MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Multispectral Digital Skin Lesion Analysis

Table of Contents

Policy Number: 748

BCBSA Reference Number: 2.01.101
NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

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.

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue[SM]	This is not a covered service.
Medicare PPO Blue[SM]	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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

Description

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.[1] 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 (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.

Summary

There is interest in noninvasive devices that will improve the diagnosis of malignant skin lesions. One such approach is multispectral digital skin lesion analysis (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.

The evidence for 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.

Policy History

Date	Action
2/2018	New references added from BCBSA National medical policy.
1/2017	New references added from BCBSA National medical policy.
5/2016	New medical policy describing investigational indications. Effective 5/1/2016.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. American Cancer Society. Survival Rates for Melanoma Skin Cancer, by Stage. 2016; http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-survival-rates-by-stage. Accessed November 3, 2017.
2. MarketWatch. 10-Q: Strata Skin Sciences, Inc. 2017; http://www.marketwatch.com/story/10-q-strata-skin-sciences-inc-2017-05-15. Accessed October 23, 2017.
3. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): MelaFind. 2011; https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090012b.pdf. Accessed October 17, 2017.
4. Luttrell MJ, McClenahan P, Hofmann-Wellenhof R, et al. Laypersons' sensitivity for melanoma identification is higher with dermoscopy images than clinical photographs. *Br J Dermatol.* Nov 2012;167(5):1037-1041. PMID 22762457
5. Soyer HP, Argenziano G, Zalaudek I, et al. Three-point checklist of dermoscopy. A new screening method for early detection of melanoma. *Dermatology.* Jan 2004;208(1):27-31. PMID 14730233

6. Rogers T, Marino M, Dusza SW, et al. Triage amalgamated dermoscopic algorithm (TADA) for skin cancer screening. *Dermatol Pract Concept.* Apr 2017;7(2):39-46. PMID 28515993
7. Vestergaard ME, Macaskill P, Holt PE, et al. Dermoscopy compared with naked eye examination for the diagnosis of primary melanoma: a meta-analysis of studies performed in a clinical setting. *Br J Dermatol.* Sep 2008;159(3):669-676. PMID 18616769
8. Argenziano G, Puig S, Zalaudek I, et al. Dermoscopy improves accuracy of primary care physicians to triage lesions suggestive of skin cancer. *J Clin Oncol.* Apr 20 2006;24(12):1877-1882. PMID 16622262
9. Carli P, De Giorgi V, Crocetti E, et al. Diagnostic and referral accuracy of family doctors in melanoma screening: effect of a short formal training. *Eur J Cancer Prev.* Feb 2005;14(1):51-55. PMID 15677895
10. Peuvrel L, Quereux G, Jumbou O, et al. Impact of a campaign to train general practitioners in screening for melanoma. *Eur J Cancer Prev.* Jun 2009;18(3):225-229. PMID 19491609
11. Westerhoff K, McCarthy WH, Menzies SW. Increase in the sensitivity for melanoma diagnosis by primary care physicians using skin surface microscopy. *Br J Dermatol.* Nov 2000;143(5):1016-1020. PMID 11069512
12. Monheit G, Cognetta AB, Ferris L, et al. The performance of MelaFind: a prospective multicenter study. *Arch Dermatol.* Feb 2011;147(2):188-194. PMID 20956633
13. Winkelmann RR, Rigel DS, Ferris L, et al. Correlation between the evaluation of pigmented lesions by a multi-spectral digital skin lesion analysis device and the clinical and histological features of melanoma. *J Clin Aesthet Dermatol.* Mar 2016;9(3):36-38. PMID 27354886
14. Winkelmann RR, Rigel DS, Kollmann E, et al. Negative predictive value of pigmented lesion evaluation by multispectral digital skin lesion analysis in a community practice setting. *J Clin Aesthet Dermatol.* Mar 2015;8(3):20-22. PMID 25852810
15. Song E, Grant-Kels JM, Swede H, et al. Paired comparison of the sensitivity and specificity of multispectral digital skin lesion analysis and reflectance confocal microscopy in the detection of melanoma in vivo: A cross-sectional study. *J Am Acad Dermatol.* Dec 2016;75(6):1187-1192 e1182. PMID 27693007
16. Fink C, Jaeger C, Jaeger K, et al. Diagnostic performance of the MelaFind device in a real-life clinical setting. *J Dtsch Dermatol Ges.* Apr 2017;15(4):414-419. PMID 28332777
17. Ferris LK, Harkes JA, Gilbert B, et al. Computer-aided classification of melanocytic lesions using dermoscopic images. *J Am Acad Dermatol.* Nov 2015;73(5):769-776. PMID 26386631
18. Hauschild A, Chen SC, Weichenthal M, et al. To excise or not: impact of MelaFind on German dermatologists' decisions to biopsy atypical lesions. *J Dtsch Dermatol Ges.* Jul 2014;12(7):606-614. PMID 24944011
19. Wells R, Gutkowicz-Krusin D, Veledar E, et al. Comparison of diagnostic and management sensitivity to melanoma between dermatologists and MelaFind: a pilot study. *Arch Dermatol.* Sep 2012;148(9):1083-1084. PMID 22986873
20. Winkelmann RR, Farberg AS, Tucker N, et al. Enhancement of International dermatologists' pigmented skin lesion biopsy decisions following dermoscopy with subsequent integration of multispectral digital skin lesion analysis. *J Clin Aesthet Dermatol.* Jul 2016;9(7):53-55. PMID 27672411
21. Winkelmann RR, Yoo J, Tucker N, et al. Impact of guidance provided by a multispectral digital skin lesion analysis device following dermoscopy on decisions to biopsy atypical melanocytic lesions. *J Clin Aesthet Dermatol.* Sep 2015;8(9):21-24. PMID 26430487
22. Winkelmann RR, Tucker N, White R, et al. Pigmented skin lesion biopsies after computer-aided multispectral digital skin lesion analysis. *J Am Osteopath Assoc.* Nov 1 2015;115(11):666-669. PMID 26501759
23. Winkelmann RR, Yoo J, Tucker N, et al. Assessment of a diagnostic predictive probability model provided by a multispectral digital skin lesion analysis device for melanoma and other high-risk pigmented lesions and its impact on biopsy decisions. *J Clin Aesthet Dermatol.* Dec 2014;7(12):16-18. PMID 25584133
24. Rigel DS, Roy M, Yoo J, et al. Impact of guidance from a computer-aided multispectral digital skin lesion analysis device on decision to biopsy lesions clinically suggestive of melanoma. *Arch Dermatol.* Apr 2012;148(4):541-543. PMID 22351788
25. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Melanoma. Version 1.2018. https://www.nccn.org/professionals/physician_gls/PDF/melanoma.pdf. Accessed October 23, 2017.
26. National Institute on Health and Care Excellence (NICE). Melanoma: assessment and management [NG14]. 2015; https://www.nice.org.uk/guidance/ng14/chapter/1-Recommendations#assessing-melanoma-2. Accessed November 3, 2017.