Blue Cross
Blue Shield
of Rhode Island

EFFECTIVE DATE: 01|01|2016
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OVERVIEW

Reflectance confocal microscopy (RCM) is a relatively new technique that allows noninvasive imaging of the epidermis and superficial dermis to more accurately evaluate both melanocytic and nonmelanocytic skin lesions. RCM acquires images in the horizontal plane (en face), allowing assessment of tissue pathology underlying dermoscopic structures of interest at a cellular-level resolution.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Reflectance confocal microscopy is considered not covered as a technique to evaluate or serially monitor pigmented skin lesions as there is insufficient evidence to determine the effects of the technology on health outcomes.

Commercial Products

Reflectance confocal microscopy is considered not medically necessary as a technique to evaluate or serially monitor pigmented skin lesions as there is insufficient evidence to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Reflectance Confocal Microscopy

Reflectance confocal microscopy, also known as confocal scanning laser microscopy (CSLM), uses a near infrared laser that emits near-infrared light (830 nm) 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 proposed for use as an adjunctive diagnostic tool to examination and dermoscopy in difficult to diagnose lesions and therefore, aid in determining if a lesion is benign or is a melanoma. 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.

RCM is considered an evolving technology with several limitations. The depth of imaging is confined to the epidermis and papillary dermis, which may result in false negatives. Penetration of RCM light may be hampered by hyperkeratosis, reflective creams and surface particles. Another limitation is the challenge that the interpreter has of distinguishing between cells with similar reflection index and shape (e.g., Langerhans cells versus dendritic melanocytes at the spinous layer). RCM is a time consuming exam taking an average of seven minutes per lesion. Clinical-dermatoscopic skills are required, as well as adequate training and

experience to read RCM images and make the correct interpretation. 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 a as benign. In some cases RCM may be used for cosmetically sensitive areas to avoid excision (Hayes, 2019; Que, et al., 2016; 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).

Pezzini et al. (2020) conducted a systematic review and meta-analysis to assess the accuracy of reflectance confocal microscopy (RCM) in diagnosing cutaneous malignant melanoma (MM) according to study design, lesion type and diagnostic modality. The meta-analysis included 32 studies (n=7352 lesions) that met the criteria of reporting RCM lesion classifications and included either histopathology diagnoses or long-term clinical follow-up data that verified the accuracy of the original diagnosis with evaluations that were performed by an expert/trained RCM investigator. Seven studies were prospective-non interventional, three were prospective interventional studies and 22 were retrospective reviews. Studies were excluded if they were case series/case reports with <10 lesions; pertained to special sites such as oral mucosa, lips, eyes, or genital area; or were for other types of skin cancers. The secondary outcome measure was a comparison of diagnostic accuracy to dermoscopy. The length of follow up was not reported. The pooled sensitivity was 92% with a pooled specificity of 70%. In regards to study design, the diagnostic sensitivity was high for all study types. The specificity was lower for prospective interventional studies. Diagnostic accuracy was high for all lesion types with the highest specificity reported in consecutive lesions (77%) highly suspicious for MM (65%). RCM diagnostic accuracy was 56% vs. dermoscopy at 38%. No serious adverse events were reported. Author noted limitations of the meta-analysis include heterogeneity of the inclusion and exclusion criteria of the studies, wide range of study designs, use of algorithms or scoring systems, and the range of RCM investigator expertise. Additional high quality studies with large patient populations and long term follow up are needed to validate the outcomes of this analysis and establish the clinical utility of RCM in the diagnosis of MM.

Edwards et al. (2016) conducted a systematic review and health technology assessment on the clinical effectiveness of the VivaScope 1500 and 3000 systems in the diagnosis of equivocal skin lesions. VivaScope 3000 was also evaluated for the assessment of lesion margin delineation prior to surgical excision of lesions. Eleven prospective observational studies and five retrospective reviews were included. No randomized controlled trials (RCTs) were found. One study suggested that VivaScope used subsequent to dermoscopy may improve diagnostic accuracy of equivocal skin lesions compared with dermoscopy alone, especially for malignant melanomas. Another study reported that the sensitivity for dermoscopy plus VivaScope 1500 were the same (100%). Clinical data regarding margin delineation are scarce. The studies were too heterogeneous to be used in a meta-analysis. The authors noted that apart from diagnostic accuracy and lesion recurrence rate (only reported by one study), none of the outcomes specified in the protocol were reported in the outcomes and in some of the studies, there was paucity of reported data on number of patients with positive and negative test results. Other limitations of the studies included: lack of a comparator; retrospective study design; small patient populations; heterogeneity in cancer types (melanoma, basal cell and squamous cell carcinoma); and variation in reporting results as patient based or lesion based. The authors suggested that high-quality RCTs are required to assess diagnostic accuracy of dermoscopy plus VivaScope compared with dermoscopy alone in people with equivocal skin lesions, as well as the margin delineation accuracy of VivaScope compared with dermoscopy alone. RCTs focusing on clinical outcomes, test failure rates, number of biopsies performed, repeat biopsies, recurrence rates and morbidity associated with surgery are required.

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.

Professional Societies/Organizations
American Academy of Dermatology (AAD): In the guidelines for the 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 the 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. AAD makes no recommendation on their use as evidence regarding effectiveness, clinical utility, and competing strategies is needed.

The AAD (2018) guidelines of care for the management of cutaneous squamous cell carcinoma (cSCC) do not address the use of noninvasive imaging/electrical data acquisition and evaluation tools. The Academy notes that the diagnosis of one cSCC puts the patient at risk for developing additional cSCC and other skin cancers such as basal cell carcinoma and melanoma.

In a position statement on reflectance confocal microscopy (RCM), the American Academy of Dermatology (ADA) (2019) states their support for "the use of RCM as a modality for in vivo microscopic examination of suspicious epidermal and superficial dermal skin lesions for diagnosing skin pathology when clinically appropriate." However, they recommend that additional research be conducted about the utility and efficacy of RCM in the diagnosis of skin lesions. The ADA's disclaimer states that the position statement is provided for educational and informational purposes only to offer physicians guiding principles and policies regarding the practice of dermatology not to establish a legal or medical standard of care.

National Cancer Institute (NCI): According to NCI (2024), squamous cell carcinoma and basal cell carcinoma are the most common forms of skin cancer. Both have a better prognosis as they are not as aggressive as melanoma. Risk factors for melanoma include sun exposure, pigmentary characteristics, multiple nevi, family and personal history of melanoma, immunosuppression and environment exposures. Fair-skinned individuals exposed to the sun are at 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. More than 90% of melanomas can be recognized with the naked eye. A biopsy should be performed for any suspicious lesion.

National Comprehensive Cancer Network® (NCCN®): In the discussion for follow-up following diagnosis and treatment of melanoma, NCCN's Clinical Practice Guidelines in Oncology™ (2024) 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 (e.g., prior multiple primary melanomas, family history of melanoma and presence of atypical/dysplastic nevi) 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.

NCCN's Clinical Practice Guidelines in Oncology (2024) on squamous cell skin cancer (SCC) states that 13–50% of patients diagnosed with one SCC will develop another within five years. These patients are also at increased risk of developing cutaneous melanoma and basal cell cancer (BCC). Long term surveillance is required. The guidelines do not address the use of noninvasive imaging/electrical data acquisition and evaluation tools.

Noninvasive imaging/electrical data acquisition and evaluation tools are not mentioned in NCCN's Clinical Practice Guidelines in Oncology (2024) on basal cell skin cancer. Follow up for those patients with basal cell skin cancer includes a complete skin exam every 6–12 months for the first five years and then annually for life.

U.S. Preventive Services Task Force (USPSTF): In 2023, the USPSTF published an update to the 2016 systematic review on visual screening for skin cancer. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of visual skin examination by a clinician to screen for skin cancer in adolescents and adults.

The 2016 systematic review included thirteen studies, mostly observational cohort studies and retrospective reviews (n=10), met inclusion criteria. Acceptable screening tests were defined as whole or partial visual skin examination with or without tools to aid examination (e.g., dermatoscopy, whole body photography). The report noted that definitive diagnosis of nonmelanoma and melanoma skin cancer is made by shave, punch or excision biopsy depending on the type of skin cancer. The authors concluded that due to the limited evidence, no firm conclusions on skin cancer screening and melanoma mortality could be made. Noted limitations of the fair-quality studies included: various follow-up times; short-term follow-ups; noncomparative study design; subjects tended to be younger women even though the incidence of skin cancer is highest in older men; lack of complete data presented; and lack of rigorous studies on skin cancer screening conducted in the United States with an application in primary care or internal medicine settings.

CODING

Medicare Advantage Plans and Commercial Products
The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:
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 (List separately in addition to code for primary procedure)

96935 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition only, each additional lesion (List separately in addition to code for primary procedure)

96936 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to code for primary procedure)

RELATED POLICIES
Not applicable

PUBLISHED
Provider Update, March 2026
Provider Update, April 2025
Provider Update, May 2024
Provider Update, May 2023
Provider Update, July 2022

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