardanelli F, Aase HS, Álvarez 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
50. 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
51. Mainiero MB, Moy L, Baron P, et al. ACR Appropriateness Criteria ® Breast Cancer Screening. J Am Coll Radiol. Nov 2017; 14(11S): S383-S390. PMID 29101979
52. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. Version 2.2025; Updated March 28, 2025 https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed October 16, 2025.
53. U.S. Preventive Services Task Force. Breast Cancer: Screening. 2016; Updated April 30, 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening. Accessed October 16, 2025.
54. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination for Thermography (220.11). 1992; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=164&ncdver=1&DocID=220.11. Accessed October 16, 2025.
55. The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Management of Women with Dense Breasts Diagnosed by Mammography. Number 625. March 2015. Reaffirmed 2024. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/03/management-of-women-with-dense-breasts-diagnosed-by-mammography. Accessed October 16, 2025.
56. Expert Panel on Neurological Imaging, Agarwal, V., Shah, L. M., Parsons, M. S., et al. (2021). ACR Appropriateness Criteria® Myelopathy: 2021 Update. Journal of the American College of Radiology: JACR, 18(5S), S73–S82. https://doi.org/10.1016/j.jacr.2021.01.020.
57. UptoDate. Elmore JG, Lee CI, Aronson MD, et al. Screening for breast cancer: Evidence for effectiveness and harms. Review current through September 2024. Last updated October, 31 2024. Available at: www.uptodate.com. Accessed October 16, 2025.
58. Hayes, a symplyr company. Health Technology Assessment. Digital Infrared Imaging (Thermography) for Detection of Breast Cancer. Published July 7, 2006. Last reviewed July 23, 2008. Available at: www.hayesinc.com. Accessed November 5, 2025.
59. Hayes, a symplyr company. Clinical Research Response. Pressure Injury Risk Assessment Devices - Product Comparison. Published September 16, 2024. Available at: www.hayesinc.com. Accessed November 5, 2025.
60. Goñi-Arana A, Pérez-Martín J, Díez FJ. Breast thermography: a systematic review and meta-analysis. Syst Rev. 2024 Nov 28;13(1):295. doi: 10.1186/s13643-024-02708-9. PMID: 39609910; PMCID: PMC11603657.

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	93740	Temperature gradient studies; (*note; there is no specific code for skin surface infrared thermography*)
	93799	Unlisted cardiovascular service or procedure *(when utilized for thermography)*
HCPCS		
	No code(s)	
Type of Service	Radiology	
Place of Service	Inpatient/ Outpatient Physician's Office	

POLICY HISTORY

Date	Reason	Action
November 2025	**Annual Review**	**Policy Renewed**
November 2024	Annual Review	Policy Renewed
November 2023	Annual Review	Policy Revised
January 2023	Annual Review	Policy Renewed
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Renewed
January 2019	Annual Review	Policy Revised

Date	Reason	Action
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Revised
January 2016	Annual Review	Policy Revised
February 2015	Annual Review	Policy Renewed
March 2014	Annual Review	Policy Revised
April 2013	Annual Review	Policy Renewed
April 2012	Annual Review	Policy Renewed
June 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.