JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans Medical Policy Manual Medical Policy	Policy Number	CMS20.04
		Effective Date	04/01/2024
		Approval Date	01/16/2024
	<u>Subject</u>	Supersedes Date	05/01/2023
	Thermography	Page	1 of 6

This document applies to the following Participating Organizations:

Advantage MD	EHP	Priority Partners	US Family Health Plan

Keywords: Thermography

Table	e of Contents	Page Number
I.	ACTION	1
II.	POLICY DISCLAIMER	1
III.	POLICY	1
IV.	POLICY CRITERIA	2
V.	DEFINITIONS	2
VI.	BACKGROUND	2
VII.	CODING DISCLAIMER	3
VIII.	CODING INFORMATION	4
IX.	REFERENCE STATEMENT	4
X.	REFERENCES	4
XI.	APPROVALS	6

I. ACTION

	New Policy	
X	Revising Policy Number	CMS20.04
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- National Coverage Determination (NCD) 220.11 Thermography
- Local Coverage Determination (LCD) L36241 Allergy Testing

For Employer Health Programs (EHP) refer to:

• Plan specific Summary Plan Descriptions (SPDs)

For Johns Hopkins Health Plan of Virginia, Inc. (JHHPVA): refer to: Medicare Coverage Database

• National Coverage Determination (NCD) 220.11 Thermography

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JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans A Medical Policy Manual Medical Policy	Policy Number	CMS20.04
		Effective Date	04/01/2024
		Approval Date	01/16/2024
	<u>Subject</u>	Supersedes Date	05/01/2023
	Thermography	Page	2 of 6

• No Local Coverage Determinations (LCD) for Thermography identified (Accessed December 20, 2023)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

• No specific information located in COMAR 10.67.01.01-10.67.06.31 (Accessed December 28, 2023)

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

• TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 5, Section 5.1 Thermography

IV. POLICY CRITERIA

Unless specific benefits are provided under the member's contract, JHHP considers Thermography experimental and investigational as it does not meet the Technology Evaluation Criteria (TEC) as defined in <u>CMS01.00 Medical Policy</u> <u>Introduction</u>.

V. DEFINITIONS

<u>Thermography</u>: Thermography is a procedure which relies upon measurement of infrared radiation from the body for diagnostic purposes. It is used for pathology of the female breast, peripheral vascular disease, musculoskeletal injuries and for detecting cervical lesions. Thermography can include various types of the telethermographic infrared detectors/imagers or heat sensitive cholesteric liquid crystal systems that are applied to the skin (Tricare Policy Manual, 2021).

VI. BACKGROUND

Thermography is a non-invasive imaging technique intended to measure temperature distribution within various organs and tissues. Thermography has been investigated for many purposes, including, but not limited to, breast cancer screening, neuromusculoskeletal conditions (e.g., thoracic outlet syndrome, fibromyalgia, small fiber peripheral neuropathy, inflammatory arthritis), perforator and vascularization assessment for reconstructive and plastic surgery, diagnosis of temporomandibular joint disorders, peripheral arterial disease, and deep and superficial venous disorders (AAT, 2021).

Breast thermography uses ultra-sensitive infrared cameras and computers to detect, analyze and produce high resolution diagnostic images of these temperature and vascular changes. The use of thermography to detect occult breast cancer was based on the observation that patients have elevated breast skin temperatures over their breast cancers. It was first investigated for screening in the Breast Cancer Detection Demonstration Project in the 1970s and was found to have poor test characteristics, with a false-positive rate of 25% and a false-negative rate of more than 60%. In 2004, a breast thermography device received approval from the US Food and Drug Administration (FDA) on the basis of prior approval for infrared imaging technology because of demonstrated safety but not necessarily efficacy. The specificity of thermography remains very low, even with modern equipment. No major organizations making screening recommendations for breast cancer recommend thermography. Of those commenting on it, the American Cancer Society states, "No study has ever shown that it is an effective screening tool for finding breast cancer early," and the American College of Radiology specifically states it does not endorse thermography for detecting clinically occult breast cancer (Elmore, 2023).

The FDA reported there is no valid scientific data to demonstrate that thermography devices, when used on their own or with another diagnostic test, are an effective screening tool for any medical condition including the early detection of breast cancer or other diseases and health conditions. According to the FDA, mammography is the most effective breast cancer screening method and the only method proven to increase the chance of survival through earlier detection (FDA, 2019).

	Johns Hopkins Health Plans	Policy Number	CMS20.04
JOHNS HOPKINS HEALTH PLANS	Medical Policy Manual Medical Policy	Effective Date	04/01/2024
		Approval Date	01/16/2024
	<u>Subject</u>	Supersedes Date	05/01/2023
	Thermography	Page	3 of 6

Thermography has also been investigated for conditions affecting circulatory, integumentary, and musculoskeletal systems with little evidence that the use of thermal studies improves health outcomes for these conditions. Berner et al. conducted a systematic review and meta-analysis on the accuracy of infrared thermography for perforator mapping for reconstructive and plastic surgery. The authors concluded that further well-designed and adequately reported diagnostic accuracy studies are required to ascertain the specificity of this technology for perforator detection (Berner et al., 2021). Wermelink et al. published the results of a systematic review evaluating the efficacy of multiple techniques used to analyze real-time tissue perfusion changes during endovascular or surgical revascularization procedures for patients with peripheral arterial disease. The systematic review provided an overview of 10 tissue perfusion assessment techniques, including plantar thermography, and concluded that it is too early to appoint one of them as a reference standard (Wermelink et al., 2021). Another systematic review evaluating circulatory system disorder suggested further evaluation is needed to support the recommendation for the use of infrared thermography for evaluation of systemic vasoconstriction (Jensen et al., 2021). Albuquerque & Lopes, in their systematic review evaluating the utilization of thermography in pain medicine argued that it can be an objective tool for monitoring the effectiveness of treatment for back and neck syndrome by identifying deviations from a healthy state: however, the number of high-quality studies of the role of infrared thermography in patients with back and neck syndromes remains limited (Albuquerque & Lopez, 2021). Similarly, Dang et al. stated that the results of their systematic review of the utilization of thermography in burn care for wound assessment suggest this tool appears to be an accurate, simple, and cost-effective method for burn wound assessment; however, the sample size of published peer reviewed literature is rather small (Dang et. al., 2021).

VII. CODING DISCLAIMER

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Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits

Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.

Johns Hopkins Health Plan of Virginia LLC (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.

US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

			Version 7.0
JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans Medical Policy Manual Medical Policy	Policy Number	CMS20.04
		Effective Date	04/01/2024
		Approval Date	01/16/2024
	<u>Subject</u> Thermography	Supersedes Date	05/01/2023
		Page	4 of 6
VIII CODINC INFORMATION			

VIII. CODING INFORMATION

CPT[®]CODES ARE FOR INFORMATIONAL PURPOSES ONLY		
CPT[®] CODES	DESCRIPTION	
93740	Temperature gradient studies	

IX. <u>REFERENCE STATEMENT</u>

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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			Version 7.0
	Johns Hopkins Health Plans	Policy Number	CMS20.04
	Medical Policy Manual Medical Policy	Effective Date	04/01/2024
JOHNS HOPKINS		Approval Date	01/16/2024
HEALTH PLANS	<u>Subject</u>	Supersedes Date	05/01/2023
	Thermography	Page	5 of 6

Version 7.0

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			Version 7.0
	Johns Hopkins Health Plans	Policy Number	CMS20.04
JOHNS HOPKINS HEALTH PLANS	Medical Policy Manual Medical Policy	Effective Date	04/01/2024
		Approval Date	01/16/2024
	<u>Subject</u>	Supersedes Date	05/01/2023
	Thermography	Page	6 of 6

XI. <u>APPROVALS</u>

Historical Effective Dates: 10/22/2007, 09/08/2008, 01/07/2011, 05/29/2012, 12/05/2014, 03/03/2017, 08/03/2020, 05/02/2022, 05/01/2023, 04/01/2024