

MEDICAL POLICY		Multi-Spectral Digital Skin Lesion Analysis	
Effective Date: 1/1/2021		Section: MED	Policy No: 279
 1/1/2021		Technology Assessment Committee Approved Date: 2/11; 2/12; 8/13; 7/14	
		Medical Policy Committee Approved Date: 8/15; 5/16; 7/17; 10/17; 12/18; 2/19; 2/2020; 8/2020	
Medical Officer	Date		

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Multi-spectral digital skin lesion analysis systems, including but not limited to MelaFind®, are considered **investigational and are not covered** for all indications.

Link to [Policy Summary](#)

CPT CODES

All Lines of Business	
Not Covered	
0400F	TERMED 12/31/2020

MEDICAL POLICY	Multi-Spectral Digital Skin Lesion Analysis
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	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
0401F	TERMED 12/31/2020 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
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
96999	Unlisted special dermatological service or procedure

DESCRIPTION

Melanoma

Melanoma is a potentially deadly skin cancer that arises in cells called melanocytes, which make the brown pigment melanin. Early diagnosis and prompt treatment improve survival. Melanoma confined to the epidermis (i.e., melanoma in situ) is virtually 100% curable by simple excision; with patients with thin melanomas (thickness ≤1 mm) having 5-year survival rate of 94%.¹

Currently, clinical diagnosis of melanoma relies on histopathologic examination of biopsy samples. Suspicious lesions are typically identified for biopsy using visual examination with the naked eye or a dermoscope, but early malignant lesions are difficult to distinguish from benign irregular and atypical pigmented skin lesions and moles. Multi-spectral analysis is one of several new technologies proposed to aid clinicians in the distinction of small malignancies from benign lesions.

Multi-Spectral Digital Skin Lesion Analysis (MSDSL A)

Multi-spectral analysis is a technology proposed to enable dermatologists to assess skin lesion properties that are not visible to the human eye, using images taken at a number of wavelengths, to improve accuracy of lesion categorization. The results from MSDSL A devices are intended to inform whether patients with pigmented lesions should undergo a biopsy for suspected melanoma. However, it is unclear if MSDSL A is intended to select patients for biopsy or to select those who may undergo observation.

MelaFind®

Currently, MelaFind® is the only multi-spectral digital skin lesion analysis (MSDSL A) system that has been approved by the U.S. Food and Drug Administration (FDA).

According to the Food & Drug Administration (FDA) safety and effectiveness data regarding MelaFind®:

“MelaFind® is a multi-spectral, non-invasive and automated (objective) computer-vision system that classifies the image of a pigmented skin lesion and classifies them based upon degree of 3-

dimensional morphological disorganization: MelaFind® Positive (high degree of morphological disorganization) or MelaFind® Negative (low degree of morphological disorganization).”²

The MelaFind® system consists of a hand-held imager that acquires 10 multi-spectral (from 430nm [blue] to 950nm [near infrared]) digital images. These images are then analyzed using an automatic imaging software with a proprietary algorithm that evaluates 75 unique features of pigment distribution within an atypical lesion to determine the level of morphological disorder and generate a classifier score (CS). A CS greater than or equal to 0 is considered to have “high” disorganization (positive MSDSLA finding warranting biopsy) and scores less than 0 have “low” disorganization (negative MSDSLA finding).

The FDA also states:

“MelaFind® is intended for use on clinically 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. MelaFind® is designed to be used when a dermatologist chooses to obtain additional information for a decision to biopsy. MelaFind® should NOT be used to confirm a clinical diagnosis of melanoma.

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 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 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). MelaFind® is not designed to detect pigmented non-melanoma skin cancers, so the dermatologist should rely on clinical experience to diagnose such lesions.”²

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of multi-spectral digital skin lesion analysis (MSDSL) systems, including MelaFind®, for the evaluation of melanoma and other skin lesions. Below is a summary of the available evidence identified through January 2020.

Evaluation of any diagnostic test used for clinical decision-making rests upon the consideration of the following principles:

1. Analytical validity: The test’s technical accuracy, including reproducibility and precision.
2. Clinical validity: The diagnostic performance of the test, reported as sensitivity, specificity, positive predictive value, and negative predictive value.
3. Clinical utility: There are three factors that may be considered while evaluating clinical utility of a test:
 - Do the results of the test confirm a diagnosis or clarify prognosis?
 - Do the results improve patient health outcomes?

- Will the results of the test be used to guide management of the patient (e.g., determine appropriate medical and/or surgical interventions)?

Analytical Validity

No studies were identified that reported on the analytical validity of MSDSLA as a diagnostic tool for malignant pigmented skin lesions.

Clinical Validity

Assessment of the clinical validity of MSDSLA technology, requires comparison with a reference standard, which for pigmented lesions is histological diagnosis. In addition, the test performance of MSDSLA systems must be assessed based on whether it is used as a stand-alone diagnostic tool or as an adjunct to standard clinical assessment (with or without dermatoscopy).

- In 2007, Haniffa et al. published the results of a prospective study that evaluated the ability of the spectrophotometric device, SIAscope, to aid in the diagnosis of melanomas.³ The investigator's diagnosis before and after spectrophotometry were compared to the histological diagnosis where available or with the expert's clinical diagnosis. Of 860 patients, 179 biopsies were performed, with 31 melanomas diagnosed. Sensitivity and specificity for melanoma diagnosis before and after spectrophotometry were 94% and 91% vs. 87% and 91%, respectively, with no significant difference in the area under the receiver operating characteristic curves.
- In 2008, Friedman et al. published the results of a small blinded comparison trial that evaluated the performance of dermatoscopists in diagnosing small pigmented skin lesions (diameter ≤ 6 mm) compared to results from the MelaFind[®] system, including (9 dermatologists and 1 nurse practitioner specializing in dermatology).⁴ All ten providers independently assessed the dermoscopic images of 99 pigmented skin lesions (i.e., 49 melanomas and 50 randomly selected non-melanomas). The authors reported that the dermatoscopists were able to recommend small melanomas for biopsy with a sensitivity of 71% and specificity of 49%. In comparison, the computer-vision system achieved 98% sensitivity and 44% specificity. While the differences in sensitivity between the clinician and the MelaFind[®] system were significant ($p < 0.001$), the difference in specificities was not statistically significant ($p = 0.75$). In addition, the MelaFind[®] system had statistically significant higher negative predictive values (NPV: 96% compared to 63%; $p = 0.02$); while the differences in positive predictive value (PPV: 63% versus 58%; $p = 0.48$) and diagnostic accuracy (62% versus 47%; $p = 0.08$) were not significantly better. Of note, since this study contained small sample sizes and only evaluated the performance of MelaFind[®] on small diameter lesions, the test performance values lack generalizability.
- In 2011, Monheit et al. published the results of the prospective, multi-center, clinician-blinded study that was the basis of the FDA PMA approval for the MelaFind[®] system.⁵ This trial examined the safety and effectiveness of MelaFind[®], including included 1383 patients having 1831 pigmented skin lesions (PSLs). For analysis, 1632 lesions (including 127 melanomas) were eligible and evaluable. The investigators reported that the measured sensitivity of MelaFind[®]

was 98.4 % (95 % lower confidence bound at 95.6%). When borderline lesions were included in the analysis (high-grade dysplastic nevi, atypical melanocytic proliferations, or hyperplasias) MelaFind®'s sensitivity was 98.3 %. On lesions that were not scheduled for biopsy (e.g., missed by the examining clinicians), MelaFind®'s average specificity was superior to that of clinicians using clinical judgment alone (9.5% versus 3.7 %; $p = 0.02$). The investigators concluded that MelaFind® is a safe and effective tool to assist in the evaluation of pigmented skin lesions. However, it is unclear if an instrument with such a low specificity is clinically useful. One author noted limitation of the study was that only pigmented lesions were biopsied and these lesions are not representative of lesions in the general population. Therefore, the specificity values reported for both the MelaFind® system and for clinicians in this study are not applicable to the general population. Another limitation to this study was the fact that the patients were enrolled in the FDA study after participating dermatologists had decided to biopsy the skin lesion. Therefore, the true diagnostic performance of MelaFind® may differ when used in standard practice and in different patient populations.

- In 2012, Rigel et al. also published the results of a prospective study that evaluated the effect of guidance provided by MelaFind® on dermatologists' decisions to biopsy PSLs and the impact of the information provided by MelaFind® on melanoma biopsy sensitivity and specificity, including 179 dermatologists.⁶ The dermatologists reviewed 24 PSLs, including five melanomas that had been previously biopsied in the Monheit study.⁵ The authors reported that the biopsy sensitivity of MelaFind® was significantly greater than the mean biopsy sensitivity of dermatologists (98% versus 71%; $p < 0.001$), and the specificities were comparable (49% for dermatologists versus 44% for MelaFind®; $p = 0.75$). Before receipt of MelaFind® information, 13% of the dermatologists reported that they chose to biopsy all five melanomas; after receipt, 70% chose to biopsy them all. However, the dermatologists did not universally follow the MelaFind® biopsy recommendation, as 25% of lesions reported as negative by the device were still biopsied.
- In 2012, Wells et al. published the results of a small prospective pilot study that compared the diagnostic abilities of MelaFind® with that of dermatologists for melanoma, including 39 dermatologists with that examined 47 randomly selected skin lesions (23 melanomas and 24 benign PSLs) from a repository of lesions collected for the Monheit trial.^{5,7} The authors reported that incorporating information from MelaFind® into these decisions significantly increased the mean biopsy sensitivity of the dermatologists (69% to 94%; $P < 0.001$). In addition, use of MelaFind® was associated with significantly lower biopsy rates of lesions that were MelaFind®-negative (43% versus 25%; $p < 0.01$).
- In 2014, Hauschild et al. published the results of a randomized two-armed online reader study to determine the biopsy sensitivity to melanoma of dermatologists in Germany and the impact of MelaFind® on their decisions to biopsy melanomas, with each physician reviewing 130 pigmented skin lesions each.⁸ In terms of melanoma detection, the authors reported that the MelaFind® system yielded greater sensitivity than dermatologists using clinical judgment alone (96.9 % versus 69.5 %; $p < 0.00001$) but much lower specificity (9.2 % versus 55.9 %, $p < 0.00001$). In addition, dermatologists who incorporated MelaFind® into their evaluation had higher sensitivity than those who did not use MelaFind® (78 % vs. 69.5 %; $p < 0.00001$) but a lower specificity (45.8 % vs. 55.9 %, one-sided $p < 0.00001$). The author concluded that the results from MelaFind® system analyses, when incorporated into the final biopsy decision, could

improve biopsy sensitivity with modest effect on biopsy specificity. The authors concluded that MelaFind® and similar systems can be useful in facilitating “early detection of small melanomas and may limit the number of biopsies to rule out melanoma performed on benign lesions”.

- In 2015, Winkelmann et al. published the results of a study that evaluated the diagnostic accuracy of MelaFind®, including patients undergoing routine skin examination in a community practice.⁹ A total of 137 consecutive lesions were selected for biopsy and then subsequently analyzed via MSDSLA. The results of the MSDSLA were compared with histopathologic analysis of samples. MSDSLA categorized 21 of these lesions as having “low disorganization” (negative MSDSLA finding), with all 21 of these lesions being histologically benign (100% negative predictive value, 95% lower confidence boundary = 96.9%). 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”. The authors also reported that specificity found in this study was significantly higher than reported in the Monheit trial described above (18% vs. 10%, $p=0.02$).⁵ However, this study did not evaluate the ability of MSDSLA to enhance the accuracy of biopsy decisions.
- In 2016, Winkelman et al. reported the results of a on further analysis of the same 1632 lesions in the Monheit trial⁵, in an effort to correlate MSDSLA results, referred to as classifier scores, with histopathologic severity and clinical features of melanoma.¹⁰ Average MSDSLA classifier scores were higher for melanomas than for high-grade lesions (3.5 versus 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 addition, there was a direct correlation between the MSDSLA classifier score and the number of clinical risk characteristics present in the studied lesions (Pearson coefficient 0.32, $p<0.0001$). The authors concluded that the correlation of classifier scores to clinical and histological melanoma features supports the effectiveness of MSDSLA. However, this study did not report if actual dermatologist decisions to biopsy suspicious pigmented lesions were enhanced by the use of MSDSLA.
- In 2016, Song et al. reported the results of a small study that compared the diagnostic accuracy of MDLSA with reflectance confocal microscopy (RCM), another potential diagnostic tool, in the prebiopsy detection of melanoma in 55 atypical-appearing lesions from 36 patients undergoing biopsy.¹¹ MDSL A was performed with MelaFind® and RCM was performed with VivaScope, by separate evaluators who were blinded to others’ evaluations. Lesions were biopsied and analyzed by histopathology. The authors reported that RCM was significantly more sensitive (85.7% versus 71.4%) and more specific (66.7% and 25.0%) than MDSL A ($p=0.001$).
- In 2017, Fink et al. published the results of an observational study that evaluated the diagnostic performance of the MelaFind® device in a clinical setting. Analysis of the diagnostic performance of MelaFind® in a real-life clinical setting, including 360 pigmented skin lesions (PSL) in 111 patients assessed by office-based dermatologists.¹² MelaFind® scores ≥ 2 (considered suspicious of malignancy) were observed in 147 of 360 PSL (40.8 %). Of the 107 excised lesions with a MelaFind®-score ≥ 2 , the diagnosis of melanoma was made in three cases; and 53 (49.5 %) lesions proved to be dysplastic nevi. Among all lesions biopsied ($n = 113$), the sensitivity and specificity of MelaFind® was 100 % and 5.5 %, respectively. The authors noted that there was incomplete follow-up data required to confirm that all non-excised lesions with a score < 2 were

actually benign. Although the authors concluded that the sensitivity of MelaFind® was high and the specificity was acceptable, test parameters may be improved by using higher cutoff scores for excisional biopsies. This study did not report whether the MelaFind® scores affected decisions regarding biopsy, since the decision for surgical excision was left to the discretion of the examining dermatologists.

- In 2017, Farberg and colleagues enlisted 160 dermatologists attending an educational conference to evaluate 50 pigmented lesions.¹³ Following assessment, investigators asked the dermatologists if they would biopsy the lesions, after which they were given quantitative MSDSLA information and asked again if they would biopsy the lesion. Investigators found that biopsy diagnostic accuracy was greater using MSDSLA than using clinical information alone (64% vs. 86 %, $p < 0.001$). Limitations included the alternative setting (i.e. an educational conference) in which assessments were made, and the conflicts of interest of two study authors with MelaFind's manufacturer. Clinicians with a strong interest in skin cancer may also have self-selected to participate in the study, thereby limiting generalizability to the average level of expertise by practicing clinicians.
- In 2018, Shrivastava and colleagues evaluated the clinical efficacy of MelaFind® in assessing high-risk pigment lesions. Investigators followed 140 high-risk patients for three years.¹⁴ Patients' lesions were assessed by both MelaFind®, and, blindly and independently, by two dermatopathologists. Investigators compared histologic severity scores (HSS) assigned both by dermatopathologists and MelaFind®, finding that MelaFind® significantly reduced the number of biopsies for clinically ambiguous lesions that would have otherwise been performed. Among 923 lesions assessed by MelaFind® as "low-risk", none developed melanomas. This obviated the need for unnecessary biopsies in a high-risk patient cohort. However, among the biopsied lesions assessed by MelaFind® as "high-risk," 89% did not ultimately develop melanomas. While there was strong correlation between the dermatopathologists' assessment and ultimate pathologic diagnoses, there was no such correlation MelaFind® scores. Investigators attributed this disparity to MelaFind's ability to discern certain features (e.g. keratotic change, lentiginous change, inflammation and melanoderma) which, in isolation, have little predictive value of melanoma. This is coupled with the device's inability to discern more predictive histologic features of malignancy (e.g. cellular size, nuclear size, and hyperchromasia), by nature of its design as a light-based multi-spectral imaging system. Investigators concluded that the device's high sensitivity thus generated reduced specificity and a high false positive rate.

Clinical Utility

The clinical utility of MSDSLA technology may be evaluated in studies that report health outcomes in patients managed with MSDSLA versus standard care (clinical assessment alone, or clinical assessment and dermatoscopy).

No studies were identified that reported on whether the use of MSDSLA as a diagnostic tool affected management of pigmented lesions. In addition, no studies were identified which demonstrated MSDSLA testing improved health outcomes of patients who were tested with MSDSLA systems compared to those who underwent standard clinical evaluation.

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

The 2019 NCCN melanoma guidelines do not address multi-spectral digital skin lesion analysis or MelaFind®.¹⁵

National Institute for Health and Care Excellence

The 2015 NICE guidelines on the assessment and management of melanoma do not address multi-spectral digital skin lesion analysis or MelaFind®.¹⁶

CENTERS FOR MEDICARE & MEDICAID (CMS)

As of 7/23/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses multi-spectral digital skin lesion analysis.

POLICY SUMMARY

There is insufficient evidence to demonstrate that the use of any multi-spectral digital skin lesion analysis systems, including MelaFind®, alter treatment management decisions or improve health outcomes for patients suspected of having melanoma. In addition, there is a paucity of evidence regarding the use of multi-spectral digital skin lesion analysis systems as a stand-alone test or as an adjunctive diagnostic test compared to diagnosis using standard clinical assessment, including visual examination, dermatoscopy, and histopathology. Furthermore, no clinical practice guidelines were identified that addressed the use of multi-spectral digital skin lesion analysis for the evaluation of pigmented skin lesions, including melanoma.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

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