Multispectral Digital Skin Lesion Analysis

Policy # 00498
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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) 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

There is interest in noninvasive devices that will improve the diagnosis of malignant skin lesions. One such approach is MSDSLA. This 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.

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 1 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 10× 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 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 (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 details in the Regulatory Status section) is intended only for suspicious pigmented lesions on intact skin and for use only by trained dermatologists.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration

In November 2011, MelaFind®‡ (MELA Sciences, Irvington, NY, now Strata Skin Sciences, Horsham PA), a multispectral digital skin lesion analysis device, was approved by the U.S. 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. 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)."

FDA product code: OYD.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

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

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The following rubric outlines the steps in assessing a medical test. The first step is to formulate the clinical context and purpose of the test. Then the evidence is reviewed to determine whether the test is technically reliable, clinically valid, and clinically useful. However, as noted below, technical reliability is outside the scope of evidence reviews.

This review addresses the use of MSDSLA for the evaluation of pigmented lesions suspicious for malignancy. No published evidence was identified on the use of MSDSLA for monitoring skin lesions or for evaluating cancerous lesions referred for surgery. The following is a summary of the key literature to date.

MSDSLA for Evaluating Pigmented Skin Lesions
Clinical Context and Test Purpose

The use of MSDSLA devices is intended to inform decisions whether patients with pigmented lesions should undergo a biopsy. It is not clearly defined whether MSDSLA is intended to select patients for biopsy (rule in) or to select those who may undergo observation (rule out). The FDA Summary of Safety and Effectiveness Data (SSED) document for MelaFind suggests that positive lesions based on MelaFind should be considered for biopsy while biopsy decisions for negative lesion based on MelaFind should be based on “the remainder of the entire clinical context”. Several algorithms have been developed to identify skin lesions that should be referred for biopsy based on dermoscopy.

The question addressed in this evidence review is: Does using MSDSLA improve the net health outcome in individuals with pigmented skin lesions?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with pigmented lesions being evaluated for melanoma. The MelaFind FDA SSED states that the test is intended for “atypical cutaneous pigmented lesions with one or more clinical or historical characteristics of melanoma, excluding those with a clinical diagnosis of melanoma or likely melanoma,” and for lesions with a diameter between 2 mm and 22 mm.

Interventions
The intervention of interest is MSDSLA. The MelaFind device is an FDA-approved MSDSLA device. In May 2017, the manufacturer of MelaFind announced it they would no longer support or commercialize the device.

Comparators
Decisions about which pigmented lesions should undergo a biopsy are typically made by naked-eye and dermoscopic examination. A 2008 meta-analysis of studies of dermoscopy and naked-eye examination in the diagnosis of melanoma estimated the sensitivity of naked-eye examination combined with dermoscopy to detect melanoma to be 90% (95% confidence interval [CI], 80% to 95%), with a specificity of 90% (95% CI, 57% to 98%). It is unclear whether MelaFind is intended to be used as an adjunct to naked-eye examination and/or dermoscopy or as a replacement.

Outcomes
The primary outcome of interest is the comparison of MSDSLA with biopsy results.

True positive tests results could lead to a correct biopsy of malignant lesions. True negative tests would potentially reduce unnecessary biopsies.

No direct harms of the device are expected. False-positive test results could lead to unnecessary increased screening or biopsy. False-negative test results could lead to delays in diagnosis, which could allow the condition to worsen before treatment.

Timing
The time frame of interest is the time to biopsy.

Setting
Many suspicious lesions are identified in primary care. Biopsies may be ordered from primary care or after referral to dermatology. Diagnostic accuracy of both naked-eye and dermoscopy is higher for dermatologists compared with primary care physicians, but accuracy of diagnosis in primary care can be improved with short training sessions. The FDA SSED states that the MelaFind device should be used by physicians trained in the diagnosis and management of skin cancer who have completed a training program for MelaFind.

Technical Reliability
As with any test, it is important to establish its technical reliability—the ability of the test to measure accurately and reliably the characteristic of interest for which the test was designed to identify or measure. Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this review. We focus on the clinical validity and clinical utility.

Clinically Valid

Similiar to other diagnostic tools, the assessment of MSDSLA technology involves a determination of its diagnostic accuracy compared with a reference standard; then, it must be determined whether the results of the diagnostic tests can be used to improve health outcomes. The reference standard for evaluation of pigmented skin lesions is excision with histologic diagnosis, in which, depending on the skill of the pathologist, sensitivity and specificity are considered near 100%. Clinically, noninvasive techniques such as MSDSLA would be used in combination with clinical assessment, either based on direct visual inspection or review of photographs. Therefore, the diagnostic performance of MSDSLA combined with clinical assessment should be compared with clinical assessment alone, and then a comparison should be made with the reference standard of histology. In addition, health outcomes in patients managed with MSDSLA vs standard care (clinical assessment alone, or clinical assessment and dermatoscopy) should be evaluated.

Most published studies to date on MSDSLA have been industry-sponsored and/or coauthored by employees of or consultants for MELA Sciences (manufacturer of MelaFind).

A study published by Monheit et al (2011) contained the data submitted to the FDA for approval of the MelaFind device. This prospective study included patients with at least 1 pigmented lesion scheduled for first-time biopsy. Lesions were between 2 mm and 22 mm in diameter. The following were exclusion criteria: anatomic site was not accessible to the device; lesion was not intact (eg, open sores, ulcers, bleeding); lesion was on a palmar, plantar, or mucosal surface or under nails; lesion was in an area of visible scarring; and the lesion contained tattoo ink, splinter, or other foreign matter. In addition, lesions with a prebiopsy diagnosis of melanoma were excluded from analysis. Histologic diagnosis was used as the reference standard.

A total of 1393 patients with 1831 lesions were enrolled at major academic centers. Of the 1831 lesions, 1632 (90%) were eligible and evaluable. There were 165 lesions not evaluable for various reasons, including operator error, camera malfunction, and ineligibility after enrollment related to scarring. Histologic analysis determined that 127 (7.8%) of 1632 lesions were melanoma. The sensitivity of MSDSLA for recommending biopsy of the melanoma lesions was 98.2% (125/127 melanomas), with a 95% lower CI bound of 95.6%. The average specificity (averaged over clinicians) of MSDSLA for melanoma was 9.5%. The accuracy of clinician diagnosis was determined by randomly selecting 25 melanoma cases and matching them with 25 nonmelanoma lesions. Clinicians were asked to classify lesions into 2 categories of melanoma: cannot rule out melanoma or not melanoma. The specificity of clinician diagnosis, as determined by the proportion of melanomas among the total number of lesions recommended for biopsy, was 3.7%, which was significantly lower than the specificity for MSDSLA (p=0.02). The Monheit study only included lesions previously examined clinically and determined to be sufficiently suspicious to warrant biopsy. The study did not include patients initially presenting with pigmented lesions to see whether MelaFind could enhance the accuracy of diagnosis based on clinical examination findings alone.

In 2016, Winkelmann et al reported on further analysis of the same 1632 lesions; the reviewers sought to correlate MSDSLA classifier scores with histopathologic severity and clinical features of melanoma. Mean

classifier scores were higher for melanomas (3.5) than for high-grade lesions (2.7; p=0.002), low-grade dysplastic nevi (7.1; p<0.001), nondysplastic nevi (1.6; p<0.001), and benign non-melanocytic lesions (2.0; p<0.001).

In 2015, Winkelmann et al also reported on the diagnostic accuracy of MelaFind for evaluating suspicious lesions obtained from patients undergoing routine skin examination in a community practice. Dermatologists identified suspicious lesions and selected them for biopsy. Prior to biopsy, the lesions were imaged with MelaFind (all met the FDA-approved indication for use of the device). (The study protocol did not involve reevaluation of images using MSDSLA findings.) Lesions were then biopsied and the diagnostic accuracy of MSDSLA for these lesions was determined and compared with histopathologic analysis of samples. A total of 137 consecutive lesions scheduled for biopsy were included in the study. MSDSLA categorized 21 of these lesions as having “low disorganization” (negative MSDSLA finding). All 21 lesions were histologically benign (11 mildly dysplastic nevi, 9 seborrheic keratosis, 1 compound nevus). The remaining 116 lesions were categorized by MSDSLA as having high disorganization (positive MSDSLA finding). Ninety-nine (85%) of these lesions were considered to be “true positives” (ie, malignant melanoma, lesions with atypical melanocytic proliferation, moderately and severely dysplastic nevi). The study population included only 1 true melanoma, and this was categorized by MSDSLA as having high disorganization. Advantages of this study were its prospective design and practice setting; however, as with the Monheit study, it did not evaluate the ability of MSDSLA to enhance the accuracy of biopsy decisions.

In 2016, Song et al reported on a smaller study comparing the diagnostic accuracy of MSDSLA with reflectance confocal microscopy in the prebiopsy detection of melanoma in 55 atypical-appearing lesions from 36 patients undergoing biopsy. MSDSLA was performed with MelaFind and reflectance confocal microscopy was performed with VivaScope (MAVIG GmbH, Munich, Germany), by separate evaluators who were blinded to others’ evaluations; reflectance confocal microscopy was more sensitive than MSDSLA (p=0.001). For the diagnosis of melanoma, MSDSLA had a sensitivity of 71.4%.

Fink et al (2017) reported the performance of MelaFind in a clinical setting. The study included retrospective analysis of 360 pigmented lesions with one or more clinical or historical characteristics of melanoma but for which there were not unequivocal features of melanoma (ie, “atypical pigmented skin lesion”). The lesions were from 111 patients evaluated by office-based dermatologists. Surgical excision decisions were made by the examining dermatologists using MelaFind results and other clinical information; a description of the other information used was not provided. Of the 360 pigmented skin lesions, 147 (41%) were graded as a MelaFind score of 2 or more (ie, suspicious for malignancy); 14 of these were excluded because they were biopsied elsewhere, and 26 were not excised at the physician’s discretion; 107 lesions with MelaFind score of 2 or more were excised (86 patients), and an additional six with a MelaFind score less than 2 were excised. Among excised lesions, the sensitivity and specificity of a MelaFind score of 2 or more were 100% and 5.5%, respectively, and the positive and negative predictive values were 2.8% and 100%, respectively; CIs were not given. Assuming the lesions with a MelaFind score less than 2 that were not biopsied were negative, the specificity would be 68.5%, although the follow-up was insufficient to confirm that the lesions were actually benign.

Other studies have reported on the clinical performance of image-based classifiers other than MelaFind. In 2015, Ferris et al reported on the training and validation of a novel classifier. The classifier was trained on a malignant test set (105 melanomas, 29 high-grade dysplastic nevi, 23 basal cell carcinomas, 3 squamous cell carcinomas) and a benign training set (93 benign melanocytic lesions, 20 other benign lesions). In receiver operating characteristic curve analysis, with a threshold severity score of 0.4, the area under the curve was 0.818. The classifier's performance was evaluated in a test set containing 39 melanomas, 11 basal cell carcinomas, 3 squamous cell carcinomas, and 120 benign lesions, all with available biopsy results, and 27 lesions considered not appropriate for biopsy by 2 dermatologists. The classifier's sensitivity for melanoma was 97.4% (95% CI, 86.5% to 99.9%). Among the 120 benign lesions, 53 were correctly classified as benign (specificity, 44.2%; 95% CI, 35.1% to 53.5%); among the 27 unbiopsied lesions, 20 were classified as benign (specificity, 74.1%; 95% CI, 53.7% to 88.9%).

Section Summary: Clinically Valid
One prospective study has reported on the sensitivity and specificity of MelaFind, with high sensitivity. These results would have to be replicated in an independent sample, with appropriate CIs.

Clinically Useful
Direct evidence of the clinical utility of MSDSLA will be demonstrated if its use leads to management changes that improve outcomes. Outcomes would ideally be evaluated in prospective randomized controlled trials examining health outcomes in patients presenting with pigmented lesions managed with and without the technology. Randomized controlled trials would ideally compare MSDSLA with clinical examination and dermatoscopy. No studies of this type were identified.

Indirect evidence of clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

One randomized controlled trial has been published; however, it was conducted over the Internet rather than in a clinical setting and involved retrospective analysis of lesions. The trial was published by Hauschild et al (2014) in Germany. It included 215 board-certified dermatologists selected on a first-come basis after receiving invitations to participate. Each participant was presented with information on 130 pigmented lesions; 93% had been biopsied in a prior study. Half the lesions were melanomas and half were nonmelanomas. (The lesions were a subset of evaluable lesions from the Monheit trial (previously described). All lesions met the FDA's indications for MelaFind. Study participants were randomized to review clinical examination information and high-quality digital images only (n=108) or clinical information, high-quality digital images, and the MSDSLA results (n=107). After reviewing each case, participants completed a survey about their lesion management decision (eg, recommendation for biopsy). A decision was considered correct if melanoma lesions were recommended for biopsy or if non-melanoma lesions were not recommended for biopsy. Before examining the cases, participants were shown an online slide presentation about MelaFind, including the devices performance data.

Among dermatologists in the arm without MSDSLA findings, the sensitivity and specificity of biopsy were 69.5% (95% CI, 64.3% to 76.0%) and 55.9% (47.3% to 60.5%), respectively. In the arm with MSDSLA findings, the sensitivity and specificity were 78.0% (95% CI, 73.9% to 83.5%) and 45.8% (38.1 to 50.8%), respectively. Differences in sensitivity and specificity between arms were statistically significant ($p<0.001$).

Some nonrandomized studies have evaluated whether the use of MSDSLA would hypothetically lead to management changes. These studies were not conducted in clinical settings, and it is unclear whether the selection of lesion types and study participants (dermatologists) were representative of actual practice.

Several industry-sponsored simulation exercises have also been conducted at professional conferences. For example, Winkelman et al (2015) reported on 60 health care providers, 30 of whom were dermatologists, who participated in an exercise at a national dermoscopy conference. Participants were shown images of 12 lesions previously analyzed by MSDSLA using the MelaFind device. They were asked 3 times whether they would biopsy the lesion: (1) based on clinical images alone; (2) with the addition of high-resolution dermoscopic images; and (3) with the addition of MSDSLA classifier scores. The 12 lesions consisted of 2 melanomas in situ, 3 invasive melanomas, and 7 low-grade dysplastic nevi. Diagnostic accuracy did not increase after being shown dermatoscopic images, but it did increase after getting MSDSLA scores. The proportion of dermatologists responding that they would biopsy all 5 malignant melanomas was 4% with clinical images alone, 10% after dermatoscopy, and 72% after MSDSLA. Proportions among nondermatologists were 13%, 6%, and 78%, respectively. Conversely, among dermatologists, the proportion of low-grade dysplastic nevi recommended for biopsy was 53% with clinical images alone, 60% after dermatoscopy, and 42% after MSDSLA. Among dermatologists, proportions were 53%, 66%, and 45%, respectively. The changes in biopsy recommendations after MSDSLA were statistically significant in all cases. Other studies conducted at conferences that used similar methodology had comparable results; biopsy decision accuracy increased significantly after clinicians were provided with MSDSLA findings. Without health outcome data, studies of how physicians use medical tests, or how they may change behavior based on medical tests, do not provide significant additional data to inform clinical utility.

Section Summary: Clinically Useful
No direct evidence for the clinical utility of MSDSLA in the management of pigmented lesions was identified. 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 the use of MSDSLA in practice. Therefore, conclusions cannot be made about the clinical utility of MSDSLA.

SUMMARY OF EVIDENCE
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.

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Policy History

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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.

Next Scheduled Review Date: 02/2019

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0400T, 0401T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
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:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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