

PATHOLOGY VISIONS **26**

CONNECTING
INNOVATION WITH
PURPOSE.

OCTOBER 16-18 | SAN DIEGO, CA

DPA

Evolving CPT Coding Policy for Digital Pathology-Enabled Clinical AI

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Topics

- ❖ Revisions to Appendix S; AI Taxonomy for Medical Services and Procedures
- ❖ Path Lab CCA; AI-specific Questions added
- ❖ Summary of Panel Actions 2026; Case Studies
- ❖ CMAA Development Plan
- ❖ Literature Documenting Evidence for Validation

Revisions to Appendix S: Artificial Intelligence Taxonomy for Medical Services and Procedures Tab 67 May 2026 CPT EP Meeting



Augmentative

...the output from the software...distinct from the input function and clinically meaningful based on documentation that the output contributes to patient management..

...reported as clinical scales, indexes, categorical classifications, risk scores, or other metrics that may be used in the diagnosis, cure, mitigation, treatment or prevention of a disease or other condition

...may be validated by equivalence to a metric currently in clinical use. If the output is novel, ie, there is no such metric currently in clinical use, it should be validated for impact on patient management (eg, novel predictive or prognostic indices).

The physician work related to augmentative services typically is captured by existing codes. For example, the output parameter(s) might be a data element in an evaluation and management service or a factor in pre-surgical planning.

Autonomous

- Software is autonomous when it automatically (without concurrent physician or other QHP involvement);
 - derives parameters *and*
 - independently generates clinically meaningful interpretations
- Reporting of the derived parameters is essential for transparency and explainability at all autonomous levels.
- Recommendations for definitive diagnostic conclusions, or specific management or interventions should provide clinical utility and have demonstrated validity.

Autonomous



Level I. The output of autonomous software includes recommendations of definitive diagnostic and/or specific management or interventions based on derived parameters. The recommendations require physician or QHP judgment to implement or reject the recommendation(s).



Level II. The output of autonomous software includes medical management actions based on interpretations of, and conclusions drawn from, derived parameters. The output from the software shall allow a reasonable opportunity to negate the impending action prior to implementation. e.g., by means of alerts.



Level III. The output of autonomous software automatically initiates actions based on interpretations of, and conclusions drawn from, derived parameters. These medical management actions require physician or QHP oversight and review of performance and will continue unless a physician or QHP intervenes. Physician oversight is warranted, typically over multiple interventions, to determine whether medical management goals are being achieved.

Key Definitions in Appendix S

...derived parameters are software output(s) that are quantitative or categorical, eg, an index, score, or classification

...software output(s) are clinically meaningful based on documentation that the output from the software contributes to patient management.

...use of the word “automated” or “automatically” refers to the work of the algorithm in getting from input to output, i.e., deriving the parameters. The “automated” or “automatic” derivation of parameters can apply to either Augmentative or Autonomous.

Primary Objective	Is clinically supportive of physician or QHP performance by providing clinically relevant data, including, eg, “likelihood of”, suggestive of”, or “risk for”	Derives clinically meaningful parameters as output, which are distinct from the input and identify a particular clinical condition, including, eg, “predictive of” or “prognostic of”	Derives clinically meaningful parameters AND from them generates interpretations or conclusions in the form of a diagnosis or intervention.
Requires Documentation of Clinical Meaningfulness	No	Yes	Yes
Output requires physician or other QHP interpretation and report	Yes	Conditionally (see note)	No
Examples in CPT code set	Algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (0764T, 0765T)	Noninvasive estimate of coronary fractional flow reserve (FFR) (75580)	Retinal imaging (92229) (Level I)

Augmentative Note to Table re; Physician Interpretation

Physician work of interpretation related to services utilizing augmentative software may be captured by existing codes.

For example, the output parameter(s) might be;

- ❖ a data element in an evaluation and management service,
 - ❖ a factor in pre-surgical planning,
- or it may otherwise be integrated into a separate service that includes physician or other QHP interpretation.

Path Lab CCA; AI-specific Questions added Tab 94 - Sept 2026 CPT EP Meeting



AI-Specific Information



Path-Lab CCA Revisions; AI section

- Identifying software as AI – does more than process data
- Flow of data – input, action, output, in chart and narrative formats
 - quality checks, reporting mechanism and content, etc
 - No proprietary information required; eg, “proprietary bioinformatics” suffices
- Level of output – select from Appendix S & provide rationale
- Documentation – to facilitate panel review and acceptance
 - Literature relevant to clinical use of the software as per the CCA
 - IFU from FDA letters of authorization or granting BDD, etc
 - Status; IDE, RUO/IUO, and other FDA programs eg RAPID, TEMPO
 - **FDA N/A; provide rationale, eg LDT, authorization not required for “service”**
- Clinical Trials; NCT#/link to [ClinicalTrials.gov](https://clinicaltrials.gov)

Summary of Panel Actions 2026; Case Studies



Tab 62 - Cat III-AI Analysis-Slide Images Breast Ca Tissue (May 2026)

Prediction of HR+/HER2- early invasive cancer prognosis

1106T Oncology (breast), **augmentative** algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slides from formalin-fixed paraffin-embedded (FFPE) breast cancer tissue, **algorithm-derived parameters reported as 5-year and 10-year risks** of distant metastasis, including digitization of glass microscope slides and hematoxylin and eosin staining of tissue sections, when performed

Accelerated Publication of Cat III Codes

CPT® Category III Codes

Most recent changes to the CPT® Category III Long Descriptor Document

- Revision of 3 Category III codes (0559T, 0560T, 0582T) and the addition of 34 Category III codes (1112T-1145T), guidelines, and parenthetical notes accepted by the CPT Editorial Panel at the September 2026 meeting.

CPT® Category III Codes

The following CPT codes are an excerpt of the CPT Category III code set, a temporary set of codes for emerging technologies, services, procedures, and service paradigms. For more information on the criteria for CPT Category I, II and III codes, see Applying for Codes.

To assist users in reporting the most recently approved Category III codes in a given CPT cycle, the AMA's CPT website publishes updates of the CPT Editorial Panel (Panel) actions of the Category III codes in April, July, and January/October according to the Category III Code Semi-Annual-Early Release Schedule. This was approved by the CPT Editorial Panel as part of the 1998- 2000 CPT-5 projects and subsequent Panel meetings. Although publication of Category III codes through early release to the CPT website allows for expedient dispersal of the code and descriptor, early availability does not imply that these codes are immediately reportable before the indicated implementation date.

Publication of the Category III codes to this website takes place on a semiannual/triannual basis when the codes have been approved by the CPT Editorial Panel. The complete set of Category III codes for emerging technologies, services, procedures, and service paradigms are published annually in the code set for each CPT publication cycle.

Accelerated Publication of Cat III Codes

The following Category III codes and parenthetical notes were accepted at the May 2026 CPT Editorial Panel meeting for the 2027 CPT production cycle. However, due to Category III code's early-release policy, these codes are effective on January 1, 2027, following the six-month implementation period, which begins July 1, 2026. These codes will be effective October 1, 2026.

●1097T	Oncology (pancreas), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded pancreatic cancer tissue; algorithm-derived parameters reported as prediction of response to fluorouracil backbone versus gemcitabine backbone chemotherapy, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed ►(Do not report 1097T in conjunction with 88305, 88307, 88309, 88363 for hematoxylin and eosin staining, when performed solely for augmentative algorithmic analysis of histomorphologic features of pancreas cancer tissue)◄	July 1, 2026	January 1, 2027 October 1, 2026	CPT® 2027
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Updated October 2, 2026

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Development and Validation of a Computational Histology Artificial Intelligence–Powered Predictive Biomarker for Selection of Chemotherapy in Advanced Pancreatic Cancer
Hendifar, et al *J Clin Oncol* 44, 2496-2506(2026) [Volume 44, Number 26](#) DOI: 10.1200/JCO-25-02199

Radiology Risk Score

Tab 82 Cat III-AI Breast Malignancy Risk Score-Screening Mammogram Data (Sept 2026)

1137T

Breast malignancy risk score **for 5-year prediction derived by augmentative algorithmic analysis** of a screening mammogram dataset acquired in separate session, with automated result

[Summary of Panel Actions](#)

Your monthly guide for using the language of medicine today to drive transformation across our healthcare ecosystem.

Summary of CPT Editorial Panel Actions

Following each CPT Editorial Panel (Panel) meeting, a document summarizing the Panel's actions on all Current Procedural Terminology (CPT®) code change applications is published on the [American Medical Association \(AMA\) website](#). These summaries reflect the decisions made at the Panel meetings and are part of the transparent and open CPT code development process led by the independent Panel and driven by direct, interactive input from representation across the healthcare community.

From September 17–19, the hybrid Panel meeting convened in Minneapolis, Minn., and virtually, with nearly 450 in-person attendees and over 900 virtual attendees. This broad participation from across healthcare enables the CPT code set to continue to represent the latest medical care available to patients.

[READ THE SUMMARY](#)

Here's how to participate in the CPT Editorial Panel process:

- Save the date to attend the February CPT Editorial Panel Meeting in Los Angeles, Calif., in person or virtually, Feb. 4–6.
- Explore [criteria for CPT codes, upcoming deadlines](#) and submitting a CPT code change application with the [CPT® Smart App](#).

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Clinically Meaningful Algorithmic Analysis (CMAA) Section

Tab 94 Option D
Sept 2025 CPT EP Meeting



Clinically Meaningful Algorithmic Analysis CMAA Opportunity Statement

The Digital Medicine Coding Committee, stakeholders, and ultimately the Editorial Panel, should consider whether algorithm-only services, or services without physician work, meet the fundamental definition of what a category I CPT code is, to wit; *“The Current Procedural Terminology (CPT®) code set is a listing of descriptive terms and five-digit codes for reporting medical services and procedures performed by physicians and other qualified health care professionals.”*

The need for a new category of codes comprising Clinically Meaningful Algorithmic Analyses (CMAA) is predicated on the idea that algorithmic service codes are novel, and so fundamentally different that they do not fit into the current structure of category III/I CPT codes.

CMS SaMS in Rule Making Proposed for 2027

A Transitional State

New SaMS technologies are continuing to be introduced to the market, each often accompanied by unique CPT codes reflecting their proprietary algorithms or specific characteristics.

If there were no laboratory methods included in the code descriptor, and only a computer analysis was described, CMS identified the code as a SaMS analysis performed on laboratory tests.

...whether the SaMS performs algorithmic analyses of an imaging test or...an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently with comparable SaMS analyses.

The Continuum of CPT Code Descriptors¹

FDA Product Description²
Software functions

...software functions that are...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease

CPT Code Descriptors³
Software outputs

...software output(s) are clinically meaningful based on documentation that the output from the software contributes to patient management

CMS Coverage and Payment⁴
Software as a Medical Service

SaMS...software-based technologies that support clinical decision making through algorithmic analysis, including ...clinical or diagnostic functionality

1. Figure 1 from “Developing current procedural terminology codes that describe the work performed by machines (Frank, Silva, et al) npj Digital Medicine (2022) 5:177 ; <https://doi.org/10.1038/s41746-022-00723-5> Open Access; <https://rdcu.be/c0Um9>

2. <https://www.fda.gov/medical-devices/digital-health-center-excellence/step-1-software-function-intended-medical-purpose>

3. Appendix S, CPT early release; <https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-taxonomy-artificial-intelligence-medical-services-procedures>

4. <https://www.federalregister.gov/documents/2026/07/07/2026-13656/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment#h-247>

Literature Documenting Evidence for Validation



Excerpts from the Literature Section of the CCA

Please provide...literature to support your application...submitted literature shall be identified in the **Publication Details and Attributes [PDA] grid** according to each of the following requirements:

- 1) Identify the Level of Evidence
- 2) Identify whether this is a U.S. based journal...and the population studied is U.S.
- 3) Identify the number of patients studied and whether the study is prospective

Provide up to 5 references ... at least 2 articles must report **different patient populations in addition to having different authors.**

Abstracts, book chapters, white papers, advertising, instructional manuals, and non-peer reviewed publications are not allowed to accompany applications and will not be accepted as substitutes for full-length journal articles.

Publication Details and Attributes (PDA) Grid

Code # [Click here to enter text.](#)

References	Study Duration	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied	Prospective Study?	Total Patients Studied
Article #1 Pellicano M, Lavi I, De Bruyne B, Vaknin-Assa H, Assali A, Valtzer O, Lotringer Y, Weisz G, Almagor Y, Xaplanteris P, Kirtane AJ, Codner P, Leon MB, Kornowski R. Validation Study of Image-Based Fractional Flow Reserve During Coronary Angiography. Circ Cardiovasc Interv.	1 year	IIb	☒ U.S. ☐ Foreign	American Heart Association	6.598 2016	☐ U.S. ☐ Foreign ☒ Both	☒ Yes ☐ No	184
A total of 203 lesions were analyzed in 184 patients from 4 centers. Values derived using FFRangio ranged from 0.5 to 0.97 (median 0.85) and correlated closely (Spearman $\rho=0.90$; $P<0.001$) with the invasive FFR measurements, which ranged from 0.5 to 1 (median 0.84). In Bland-Altman analyses, the 95% limits of agreement between these methods ranged from -0.096 to 0.112. Using an FFR cutoff value of 0.80, the sensitivity, specificity, and diagnostic accuracy of FFRangio were 88%, 95%, and 93%, respectively. The intraclass coefficient between 2 blinded operators was 0.962 with a 95% confidence interval from 0.950 to 0.971, $P<0.001$. There is a high concordance between FFRangio and invasive FFR. The color-coded display of FFR values during coronary angiography facilitates the integration of physiology and anatomy for decision making on revascularization in patients with stable coronary artery disease.								
References	Study Duration	Level of Evidence Based on LOE Table	U.S. or Foreign Peer Reviewed	Organization Sponsoring Journal	Impact Factor	U.S. or Foreign Population Studied	Prospective Study?	Total Patients Studied
https://clinicaltrials.gov/ct2/show/record/NCT03226262?term=cat-hworks&rank=1	Ongoing	IIb	☐ U.S. ☐ Foreign			☐ U.S. ☐ Foreign ☒ Both	☒ Yes ☐ No	386 estimate

What “Good” looks like in the Publication Details and Attributes Grid

- ✓ Correlation with SoC
- ✓ Patient population

“...correlated closely with the invasive FFR measurements...the sensitivity, specificity, and diagnostic accuracy...were 88%, 95%, and 93%.”

“The color-coded display of FFR values during coronary angiography facilitated the integration of physiology and anatomy for decision-making during revascularization in patients with stable coronary artery disease.”

More Excerpts from the Literature Section of the CCA

- 1) Provide a concise “relevance statement”.
- 2) Well-designed studies submitted for consideration should represent the most informative and compelling peer-reviewed publications...well-designed and executed, ethical in nature, and...
- 3) directly support the code change request.



This is not a
box-ticking
exercise

For Discussion; Relevance to the CCA of Literature & Clinical Trials

This is not a
box-ticking
exercise

Are the cohorts (study population) the same as the Typical Patient?

Is the output from the algorithm as described in the CCA similar to that in the literature?

Does the evidence provide support for;

- ☐ Analytical Validity (it measures what it claims to measure, ie the metric *per se*)
- ☐ Clinical Validity (the output contributes to defining the state of disease)
- ☐ Clinical Utility (the output contributes to improved outcomes)

Does the Description of Procedure (DoP) align with the

- ☐ clinical context (user and immediate impact on patient management)
- ☐ materials and methods in the study

Does the DoP align with how the results were generated (eg, materials and methods)?

Do the pre-determined success criteria (hypothesis, endpoints, analyses, results, and conclusions regarding use in medical management) align with the code descriptor?

THANK YOU

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