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

EFFECTIVE DATE: 06|01|2009
POLICY LAST UPDATED: 04|20|2022

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, or multispectral digital skin lesion analysis (MSDSLA). MSDSLA is a noninvasive approach to diagnosing skin lesions. 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

Medicare Advantage Plans

Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is not covered 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 is not covered 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.

Multispectral digital skin lesion analysis is not covered in all situations including but not limited to the following, as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Evaluating pigmented skin lesions;
- Serially monitoring pigmented skin lesions;
- Defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision.

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

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.

Dermatoscopy is 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.

Multispectral digital skin lesion analysis is considered not medically necessary in all situations including but not limited to the following, as the evidence is insufficient to determine the effects of the technology on health outcomes:

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COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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.

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 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 dermatoscopy in patients who have cancerous skin lesions referred for surgery includes 1 RCT and several observational studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity. The single RCT did not report superior outcomes using dermatoscopy compared with visual inspection or curettage. The published studies were all conducted outside of the United States and at least 2 did not use U.S. Food and Drug Administration–approved devices. None addressed computer-based optical devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

Multispectral Digital Skin Lesion Analysis

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. For example, for thin (ie, <1.0 mm) localized stage I cancers the 5-year survival rate is over 90%, and this decreases to 15% to 20% for metastatic stage IV cancers.1 Thus, early detection of disease is important for increasing survival.

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.

There is interest in noninvasive approaches that will improve the diagnosis of malignant skin lesions. One technology that could improve melanoma detection and outcomes is multispectral digital skin lesion analysis (MSDSLA). A U.S. Food and Drug Administration (FDA)–approved MSDSLA device uses a handheld scanner to shine a visible light on the suspicious lesion. The light is of 10 wavelengths, varying from blue (430 nm) and near-infrared (950 nm). This 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 (ie, high degree of morphologic disorganization) or negative (ie, 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 to refer for biopsy. The FDA-approved system is intended only for suspicious pigmented lesions on intact skin and for use by trained dermatologists.

In November 2011, MelaFind® (MELA Sciences, Irvington, NY, now Strata Skin Sciences, Horsham PA), a MSDSLA device, was approved by the FDA through the premarket approval process. 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 (ie, dermatologists) and only those who have successfully completed training on the MelaFind® device. The FDA documents have further noted: "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 nonpigmented 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., nonulcerated or nonbleeding 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)."

In May 2017, the manufacturer of MelaFind announced that it would no longer support or commercialize the device.

For individuals who have pigmented lesions being evaluated for melanoma who receive MSDSLA, the evidence includes 2 prospective diagnostic accuracy studies of MelaFind, a retrospective analysis of MelaFind in a clinical setting, and additional studies of other MSDSLA devices. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, other test performance measures, and change in disease status. The diagnostic accuracy study found that MSDSLA had a sensitivity of 98.2% for recommending biopsy of melanoma lesions (8% of the pigmented lesions were melanoma). The average specificity of MSDSLA was 9.5% compared with 3.7% among clinicians. However, the study only included lesions already determined by a clinician to be sufficiently suspicious to warrant excision. No prospective studies conducted in a clinical setting have evaluated the utility of MSDSLA as a diagnostic tool in the initial evaluation of pigmented lesions. In addition, given the absence of firm evidence about the clinical validity of MSDSLA, a chain of evidence cannot be built to support conclusions about the magnitude of benefits and harms of MSDSLA use in practice. The manufacturer discontinued support and commercialization of the MelaFind device in 2017. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

The following codes, when performed with or without dermatoscopy, are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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

There is no specific code for Multispectral digital skin lesion analysis. Claims should be filed with the following code:

96999 Unlisted special dermatological service or procedure

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

RELATED POLICIES

New Technology

PUBLISHED

Provider Update, June 2022
Provider Update, October 2021
Provider Update, January 2021
Provider Update, January 2020

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