Regence

Medicare Advantage Policy Manual **Policy ID:** M-MED174

Skin Lesion Imaging and Spectroscopy

Published: 11/01/2025

Next Review: 07/2026

Last Review: 09/2025

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual but they may also be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Various non-invasive technologies have been proposed for use in diagnosing skin lesions. Such techniques include, multispectral digital image analysis, electrical impedance spectroscopy, optical coherence tomography and reflectance confocal microscopy. These have been proposed 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.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals

None

National Coverage Determinations (NCDs)

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles

For Medicare Coverage Determinations and Articles, see the Medicare Coverage Database

None

Medical Policy Manual

Medicare coverage guidance is not available for reflectance confocal microscopy (RCM) for the evaluation of skin lesions. Therefore, the health plan's medical policy is applicable.

Skin Lesion Imaging and Spectroscopy, Medicine, Policy No. 174 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

The following are examples of devices or systems approved by the U.S. Food and Drug Administration (FDA), but may not represent all available technology:

- VivaScope® System (Lucid, Inc.) (K080788) received approval through the FDA 510(k) process in 2008. This system 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."[1]
- The MicroDERM® (Visiorned AG; K040171) received FDA 510(k) approval in 2004 and is intended for the "acquisition and storage of images of skin surfaces.[2]
- The SIAscope II (Visiorned AG Astron Clinica, Ltd.) (K023729) received FDA 510(k) approval in 2003. This system is described as a "non-invasive skin analysis system, which provides a synthesized 'image' showing the relative location of blood collagen and pigment."[3]
- The APAX™ PACS System (TIS, Inc.; K032760) received FDA 510(k) approval in 2003.[4]

- VivoSight Dx (Michelson Diagnostics Inc.).

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

1. Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. https://www.accessdata.fda.gov/cdrh_docs/pdf8/k080788.pdf
2. https://www.accessdata.fda.gov/cdrh_docs/pdf4/K040171.pdf
3. https://www.accessdata.fda.gov/cdrh_docs/pdf2/K023729.pdf
4. https://www.accessdata.fda.gov/cdrh_docs/pdf3/K032760.pdf

CODING

NOTE: CPT codes 96931-96936 are not used for RCM examination **without** generated mosaic images. Unlisted code 96999 *(Unlisted special dermatological service or procedure)* would be used for this procedure. In addition, prior to January 1, 2021, multi-spectral digital skin lesion analysis was reported with Category III codes 0400T and 0401T; however, these codes were deleted effective January 1, 2021, and unlisted code 96999 is now used instead.

Codes	Number	Description
CPT	0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk
	0700T	Molecular fluorescent imaging of suspicious nevus; first lesion
	0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion
	96931	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion
	96932	; image acquisition only, first lesion
	96933	; interpretation and report only, first lesion
	96934	; image acquisition and interpretation and report, each additional lesion (List separately in addition to code for primary procedure)
	96935	; image acquisition only, each additional lesion (List separately in addition to code for primary procedure)
	96936	; interpretation and report only, each additional lesion (List separately in addition to code for primary procedure)

	96999	Unlisted special dermatological service or procedure
HCPCS	None	