MEDICAL POLICY

POLICY TITLE	OPTICAL DIAGNOSTIC DEVICES FOR EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP-2.066

Original Issue Date (Created):	**8/23/2002**
Most Recent Review Date (Revised):	**12/1/2021**
Effective Date:	**3/1/2022**

I. POLICY

Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered **investigational** as a technique to evaluate or serially monitor pigmented skin lesions.

Computer-based optical imaging devices e.g., multispectral digital skin lesion analysis, are considered **investigational** as a technique to evaluate or serially monitor pigmented skin lesions.

Dermatoscopy and computer-based optical imaging devices are considered **investigational** for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision.

Optical coherence tomography (OCT) is considered **investigational** for evaluation of skin lesions.

Reflectance confocal microscopy (RCM) is considered **investigational** for detecting and monitoring dysplastic and atypical nevi for early detection of malignant cutaneous melanoma.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital BlueCross when determining medical necessity according to this policy.

POLICY TITLE	OPTICAL DIAGNOSTIC DEVICES FOR EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP-2.066

II. PRODUCT VARIATIONS

Top

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

FEP PPO: Refer to FEP Benefit Brochure for information on diagnostic services: https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms
Note: The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

Top

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.[1] 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.

POLICY TITLE	OPTICAL DIAGNOSTIC DEVICES FOR EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP-2.066

Computer-Based Optical Diagnostic Devices
A U.S. Food and Drug Administration (FDA)-approved multispectral digital skin lesion analysis (MSDSLA) device uses a handheld scanner to shine visible light on the suspicious lesion. The light is of 10 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.

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 1 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.

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 documents further note:
"MelaFind is indicated only for use on lesions with a diameter between 2 mm and 22 mm, lesions that are accessible by the MelaFind imager, lesions that are sufficiently pigmented (i.e., not for use on non-pigmented or skin-colored lesions), lesions that do not contain a scar or fibrosis consistent with previous trauma, lesions where the skin is intact (i.e., non-ulcerated or non-bleeding lesions), lesions greater than 1 cm away from the eye, lesions which do not contain foreign matter, and lesions not on special anatomic sites (i.e., not for use on acral, palmar, plantar, mucosal, or subungual areas). MelaFind is not designed to detect pigmented non-melanoma skin cancers, so the dermatologist should rely on clinical experience to diagnose such lesions."

FDA product code: OYD.

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

IV. RATIONALE

Top

Summary of Evidence
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 evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for computer-based optical diagnostic devices in patients who have lesions suspicious of melanoma includes several prospective diagnostic accuracy studies and a simulation study. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. In the diagnostic accuracy study, 10% of samples were not evaluable and the simulation study had a number of potential biases. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for dermatoscopy in patients who have pigmented lesions being monitored for suspicious changes consists of noncomparative studies. Relevant outcomes are overall

survival, disease-specific survival, test accuracy, and change in disease status. The available does not clearly indicate that dermatoscopy results in better patient management decisions. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for computer-based optical diagnostic device in patients who have pigmented lesions being monitored for suspicious changes includes no published studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for dermatoscopy and computer-based optical diagnostic devices in patients who have cancerous skin lesions is limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

2021
Review of the literature revealed no new information that would alter the current coverage position. Therefore, the policy statements are unchanged.

V. DEFINITIONS

Top

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.

VI. BENEFIT VARIATIONS

Top

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

VII. DISCLAIMER

Top

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

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

VIII. CODING INFORMATION

Top

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

Investigational and therefore not covered:

CPT Codes®								
0470T	0471T	0658T	0700T	0701T	96904	96931	96932	96933
96934	96935	96936	96999					

IX. REFERENCES

Top

1. *Kardynal A, Olszewska M. Modern non-invasive diagnostic techniques in the detection of early cutaneous melanoma. J Dermatol Case Rep. Mar 31 2014; 8(1):1-8. PMID 24748903*
2. *Vestergaard ME, Macaskill P, Holt PE, et al. Dermoscopy compared with naked eye examination for the diagnosis of primary melanoma: a meta-analysis of studies performed in a clinical setting. Br J Dermatol. 2008;159(3):669-676. PMID*
3. *Rajpara SM, Botello AP, Townend J, et al. Systematic review of dermoscopy and digital dermoscopy/artificial intelligence for the diagnosis of melanoma. Br J Dermatol. 2009; 161(3):591-604.*
4. *Koelink CJ, Vermeulen KM, Kollen BJ, et al. Diagnostic accuracy and cost-effectiveness of dermoscopy in primary care: a cluster randomized clinical trial. J Eur Acad Dermatol Venereol. Nov 2014;28(11):1442-1449. PMID 25493316*
5. *Unlu E, Akay BN, Erdem C. Comparison of dermatoscopic diagnostic algorithms based on calculation: The ABCD rule of dermatoscopy, the seven-point checklist, the three-point checklist and the CASH algorithm in dermatoscopic evaluation of melanocytic lesions. J Dermatol. Jul 2014; 41(7):598-603. PMID 24807635*
6. *De Giorgi V, Grazzini M, Rossari S, et al. Adding dermatoscopy to naked eye examination of equivocal melanocytic skin lesions: effect on intention to excise by general dermatologists. Clin Exp Dermatol. 2011; 36(3):255-259*
7. *Rosendahl C, Tschandl P, Cameron A, et al. Diagnostic accuracy of dermatoscopy for melonocytic and nonmelanocytic pigmented lesions. J Am Acad Dermatol. 2011;64(6):1068-1073*

8. *Annessi G, Bono R, Sampogna F, et al. Sensitivity, specificity, and diagnostic accuracy of three dermoscopic algorithmic methods in the diagnosis of doubtful melanocytic lesions: the importance of light brown structureless areas in differentiating atypical melanocytic nevi from thin melanomas. J Am Acad Dermatol. 2007;56(5):759-767*
9. *Carli P, de Giorgi V, Chiarugi A, et al. Addition of dermoscopy to conventional naked-eye examination in melanoma screening: a randomized study. J Am Acad Dermatol. May 2004;50(5):683-689. PMID 15097950*
10. *Argenziano G, Puig S, Zalaudek I, et al. Dermoscopy improves accuracy of primary care physicians to triage lesions suggestive of skin cancer. J Clin Oncol. Apr 20 2006;24(12):1877-1882. PMID 16622262*
11. *Salerni G, Teran T, Puig S, et al. Meta-analysis of digital dermoscopy follow-up of melanocytic skin lesions: a study on behalf of the International Dermoscopy Society. J Eur Acad Dermatol Venereol. Jul 2013;27(7):805-814. PMID 23181611*
12. *Menzies SW, Emery J, Staples M, et al. Impact of dermoscopy and short-term sequential digital dermoscopy imaging for the management of pigmented lesions in primary care: a sequential intervention trial. Br J Dermatol. 2009;161(6):1270-1277*
13. *Asilian A, Momeni I. Comparison between examination with naked eye, curretage and dermoscopy in determining tumor extension before Mohs micrographic surgery. Adv Biomed Res. 2013;2:2. PMID 23930247*
14. *Suzuki HS, Serafini SZ, Sato MS. Utility of dermoscopy for demarcation of surgical margins in Mohs micrographic surgery. An Bras Dermatol. Jan-Feb 2014;89(1):38-43. PMID 24626646*
15. *Carducci M, Bozzetti M, de Marco G, et al. Preoperative margin detection by digital dermoscopy in the traditional surgical excision of cutaneous squamous cell carcinomas. J Dermatolog Treat. Apr 12 2013;24(3):221-226. PMID 22390630*
16. *Carducci M, Bozzetti M, Foscolo AM, et al. Margin detection using digital dermatoscopy improves the performance of traditional surgical excision of basal cell carcinomas of the head and neck. Dermatol Surg. 2011;37(2):280-285*
17. *Caresana G, Giardini R. Dermoscopy-guided surgery in basal cell carcinoma. J Eur Acad Dermatol Venereol. 2010;24(12):1395-1399*
18. *Monheit G, Cognetta AB, Ferris L, et al. The performance of MelaFind: a prospective multicenter study. Arch Dermatol. Feb 2011;147(2):188-194. PMID 20956633*
19. *Wells R, Gutkowicz-Krusin D, Veledar E, et al. Comparison of diagnostic and management sensitivity to melanoma between dermatologists and MelaFind: a pilot study. Arch Dermatol. Sep 2012;148(9):1083-1084. PMID 22986873*
20. *Rigel DS, Roy M, Yoo J, et al. Impact of guidance from a computer-aided multispectral digital skin lesion analysis device on decision to biopsy lesions clinically suggestive of melanoma. Arch Dermatol. Apr 2012;148(4):541-543. PMID 22351788*
21. *Malvehy J, Puig S, Argenziano G. Dermoscopy report: proposal for standardization. Results of a consensus meeting of the International Dermoscopy Society. J Am Acad Dermatol. 2007;57(1):84-95*

22. *National Comprehensive Cancer Network. Melanoma. Clinical practice guidelines in oncology, V2.2021; https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed August 18, 2021.*
23. *Swetter SM, Tsao H, Bichakjian CK, Curiel-Lewandrowski C, Elder DE, Gershenwald JE, Guild V, Grant-Kels JM, Halpern AC, Johnson TM, Sober AJ. Guidelines of care for the management of primary cutaneous melanoma. Journal of the American Academy of Dermatology. 2019 Jan 1;80(1):208-50. DOI:https://doi.org/10.1016/j.jaad.2018.08.055. Accessed August 18, 2021*
24. *Gerger A, Koller S, Kern T, Diagnostic applicability of in vivo confocal laser scanning microscopy in melanocytic skin tumors. J Invest Dermatol. 2005;124(3):493-498*
25. *Marghoob AA, Charles CA, Busam KJ, et al. In vivo confocal scanning laser microscopy of a series of congenital melanocytic nevi suggestive of having developed malignant melanoma. Arch Dermatol. 2005;141(11):1401-1412*
26. *Taber's Cyclopedic Medical Dictionary, 20th edition.*
27. *Cheng H, Guitera P. Systematic Review of Optical Coherence Tomography Usage in the Diagnosis and Management of Basal Cell Carcinoma. The British Journal of Dermatology. 2015;173(6):1371-1380. [Website]: http://www.medscape.com/viewarticle/856840_6. Accessed August 18, 2021*
28. *US Food and Drug Administration (FDA). 501(k) Premarket Notification :number K192829. Demetra BDEM-01. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192829.pdf. Accessed August 18, 2021.*
29. *Swetter S, Geller AC. Melanoma: Clinical features and diagnosis. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated February 22, 2021. [Website]: www.uptodate.com. Accessed August 18, 2021.*
30. *Marghoob A, Jaimes N. Overview of dermoscopy. In: UpToDate, Online Journal [serial online]. Waltham, MA: UpToDate; updated September 9, 2019. [Website]: www.uptodate.com.. Accessed on August 18, 2021.*
31. *Dinnes J, Deeks JJ, Chuchu N, et al. Dermoscopy, with and without visual inspection, for diagnosing melanoma in adults. Cochrane Database of Systematic Reviews 2018, Issue 12. Art. No.: CD011902. DOI: 10.1002/14651858.CD011902.pub2*
32. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.42, Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy. October 2015 (Archived).*

POLICY TITLE	OPTICAL DIAGNOSTIC DEVICES FOR EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP-2.066

X. POLICY HISTORY

TOP

MP 2.066	**CAC 9/30/03**
	CAC 5/31/05
	CAC 4/25/06
	CAC 3/27/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 11/24/09 Consensus review.
	CAC 11/30/10 Minor Revision. Existing policy statement changed from not medically necessary to investigational. New policy statement added that dermatoscopy is investigational as a technique to define surgical margins in basal cell carcinomas.
	CAC 8/28/12 Adopt BCBSA. No changes to policy criteria. FEP variation added. Codes reviewed 8/10/12
	CAC 1/29/13 Minor revision. Computer-based optical imaging devices (e.g. multispectral digital skin lesion analysis) added as investigational. Statement regarding whole body photography removed. Policy title revised to Optical Diagnostic Devices for Evaluation Skin Lesions Suspected of Malignancy Codes reviewed 11/12/12
	CAC 1/28/14 Consensus review. References updated. No changes to the policy statements. Rationale added.
	CAC 1/27/15 Consensus review. References and rationale updated. No change to policy statements. Codes reviewed.
	CAC 1/26/16 Consensus review. No changes to the policy statements. References and rationale updated. 2016 Codes added. Coding reviewed.
	CAC 3/29/16 Minor revision. Reflectance confocal microscopy (RCM) added as investigational. Rationale and references updated. New codes added to coding.
	11/15/16 Administrative update. Variation Reformatting
	CAC 3/28/17 Consensus review. No change to policy statements. References and rationale reviewed. Deleted FEP variation referencing 2.01.42 – archived. Added standard FEP investigational variation. Coding reviewed.
	7/3/17 Administrative update. Added new codes 0470T-0471T; effective 7/1/17.
	CAC 7/25/17 Minor review. Added investigational statement for use of optical coherence tomography for evaluation of skin. Added Medicare variation to reference L35094. Coding Reviewed.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
	5/11/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	3/29/19 Consensus review. Policy statements unchanged. References updated.
	3/26/20 Consensus review. Policy statement unchanged. References and Variation updated. Coding reviewed.

MEDICAL POLICY

POLICY TITLE	OPTICAL DIAGNOSTIC DEVICES FOR EVALUATION OF SKIN LESIONS SUSPECTED OF MALIGNANCY
POLICY NUMBER	MP-2.066

	11/17/20 Administrative update. Codes 0400T and 0401T removed for 2021 coding update; eff 1/1/2021
	6/15/21Administrative update. : Added new code 0658T
	8/18/21. Consensus review. No change to policy statement. References updated. NCCN statement added to policy statement.
	12/1/21 Administrative update. Added new codes 0700T and 0701T. Effective 1/1/22.

Top