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

**EFFECTIVE DATE:** 06|01|2023
**POLICY LAST REVIEWED:** 02|21|2024

## 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 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

**Medicare Advantage Plans**

The following services are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis as a technique to evaluate or serially monitor pigmented skin lesions
- Dermatoscopy for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision
- Computer-based optical imaging devices, eg, multispectral digital skin lesion analysis, as a technique to evaluate or serially monitor pigmented skin lesions

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

**Commercial Products**

The following services are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis as a technique to evaluate or serially monitor pigmented skin lesions
- Dermatoscopy for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision
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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

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 comparator 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 (ABCD) structures rule of dermatoscopy, the 3-point and 7-point checklists of dermatoscopy by Argenziano, the Menzies method, and the CASH algorithm.1 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 before surgical excision of skin tumors.

Computer-Based Optical Diagnostic Devices

A U.S. Food and Drug Administration (FDA)–approved multispectral digital skin lesion analysis 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 (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 to biopsy. The FDA approved system (see details in the Regulatory Status section) is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

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 computer-based optical diagnostic devices in patients who have lesions suspicious of

melanoma includes several prospective diagnostic accuracy studies and a simulation study. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. In the diagnostic accuracy study, 10% of samples were not evaluable and the simulation study had a number of potential biases. There are no studies comparing patient management decisions and health outcomes with and without these devices. 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 computer-based optical diagnostic device in patients who have pigmented lesions being monitored for suspicious changes includes no published studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for dermatoscopy and computer-based optical diagnostic devices 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.

## CODING

**Medicare Advantage Plans and Commercial Products**

The following CPT code(s), 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 computer-based optical imaging devices. Claims should be filed with the following Unlisted CPT code(s):

**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

Unlisted Procedures

## PUBLISHED

Provider Update, April 2024
Provider Update, April 2023
Provider Update, June 2022
Provider Update, October 2021
Provider Update, January 2021

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