



Multispectral Digital Skin Lesion Analysis and Reflectance Confocal Microscopy

Policy # 00498

Original Effective Date: 01/22/2016

Current Effective Date: 03/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers multispectral digital skin lesion analysis (MSDSLA) and reflectance confocal microscopy (RCM) to be **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.

Background/Overview

MELANOMA

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.

Diagnosis

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

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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 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 a more detailed examination of suspicious skin lesions. The available evidence from prospective randomized controlled trials and other studies has suggested 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 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 (see the FDA section) is intended only for suspicious pigmented lesions on intact skin and for use by trained dermatologists.

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

Reflectance Confocal Microscopy (RCM)

Reflectance confocal microscopy (RCM), also known as confocal scanning laser microscopy, is an imaging technology that allows the in vivo identification of cells and tissues of the epidermis and papillary dermis with nearly histologic resolution. RCM uses a low-power laser that emits near-infrared light (830 nm) that reflects off structures in the epidermis and creates a three-dimensional

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image, with resolution of approximately 1 millimicron, comparable with standard histology at approximately 30x magnification. Melanin granules have a high refractive index, resulting in more light to be reflected back to the confocal microscope. Thus, areas of higher melanin concentration will appear as bright areas on a confocal image.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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).”

Confocal microscopes are approved by the FDA 510(k) process. Examples of these devices include the VivaScope System 1500 and the handheld VivaScope 3000 (Lucid, Inc., Rochester, New York). The VivaScope is intended “to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment”. The SIAscope II (Astron Clinica Limited, Crofton MD) is FDA approved as a “non-invasive skin analysis system, which provides a synthesized ‘image’ showing the relative location of blood collagen and pigment” (FDA, 2008; 2003).

FDA product code: OYD.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Multispectral digital skin lesion analysis (MSDSLA) is a noninvasive approach to diagnosing skin lesions; the technique has 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.

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.

Reflectance confocal microscopy (RCM) is a diagnostic tool that provides noninvasive images at multiple levels of the epidermis and superficial dermis.

Cochrane Systematic Review through August 2016 included 18 publications. Studies were generally at high or unclear risk of bias across almost all domains and of high or unclear concern regarding

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applicability of the evidence. Selective participant recruitment, lack of blinding of the reference test to the RCM result, and differential verification were particularly problematic. Authors concluded that RCM may have a potential role in clinical practice, particularly for the assessment of lesions that are difficult to diagnose using visual inspection and dermatoscopy alone, where the evidence suggests that RCM may be both more sensitive and specific in comparison to dermatoscopy. Given the paucity of data to allow comparison with dermatoscopy, the results presented require further confirmation in prospective studies comparing RCM with dermatoscopy in a real-world setting in a representative population.

No randomized controlled trials were identified assessing the use of RCM compared to biopsy in the evaluation, diagnosis, and management of skin lesions. There is insufficient evidence supporting to determine the effects of the technology on health outcomes.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) addresses these technologies in their guideline on cutaneous melanoma (V2.2023):

Pre-diagnostic clinical modalities (i.e., dermoscopy, total-body photography and sequential digital dermoscopy), noninvasive imaging and other technologies (e.g., reflectance confocal microscopy, electrical impedance spectroscopy) may aid in surveillance for new primary melanoma, particularly in patients with high mole count and/or presence of clinically atypical nevi.

This is not a recommendation, and no evidentiary basis was provided for this statement.

National Institute for Health and Care Excellence

National Institute for Health and Care Excellence guidance (2015) on the assessment and management of melanoma does not address multispectral digital skin lesion analysis.

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National Institute for Health and Clinical Excellence (NICE)

The 2015 NICE guidelines on the assessment and management of melanoma included a review of the literature on dermoscopy and other visualization techniques. NICE stated that dermoscopy is an accepted practice but the accuracy and clinical utility depends on the experience of the practitioner who is using it and recommends its use in the assessment of lesions when performed by a trained professional.

Based on the literature review, NICE did not recommend the routine use of confocal microscopy or computer-assisted diagnostic tools. It was noted that the VivaScope 1500 and 3000 imaging systems show promise but there is currently insufficient evidence to recommend their routine adoption and further research on their use is recommended.

NICE recommended that baseline photography (preferably dermoscopic) be used for a clinically atypical melanocytic lesion that does not need excision and to review the clinical appearance with the images every three months. NICE noted that photography, mole mapping, might help to identify changes in moles but the quality is variable. The Guideline Development Group was uncertain about the most appropriate timing for sequential photography to detect significant changes in pigmented lesions to aide in the diagnosis of early melanoma.

American Academy of Dermatology Association (AAD)

Position Statement on Reflectance Confocal Microscopy (2018), provided for educational and informational purposes, notes that the Academy supports the use of RCM as a modality for in vivo microscopic examination of suspicious epidermal and superficial dermal skin lesions for diagnosing skin pathology when clinically appropriate. It also notes that many payers have regulations that establish coverage guidelines and reimbursement criteria for RCM.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

MEDICARE NATIONAL COVERAGE

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

Table 1. Summary of Key Trials NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01700114a	Post-Approval Study of MelaFind	487	Mar 2016 (terminated)

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

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01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. New Policy.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Added Reflectance confocal microscopy (RCM) as investigational.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Title changed from "Multispectral Digital Skin Lesion Analysis" to "Optical Diagnostic Devices for Evaluation of Skin Lesions Suspected of Malignancy". Investigational statement clarified.
02/06/2020	Medical Policy Committee review
02/12/2020	Medical Policy Implementation Committee approval. Policy title changed from "Optical Diagnostic Devices for Evaluation of Skin Lesions Suspected of Malignancy" to "Multispectral Digital Skin Lesion Analysis and Reflectance Confocal Microscopy".
12/11/2020	Coding update
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review

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02/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. NCCN guidelines updated.
Next Scheduled Review Date: 02/2025

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HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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