Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy

Policy #: 113
Latest Review Date: December 2022
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **dermatoscopy**, using either direct inspection, digitization of images, or computer-assisted analysis as a technique to evaluate or serially monitor pigmented skin lesions as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **total (whole) body photography** as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **dermatoscopy and computer-based optical imaging devices for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision** as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **computer-based optical imaging devices** (e.g., multispectral digital skin lesion analysis) used as a technique to evaluate or serially monitor pigmented skin lesions as a **non-covered benefit** and as **investigational.**

Refer to policy # 616, *Multispectral Digital Skin Lesion Analysis* for additional information on MelaFind®.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 the 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.

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 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 three-point and seven-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.

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 often wavelengths, varying from blue (430nm) and near infrared (950nm). The light can penetrate up to 2.5mm 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 Governing Bodies section) is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

Total Body Photography
Total Body Photography is another development for diagnosing and tracking melanoma but is separate and distinct from dermoscopy. This is a photographic display system on CD-ROM, designed to serve as an adjunct to the physical examination when following patients who are at high risk for developing cutaneous melanoma. This method is the MoleMapCD and marketed by DigitalDerm, Inc. This allows rapid display of 33 high-resolution color images of the patient's skin surface and permits efficient comparison of the patient's current condition with a set of base line images. The use and focus of total body photography imaging is a significant change from the use of dermatoscopy and should not be considered a component of dermatoscopy or be

evaluated as the same as MoleMap II, MS 500 B Micro-Scopeman, Moritex or any other instrument used for dermatoscopy. Total Body Photography looks at the total body surface and dermatoscopy looks at single moles. Dermatoscopy 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. Dermatoscopy may also be referred to as dermoscopy, skin surface microscopy, epiluminescence microscopy (ELM). This involves application of immersion oil to skin, which eliminates light reflection from the skin surface and renders the stratum corneum transparent.

Total Body Photography is a service that offers a comprehensive photographic archive of the patient's skin surface at a particular time. A professional photographer takes a series of 33 images of the patient's body. The images are forwarded on two compact disks to the physician. The physician keeps one disk and gives the other disk to the patient during the follow-up visit and may be instructed in the best use of the MoleMapCD for home self-examination.

KEY POINTS:

The literature search for this policy was performed through December 9, 2022.

Summary of Evidence

The evidence on dermatoscopy for selecting or deselecting lesions for excision 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 on computer-based optical diagnostic devices for selecting or deselecting lesions for excision includes a one published diagnostic accuracy study and stimulation 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 on dermatoscopy and computer-based optical diagnostic devices for serial monitoring suspicious lesions includes no published studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and change in disease status. No studies were found that specifically addressed diagnostic accuracy or clinical utility in this population. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on dermatoscopy and computer-based optical diagnostic devices for defining peripheral margins of basal cell carcinomas or squamous cell carcinomas prior to surgery includes one RCT and several observational studies. Relevant outcomes include 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 two 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.

Practice Guidelines and Position Statements
In July 2007, the International Dermoscopy Society (IDS) embarked on creating a consensus document for the standardization and recommended criteria necessary to be able to effectively convey dermatoscopic findings to consulting physicians and colleagues. The final items included in the document are as follows: 1) pertinent personal and family history (recommended); 2) clinical description of the lesion (recommended); 3) the two-step method of dermatoscopy differentiating melanocytic from nonmelanocytic tumors (recommended); 4) the use of standardized terms to describe structures (recommended); 5) the dermatoscopic algorithm used (optional); 6) information on the imaging equipment and magnification (recommended); 7) clinical and dermatoscopic images of the tumor (recommended); 8) a diagnosis or differential diagnosis (recommended); 9) decision concerning the management (recommended); 10) specific comments for the pathologist when excision and histopathologic examination are recommended (optional).

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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Dermoscopy, dermatoscopy, epiluminescence light microscopy, ELM, pigmented skin lesions, PSLs, and digital epiluminescence light microscopy, DELM, Episcope, Nevoscope, Dermascope, MoleMax, melanomagram, total body photography, optical diagnostic devices, computer-based optical imaging devices, MelaFind, MoleMapCD, Vivascope, RCM, Reflectance confocal microscopy

APPROVED BY GOVERNING BODIES:
Dermatoscopic devices cleared by the FDA include:

- Episcope™ (Welch Allyn, Inc.) approved in 1995, intended use 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
- Dermascope™ (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

MelaFind (MelaSciences, Inc. Irvington, NY) was approved in November 2011. Its intended use is to evaluate pigmented lesions with clinical or histological 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 2mm and 22mm, lesions that are accessible by the MelaFind imager, lesions that are sufficiently pigmented (i.e., not for use on non-pigmented 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., non-ulcerated or non-bleeding lesions), lesions greater than 1cm 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). MelaFind is not designed to detect pigmented non-melanoma skin cancers, so the dermatologist should rely on clinical experience to diagnose such lesions."

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

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
96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion

96932	; image acquisition only, first lesion
96933	; interpretation and report only, first lesion
96934	; image acquisition and interpretation and report, each additional lesion
96935	; image acquisition only, each additional lesion
96936	; interpretation and report only, each additional lesion
96999	Unlisted special dermatological service or procedure (This is the code that should be used for dermatoscopy)
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.

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POLIC HISTORY:

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Medical Policy Group, May 2007
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Medical Policy Group, November 2020: 2021 Annual Coding Update. Moved CPT codes 0400T and 0401T from Current Coding Section. Created Previous Coding section to include 0400T and 0401T.
Medical Policy Group, January 2021
Medical Policy Group, May 2021: Created Previous Coding section. Moved CPT codes 0400T and 0401T from Current Coding section to Previous Coding section.

Medical Policy Group, January 2022: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, December 2022: Reviewed by consensus. Updates to Key Points and References. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
