6.01.12	Thermography		
Original Policy Date:	January 11, 2008	**Effective Date:**	November 1, 2023
Section:	6.0 Radiology	**Page:**	Page 1 of 23

Policy Statement

I. The use of all forms of thermography is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

There is no specific code for skin surface infrared thermography.

The following CPT code is specific for temperature gradient studies:

- 93740: Temperature gradient studies

These services are reported using the following unlisted code:

- 93799: Unlisted cardiovascular service or procedure

Description

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.

Related Policies

- Cardiac Applications of Positron Emission Tomography Scanning
- Interim Positron Emission Tomography Scanning in Oncology to Detect Early Response During Treatment
- Magnetic Resonance Imaging for Detection and Diagnosis of Breast Cancer
- Miscellaneous (Noncardiac, Nononcologic) Applications of Fluorine 18 Fluorodeoxyglucose Positron Emission Tomography
- Oncologic Applications of Positron Emission Tomography Scanning
- Scintimammography and Gamma Imaging of the Breast and Axilla
- Temporomandibular Joint Disorder

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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.

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

Device Name	Manufacturer	Clearance Date	510(K) No.
Infrared Sciences Breastscan IR System	Infrared Sciences	Feb 2004	K032350
Telethermographic Camera, Series A, E, S, and P	FLIR Systems	Mar 2004	K033967
Notouch Breastscan	UE Lifesciences	Feb 2012	K113259
WoundVision Scout™	WoundVision	Dec 2013	K131596
AlfaSight 9000 Thermographic System™	Alfa Thermodiagnostics	Apr 2015	K150457
FirstSense Breast Exam®	First Sense Medical	Jun 2016	K160573
Sentinel BreastScan II System	First Sense Medical	Jan 2017	K162767
InTouchThermal Camera	InTouch Technologies	Feb 2019	K181716
Smile-100 System	Niramai Health Analytix Private Limited	Mar 2022	K212965
ThermPix™ Thermovisual Camera	USA Therm	Apr 2022	K213650

Rationale

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.

Literature Review

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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 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).[1] 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.[2] 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.

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)[1]	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 histo-pathologic 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)[2]	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 • NR cohort;	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 utilized

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
		sample selection NR			timing of index and reference tests poorly reported.		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)[1]; Diagnostic studies	NR	1709 (29 to 769)	565 (13 to 524)*	NR	25-97%	12-85%	24-81%	36-95%
Fitzgerald et al (2012)[2]; Diagnostic studies	1224 (63 to 769)	NR	NR	NR	25-97%	12-85%	24-83%	36-95%
Fitzgerald et al (2012)[2]; Screening studies, at initial screening	10,229 (NR)	NR	NR	NR	61%	74%	0.01%	1.00%
Fitzgerald et al (2012)[2]; 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

Several studies have been published since the systematic reviews. Morales-Cervantes et al (2018) compared the accuracy of automated or manual thermography screening in 206 women scheduled for mammography in Mexico.[3,] 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.[4,] 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.[5,] Rassiwala et al (2014) in India reported on 1008 women being screened for breast cancer.[6,] 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)[3,]	For screening study:	Prospective cohort, NR	Biopsy with histopathologic	Automated Thermography (Thermal Score)[c]	Reference testing performed for women with	Blinding of mammography assessor	Blinding and allocation poorly

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
	• women scheduled for consultation with clinical evidence of tumor suspicious for breast cancer and breast cancer risk factors	sample allocation	confirmation	• + (Thermal Score ≥ 2.5) • - (Thermal Score < 2.5) Manual Thermography • NR Mammography (BI-RADS Rating): • NR	mammography BI-RADS score indicating suspicion for cancer. Mammography performed after thermography.	with respect to thermography not described. Double-blinding indicated for manual assessment of thermograms by oncologist. Blinding of biopsy assessor not described.	described. No data reported for mammography despite inclusion as comparator. Reported results may be biased and inaccurate due to selective use of reference tests.
Neal et al (2018)[4],	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.
Omranipour et al (2016)[5],	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.

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Rassiwala et al (2014)[6,]	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)[3,]								
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)[4,]								
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)[5,]								
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)[6,]								
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%.[3,] 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.[4,] According to Omranipour et al (2016),[5,] 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.[6,] 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)[3,]	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)[4,]		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)[5,]				1, 5. Study does not directly assess a key health outcome; adverse events of the test not described.	
Rassiwala et al (2014)[6,]	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	

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
				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)[3],	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)[4],	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.
Omranipour et al (2016)[5],	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)[6],	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 (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. 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.

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 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

A systematic review by Sanchis-Sanchez et al (2014) evaluated the literature on thermography for diagnosing musculoskeletal injuries.[7] 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)[7]	For diagnostic studies: • studies reporting on the diagnostic accuracy of infrared thermal imaging in the diagnosis of musculoskeletal injuries (e.g., bone fractures, dislocations, sprains, muscle contractures, tendinopathy, contusions, or compartment syndrome) that utilized a recognized reference standard (e.g., radiographs,	• 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.

Study	Study Population	Design[a]	Reference Standard	Threshold for Positive Index Test	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
	CT, MRI, or ultrasoundscanning)						

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; Subgroup	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[7,]	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

Côrte et al (2019) published pilot data from a longitudinal prospective study on the screening and prevention of muscle injuries in 28 professional Brazilian soccer players.[8,] Players were monitored for musculoskeletal imaging during the 2015-2016 seasons with ultrasound. In the second season, a thermographic monitoring regimen was added twice-weekly 48 hours after matches, and an injury prevention protocol was followed based on the results of thermographic imaging. The number of musculoskeletal injuries was compared for both seasons based on these management protocols. The total number of muscle injuries reported decreased from 11 in 2015 to 4 in 2016 (p=.04). Seven players were on the team roster across both seasons. There was no statistically significant reduction in muscle injury in this subgroup (p=.06). Limitations of this study are addressed in Tables 10 and 11.

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)[8],	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)[8],	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
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.[9,] 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)[9,]	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)[9,]	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.

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.

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,[10,11,] surgical site healing in patients who underwent knee replacements,[12,]predicting pressure ulcers[13,] and pressure ulcer healing,[14,15,] posttreatment pain in patients with coccygodynia,[16,] evaluation of allergic conjunctivitis,[17,] evaluation of burn depth,[18,19,] association between thermographic findings and burn treatment,[20,] detecting cervical lymph node metastasis from oral cavity cancer,[21,] monitoring lesions or inflammation in patients with scleroderma,[22,23,] detection of vascular obstruction[24,] or perforator vessels during surgery,[25,26,] diagnosis of lower extremity cellulitis,[27,] prediction of infrainguinal bypass surgery,[28,] detection of melanoma,[29,] detection of contact dermatitis during allergy patch testing,[30,]diagnosis of acute appendicitis,[31,]and measuring disease activity in patients with rheumatoid arthritis, osteoarthritis, or other rheumatic diseases.[32,33,34,35,]

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.[36,37,38,39,40,] Another study used thermography to diagnose infections in patients admitted with diabetic foot complications.[41,] 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.[42,] After 12 months followup, 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.

European Society of Breast Imaging

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 "screening with thermography or other optical tools as alternatives to mammography is discouraged."[43,]

American College of Physicians

The American College of Physicians (2019) issued a guidance statement for breast cancer screening in average-risk women that reviews existing screening guidelines.[44,] While the use of thermography was not mentioned in this statement, the authors concluded 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

The American College of Radiology guidelines for breast cancer screening (revised 2017) do not mention the use of thermography for breast cancer screening.[45,]

National Comprehensive Cancer Network

National Comprehensive Cancer Network guideline on breast cancer screening and diagnosis (v.1.2023) states that: "Current evidence does not support the routine use of thermography as screening procedures."[46,]

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2016) 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, magnetic resonance imaging, digital breast tomosynthesis, or other methods) in women identified to have dense breasts on a negative screening mammogram.[47,]

Medicare National Coverage

Medicare does not cover thermography. Current Medicare coverage policy states: "Thermography for any indication (including breast lesions which were excluded from Medicare coverage ...) is excluded from Medicare coverage because the available evidence does not support this test as a useful aid in the diagnosis or treatment of illness or injury. Therefore, it is not considered effective..."[48,]

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 14.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT04013711	Quantitative Thermal Imaging to Evaluate Skin Toxicity from Radiation Treatment	200	Jul 2022

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03735550	Investigation of the Effectiveness of Liquid Crystal Contact Thermography in Detecting Pathological Changes in Female Breasts Compared to Standard Diagnostic Methods of Breast Cancer	3000	Jan 2019
NCT03217214	Investigation of Contact Based Method for Diagnosis of Cardiovascular Disease (INDICES)	67	Sep 2019
NCT02776995	Tumor Monitoring Using Thermography During Radiation Therapy	80	Dec 2020

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	93740	Temperature gradient studies
	93799	Unlisted cardiovascular service or procedure
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
01/11/2008	BCBSA Medical Policy adoption
09/25/2009	Criteria Revised Policy title change. Prior Policy title: Thermography
08/23/2013	Policy revision without position change. Policy placed on No Further Routine Literature Review and Update status.
06/30/2015	Coding update
11/01/2016	Policy title change from Thermography/Temperature Gradient Studies Policy revision without position change
11/01/2017	Policy revision without position change
11/01/2018	Policy revision without position change
12/01/2019	Policy revision without position change
11/01/2023	Policy reactivated. Previously archived from 08/01/2020 to 10/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with

generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	Thermography 6.01.12 **Policy Statement:** I. The use of all forms of thermography is considered **investigational**.