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:

Multispectral Digital Skin Lesion Analysis

Policy #: 616
Latest Review Date: September 2023
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 **multispectral digital skin lesion analysis** as a **non-covered benefit** in all situations and as **investigational** 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 excision.

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:

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.

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 (i.e., ≥1.0mm) 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.

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 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 (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.

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 multispectral digital skin lesion analysis 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 (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 to refer to 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.

KEY POINTS:

The most recent literature update was performed through September 21, 2023.

Summary of Evidence

For individuals who have pigmented lesions being evaluated for melanoma who receive MSDSLA, the evidence includes two 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 inference 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.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on melanoma (v.1.2018)14 do not address multispectral digital skin lesion analysis.

National Institute for Health and Care Excellence

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

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Digital skin lesion analysis, MelaFind, MSDSLA, pigmented skin lesions

APPROVED BY GOVERNING BODIES:

A multispectral digital skin lesion analysis device called MelaFind® (MELA Sciences, Irvington, NY, now Strata Skin Sciences, Horsham, PA) was approved by the U.S. Food and Drug Administration (FDA) in November 2011 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 (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 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)."

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT Codes:

96999	Unlisted special dermatological service or procedure (Effective 01/01/2021)

PREVIOUS CODING:

CPT Codes:

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 (Deleted 12/31/2020)
0401T	; six or more lesions (Deleted 12/31/2020)

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POLICY HISTORY:

Adopted for Blue Advantage, December 2015
Available for comment January 1 through February 14, 2016
Medical Policy Group, December 2016
Medical Policy Group, December 2017
Medical Policy Group, February 2018

Medical Policy Group, April 2021
Medical Policy Group, August 2021
Medical Policy Group, September 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, September 2023: Reviewed by consensus. 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.
