01-96900-03

Original Effective Date: 03/15/03

Reviewed: 08/22/24

Revised: 09/15/24

Subject: Technologies for the Evaluation of Malignant Melanoma

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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 melanoma. Noninvasive approaches are methods that do not require a biopsy or surgical excision of tissue. These approaches aim to diagnose melanoma by analyzing the skin lesions characteristics using various techniques, such as imaging, spectroscopy, or other non-invasive methods.

Summary and Analysis of Evidence: The evidence for dermatoscopy in patients who have lesions suspicious of melanoma includes several diagnostic accuracy studies and several meta-analyses. Dermatoscopy is used in combination with clinical assessment, either based on direct visual inspection or review of photographs. 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. Evidence for the use of total body photography includes systematic reviews, studies, meta-analysis, and research papers. Brown et al (2023) stated, "Our data raises, the possibility that traditional surveillance using full skin examination and targeted removal or biopsy of suspect lesions results in higher ratios of in situ to invasive melanomas and a lower incidence of thick invasive melanomas than total body photography (TBP) and/or serial digital dermoscopic imaging (SDDI). Delayed excision, inherent to photographic monitoring, carries at least some risk of melanoma progressing from a lower to a higher risk category. Whether TBP or SDDI is a safer and more effective intervention than traditional surveillance can only be addressed by the standard method of a prospective, randomised and controlled trial. Parameters measured should include effects on patient welfare, mortality and cost effectiveness. The absence of control groups and any attempt to measure the effect on mortality are major shortcomings in the literature supporting the use of TBP and SDDI. Until these studies are done, guidelines recommending TBP and SDDI in melanoma surveillance should make it clear that there is no proven survival benefit." The National Comprehensive Cancer Network (NCCN) clinical guidelines for cutaneous melanoma (v2024) include the following statement regarding the use of noninvasive technology for follow-up surveillance after a melanoma diagnosis: "Pre-diagnostic clinical modalities (i.e., dermoscopy, total-body photography and sequential digital dermoscopy), noninvasive imaging and other technologies (e.g., reflectance confocal microscopy, electrical impedance spectroscopy) may aid in surveillance for new primary melanoma, particularly in patients with high mole count and/or presence of clinically atypical nevi." Evidence for the use of electrical impedance spectroscopy (EIS) for melanoma diagnosis includes case series, meta-analyses, studies, and clinical trials. Zakria et al (2023) stated, "The findings from this study demonstrate that the integration of EIS technology into PSL biopsy decisions has the potential to significantly improve the accuracy of lesion selection for biopsy beyond clinical and dermoscopic evaluation alone". Chavez-Bourgeois et al (2022) concluded that "Results of electrical impedance spectroscopy in this subset of very early lesions should be carefully considered due to the risk of false negatives". Rocha et al (2017) stated "Further studies in other centres with larger samples are also needed to confirm the role of EIS in investigating suspicious melanocytic lesions using this protocol." Mohr et al (2013) concluded "EIS has the potential to be an adjunct diagnostic tool to help clinicians differentiate between benign and malignant (melanocytic and non-melanocytic) skin lesions. Further studies are needed to confirm the validity of the automatic assessment algorithm". Numerous other noninvasive technologies have been proposed for diagnosis and surveillance of melanoma. They include technologies such as: 3D imaging/mapping, melanomagram, tow-photon spectroscopy, skin lesion imaging and analysis, microscopy, tomography, or diascopy. Some have not been FDA approved and/or clinical utility has not been proven. Research is lacking for these technologies and the effects on health outcomes cannot be determined due to the lack of evidence. Further research is needed to validate effectiveness and safety.

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 nevi, 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.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

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.
09/15/24	Review: Position statement maintained; description and references updated.