Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy

Description of Procedure or Service

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 (i.e., <1.0 mm) localized stage I cancers the 5-year survival rate is over 90% and this decreases to around 15% to 20% for metastatic stage IV cancers. 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, 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 technique is dermatoscopy (also called dermoscopy), which enables the clinician to perform direct microscopic examination of diagnostic features in pigmented skin lesions. Devices consist of a 10x magnifier lens in combination with a liquid medium or polarized light to eliminate reflection and allow for more-detailed examination of suspicious skin lesions. The available evidence from prospective randomized controlled trials 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.

Another technology that can potentially 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 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 to refer for biopsy. The FDA-
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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.

Computer-based optical diagnostic devices

A U.S. Food and Drug Administration (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 (see additional details in the Regulatory Status section) is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

Regulatory Status:

Dermatoscopic devices cleared by the FDA include:

- Episcope™ (Welch Allyn, Inc.) approved in 1995; intended use is to illuminate body surfaces and cavities during medical examination.
- Nevoscope™ (TRANSLITE) approved in 1996; intended use is to view skin lesions by either illumination or transillumination.
- Dermascop™ (American Diagnostic Corp.) approved in 1999; intended use is to enlarge images for medical purposes.
- MoleMax™ (Derma Instruments) approved in 1999; intended use is to enlarge images for medical purposes.
- A multispectral digital skin lesion analysis device called MelaFind® (MELA Sciences, Irvington, NY) was approved by the U.S. Food and Drug Administration (FDA) 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. FDA documents further note:

“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).”

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.
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**Policy**

BCBSNC will not provide coverage for the use of optical diagnostic devices for evaluating skin lesions suspected of malignancy because it is considered investigational. BCBSNC does not cover investigational services or procedures.

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Optical Diagnostic Devices for Evaluating Skin Lesions is covered**

Not applicable.

**When Optical Diagnostic Devices for Evaluating Skin Lesions is not covered**

Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered investigational as a technique to evaluate or serially monitor pigmented skin lesions.

Dermatoscopy and computer-based optical imaging devices are considered investigational for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision.

Multispectral digital skin lesion analysis is considered investigational in all situations including but not limited to:

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

**Policy Guidelines**

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.
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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.

The National Comprehensive Cancer Network (NCCN) melanoma guideline does not mention dermatoscopy. Biopsy is recommended for suspicious pigmented lesions.

The American Academy of Dermatology 2011 guidelines of care and treatment of melanoma do not mention dermatoscopy, e.g., in the discussion of determining surgical margins before surgery. The guidelines did not address evaluation of suspicious lesions.

The evidence for multispectral digital skin lesion analysis (MSDSLA) in patients who have pigmented lesions being evaluated for melanoma includes 2 prospective diagnostic accuracy studies and several online studies or simulation exercises addressing clinical utility. 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 included only lesions that had already been determined by a clinician to be sufficiently suspicious to warrant excision. The online randomized controlled trial included images of a subset of lesions from the diagnostic accuracy study. The sensitivity and specificity of a correct biopsy decision was significantly higher among dermatologists who had MSDSLA results than among those who only had clinical information and digital images. Study participants did not actually examine patients. There are no studies conducted in a clinical setting that evaluate the utility of MSDSLA as a diagnostic tool in the initial evaluation of pigmented lesions. In addition, there are no studies conducted in clinical settings that compared 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.

Billing/Coding/Physician Documentation Information
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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: Prior to 1/1/16 there was no specific code describing Dermatoscopy or computer-based optical imaging. Providers could have billed the most appropriate unlisted code, such as 96999*

*Codes effective January 1, 2016: 96931, 96932, 96933, 96934, 96935, 96936, 0400T, 0401T, 0470T, 0471T*

*Codes effective February 29, 2016: 96904*

*Whole body photography represents 1 component of dermatoscopy. CPT code 96904 may also be submitted to describe whole body photography without dermatoscopy.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

**Scientific Background and Reference Sources**

**From Policy Entitled: Whole Body Photography, Dermatoscopy**

BCBSA Medical Policy Reference Manual. 2.01.42, 8/15/01


**Policy retitled: Dermatoscopy**


BCBSA Medical Policy Reference Manual. 2.01.42, 7/20/06.

BCBSA Medical Policy Reference Manual. 2.01.42, 12/12/06.


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Senior Medical Director review

Specialty Matched Consultant Advisory Panel review 1/2011


Medical Director review 1/2012

Specialty Matched Consultant Advisory Panel review 1/2012

For policy retitled: Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy


Medical Director review 11/2012
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Specialty Matched Consultant Advisory Panel review 1/2014


Medical Director review 1/2015

Specialty Matched Consultant Advisory Panel review 1/2015


Policy Implementation/Update Information

From Policy Entitled: Whole Body Photography, Dermatoscopy

11/03 Original policy issued.

3/17/05 Specialty Matched Consultant Advisory Panel review - 2/11/05. No changes to criteria. Description section revised to include information regarding whole body integumentary photography. Added Whole Body Integumentary Photography to Policy section and to header for When Covered and When not Covered. Policy Guidelines, key words, medical terms and reference sources added.

1/17/07 CPT code 96904 effective January 1, 2007 added to Billing/Coding section. Removed deleted CPT codes 0044T and 0045T. No changes in policy criteria. (pmo)

Policy retitled: Dermatoscopy

5/21/07 Policy titled "Whole Body Photography, Dermatoscopy" renamed "Dermatoscopy". CPT code 96904 removed from Billing/Coding section. There is no specific code for Dermatoscopy. Reference sources added. No changes in policy criteria. (pmo)
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6/22/09  Reference sources added. No changes in policy criteria. (pmo)

6/22/10  Policy Number(s) removed (amw)

12/7/10  Senior Medical Director review. Description section and Policy Guidelines section extensively revised. Reference sources updated. Policy Statement changed to state “BCBSNC will not provide coverage for Dermatoscopy because it is considered investigational as a technique to evaluate or serially monitor pigmented skin lesions or as a technique to define peripheral margins of basal cell carcinomas. BCBSNC does not cover investigational services or procedures.” Under section “When Dermatoscopy is not covered”, the not medically necessary statement was removed and the following statements were added: “Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered investigational as a technique to evaluate or serially monitor pigmented skin lesions. Dermatoscopy as a technique to define peripheral margins of basal cell carcinomas is investigational.” (mco)


11/8/11  References updated. No changes to Policy Statements. (mco)

2/7/12  Specialty Matched Consultant Advisory Panel review 1/2012. Description section updated. References updated. Medical Director review 1/2012. (mco)

For policy retitled: Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy

11/27/12  Policy re-titled from “Dermatoscopy” to “Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy.” Description section updated to include computer based optical imaging information. “When not Covered” section revised to state: “Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, is considered investigational as a technique to evaluate or serially monitor pigmented skin lesions. Computer-based optical imaging devices e.g., multispectral digital skin lesion analysis, are considered investigational as a technique to evaluate or serially monitor pigmented skin lesions. Dermatoscopy and computer-based optical imaging devices are considered investigational for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision.” Policy Guidelines updated. References updated. Medical Director review 11/2012. Policy noticed on 11/27/12 for effective date of 2/26/13. (mco)

2/12/13  Specialty Matched Consultant Advisory Panel review 1/2013


12/30/14  References updated. Description section updated. Policy Guidelines section updated. No changes to Policy Statements. (td)


12/30/15  Billing/coding section updated to include code 96904 effective 2/29/15. Policy noticed 12/30/15 for effective date 2/29/16. (td)
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5/31/16 Description section updated. Policy Guidelines section updated. Billing/Coding section updated to include codes: 0400T, 0401T. References updated.

9/30/16 Statement in the non-covered section regarding multispectral digital skin lesion analysis was clarified to read: Multispectral digital skin lesion analysis is considered investigational in all situations including but not limited to: Evaluating pigmented skin lesions; Serially monitoring pigmented skin lesions; Defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision. In the Billing/Coding section, the following statement added for code 96904: *Whole body photography represents 1 component of dermatoscopy. CPT code 96904 may also be submitted to describe whole body photography without dermatoscopy.* Policy intent unchanged. (an)

1/27/17 Specialty Matched Consultant Advisory Panel review 11/30/2016. No change to policy statement. (an)

6/30/17 Codes 0470T and 0471T added to Billing/Coding section. (an)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.