01-96900-03

Original Effective Date: 03/15/03

Reviewed: 09/28/23

Revised: 10/15/23

Subject: Technologies for the Evaluation of Malignant Melanoma

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	<u>Definitions</u>	Related Guidelines
<u>Other</u>	References	<u>Updates</u>			

DESCRIPTION:

Melanoma is a form of skin cancer that originates in the pigment-producing melanocytes. Most melanocytes produce melanin, and the tumors are commonly pigmented brown or black. Melanoma is less common than basal and squamous cell skin cancer, but it is more likely to metastasize than other skin cancers. Prognosis is highly associated with stage of the disease at diagnosis, characterized by the depth of the tumor, the degree of ulceration, and the extent of spread to lymph nodes and distant organs. Differentiating melanoma lesions from benign pigmented lesions in the clinical setting is challenging. Diagnostic aids such as the "ABCDE rule" have been developed to assist clinicians when they visually inspect suspicious lesions. The diagnostic accuracy of the ABCDE criteria varies depending on whether they are used singly or together. Use of a single criterion is sensitive but not specific, which would result in many benign lesions being referred or biopsied. Conversely, the use of all criteria together is specific but not sensitive, meaning that a number of melanomas are missed.

Although more than 90% of melanomas that arise in the skin can be recognized with the naked eye (National Cancer Institute), noninvasive approaches have been developed in an attempt to improve early detection and the diagnosis of malignant skin lesions. Numerous technologies are available including but not limited to:

- Whole body photography, also known as full-body photography, full-body screening, photographic surveillance, or dermal screening, involves the taking of photographs of specific lesions or of the whole body, in order to identify suspicious areas which might be malignant melanoma.
- Dermatoscopy, also known as dermoscopy, epiluminescence microscopy, or in vivo cutaneous microscopy, 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.

 Multispectral image analysis, also known as computer-aided multispectral imaging analysis, uses a handheld scanner to shine visible light on the suspicious lesion.

Several devices have received approval from the U.S. Food & Drug Administration (FDA).

POSITION STATEMENT:

The use of the following methods for early detection, surveillance, or screening of melanoma is considered **experimental or investigational** (the list is not all-inclusive):

- 3D color histogram mapping
- 3D imagery
- Dermatoscopy/Dermoscopy
- Digital epiluminescence microscopy
- Electrical impedance spectroscopy
- Infrared imaging
- Laser microscopy
- Magnified oil immersion diascopy
- Melanomagram
- Multiphoton microscopy
- Multiphoton tomography
- Multispectral image analysis
- Optical coherence tomography
- Partial body photography
- Photoacoustic microscopy
- Raman spectroscopy
- Reflectance confocal microscopy
- Skin videomicroscopy
- Thermal imaging
- Total or whole-body photography
- Total body photography systems
- Two-photon spectroscopy
- Ultrasound
- Visual image analysis.

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

BILLING/CODING INFORMATION:

CPT Coding:

96904	Whole body integumentary photography, for monitoring of high-risk patients with
	dysplastic nevus syndrome or a history of dysplastic <u>nevi</u> , or patients with a personal or
	familial history of melanoma (Investigational)
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	image acquisition and interpretation and report, first lesion (Investigational)
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	image acquisition only, first lesion (Investigational)
96933	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	interpretation and report only, first lesion (Investigational)
96934	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	image acquisition and interpretation and report, each additional lesion (List separately
	in addition to code for primary procedure) (Investigational)
96935	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	image acquisition only, each additional lesion (List separately in addition to code for
	primary procedure) (Investigational)
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin;
	interpretation and report only, each additional lesion (List separately in addition to
	code for primary procedure) (Investigational)
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma
	risk score (Investigational)
0700T	Molecular fluorescent imaging of suspicious nevus; first lesion (Investigational)
0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion (List
	separately in addition to code for primary procedure) (Investigational)
· · · · · · · · · · · · · · · · · · ·	

Unlisted code 96999 may be used to report other dermatological technologies.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline revised date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Genetic Testing, 05-82000-28

Tumor/Genetic Markers, 05-86000-22

OTHER:

None applicable.

REFERENCES:

- 1. American Academy of Dermatology, Position Statement on Reflectance Confocal Microscopy (RCM); accessed at aad.org.
- 2. American Cancer Society, What's New in Melanoma Skin Cancer Research? Accessed at cancer.org.
- 3. Bono A, Tolomio E, Trincone S, et al; Micro-Melanoma Detection: A Clinical Study On 206 Consecutive Cases of Pigmented Skin Lesions with a Diameter < or = 3mm; Br J Dermatol. 2006 Sep; 155(3): 570-3.
- 4. Borsari S, Pampena R, et al. In vivo dermoscopic and confocal microscopy multistep algorithm to detect in situ melanomas. Br J Dermatol. 2018 Jul;179(1):163-172. PMID: 29355898.
- 5. Caliber Imaging & Diagnostics, Inc. Reflectance Confocal Microscopy (RCM) Dossier, March 2019.
- 6. Chavez-Bourgeois M, Ribero S. et al. Reflectance Confocal Microscopy and Electrical Impedance Spectroscopy in the Early Detection of Melanoma in Changing Lesions during Long-term Follow-up of Very High-risk Patients. Acta Derm Venereol. 2022 Jul 26;102: adv00751.
- 7. Christensen L, Scott J, Bordeaux J. Use of gene expression profile testing as a prognostic tool in early-stage cutaneous melanoma compelling but not ready for primetime. PMID: 30211811.
- 8. ClinicalTrials.gov. Ex-vivo Examination of Excisions of Skin Tumors by Confocal Optical Coherence Tomography (LC-OCT) With Integrated Dermoscopy and Comparison with Histology (DERMOCTAV); accessed August 2023.
- 9. ClinicalTrials.gov. Noninvasive Assessment of Muco-cutaneous Lesions In Vivo; accessed August 2023.
- 10. ClinicalTrials.gov. Performance of Nevisense Electrical Impedance Spectroscopy in Patients with Multiple Nevi and Large Acquired Nevi (LAN); accessed August 2023.
- 11. Feit, N. E., Dusza, S. W. & Marghoob, A. A. (2004). Melanomas detected with the aid of total cutaneous photography. British Journal of Dermatology, 150(4), 706-714.
- 12. Gareau DS, da Rosa JC, et al. Digital imaging biomarkers feed machine learning for melanoma screening. Exp Dermatol. 2017 Jul; 26(7): 615–618.
- 13. Guida S, Alma A, et al. Non-Melanoma Skin Cancer Clearance after Medical Treatment Detected with Noninvasive Skin Imaging: A Systematic Review and Meta-Analysis. Cancers (Basel). 2022 Jun 8;14(12):2836. PMID: 35740502.
- 14. Hanrahan, P. F., D'Este, C. A., Menzies, S. W., Plummer, T. & Hersey, P. (2002). A randomized trial of skin photography as an aid to screening skin lesions in older males. Journal of Medical Screening, 9, 128-132.

- 15. Jung JM, Cho JY, et al. Emerging Minimally Invasive Technologies for the Detection of Skin Cancer. J Pers Med. 2021 Sep 24;11(10): 951.PMID: 34683091.
- 16. Kanzler, M. H., & Mraz-Gernhard, S. (2001). Primary cutaneous malignant melanoma and its precursor lesions: Diagnostic and therapeutic overview. Journal of the American Academy of Dermatology, 45(2), 260-276.
- 17. Kashani-Sabet M, Leachman SA, et al. Early Detection and Prognostic Assessment of Cutaneous Melanoma: Consensus on Optimal Practice and the Role of Gene Expression Profile Testing. JAMA Dermatol. 2023 May 1;159(5):545-553. PMID: 36920356.
- 18. Kolla A, Fried L, et al. Impact of Electrical Impedance Spectroscopy on Clinician Confidence and Diagnostic Accuracy in Evaluating Melanocytic Skin Lesions Suspicious for Melanoma: A Pilot Study. SKIN The Journal of Cutaneous Medicine, 6(1), 20–28. https://doi.org/10.25251/skin.6.1.4.
- 19. Malvehy J, Pellacani G, Dermoscopy, Confocal Microscopy and other Non-invasive Tools for the Diagnosis of Non-Melanoma Skin Cancers and Other Skin Conditions. Acta Derm Venereol. 2017 Jul 5. Doi: 10.2340/00015555-2720.
- 20. Marghoob AA, Jaimes N. Dermoscopic evaluation of skin lesions. In: UpToDate, Tsao H, Corona R (Eds), UpToDate, Waltham, MA; accessed August 2023 at uptodate.com.
- 21. Marushchak O, Yakubov R, et al. New Technologies in Diagnosis and Prognosis of Melanocytic Lesions. J Clin Aesthet Dermatol. 2023 Feb;16(2):44-49.
- 22. Mataca E, Migaldi M, et al. Impact of Dermoscopy and Reflectance Confocal Microscopy on the Histopathologic Diagnosis of Lentigo Maligna/Lentigo Maligna Melanoma. Am J Dermatopathol. 2018 Dec;40(12):884-889. PMID: 29933314.
- 23. National Cancer Institute (NCI), Skin Cancer Screening (PDQ®)—Health Professional Version; updated Dec. 2020; accessed at cancer.gov.
- 24. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Melanoma- Cutaneous. Version 2.2023; accessed at nccn.org.
- 25. National Institute on Health and Care Excellence (NICE). Melanoma: assessment and management [NG14]. 2015; accessed at nice.org.uk March 2020.
- 26. National Institute on Health and Care Excellence (NICE). VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions [DG19], 2015; accessed at nice.org.uk March 2020.
- 27. Oliveria, S. A., Chau, D., Christos, P. J., Charles, C. A., Muslin, A. L. & Halpern, A. C. (2004). Diagnostic accuracy of patients in performed skin self-examination and the impact of photography. Archives of Dermatology, 140, 57-62.
- 28. Oliveria, S. A., Dusza, S. W., Phelan, D. L., Ostroff, J. S., Berwick, M. & Halpern, A. C. (2004). Patient adherence to skin self-examination. Effect of nurse intervention with photographs. American Journal of Preventive Medicine, 26(2), 152-155.
- 29. Peccerillo F, Mandel VD, et al. Lesions Mimicking Melanoma at Dermoscopy Confirmed Basal Cell Carcinoma: Evaluation with Reflectance Confocal Microscopy. Dermatology. 2019;235(1):35-44. PMID: 30404078.
- 30. Pellacani G, DeCarvalho N, et al. The smart approach: feasibility of lentigo maligna superficial margin assessment with hand-held reflectance confocal microscopy technology. J Eur Acad Dermatol Venereol. 2018 Oct;32(10):1687-1694. PMID: 29704275.
- 31. Pellacani G, Farnetani F, et al. Effect of Reflectance Confocal Microscopy for Suspect Lesions on Diagnostic Accuracy in Melanoma: A Randomized Clinical Trial. Jama Dermatol. 2022 Jun 1; e221570. PMID: 35648432.
- 32. Persechino F, DeCarvalho N, et al. Folliculotropism in pigmented facial macules: Differential diagnosis with reflectance confocal microscopy. Exp Dermatol. 2018 Mar;27(3):227-232. PMID: 29274094.

- 33. Pezzini C, Mandel VD, et al. Seborrheic keratoses mimicking melanoma unveiled by in vivo reflectance confocal microscopy. Skin Res Technol. 2018 May;24(2):285-293. PMID: 29363175.
- 34. Rayner JE, Laino AM, et al. Clinical Perspective of 3D Total Body Photography for Early Detection and Screening of Melanoma. Front Med (Lausanne). 2018 May 23; 5:152.
- 35. Rao BK, John AM, et al. Diagnostic Accuracy of Reflectance Confocal Microscopy for Diagnosis of Skin Lesions: An Update. Arch Pathol Lab Med. 2019 Mar;143(3):326-329.
- 36. Rice, ZP, Utilization and Rationale for the Implementation of Total Body (Digital) Photography as an Adjunct Screening Measure for Melanoma, Melanoma Research, October 2010-Volume 20- Issue 5, pp 417-421.
- 37. Risser, J, Pressley Z, Veledar E, et al. The Impact of Total Body Photography on Biopsy Rate in Patients From a Pigmented Lesion Clinic, Journal of the American Academy of Dermatology, Vol 57, Issue 3, pages 428-434, 09/07.
- 38. SciBase. Nevisense[™] Product Information; August 2023.
- 39. Seidenari S, Longo C, Giusti F, Pellacani G, Clinical Selection of Melanocytic Lesions for Dermoscopy Decreases the Identification of Suspicious Lesions in Comparison with Dermoscopy Without clinical Preselection, Br J Dermatol. 2006 May; 154(5): 873-9.
- 40. Shahriari N, Grant-Kels JM, et al. Reflectance confocal microscopy features of melanomas on the body and non-glabrous chronically sun-damaged skin. J Cutan Pathol. 2018 Oct;45(10):754-759. PMID: 29971811
- 41. Swetter S, Geller AC. Melanoma: Clinical features and diagnosis. In: UpToDate, Tsao H, Corona R (Eds), UpToDate, Waltham, MA; accessed August 2023 at uptodate.com.
- 42. Swetter SM, Tsao H, et al. Guidelines of care for the management of primary cutaneous melanoma. J Am Acad Dermatol. 2019 Jan;80(1):208-250.
- 43. Terushkin V, Oliveria SA, et al, Use of and Beliefs About Total Body Photography and Dermatoscopy Among US Dermatology Training Programs: An Update, JAAD, Volume 62, Issue 5, pp 794-803, May 2010.
- 44. Thomas L, Puiq S, Dermoscopy, Digital Dermoscopy and Other Diagnostic Tools in the Early Detection of Melanoma and Follow-up of High-risk Skin Cancer Patients. Acta Derm Venereol. 2017 Jul 5. Doi: 10.2340/00015555-2719.
- 45. Tkaczyk E, Innovations and Developments in Dermatologic Non-invasive Optical Imaging and Potential Clinical Applications. Acta Derm Venereol. 2017 Jul 5. Doi: 10.2340/00015555-2717.
- 46. U.S. Food & Drug Administration (FDA), accessed at fda.gov.
- 47. U.S. Preventive Services Task Force (USPSTF), Skin Cancer: Screening; accessed at uspreventiveservicestaskforce.org.
- 48. Wang, S. Q., Kopf, A. W., Koenig, K., Polsky, D., Nudel, K. & Bart, R. S. (2004). Detection of melanomas in patients followed up with total cutaneous examinations, total cutaneous photography and dermoscopy. Journal of the American Academy of Dermatology, 50(1), 15-20.
- 49. Zakria D, Brownstone N, et al. Electrical impedance spectroscopy significantly enhances correct biopsy choice for pigmented skin lesions beyond clinical evaluation and dermoscopy. https://pubmed.ncbi.nlm.nih.gov/36223289/#:~:text=Melanoma%20Res,1)%3A80%2D83. PMID:36223289.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/28/23.

GUIDELINE UPDATE INFORMATION:

03/15/03	New Medical Coverage Guideline.
07/01/03	Revision to guideline; added new code 0045T.
03/15/04	Annual review for investigational; no change.
03/15/05	Annual review for investigational; no change.
03/15/06	Enhanced annual review for investigational; no change.
01/01/07	2007 HCPCS update; added 96904, deleted 0044T, and 0045T.
02/15/07	Scheduled review; title revision; no change in coverage, references updated.
06/15/07	Reformatted guideline.
02/15/08	Annual review: position statement maintained; references updated.
02/15/09	Annual review: position statement maintained; references updated.
02/15/10	Annual review: position statement maintained; description section and references
	updated.
12/15/10	Annual review: position statement maintained and references updated.
05/11/14	Revision: Program Exceptions section updated.
01/01/16	Annual HCPCS/CPT update; codes 0400T and 0401T added.
02/15/16	Revision; title, description, position statements, coding, and references updated.
06/15/18	Review; description, position statement, coding, and references updated.
05/15/19	Review; position statement maintained and references updated.
07/01/19	Revision; Pigmented Lesion Assay (PLA) removed (refer to MCG 05-86000-22).
01/01/21	Annual CPT/HCPCS update. Codes 0400T and 0401T deleted.
05/15/21	Review; Position statement maintained; coding and references updated.
01/01/22	Annual CPT/HCPCS coding update. Codes 0700T, 0701T added.
04/15/22	Coding section updated.
09/15/22	Review: Position statements maintained; references updated.
01/01/23	Annual CPT/HCPCS update. Codes 0470T and 0471T deleted.
05/22/23	Update to Program Exceptions section.
10/15/23	Review: Position statement and references updated.
-	