

01-96900-03

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Subject: Technologies for the Evaluation of Malignant Melanoma

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[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

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
- Digital epiluminescence microscopy
- Infrared imaging
- Laser microscopy
- Magnified oil immersion diascopy
- Melanogram
- 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)
0400T	Multi-spectral digital skin lesion analysis of clinically atypical cutaneous pigmented lesions for detection of melanomas and high risk melanocytic atypia; one to five lesions (Investigational)
0401T	Multi-spectral digital skin lesion analysis of clinically atypical cutaneous pigmented lesions for detection of melanomas and high risk melanocytic atypia; six or more lesions (Investigational)
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion (Investigational)
0471T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure) (Investigational)

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.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

[Genetic Testing, 05-82000-28](#)

[Tumor/Genetic Markers, 05-86000-22](#)

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 04/25/19.

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).

