Skin Cancer Detection, **Simplifed.**

Indications for use

The U.S. Food and Drug Administration (FDA) cleared the DermaSensor™ device on January 12, 2024 (DEN230008) with the following Indications for Use (IFU):

The DermaSensor™ device is indicated for use to evaluate skin lesions suggestive of melanoma, basal cell carcinoma, and/or squamous cell carcinoma in patients aged 40 and above to assist in the decision regarding referral of the patient to a dermatologist. The DermaSensor™ device should be used in conjunction with the totality of clinically relevant information from the clinical assessment, including visual analysis of the lesion, by physicians who are not dermatologists. The device should be used on lesions already assessed as suspicious for skin cancer and not as a screening tool. The device should not be used as the sole diagnostic criterion nor to confirm clinical diagnosis of skin cancer.

This guide presents representative codes that may be helpful for reporting the use of DermaSensor™ device on health care claims. Coding may vary based on patient circumstances, services provided, and payer requirements. It is the responsibility of the provider to select the most appropriate code based on the care furnished to an individual patient.

AMA CPT® reporting

A coding analysis for reporting the use of DermaSensor™ related services was conducted by The Reimbursement Group (TRG). No coding guidance statements have been made by the American Medical Association (AMA) or the Centers for Medicare & Medicaid Services (CMS) related to the use and reporting of this service. In the absence of a specific unique coding selection or formal coding guidance from a primary source, it is TRG's opinion that the device operation procedure may be reported using an unlisted Current Procedural Terminology (CPT®)* procedure code.

It is the responsibility of the provider to ensure all information required to process an unlisted procedure or not otherwise classified (NOC) code is included on the CMS-1500 form or the electronic media claim (EMC) when the claim is submitted. If required information is missing, the claim may be deemed unprocessable and a denial forwarded to the provider.

An unlisted procedure or NOC code must have a concise description of the service or procedure rendered in Item 19 on the CMS-1500 claim form or electronic equivalent. In the concise description of the procedure, it is helpful to include how the procedure was performed and to name the primary procedure.

The electronic equivalent for Item 19 holds up to 80 characters for the concise statement. If the description does not fit in Item 19, providers who submit paper claims should include an attachment to describe the service or procedure. Also, an attachment can be submitted for EMC claims using the PWK submission method. See PWK article titled "Submitting Paperwork (PWK) Electronically."

TRG suggests the following documentation requirements for DermaSensor™ related services. Additionally, we suggest the inclusion of the FDA clearance number (DEN230008) in the Local Use field, Box 19 (Loop 2300 in the electronic filing systems):

1. A clear description of the nature, extent, and need
2. Indicate whether the procedure was performed independently from other medical service provided or if it was performed to supplement an evaluation and management (E/M) or another service
3. List any extenuating circumstances that may have complicated the service or procedure
4. Note the time, effort, and equipment necessary to provide the service

TABLE 1: Unlisted CPT code options to consider for DermaSensor™ services

CPT CODE	DESCRIPTOR	APC	APC PAYMENT*	RW**
96999	Unlisted special dermatological service or procedure	5051	$198.70	2.2284
17999	Unlisted procedure; skin, mucuous membrane and subcutaneous tissue	5051	$198.70	2.2284

The Current Procedural Terminology (CPT) code set is a medical code set copyrighted and maintained by the American Medical Association (AMA) through the CPT Editorial Panel. The information in this table is an abstract of the possible eighty-nine

(89) Unlisted procedural CPT codes and is provided as a reference in this Guide.

*The APC Payment amount in Table 1 is for the Outpatient Prospective Payment System (OPPS). Providers billing under site of service 11 are not paid under the OPPS. Payment will be determined by the Medicare contractor or pursuant to payer contract.

**(RW): Relative Weight

Supporting medical necessity

It is the obligation of the treating provider to obtain and retain information relative to patient care and subsequent treatment decision-making. However the strict definition of "medical necessity" varies by perspective (patient, plan, and provider) and valuation of evidence (quality and quantity of the evidence).

The initial check for medical necessity is the listed primary and secondary ICD-10 diagnoses, as listed on the submitted claim. Beyond this check edit, plans generally defer to independent agencies in the development of indication-specific Care Guidelines. The two most notable agencies are MCG and InterQual.

Unlisted codes have not been surveyed and valued within the Resource-based Relative Value System (RBRVS); therefore, it is the responsibility of the reporting provider to develop and support a reasonable charge. TRG recommends consideration of physician and other non-physician time, material resources and supply item costs, as well as comparable procedural valuation when establishing a billed charge for DermaSensor™ services.

Coding tips from the AMA

- A service or procedure may be provided that is not listed in this edition
- A service that is rarely provided, unusual, variable, or new may require a special report. Pertinent information should include an adequate definition or description of the nature, extent, and need for the procedure, and the time, effort, and equipment necessary to provide the service.
- Ideally, anytime you file a claim using an unlisted procedure code, you should include an explanation of the procedure "in plain English," along with full documentation of services. Avoid or explain medical jargon and difficult terminology. If appropriate, include diagrams or photos to describe further the procedure you are reporting.

Coding options-modifier 25 unusual procedural services

If the DermaSensor™ scans are performed as an adjunct to an E/M visit, modifier 25 may be considered for inclusion on the claim. Modifier 25 is described by the American Medical Association's (AMA) CPT as identifying a significant, separately identifiable E&M Service by the Same Physician or Other Qualified increased procedural service. Its use allows two E/M services or a procedure plus an E/M service that are distinctly different but required for the patient's condition to be appropriately reported and, therefore, appropriately paid," the issue brief says.

The use of modifiers provides supplementary information for payer policy requirements. Payers, however, may not be aware that this is what the modifier is telling them. The use of modifier 25 "indicates that documentation is available in the patient's record to support the reported E/M service as significant and separately identifiable," the council report (PDF) adds.

If two services are rendered to the same patient on the same day, but the procedures were performed on different structures or organs, consider appending -59 or XS modifier. Not using a modifier when multiple lesions are scanned by the DermaSensor™ device may result in bundling of the multiple procedures performed on the same day for the same patient as per the National Correct Coding Initiative (NCCI) edits. According to CMS' MedLearn Matters, "Use modifier 59 or XS for different anatomic sites during the same encounter only when procedures which aren't ordinarily performed or encountered on the same day are performed on: different organs, different anatomic regions, in limited situations on different, non-contiguous lesions in different anatomic regions of the same organ."

Charting, coding, and reimbursement assistance

DermaSensor has engaged TRG to assist patients with respect to coverage effort. TRG is staffed by certified professional coders and nurse case managers to provide expert guidance.

Healthcare providers and facilities (on behalf of their patients) may contact TRG Monday through Friday from 8:00am to 8:00pm Eastern Time by calling 1.888.298.8848 or email reimbursement@dermasensor.com.

To schedule a no-charge online-inservice for coding and reporting of DermaSensor related serivces, please contact us with your availability and expected attendees.

DermaSensor.com

Reimbursement assistance
reimbursement@dermasensor.com