Cigna Medical Coverage Policy

Subject: Malignant Melanoma Surveillance Technologies

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Coverage Policy

Cigna does not cover ANY of the following technologies for the early detection, screening or surveillance of melanoma because each is considered experimental, investigational or unproven (this list may not be all inclusive):

- total body photography
- visual image analysis
- electrical impedance devices
- multispectral image analysis
- ultrasound
- optical coherence tomography [OCT]
- reflectance confocal microscopy [RCM]

Cigna considers dermoscopy to be an integral part of a normal evaluation of a pigmented skin lesion and not separately reimbursable.

General Background

Melanoma, also called cutaneous melanoma or malignant melanoma, is a malignant disease of the skin and one of the most dangerous forms of skin cancer. Although melanoma accounts for less than 5% of skin cancer cases, it accounts for approximately three-fourths of all skin cancer deaths. Early detection and treatment are the best strategies to reduce the mortality and morbidity associated with melanoma.
High-risk individuals for melanoma include a personal history of melanoma, three or more atypical moles (i.e., atypical nevi, dysplastic nevi) or a first-(i.e., parent, sibling or child) or second-degree relative with melanoma (National Comprehensive Cancer Network® [NCCN], 2014; National Cancer Institute [NCI], 2014; van der Rhee, et al., 2011; Goodson, et al., 2010; Banky, et al., 2005; Oliveria, et al., 2004; Robinson, et al., 2004; Haenssle, et al., 2004).

The assessment of suspicious skin lesions begins with a physical examination and visual inspection of the skin with the naked eye. Dermoscopy including digital epiluminescence microscopy (DELM) has evolved into an established technology used as an adjunct to a normal eye exam and is considered to be an integral part of the exam depending on the lesions being examined. Additional noninvasive technologies are proposed to provide better examination of lesions and assist the examiner in deciding whether a lesion should be biopsied. None of these devices can diagnose skin cancer. Biopsy is considered the diagnostic “gold standard”. Noninvasive technologies include: total-body photography (TBP); visual image analysis; electrical impedance devices; multispectral image analysis; ultrasound, optical coherence tomography [OCT]; and reflectance confocal microscopy (RCM). There is insufficient evidence in the peer-reviewed literature to support the use of these noninvasive technologies for the evaluation and surveillance of melanoma.

**Total Body Photography (TBP)**

TBP, also known as whole body photography, surveillance photography, total body mapping, has been proposed for screening and monitoring for the early detection of skin cancers, especially for people at high risk for melanoma. A proposed disadvantage of TBP is the poor resolution of images and loss of follow-up in noncompliant patients. TBP involves a series of multiple photographs (25–40) of head-to-toe images of the patient's entire cutaneous (skin) surface and is proposed for high-risk patients with multiple lesions. The photographs may be enlarged to show the details of lesions. New photographs can be compared with previous photographs to determine if a lesion has changed. Photographs are generally useful for 5–8 years. Available software can automatically match lesions on two standardized photographs and highlight new or changed lesions. Examples of this software are the Fotofinder™ bodystudio LITE (FotoFinder Systems Inc. Columbia, MD) and MIRROR® Body Mapping Module (Digitale Photographie Gmbh, Fairfield, NJ) (Guitera and Menzies, 2011; AHRQ, 2011).

**US Food and Drug Administration (FDA):** Because the cameras used for surveillance are not considered medical devices, they are not regulated by the FDA (AHRQ, 2011).

**Literature Review:** Salerni et al. (2011) reported surveillance of 618 patients at high risk for melanoma using digital total body photography and digital dermatoscopy. A total of 11,396 lesions were monitored (mean 18.44/patient) during a median follow-up of 96 months (median 10 visits/patient). In the multivariable logistic regression analysis, older age at inclusion and higher number of lesions excised during follow-up were the variables most associated with melanoma diagnosis during surveillance (p=0.003 and p<0.001, respectively). A total of 98 melanomas (8.5% of excised lesions) were diagnosed in 78 patients (12.6%). No conclusions regarding the impact of TBP on long-term health outcomes can be drawn from this study as there were no control groups.

In a prospective trial, Goodson et al. (2010) sought to determine whether biopsy rate, rate of melanoma detection, and melanoma derivation (nevus derived versus de novo) differed, using total body and digital epiluminescence microscopy (DELM) photography. A total of 889 new patients and 187 established patients were included. Most patients had one or more of the following melanoma risk factors: three or more clinically atypical nevi, more than 50 nevi, personal history of melanoma, and two or more family members with history of melanoma. Follow-ups occurred for 6-12 months. A total of 110 patients were lost to follow-up. The patients underwent total body photography and were monitored using photographs obtained at the initial visit. Risk factors and median monitoring periods for these patients were comparable with those of patients previously monitored using DELM photography. A total of 275 biopsies were performed on 467 patients on follow-up visits. The authors cited low biopsy rates on follow-up visits with both approaches (0.59 biopsies per patient with total body photography versus 1.1 per patient with DELM photography, statistically significant). The significantly higher biopsy rate with DELM photography may be a consequence of the greater sensitivity for detecting morphologic changes in nevi because of higher resolution of these photographs and the fact that lesions exhibiting photographic change were more likely to be biopsied.
Banky et al. (2005) conducted a prospective case series (n=309) to assess the effectiveness of total body photography and dermoscopy in the evaluation of new, changed and regressed nevi and melanomas. Included patients were referred to a dermatologist for clinical examination and had at least one of the following risk factors for melanoma: four or more clinically dysplastic nevi, 100 or more melanocytic nevi, a personal history of melanoma, or a family history of melanoma. Individuals with one of these risk factors underwent total body photography. Biopsy specimens were not obtained of all changed and new pigmented lesions. If melanoma could not be confidently excluded by clinical examination and dermoscopy, an excisional biopsy was performed. The median number of follow-up visits following photography was three. The median length of follow-up was 34 months. A total of 311 changed nevi and 262 new pigmented lesions were detected. Eighty-six nevi regressed completely. Eighteen melanomas were detected in 16 patients. The benign-malignant ratio of biopsied specimens was almost 3:1. Patients younger than age 50 years had a lower incidence of melanomas and a higher rate of new, changed, and regressed nevi when compared with patients older than age 50 years.

Visual Image Analysis
Visual image analysis involves image acquisition, segmentation (a step that often has to be overseen by the human operator), extraction of morphological data and numeric conversion of the data. A classification by mathematical algorithm is used to give a diagnosis. To date, no mechanized systems have proven to be reliable enough to produce a fully automated diagnosis with high diagnostic accuracy. Image-based systems require the lesion to be pigmented which means light-colored lesions are usually poorly diagnosed (Guitera and Menzies, 2011).

Electrical Impedance Devices
These devices utilize resistance or impedance measured between two electrodes in contact with the epidermis. Different tissues have different electrical impedance spectra. Normalized conductivity and capacitance recorded on growing skin tumors have been shown to change relative to the lesion. Necrosis, present in larger lesions, was associated with a decrease in the electrical conductivity. Studies are still investigating the role of electrical impedance in the diagnosis of melanoma.

Literature Review: In a multi-center study, Har-Shai et al. (2005) prospectively evaluated the ability of electrical impedance scanning to differentiate between benign and malignant skin lesions in 382 patients (449 lesions), including 53 melanomas from the trunk and extremities. Results were correlated with histopathologic findings. Electrical impedance scanning detected melanomas of the trunk and extremities with 91% sensitivity and 64% specificity. Visual examination identified 67% of small, thin malignant lesions (n=27) compared to 100% by electrical impedance scanning (p=0.002). Clinical examination detected 96% of larger or thicker melanomas (n=26) compared to 81% by electrical impedance scanning.

Multispectral Image Analysis
Multispectral imaging or scanning technique is proposed to allow analysis of sequences of images taken at different wavelengths. With similar segmenting and image analysis as the first devices, they may also provide information on skin chromophores (mostly collagen, melanin and hemoglobin).

U. S. Food and Drug Administration (FDA): An example of a multispectral device is the MelaFind® (MELA Sciences, Irvington, New York) which received FDA pre-market approval (PMA) 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”. The device is proposed to help a dermatologist make a decision to biopsy. It is not to be used alone for making biopsy decisions. 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 one centimeter 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” (FDA, 2011).

SIAScope II® (Astron Clinica Ltd., Cambridge, UK), a Class II device, is a non-invasive skin analysis system proposed to show the location of blood, collagen and pigment. Using spectrophotometric intracutaneous analysis (SIAscopy) to identify and graphically display the separate components of the skin, the device provides
color bitmaps called SlAscans. SlAscopy uses a digital camera and light (both visible and near-infrared) to investigate the skin's interior structure.

**Literature Review:** Monheit et al. (2011) conducted a prospective multicenter study to evaluate the safety and effectiveness of MelaFind (n=1612 lesions; 114 melanomas). The pooled data on melanoma reported a sensitivity of 98.4%, specificity ranged from 0%–25% (average 9%), negative predictive value was > 98%, and biopsy ratio of 10.8:1. MelaFind had an average specificity of 9.5% which was significantly higher than that of investigators (3.7%) (p=0.02). The study also included a pilot study of biopsy sensitivity (reader study) using 25 randomly selected melanomas and 25 nonmelanomas which showed that dermatologists misdiagnosed thin melanomas. The average biopsy sensitivity of 39 dermatologist readers was 78%. An author noted limitation of the study was that only pigmented lesions were scheduled for biopsy and these benign lesions are not representative of lesions in the general population. Thus, the specificity in this study is not applicable to the general population for clinicians or MelaFind.

In a prospective study, Haniffa et al. (2007) evaluated the ability of the spectrophotometric device, SlAscope, to aid in the diagnosis of melanomas. 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.

**Technology Report:** ECRI (2012) conducted a technology report on MelaFind and reported that the quality, quantity and consistency of evidence were low due to the limited number of studies. A potential safety issue for MelaFind was the number of false negative results that could cause a delay in diagnosis and treatment of melanoma. However, the false negative rate from two small studies was only 0.17%. There was only one study that reported that MelaFind added to standard practice. The results of two low-quality studies suggested that using MelaFind with standard practice would not significantly decrease the number of unnecessary biopsies.

**Ultrasound**
Ultrasound/reflex transmission imaging relies on the properties of reflected sound waves through tissue. The ultrasound impulsion is administered by a probe and transmitted to the skin. The probe acts as a receptor that will collect the backscattered or diffused ultrasound and transform it into an electric signal. Ultrasound creates an image of the strain on the tissue imposed by presence of an abnormal growth. Ultrasound is not currently a widely accepted technology for evaluating melanomas. Refinement of the technology and equipment and its clinical utility are still being investigated.

**U.S. Food and Drug Administration (FDA):** Ultrasounds are approved by the FDA as a Class II, 510(k) device. An example of an approved device is the DermaScan C Ultrasonic System (Cortex Technology, Denmark). The device is intended “to be used to visualize the layers of the skin, including blood vessels, and to make approximate measurements of dimensions in the layers of the skin and blood vessels by ultrasonic means” (FDA, 1999).

**Literature Review:** Rallan et al. (2007) conducted a prospective study (n=87) to determine if high-resolution ultrasound reflex transmission imaging (RTI) could differentiate common benign pigmented lesions (BPLs) from melanoma. RTI was used to determine the lesion attenuation properties. The study also assessed if the “lesional backspatter image” (LBI) which depicts intralesional sound reflection characteristics and the “entry echo image” (EEI), which depicts surface sound reflectance characteristics, could aid in diagnosis. Twenty-five malignant melanomas (MM) and 62 noncancerous lesions, as classified by a dermatologist, were analyzed by RTI. Of the noncancerous lesions, 24 were seborrheic keratosis (SK) and 38 were BPLs. When the sensitivity of diagnosing melanoma was set at 100%, RTI, LBI, and EEI were compared in the diagnosis of SK. A total of nine of the 24 SK were detected by RTI and LBI for a specificity of 38%. EEI detected seven out of 24 for a specificity of 29%. Each of the three methods was compared in its ability to diagnose BPLs (with sensitivity set at 100%). The specificity of EEI, LBI, and RTI were 30%, 15%, and 10%, respectively.

**Reflectance Confocal Microscopy**
Reflectance confocal microscopy (RCM), also known as confocal scanning laser microscopy (CSLM), uses a near infrared laser to obtain images of the top layers of the skin. The images are magnified and information regarding cell structure and the architecture of the surrounding tissues is evaluated. Combinations of features
are assessed to give a positive or negative diagnosis of melanoma. RCM is proposed to be comparable to conventional histology and is proposed for use as an adjunctive diagnostic tool to examination and dermoscopy in difficult to diagnose lesions to determine melanomas from benign lesions. The disadvantages of RCM is the time it takes to perform the exam (average of seven minutes per lesion), clinical-dermatoscopic skills are required, as well as adequate training and experience to read RCM images to make the correct interpretation of lesions. Studies evaluating the accuracy of confocal scanning laser RCM/CSLM in assessing skin lesions for melanoma have reported sensitivity, specificity, positive and negative predictive values ranging from 90.74% to 97.5%, 83% to 99%, 70.6% to 97.5%, and 98.17% to 99%, respectively. It has yet to be determined if the advantages of the clinical utility of RCM as an adjunctive diagnostic tool are greater than the risk of over-excising benign lesion and misdiagnosing melanomas as benign. In some cases RCM may be used for cosmetically sensitive areas to avoid excision (Stevenson, et al., 2013; Gerger, 2008; Langley, 2007; Gerger, 2006). There is insufficient evidence to support the clinical utility of RCM.

U.S. Food and Drug Administration (FDA): 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).

Literature Review: Pellacani et al. (2014) conducted a prospective case series (n=1005) to assess the impact of reflectance confocal microscopy (RCM) in the routine diagnosis of melanoma. Patients had atypical moles and were initially referred to either no further examination or to RCM. The RCM group was further subdivided into RCM documentation (suspicious lesions already qualified for excision) or RCM consultation (i.e., RCM would determine if the lesion was excised or monitored with digital dermoscopy). RCM did not affect the outcome in patients already scheduled for excision. Patients referred for RCM had a higher number of nevi (>100 nevi; 19%) and atypical nevi (>5; 15%) compared to patients referred for RCM documentation and patients without RCM referral (p<0.0001). Personal and/or familial history of melanoma was recorded in approximately 8% of patients. A total of 493 lesions were referred to RCM of which 183 underwent RCM documentation and 308 RCM consultations. Histopathology identified 23 melanomas. RCM proposed the same diagnosis as histopathology in 82.6% of melanomas. A total of 109 of 308 RCM consultation lesions were excised, six cases of melanoma were diagnosed and five cases were confirmed as melanomas. Twenty-eight lesions deferred to follow-up were excised based on dermoscopic changes. Overall RCM proposed diagnosis was concordant with histopathological diagnosis in 76.3% of cases and reduced the number of excision by 46.5%. Limitations of the study include: 12.3% of patients were lost to follow-up; 11 patients either refused RCM or were unable to undergo RCM; and the study population was a low risk group referred for screening.

Stevenson et al. (2013) conducted a systematic review of the literature to determine the diagnostic accuracy of reflectance confocal microscopy (RCM) as an adjunctive tool to dermoscopy for the evaluation of melanoma. No systematic reviews or meta-analysis were found. Studies were primarily in the form of case series, case reports, and descriptive correlation studies that only described RCM features and narrative reviews. Five studies (n=909 lesions) met inclusion criteria and were eligible for meta-analysis. Meta-analysis returned a per lesion sensitivity of 93% (range 91%–97%) and a specificity of 76% (range 68%–86%). The average prevalence of melanoma was 36%. The authors noted that a weakness of the study was that the studies may not have focused on the pertinent patient populations to test the ability of RCM as an add-on test to dermoscopy. Limitations of the studies included use of various types of melanoma scoring systems and outcome measures, heterogeneity of lesion locations, and two studies did not list number of patients evaluated.

Other Noninvasive Technologies
Multiple other noninvasive technologies have been proposed for use in melanoma diagnosis and surveillance. To date, many of these technologies have not been FDA approved nor has the accuracy and/or clinical utility been established. Other proposed noninvasive diagnostic surveillance techniques include: conventional optical coherence tomography (OCT), ultra-high resolution/high-definition OCT (HD-OCT), multiphoton microscopy, Raman spectroscopy, infrared multispectral, 3D imageries, functional photoacoustic microscopy laser system, epidermal genetic tape stripping (i.e., samples cells from stratum corneum using adhesive tape), fluorescence, and 3-D histograms of color mapping. OCT is based on a similar principle to ultrasound but uses an infrared broadband light source. The image of the tissue is formed by the light that is reflected back from the tissue, but
the back-scattered light is focused by the objective lens through a pinhole aperture (AHRQ, 2011; Wachsman, et al., 2011; Guitera and Menzies, 2011; Stanley, et al., 2007). There is insufficient evidence to support the accuracy and clinical utility of other noninvasive technologies for the screen, diagnosis and surveillance of melanoma. Studies are primarily in the form of small case series, case reports and retrospective reviews.

**Technology Assessment for Multiple Technologies**
Following a systematic review of the literature, the Agency for Healthcare Research and Quality (AHRQ) (2011) published a technology brief assessing noninvasive diagnostic techniques for the detection of skin cancers including melanoma. A technology brief provides an overview of interventions "for which there are limited published data and too few completed protocol-driven studies to support definitive conclusions". A total of 629 abstracts were accepted for final review including five systematic reviews, 118 narrative reviews, 108 technical reports, 11 randomized controlled trials, 77 diagnostic tests, 64 comparative cohort study, 143 noncomparative cohort studies, 55 case reports and 48 other/not classified studies.

In regards to dermoscopy, 238 abstracts were found that addressed melanoma. A total of 86 primary studies and five systematic reviews evaluated general and digital dermoscopy. Only two randomized controlled trials were found. Per AHRQ, “The studies on early melanoma identified by this brief were largely confined to the use of algorithms or classifiers of dermoscopic images to differentiate early melanoma from other stages of melanoma”. According to this report, the “non-randomized studies focused on features of dermoscopic image that would be of diagnostic interest, digital dermoscopy, the use of computer-based analyses, evaluations of different algorithms and classification schemes”. No controlled studies were found that examined the use of dermoscopy to increase the detection rate of early stage melanoma, and no study reported on how the addition of dermoscopy affected survival from melanoma.

Six randomized controlled trials evaluated the diagnostic accuracy, excision rates, patient satisfaction treatment adherence and follow-up of photography. Additional abstracts of comparative and noncomparative cohorts were reviewed. According to AHRQ, the available data are limited on the role of photography in changing clinical outcomes. Evidence that baseline photography improves the detection of melanoma and results in detection of earlier stage lesions or recurrent lesions is lacking. Data are also limited on the role of photography for specific racial/ethnic groups.

Based on the evidence, confocal scanning laser microscopy (CSML) and ultrasound are not generally used and there are no FDA approved devices. AHRQ noted that multiphoton laser scanning microscopy, multispectral imaging and fully automated computer-based analysis, electrical bio-impedance, optical coherence tomography and tape stripping are investigational modalities.

AHRQ concluded that predominant use of noninvasive devices is by dermatologists with limited diffusion of this technology in primary care. “When compared with the use of biopsy, future research is needed to evaluate the test accuracies, clinical impact, and the potential adverse events associated with the use of noninvasive imaging technologies”.

**Professional Societies/Organizations**

**American Academy of Dermatology (AAD):** AAD (2011) stated that biopsy is the first step for a definitive diagnosis of cancer. They do not discuss the use of noninvasive technologies in their guidelines for the management of melanoma.

**National Cancer Institute (NCI):** According to NCI (2014), the incidence of melanoma rises rapidly in Caucasians after age 20 years. Fair-skinned individuals exposed to the sun are high risk and certain types of pigmented lesions (dysplastic or atypical nevi), with several large nondysplastic nevi, with many small nevi, or with moderate freckling have a twofold to threefold increased risk of developing melanoma. Familial dysplastic nevus syndrome or the presence of several dysplastic or atypical nevi increases the risk of developing melanoma greater than fivefold. NCI stated that the only widely proposed screening procedure for skin cancer is visual examination of the skin, including both self-examination and clinical examination.

**National Comprehensive Cancer Network® (NCCN®):** In the discussion for follow-up following diagnosis and treatment of melanoma, NCCN's Clinical Practice Guidelines in Oncology™ (2014) states that patients cured of an initial primary melanoma are at increased risk for a second melanoma. Patients with risk factors that increase the chance for recurrence should be enrolled in a more intensive surveillance program and may benefit from
adjuncts such as high-resolution total body photography. These risk factors include multiple primary melanomas, positive family history and the presence of multiple dysplastic nevi. Regarding imagining (ultrasound, CT, PET and PET/CT) NCCN states that studies have reported low yield with significant false positives and cumulative risk from radiation exposure.

**U.S. Preventive Services Task Force (USPSTF):** The USPSTF Screening for Skin Cancer recommendation statement (2009) for an adult in the general population stated that the current evidence is insufficient to assess the balance of benefits and harms of using a whole-body skin examination screening for the early detection of skin cancer by primary care clinicians or by patient skin self-examination.

**Use Outside of the US**

**National Institute for Health and Clinical Excellence (NICE):** A 2006 NICE guidance on skin tumors, including melanoma, reported that one randomized controlled trial showed a significant improvement in accuracy in the diagnosis of melanoma using dermoscopy and clinical diagnosis compared to clinical diagnosis alone. Dermatoscopy should be available in all multidisciplinary teams for investigation and diagnosis of melanoma. NICE also noted that the degree of accuracy of dermoscopy depends on the experience of the user and that training is required.

**Summary**

There is insufficient evidence in the published peer reviewed literature to support the accuracy and/or clinical utility of noninvasive surveillance technologies (e.g., whole body phototherapy, multispectral image analysis). Studies are primarily in the form of case studies and retrospective reviews with short-term follow-ups and used various dermatologic algorithms and comparators (e.g., naked eye, histology, other noninvasive technologies). Reported outcomes are conflicting and results varied based on the size of the lesions. Some studies evaluated the lesions while others evaluated images of lesions. Overall, published studies have not addressed whether or not these technologies resulted in earlier diagnosis of melanoma, identified recurrent lesions, resulted in fewer missed diagnosis or affected survival. Patient selection criteria for these devices have not been established. Dermoscopy is considered part of a normal evaluation of a pigmented skin lesion and is not reimbursable as a separate examination.

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.
   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Experimental/Investigational/Unproven/Not Covered:**

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<td>96999</td>
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**References**


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