Healthy Blue

Medical Policy

Subject:	Technologies for the Evaluation of Skin Lesions (including Dermatoscopy, Epiluminescence Microscopy, Videomicroscopy and Ultrasonography)		
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Description/Scope

This document addresses the use of photographic, optical, video, and other imaging technologies for the evaluation of skin lesions.

Position Statement

Not Medically Necessary:

Dermatoscopy (also known as dermoscopy, epiluminescence microscopy [ELM], or digital epiluminescence microscopy [DELM], skin surface microscopy, skin videomicroscopy, or incidence light microscopy) using either direct inspection, digitization of images, or computer-assisted analysis is considered **not medically necessary** in all cases.

Reflectance confocal microscopy for the evaluation of skin lesions is considered **not medically necessary** in all cases.

Investigational and Not Medically Necessary:

Whole body integumentary photography, including melanomagram, is considered **investigational and not medically necessary** in all cases.

Ultrasonography for the evaluation of skin lesions is considered **investigational and not medically necessary.**

Electrical impedance spectroscopy for the evaluation of skin lesions is considered **investigational and not medically necessary.**

Rationale

Dermatoscopy

While there is extensive literature regarding dermatoscopy, the literature is inconclusive regarding its clinical role in the management of pigmented skin lesions, for instance, as a technique to select or deselect lesions for excision. At this time, there is insufficient evidence to support the use of this technology to improve outcomes either by reducing the frequency of unnecessary biopsies or by improving early detection of malignant melanoma.

The diagnostic performance of dermatoscopy combined with clinical assessment must be compared with clinical assessment alone and with the "gold standard," histology. There are three clinical scenarios in which dermatoscopy might be of benefit:

(1) Use of dermatoscopy to evaluate a lesion with low pretest possibility of malignancy to determine if excisional biopsy is necessary. In this scenario, the negative predictive value is the most relevant diagnostic parameter.
(2) Use of dermatoscopy to evaluate multiple suspicious pigmented lesions to determine which of the multiple lesions are most clinically suspicious and in need of excision. In this scenario, the positive predictive value of dermatoscopy is the relevant diagnostic parameter. and
(3) Serial assessment of lesions over time, as a means to prompt excision when a lesion changes in character in an individual with multiple pigmented lesions, or for lesions in a location difficult to excise. In this scenario, both the positive and negative predictive values of the results of serial imaging and clinical assessment are relevant.

In one study, sensitivity, specificity, and positive and negative predictive values were reported as 79.2%, 71.8%, 16.1%, and 98.1%, respectively (Argenziano, 2006). These results are in conflict with earlier reports of negative predictive value of 85% (Carli, 2003). Additionally, there is little data addressing the use of dermatoscopy in eliminating the need for biopsy and histologic examination of the lesion for the definitive diagnosis. While there have been randomized controlled trials of dermatoscopy, this technology is considered to be an adjunct in the work-up of equivocal melanocytic lesions. Biopsy and histologic examination are still required for the definitive diagnosis.

Cristofolini (1994) reported a case series of 220 pigmented skin lesions in which the sensitivity and specificity of dermatoscopy alone, clinical assessment alone or dermatoscopy combined with clinical assessment were compared with the histologic "gold standard." The sensitivities of clinical assessment alone, dermatoscopy, and dermatoscopy combined with clinical assessment were 85%, 88%, and 95% respectively. The measured specificities for clinical assessment alone, dermatoscopy, and dermatoscopy combined with clinical assessment were 75%, 79%, and 72%. While this study showed a modest increase in sensitivity with the combined use of dermatoscopy and clinical assessment, it is unclear whether this improved sensitivity is statistically or clinically significant.

A study of digital dermoscopy by Wollina and colleagues reported on their findings in 1308 subjects with 3354 pigmented lesions (2007). The authors reported sensitivity between 90% and 95%, and specificity between 79.6% and 93.3%. This is an improvement upon previous reports involving non-digital dermatoscopic methods, but further investigation is needed to confirm these findings.

Moloney and colleagues (2014) conducted a study evaluating the impact of full-body examinations every 6 months supported by dermoscopy and total-body photography (TBP) on all subjects and sequential digital dermoscopy imaging (SDDI), when indicated, on detecting primary melanoma in an extreme-risk population. The study population consisted of 311 subjects who had a history of invasive melanoma and dysplastic nevus syndrome, or a history of invasive melanoma and at least three first- or second-degree relatives with prior melanoma, or a history of at least two primary invasive melanomas, or a known CDKN2A or CDK4 gene mutation. Out of the 311 subjects followed, 75 primary melanomas were detected, and of these 38% were detected using TBP and 39% with SDDI. The benign to malignant excision ratio was 1.6:1 for all lesions excised and 4.4:1 for melanocytic lesions.

Cumulative risk of developing a novel primary melanoma was 12.7% by year 2, with new primary melanoma incidence during the final 3 years of follow-up half of that observed during the first 2 years (incidence density ratio 0.43; 95% confidence interval [CI], 0.25-0.74; p=0.002). Unfortunately, this study does not provide any data regarding comparative health outcomes vs. standard surveillance and follow-up methods.

In 2018, Cochrane published a review on dermoscopy with and without visual inspection for diagnosing melanoma in adults (Dinnes, 2018a). The review included a literature search from the introduction of dermoscopy to August 2016. All studies that evaluated dermoscopy for diagnosing melanoma in adults compared with either clinical follow-up or histological confirmation were included. There were 104 studies with 42,788 lesions included in the analysis. Studies on the diagnosis being made face-to-face were separated from those based on remote assessment. Face-to-face diagnosis accuracy was significantly higher than remote assessment (relative diagnostic odds ratio [RDOR] 4.6; 95% CI, 2.4 to 9.0; p<0.001). The evaluators found dermoscopy to be more accurate than visual inspection alone during face-to-face assessments (RDOR 4.6; 95% CI, 3.0 to 7.5; p<0.001), and during remote assessments (RDOR 5.6; 95% CI, 3.7 to 8.5; p<0.001). For face-to-face assessments with dermoscopy, the predicted difference in sensitivity at a fixed specificity of 80% was 16% (95% CI, 8% to 23%; 92% for dermoscopy with visual inspection versus 76% for visual inspection), and predicted difference in specificity at a fixed sensitivity of 80% was 20% (95% CI, 7% to 33%; 95% for dermoscopy with visual inspection versus 75% for visual inspection). For remote assessment of dermoscopy, the predicted difference in sensitivity was 34% (95% CI, 24% to 46%; 81% for dermoscopy versus 47% for visual inspection), at a fixed specificity of 80%, and predicted difference in specificity was 40% (95% CI, 27% to 57%; 82% for dermoscopy versus 42% for visual inspection), at a fixed sensitivity of 80%. While these findings are significant, there are concerns with the applicability. Most of the studies included were either case-control or case-series studies. Other areas of concern as noted by the evaluators include "selective participant recruitment, lack of reproducibility of diagnostic thresholds and lack of detail on observer expertise" (Dinnes, 2018a).

Another Cochrane review was published in 2018 on visual inspection and dermoscopy, alone or in combination, for diagnosing keratinocyte skin cancers in adults (Dinnes, 2018b). The literature search, which included studies from the introduction of dermoscopy to August 2016 that evaluated dermoscopy, visual inspection, or both in adults with lesions suspicious for skin cancer compared with either clinical follow-up or histological confirmation, yielded 24 studies with 27 visual inspection datasets (8805 lesions; 2579 malignancies) and 33 dermoscopy datasets (6855 lesions; 1444 malignancies). Studies on the diagnosis being made face-to-face were separated from those based on remote assessment; however, no significant difference was found between the accuracy of the two. Face-to-face evaluations of dermoscopy was more accurate than visual inspection alone in the detection of basal cell carcinoma (RDOR of 8.2, 95% CI 3.5 to 19.3; p<0.001). "This corresponds to predicted differences in sensitivity of 14% (93% versus 79%) at a fixed specificity of 80% and predicted differences in specificity of 22% (99% versus 77%) at a fixed sensitivity of 80%" (Dinnes, 2018b). The data showed very similar results for the remote assessments. There was insufficient data in the included studies to draw conclusions on the accuracy of dermoscopy through face-to-face or remote assessment for the detection of cutaneous squamous cell carcinomas. Limitations to this review and the applicability of the results include most of the studies included being either case-control or case-series studies, potential bias participant recruitment due to selection processes, lack of reproducibility of diagnostic thresholds, and unclear observer expertise.

There are no conclusive data regarding the role of serial dermatoscopic monitoring compared to serial clinical monitoring. In addition, there is insufficient data to assess the impact of dermatoscopy on skin cancer-related morbidity and mortality.

Reflectance confocal microscopy

The peer-reviewed literature investigating reflectance confocal microscopy (RCM) as a technology for the evaluation of skin lesions mainly consists of case-series and retrospective studies. There have been several combined systematic reviews and meta-analyses conducted to evaluate RCM for this indication.

In 2016, Xiong and colleagues reported the results of a systematic review and meta-analysis with a primary objective to investigate the accuracy of RCM for the diagnosis of malignant skin lesions when compared to histopathology. The literature search resulted in 21 studies that included 3108 individuals with a total of 3602 lesions. Data from the meta-analysis showed the sensitivity and the specificity ranged from 83% to 100% and 67% to 100%, respectively, with a pooled sensitivity and specificity of 93.6% (95% CI, 0.92-0.95; I^2=56.1%) and 82.7% (95% CI, 0.81-0.84; I^2=93.4%), respectively. In addition, the positive likelihood ratio (PLR) and negative likelihood ratio (NLR) were 5.84 (95% CI, 4.27-7.98) and 0.08 (95% CI, 0.07-0.10), respectively. These results are limited due to heterogeneity and potential bias caused by the included studies varying in provider experience, different inclusion and exclusion criteria, and diagnostic protocols, and low-quality study designs, including retrospective, non-randomized, and single center characteristics.

Edwards and colleagues (2017) aimed to perform a systematic review and meta-analysis to evaluate the diagnostic and margin delineation accuracy of the VivaScope® (Caliber Imaging & Diagnostics, Inc., Andover, MA), which is an RCM system designed to be used in combination with dermoscopy for the diagnosis of malignant skin lesions. There were 11 studies identified from the systematic review. The review suggested RCM using the VivaScope along with dermoscopy might improve diagnostic accuracy compared to dermoscopy alone; however, this could not be confirmed by meta-analysis. Due to variations in study designs, subject population, and reporting of results, the included studies were considered too heterogeneous for a meta-analysis to be performed. Furthermore, this review did not assess the VivaScope in comparison to standard care.

A Cochrane review on RCM for diagnosing cutaneous melanoma in adults in comparison to visual inspection and dermoscopy alone was published in 2018 by Dinnes and colleagues (Dinnes, 2018d). There were 18 studies with 19 cohorts (67 datasets for RCM and 7 datasets for dermoscopy), which included 2838 lesions, 658 of which were melanoma, that were identified for inclusion in the meta-analysis. The data showed the following:

> Meta-analysis found RCM to be more accurate than dermoscopy in studies of participants with any lesion suspicious for melanoma and in participants with lesions that were more difficult to diagnose (equivocal lesion populations). Assuming a fixed sensitivity of 90% for both tests, specificities were 82% for RCM and 42% for dermoscopy for any lesion suspicious for melanoma (9 RCM datasets; 1452 lesions and 370 melanomas). For a hypothetical population of 1000 lesions at the median observed melanoma prevalence of 30%, this equated to a reduction in unnecessary excisions with RCM of 280 compared to dermoscopy, with 30 melanomas missed by both tests. For studies in equivocal lesions, specificities of 86% would be observed for RCM and

> 49% for dermoscopy (7 RCM datasets; 1177 lesions and 180 melanomas). At the median observed melanoma prevalence of 20%, this reduced unnecessary excisions by 296 with RCM compared with dermoscopy, with 20 melanomas missed by both tests. Across all populations, algorithms and thresholds assessed, the sensitivity and specificity of the Pellacani RCM score at a threshold of three or greater were estimated at 92% (95% confidence interval (CI) 87 to 95) for RCM and 72% (95% CI 62 to 81) for dermoscopy.

While the sensitivity in most areas evaluated was high, the specificity was overall heterogeneous. Risk of bias and applicability concerns of the included studies was evaluated in five domains: participant selection, index test – RCM, reference standard, flow and timing, and comparative. The majority of domains for all studies were rated high or unclear bias in relation to the applicability of the evidence. Due to inconsistencies in reporting of data in the included studies, assumptions had to be made for the results of this meta-analysis. These limitations, along with lacking a focus to compare RCM to standard care, restrict the relevancy of the results to show the clinical utility of RCM.

Dinnes and colleagues reported on a second Cochrane review investigating RCM for diagnosing keratinocyte skin cancers (basal cell carcinoma [BCC] and cutaneous squamous cell carcinoma [cSCC]) in comparison to visual inspection or dermoscopy, or both in adults (Dinnes, 2018c). Eleven study cohorts in 10 studies met inclusion criteria. All 11 cohorts included data on the detection of BCC, with 464 BCC lesions reported out of a total of 2037 lesions. There were 4 cohorts that reported on the detection of cSCC, with 71 cSCC lesions reported out of a total of 834 lesions. Equivocal lesions were defined as those for which a management plan could not clearly be made following visual inspection or dermoscopy, and any suspicious lesions were defined as those that were obvious BCCs and were scheduled for excision. Results of the meta-analysis showed that in comparison to studies that included any suspicious lesion (sensitivity 76%, 95% CI: 45% to 92%; specificity 95%, 95% CI: 66% to 99%; 4 studies), RCM was more sensitive but less specific for the detection of BCC in studies of participants with equivocal lesions (sensitivity 94%, 95% CI: 79% to 98%; specificity 85%, 95% CI: 72% to 92%; 3 studies); however, CI ranges were wide. The investigators were unable to compare RCM to visual inspection or dermoscopy due to a lack of studies with this type of data. Variations in study designs and results, including provider training and reporting of study details such as population eligibility, and high or unclear bias in all risk domains are some of the limitations to this review and the included studies. Without sufficient data to compare RCM to standard care for diagnosing keratinocyte skin cancers, any potential clinical utility of this technology cannot be validated.

In 2020, Pezzini and colleagues released the results of a systematic review and meta-analysis with the objective to update the data evaluation on RCM diagnostic accuracy for malignant melanoma since the previously discussed Cochrane review (Dinnes, 2018d). After a systematic search of the literature, the investigators identified 32 studies with 7352 lesions for inclusion in the meta-analysis. All studies were observational with 10 studies having a prospective design and 24 studies having a retrospective design. "Pooled sensitivity and specificity were 92% (95% CI: 0.91-0.93, I^2=70%) and 70% (95% CI: 0.69-0.71, I^2=94), respectively. Pooled PLR and NLR were 3.6 (95% CI: 3.1-4.3, I^2=93%) and 0.11 (95% CI: 0.08-0.15, I^2=64%), respectively" (Pezzini, 2020). The investigators assessed the risk of bias across all domains as low or unclear with a low concern in relation to applicability of the evidence; however, there are other limitations to this study. There were no randomized controlled studies identified for analysis. Also, the inclusion and exclusion criteria were heterogeneous across all studies, RCM provider expertise

varied, and several included studies were missing important data such as detailed differential diagnostic information regarding false-negative results.

The results of the current published literature on RCM for the evaluation of skin lesions lacks the data needed to conclude its clinical utility. Large, well-designed studies are needed in order to properly assess the clinical utility of this technology.

Whole body integumentary photography

The body of evidence addressing the use of whole body integumentary photography (also known as whole body photography or TBP) is limited. Only three peer-reviewed articles discuss the results of clinical trials using TBP (Feit, 2004; Menon, 2006; Risser, 2007). The first two studies lack control groups, do not address specificity or sensitivity issues, and do not report any data regarding alterations in health outcomes as a result of the use of this technique. The third study, by Risser and colleagues, retrospectively investigated the impact of TBP on the clinical treatment of individuals seen in a pigmented lesion clinic. The authors reviewed the charts of 64 subjects who had undergone TBP and 64 who had not. The authors report that TBP had no impact on the number of biopsies or on the number of dysplastic nevi diagnosed in the first year of the clinic. Further evidence from well-controlled trials is needed to properly evaluate the health benefits of TBP.

Another device, the DZ-D100 DERMOCAMERA™ and the DZ-S50 scope (Casio America, Inc., Dover, NJ) obtained FDA clearance in 2022 for skin observation and delivers both standard sized and close-up shots of an affected area with a single unit. It can be used with the D'z IMAGE Viewer, a free downloadable software that manages the captured images. According to the manufacturer, the unit can capture polarized, non-polarized and UV photos at the same viewpoint with a single click of the shutter button. These devices are due to be available on the Casio America's eCommerce site in 2022. According to the user's manual, "This product is not a diagnostic device and should only be used for observing skin lesions. This product is a digital camera for dermal observations and is intended for photographing the surface of the skin over the entire body."

Ultrasonography

Ultrasonography (US) has been proposed for use in the assessment of skin tumors. US has been described as a tool for differentiation of common benign pigmented skin lesions from melanoma. There are only a few small nonrandomized controlled studies currently available in the literature describing this technique. US has also been used in the preoperative measurement of melanoma thickness in preparation for lesion excision. The studies addressing this procedure have been small nonrandomized controlled studies and the impact of US assistance in melanoma excision planning was not addressed in relation to any potential decrease in repeat excisions or other outcome measures. Other studies have investigated the use of US in the assessment of inflammatory skin lesions and connective tissue diseases. The evidence is limited to small case series studies that do not evaluate the impact of US on health outcomes or on clinical management. Additional research is needed to establish the clinical utility of US for evaluation and management of skin lesions.

Electrical Impedance Spectroscopy

The Nevisense™ System (Scibase AB, Stockholm, Sweden) is a new non-invasive test proposed for early detection of malignant melanoma. This test utilizes electrical impedance spectroscopy to measure resistance between two electrodes in contact with the epidermis to detect irregularities in electrical conductivity, which are associated with skin tumors. In June 2017 the FDA granted premarket approval for the Nevisense system which is indicated for:

> Use on cutaneous lesions with one or more clinical or historical characteristics of melanoma, when a dermatologist chooses to obtain additional information when considering biopsy. Nevisense should not be used on clinically obvious melanoma. The Nevisense result is one element of the overall clinical assessment. The output of Nevisense should be used in combination with clinical and historical signs of melanoma to obtain additional information prior to a decision to biopsy. Nevisense is indicated only for use on:
>
> - primary skin lesions with a diameter between 2 mm and 20 mm;
> - lesions that are accessible by the Nevisense probe;
> - lesions where the skin is intact (that is, non-ulcerated or non-bleeding lesions);
> - lesions that do not contain a scar or fibrosis consistent with previous trauma;
> - lesions not located in areas of psoriasis, eczema, acute sunburn, or similar skin conditions;
> - lesions not in hair-covered areas;
> - lesions which do not contain foreign matter;
> - lesions not on special anatomic sites (that is, not for use on acral skin, genitalia, eyes, mucosal areas).

To date, there has been very little published evidence regarding this technology, and studies are still investigating the role of electrical impedance spectroscopy in the diagnosis of melanoma. The American Academy of Dermatology (AAD) in its guideline on management of primary cutaneous melanoma (AAD 2019) states that:

> Biopsy is the first step for a definitive diagnosis of cancer. In the discussion on emerging diagnostic technologies, the Academy notes that use of noninvasive imaging/electrical data acquisition and evaluation tools, including RCM, electrical impedance spectroscopy combined with digital dermoscopy, optical coherence tomography, cross-polarized light and fluorescence photography, and high frequency ultrasound, are being investigated to further classify melanocytic lesions as either benign or malignant and to guide the need for further biopsy…The AAD makes no recommendation on their use as evidence regarding effectiveness, clinical utility, and competing strategies is needed.

Background/Overview

Of the three main types of skin cancer, melanoma is the most aggressive and accounts for approximately 75% of all skin cancer related deaths. Treatment of melanoma is highly successful if caught early. The gold standard for evaluation of pigmented skin lesions is excision with examination of the lesion under a microscope for diagnosis. The sensitivity and specificity are nearly 100% for a skilled pathologist. The early phase of malignant melanoma can be particularly difficult to identify since malignant melanomas of skin can share many clinical features with atypical birthmarks, moles, or other benign skin lesions. Because of this diagnostic difficulty, multiple tools have

been proposed in order to improve the accuracy of diagnosis of malignancies in pigmented skin lesions and therefore improve health outcomes, without necessarily requiring biopsy or excision of lesions for testing.

Dermatoscopy, epiluminescence microscopy (ELM), and the other techniques mentioned in this document have been introduced as non-invasive aids in the visual examination of pigmented skin lesions in-vivo (on the individual's body). While dermatoscopy is extensively used in Western Europe, it has gained only limited acceptance in the U.S. It is considered to be an extraneous diagnostic step in the work-up of suspected melanoma.

In addition, the use of the dermatoscope requires adequate training and experience to use it effectively and studies have shown that its use by practitioners without adequate training actually decreases diagnostic accuracy below that obtained from clinical examination alone. The brand names of epiluminescence microscopes that are available include, but are not limited to, the Nevoscope™, the Episcope™, the Dermascope™, and MoleMax™.

Dermatoscopy and all its forms use magnification of in vivo skin lesions for better visualization of surface and subsurface structures without requiring excision. This diagnostic tool permits the recognition of morphologic structures not visible to the naked eye. The technique involves placing mineral oil, alcohol or water on the skin lesion and inspecting it using a hand-held lens, a hand-held scope, a stereomicroscope, a camera, or a digital imaging system. The magnifications of these various instruments range from 6x up to 100x. The most commonly used dermatoscope has a 10x magnification. The fluid placed on the lesion eliminates surface reflection and renders the hardened external layer translucent, thus allowing a better visualization of pigmented structures within the epidermis, the dermoepidermal junction and the superficial dermis. Moreover, size and shape of vessels of the superficial vascular plexus can be easily visualized by this procedure. Dermatoscopy is proposed to increase the accuracy of the clinical diagnosis of pigmented lesions and particularly to aid in the early recognition of malignant melanoma.

Reflectance confocal microscopy (RCM), which is also known as confocal laser scanning microscopy and confocal microscopy, is a microscopic technique that visualizes deep layers of the skin and provides a more detailed, magnified evaluation of potential lesions than other microscopic techniques. It has been evaluated as a possible alternative or adjunct to dermoscopy for the evaluation of skin lesions. While RCM is painless, it is more time consuming and requires additional training than other microscopic technologies.

Whole body integumentary photography involves photographing an individual's entire body surface. Photographs may be taken using either conventional or digital photography. The purpose of this procedure is to attain a visual record of the skin with the hope of being able to compare with future examinations to assist in the identification of new or changed skin lesions. This technology has been proposed as a tool in the management of individuals at high risk for skin cancer.

Ultrasound (US) imaging is a method of obtaining images from inside the body through the use of high frequency sound waves. Sound waves are emitted by a handheld probe and penetrate the body without any discomfort or sensation. These sound waves are reflected by the structures inside the body and received by a receiver in the probe. The echoes are then processed by a computer and displayed as a real-time visual image on a monitor. The image that is displayed shows movement of internal structures of the body as they occur, including blood flow in the veins and arteries, aiding diagnosis of a variety of conditions. US for use in evaluating skin lesions has been proposed as a method to allow assessment of blood supply, thickness and depth of the growth into the skin.

Definitions

Dermatoscope: A hand-held device used for the examination of the structures of the epidermis and epidermal-dermal junction using magnification of about 10x.

Dermatoscopy (Dermascopy, Dermoscopy, DS): A family of noninvasive techniques (skin videomicroscopy, epiluminescence microscopy [ELM], incident light microscopy, skin surface microscopy) that allow microscopic examination of skin lesions. These techniques are intended to help distinguish between benign and malignant pigmented skin lesions using a dermatoscope, stereomicroscope, camera, or a digital imaging system. The magnifications of these various instruments range from 6x to 40x and up to 100x.

Dermoscopy (DS): Another name for Dermatoscopy; see Dermatoscopy.

Digital epiluminescence microscopy (D-ELM): A version of dermatoscopy that involves using digital photography of the dermatoscopic images; the computerized digital images are stored for comparison of the skin lesion(s) at a later date.

Epiluminescence microscopy (ELM): Another dermatoscopic technique that allows microscopic examination of skin lesions directly on the person, without requiring excision.

Incidence or incident light microscopy: Another term sometimes used for dermatoscopy, dermoscopy or ELM.

Melanomagram: A whole-body image produced by using a digital-picture dermatoscope (MoleMax). A full set of digital computer images are evaluated for the presence of skin lesions and then digitally archived for future use. These images are used to do side-by-side comparisons of past and current images to determine changes in size, color, or other skin cancer risk factors.

Reflectance confocal microscopy: A technique performed with a hand-held device that uses infrared light to visualize deeper layers of the skin than compared to other microscopy technologies.

Skin fluorescent imaging (SFI): Refers to the Orlucent® System (Orlucent, Inc. Los Gatos, CA), which is a hand-held molecular-based imaging system that is intended for in-office use in the clinical assessment of suspicious moles prior to biopsy. The Orlucent system uses a novel fluorescent biotag that is topically applied to non-invasively detect a biomarker of early tissue changes that occur during a mole's transition from benign to atypia. Full FDA clearance for this device is pending.

Skin surface microscopy: Another name for dermatoscopy.

Ultrasonography: The diagnostic or therapeutic use of ultrasound, which uses sound waves to create two-dimensional images used for the examination and measurement of body structures and the detection of abnormalities.

Videomicroscope, videomicroscopy, or videodermatoscopy: A technique that uses a video-microscope linked to a computer that generates a melanomagram of the whole body or body region.

Whole body integumentary photography**:** A procedure where the entire skin surface of an individual is photographed. The purpose of this procedure is to provide a reference source of skin lesions over time; pictures may be conventional pictures or digital images stored electronically; also see melanomagram.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Not Medically Necessary:

CPT

96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion
96932	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, first lesion
96933	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion
96934	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion
96935	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion
96936	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion
96999	Unlisted special dermatological service or procedure [when specified as dermatoscopy techniques such as dermoscopy, epiluminescence microscopy, or digital epiluminescence microscopy, skin surface microscopy, skin videomicroscopy, incidence light microscopy or reflectance confocal microscopy not generating mosaic images]

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:

CPT

96904	Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma

96999	Unlisted special dermatological service or procedure [when specified as ultrasonography of the skin for skin lesions]
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score
0700T	Molecular fluorescent imaging of suspicious nevus; first lesion
0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion

ICD-10 Diagnosis

All diagnoses

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Document History

Status	Date	Action
Reviewed	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. The Rationale, Definitions, References and Index sections were updated.
	12/29/2021	Updated Coding section with 01/01/2022 CPT changes; added 0700T, 0701T effective 01/01/2022.
Revised	05/13/2021	MPTAC review. A new position statement was added for electrical impedance spectroscopy which is considered INV and NMN. The Rationale, References and Index sections were updated. Updated Coding section with 07/01/2021 CPT changes; added 0658T.
Revised	05/14/2020	MPTAC review. Added reflectance confocal microscopy to the Not Medically Necessary section of the Position Statement. Removed Cosmetic and Not Medically Necessary statement on ultrasonographic evaluation of photoaging, intrinsic aging and skin rejuvenation techniques from the Position Statement.

		Updated Description, Rationale, Background, Definitions, References, Websites, and Index sections. Updated Coding section; added CPT code range 96931-96936.
Reviewed	02/20/2020	MPTAC review. Updated References and Websites sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale, References, and Websites sections.
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Reviewed	05/07/2015	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/15/2014	MPTAC review. Updated Reference section.
Reviewed	05/09/2013	MPTAC review. Updated Reference section.
Reviewed	05/10/2012	MPTAC review. Updated Reference section.
Reviewed	05/19/2011	MPTAC review. Updated Reference section.
Reviewed	05/13/2010	MPTAC review. Updated Reference section,
Reviewed	05/21/2009	MPTAC review. Updated Reference section
Reviewed	05/15/2008	MPTAC review. The phrase "cosmetic/not medically necessary" was clarified to read "cosmetic and not medically necessary." Updated Coding and Reference sections.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	05/17/2007	MPTAC review. Added investigational/not medically necessary statement regarding whole body photography. Updated Rationale, Reference Coding and Index sections.
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes; removed CPT codes 0044T, 0045T deleted 12/31/2006.
Reviewed	06/08/2006	MPTAC annual review. References updated.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organization	**Last Date Reviewed**	**Document Number**	**Title**
Anthem, Inc.	01/28/2004	MED.00004	Technologies for the Evaluation of Skin Lesions (including Dermatoscopy, Epiluminescence Microscopy, Videomicroscopy and Ultrasonography)
WellPoint Health Networks, Inc.	09/23/2004	2.02.03	Dermatoscopy

06/24/2004	4.02.02	Ultrasonographic Evaluation of Skin Lesions