Medical Coverage Policy | Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy

EFFECTIVE DATE: 06|01|2009
POLICY LAST UPDATED: 09|19|2017

OVERVIEW
There is interest in noninvasive devices that will improve the diagnosis of malignant skin lesions. One technique is dermatoscopy (dermoscopy, epiluminescence microscopy, in vivo cutaneous microscopy), which enables the clinician to perform direct microscopic examination of diagnostic features in pigmented skin lesions. Another approach is use of computer-based light imaging systems. These techniques have the potential to improve diagnostic accuracy for suspicious skin lesions and may increase the detection rate of malignant skin lesions and/or reduce the rate of unnecessary biopsies.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered not medically necessary as a technique to evaluate or serially monitor pigmented skin lesions as the evidence is insufficient to determine the effects of the technology on health outcomes.

Computer-based optical imaging devices, e.g., multispectral digital skin lesion analysis, are considered not medically necessary as a technique to evaluate or serially monitor pigmented skin lesions as the evidence is insufficient to determine the effects of the technology on health outcomes.

Dermatoscopy and computer-based optical imaging devices are considered not medically necessary for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision as the evidence is insufficient to determine the effects of the technology on health outcomes.

Note: Limited photography for documentation is considered part of record keeping and not separately reimbursed.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
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, is often used for comparison purposes if a lesion is being followed 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.

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.

Recent meta-analyses found that overall, the diagnostic accuracy of dermatoscopy was higher than clinical assessment/naked eye examination. However, most studies are retrospective, reported on the performance of clinicians who have extensive experience with dermatoscopic imaging, and were conducted outside of the United States.

The evidence for dermatoscopy in patients who have lesions suspicious of melanoma is limited. 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, and the service is considered not medically necessary.

The evidence for dermatoscopy in patients who have pigmented lesions being monitored for suspicious changes 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. Therefore, the service is considered not medically necessary.

Computer-Based Optical Diagnostic Devices

An 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 noted below is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

One computer-based optical imaging device has been cleared by FDA. MelaFind® (MelaSciences Inc. Irvington, NY) was approved in November 2011. Its intended use is to evaluate pigmented lesions with clinical or histologic 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.

The evidence for computer-based optical diagnostic devices in patients who have lesions suspicious of melanoma 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. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, the service is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following code, when performed with or without dermatoscopy, is considered **not medically necessary:**

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

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

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

Whole body photography represents one component of dermatoscopy. CPT code 96904 may also be submitted to describe whole body photography without dermatoscopy.

RELATED POLICIES

CPT Category III Codes

PUBLISHED

Provider Update, November 2017
Provider Update, November 2016
Provider Update, January 2016
Provider Update, September 2014
Provider Update, September 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, May 2010

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