MEDICAL POLICY

POLICY TITLE	TECHNOLOGIES FOR THE EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP 2.066

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**1/1/2025**

I. POLICY

Whole body photography or digital dermatoscopy, without use of computer-assisted analysis, may be considered **medically necessary** when used to evaluate and monitor members with a history of primary melanoma and one of the following:

- greater than or equal to 25 nevi; OR
- presence of atypical/dysplastic nevi

Whole body photography or dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, may be considered **not medically necessary** in all other situations. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Dermatoscopy and computer-assisted adjunctive devices are considered **investigational** for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

The following technologies for the evaluation or monitoring of skin lesions are considered **investigational.** There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

- electrical impedance devices (i.e., Nevisense)
- molecular fluorescent imaging
- multispectral image analysis (i.e., MelaFind)
- optical coherence tomography (OCT)
- reflectance confocal microscopy (RCM)

Cross-references:

POLICY TITLE	TECHNOLOGIES FOR THE EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
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MP 2.246 Genetic Testing for Familial Cutaneous Malignant Melanoma
MP 2.360 Gene Expression Profiling for Melanoma

II. PRODUCT VARIATIONS

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

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

III. DESCRIPTION/BACKGROUND

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Dermatoscopy

Dermatoscopy, also known as dermoscopy, describes a family of noninvasive techniques that allow in vivo microscopic examination of skin lesions, and is intended to help distinguish between benign and malignant pigmented skin lesions. The technique involves application of immersion oil to the skin, which eliminates light reflection from the skin surface and renders the stratum corneum transparent. Using a magnifying lens, the structures of the epidermis and epidermal-dermal junction can then be visualized.

A handheld or stereomicroscope may be used for direct visual examination. Digitization of images, typically after initial visual assessment, permits storage and facilitates their retrieval, often used for comparison purposes if a lesion is being followed up over time.

A variety of dermatoscopic features have been identified that are suggestive of malignancy, including pseudopods, radial streaming, the pattern of the pigment network, and black dots. These features in combination with other standard assessment criteria of pigmented lesions, such as asymmetry, borders, and color, have been organized into algorithms to enhance the differential diagnosis of pigmented skin lesions. Dermatoscopic images may be assessed by direct visual examination or by review of standard or digitized photographs. Digitization of images, either surface or dermatoscopic images, may permit qualitative image enhancement for better visual perception and discrimination of certain features, or actual computer-assisted diagnosis.

Interpretation of dermatoscopy findings have evolved over time. Initially, lesions were evaluated using pattern analysis. More recently, several algorithms were developed, including the asymmetry, border, color, and dermatoscopic structures (ABCD) rule of dermatoscopy, the 3-point and 7-point checklists of dermatoscopy by Argenziano, the Menzies method, and the CASH algorithm. There remains a lack of consensus in the literature regarding the optimal dermatoscopic criteria for malignancy.

Dermatoscopy is also proposed in the serial assessment of lesions over time and for defining peripheral margins prior to surgical excision of skin tumors.

Computer-Based Optical Diagnostic Devices

A U.S. Food and Drug Administration (FDA)-approved multispectral digital skin lesion analysis (MSDSLA) device, also known as MelaFind, uses a handheld scanner to shine visible light on the suspicious lesion. The light is of ten wavelengths, varying from blue (430 nm) and near infrared (950 nm). The light can penetrate up to 2.5 mm under the surface of the skin. The data acquired by the scanner are analyzed by a data processor; the characteristics of each lesion are evaluated using proprietary computer algorithms. Lesions are classified as positive (i.e., high degree of morphologic disorganization) or negative (i.e., low degree of morphologic disorganization) according to the algorithms. Positive lesions are recommended for biopsy. For negative lesions, other clinical factors are considered in the decision of whether or not to refer to biopsy. The FDA-approved system is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

Electrical Impedance Spectroscopy

The Nevisense device is an electrical impedance spectrometer for melanoma detection. A handpiece connected to the tabletop device applies low current electrical signals to the skin and measures the impedance (resistance) to the flow of current in the tissue. The tip is placed on normal skin to measure baseline impedance and then on the suspicious lesion. The device screen then provides a score from 0 to 10 that reflects the degree of atypia in the lesion along with the positive and negative predictive value of the score. The device refers to lesions with scores up to 3.5 as “EIS negative” and scores from 3.5 to 10 as “EIS positives.”

Optical Coherence Tomography (OCT)

OCT is a noninvasive technique using an imaging technology based on light and optics. OCT uses eye-safe infrared light to obtain a 3D block of image data at a higher resolution compared to other modalities. OCT is indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. This allows imaging of the tissue microstructure, including skin, to aid trained and competent clinicians in their assessment of clinical conditions.

Reflectance Confocal Microscopy (RCM)

Reflectance confocal microscopy (RCM), also known as confocal scanning laser microscopy, is an imaging technology that allows the in vivo identification of cells and tissues of the epidermis and papillary dermis with nearly histologic resolution. RCM uses a low-power laser that emits near-infrared light (830 nm) that reflects off structures in the epidermis and creates a three-dimensional image, with resolution of approximately one millimicron, comparable with standard histology at approximately 30x magnification. Melanin granules have a high refractive index, resulting in more light to be reflected back to the confocal microscope. Thus, areas of higher melanin concentration will appear as bright areas on a confocal image.

Molecular Fluorescent Imaging

The Orlucent® system uses a proprietary biocompatible fluorescent peptide dye that binds to over expressed biomarker protein-receptors in the mole macroenvironment during tissue remodeling. The handheld imager uses near infrared light to excite the retained dye to capture the fluorescence from the target tissue delineating tissue undergoing remodeling as part of the transition process. The analysis software integrates tissue remodeling, including neoangiogensis and tissue reorganization, with nevus characteristics (e.g., size, shape, and pigment) to create a probability score for the presence of tissue remodeling associated with the transition from benign to atypia. The Orlucent system identifies the presence of a biomarker preceding the structural changes that occur during transition from benign to atypia. This is unlike spectral imaging or impedance-based products that evaluate structural tissue reorganization.

Regulatory Status

Dermatoscopic devices cleared by the U.S. Food and Drug Administration (FDA) include:

- Episcope™ (Welch Allyn, Inc., Skaneateles Falls, NY) approved in 1995, intended use is to illuminate body surfaces and cavities during medical examination.
- Nevoscope™ (TRANSLITE, Sugar Land, TX) approved in 1996, intended use is to view skin lesions by either illumination or transillumination.
- Dermascope™ (American Diagnostic Corp., Hauppauge, NY) approved in 1999, intended use is to enlarge images for medical purposes.
  MoleMax™ (Derma Instruments, Austria) approved in 1999, intended use is to enlarge images for medical purposes.
  Product code: KZF.
- Demetra BDEM-01 (Barco N.V.), approved 2019, intended use to capture images of the skin and optimize the imaging and documentation workflow.
  Product code: PSN

MelaFind® (MelaSciences Inc. Irvington, NY), a computer-based optical imaging device, was cleared by the FDA in November of 2011. Its intended use is to evaluate pigmented lesions with clinical or histological characteristics suggestive of melanoma. It is not intended for lesions with a diagnosis of melanoma or likely melanoma. MelaFind is intended for use only by physicians trained in the clinical diagnosis and management of skin cancer (i.e., dermatologists) and only those who have additionally successfully completed training on the MelaFind device.
FDA product code: OYD.

On December 7, 2015, FDA received a PMA (P150046) from SCIBASE AB for the Nevisense device, an electrical impedance spectrometer for melanoma detection. The Nevisense™ (Scibase AB, Stockholm, Sweden) received FDA PMA approval in June 2017. FDA product code: ONV

VivoSight™ is an OCT device that has received FDA-510(k) approval.

IV. RATIONALE

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Summary of Evidence

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The evidence for dermatoscopy in patients who have lesions suspicious of melanoma includes a number of diagnostic accuracy studies and several meta-analyses. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. The literature suggests that dermatoscopy is more accurate than naked eye examination when used in the expert clinical setting. The available evidence from prospective randomized controlled trials (RCTs) and other studies suggests that dermatoscopy used by specialists may lead to a decrease in the number of benign lesions excised and, when used by primary care physicians, may lead to fewer benign lesions being referred to specialists. The number of studies on the impact of dermatoscopy on patient management and clinical outcomes remains limited.

The American Academy of Dermatology in their 2019 Guidelines of Care for the Management of Primary Cutaneous Melanoma states that dermoscopy can improve diagnostic accuracy and/or help direct optimal and adequate tissue sampling in the case of very large lesions.

The European Consensus-Based Interdisciplinary Guideline for Melanoma in their 2019 update states that whole-body photography with sequential examinations should be used for the early detection of melanoma in high-risk patients. They further state that sequential digital dermatoscopy can improve the early detection of melanoma and should be used in high-risk patients, with a high total nevus count.

NCCN, in their guideline for follow-up of patients with cutaneous melanoma, states that total-body photography and sequential digital dermoscopy may enhance early detection of new primary melanoma in patients with high mole count and/or presence of clinically atypical nevi.

Due to input from societal organizations, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

The evidence for dermatoscopy and computer-assisted adjunctive devices in defining peripheral margin of skin lesions suspected of malignancy prior to surgical excision is limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for technologies for the evaluation or monitoring of skin lesions includes several prospective diagnostic accuracy studies, case-studies, retrospective studies, and a simulation study. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. The results of the current published literature for the evaluation of skin lesions lacks the data needed to conclude its clinical utility. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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DERMATOSCOPE is an instrument used to perform dermatoscopy. Older dermatoscopes consist of a low-power (10×) magnifier, a nonpolarized light source, a transparent plate, and a light layer of mineral oil between the instrument and the skin. The mineral oil allows inspection of skin lesions without reflection from the skin surface. More recent dermatoscopes use polarized light to eliminate skin surface reflections.

DERMATOSCOPY refers to the examination of the skin using skin surface microscopy and is also called 'epiluminoscopy' and 'epiluminescent microscopy.' Dermatoscopy requires a high-quality magnifying lens and a powerful lighting system (a dermatoscope).

DERMOSCOPY another name for dermatoscopy.

DIGITAL DERMATOSCOPY is a version of dermatoscopy that involves using digital photography of the dermatoscopic images.

MELANOMA is a malignant tumor of melanocytes that often begins in a darkly pigmented mole and can metastasize widely.

NON-INVASIVE refers to a device or procedure that does not penetrate the skin or enter any orifice in the body.

STRATUM CORNEUM refers to the outermost horny layer of the epidermis.

WHOLE BODY PHOTOGRAPHY is a procedure where the entire skin surface of an individual is photographed. The purpose of this procedure is to provide a reference source of skin lesions over time; pictures may be conventional pictures or digital images stored electronically.

VI. BENEFIT VARIATIONS

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

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit

information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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

Covered when medically necessary

Procedure Codes								
96904	96999*							

*If used for digital dermatoscopy

Investigational and therefore not covered:

Procedure Codes								
0658T	0700T	0701T	96931	96932	96933	96934	96935	96936

ICD-10-CM Diagnosis Code	Description
C43.0	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck

ICD-10-CM Diagnosis Code	Description
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
Z85.820	Personal history of malignant melanoma of skin
Z86.006	Personal history of melanoma in-situ

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.066	**05/11/2018 Consensus Review.** Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	03/29/2019 Consensus Review. Policy statements unchanged. References updated.
	03/26/2020 Consensus Review. Policy statement unchanged. References and Variation updated. Coding reviewed.
	11/17/2020 Administrative Update. Codes 0400T and 0401T removed for 2021 coding update; eff 1/1/2021
	06/15/2021Administrative Update. Added new code 0658T
	08/18/2021. Consensus Review. No change to policy statement. References updated. NCCN statement added to policy statement.
	12/01/2021 Administrative Update. Added new codes 0700T and 0701T. Effective 1/1/22.
	08/19/2022 Major Review. Added MN criteria for whole body photography and digital dermoscopy. Changed title of policy. Updated FEP, background, rationale, coding table, and references.
	12/01/2022 Administrative Update. Deleted Codes 0470T & 0471T effective 1/1/23
	08/15/2023 Consensus Review. Updated cross-references, regulatory status, and references. No changes to coding.
	01/19/2024 Administrative Update. Clinical benefit added.
	09/15/2024 Consensus Review. No changes to coding. Updated references.
	12/16/2024 Administrative Update. Removed NCCN statement

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