



CPT[®]: The Language of Medicine for Innovators

Stanford Biodesign and Fogarty Innovation – 9/17/21

Our presenters



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American Medical Association

Objectives

The AMA and Innovation

What is CPT (and why you should care)

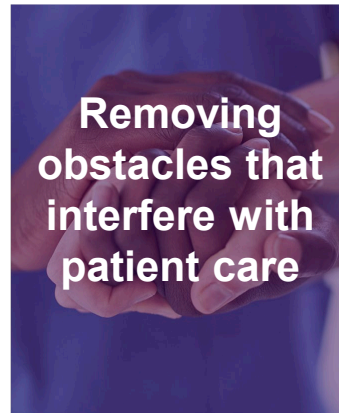
CPT: What You Need To Know	The Who	Key CPT Groups
	The What	The Payer Landscape: How does coding relate to value and reimbursement How CPT Enhancements Embrace Innovation
	The When and The How	Innovation lifecycles and the CPT process How innovators interact with the CPT process <i>Enhanced Literature Standards, Open Collaboration</i>

Debunking common myths

Q&A

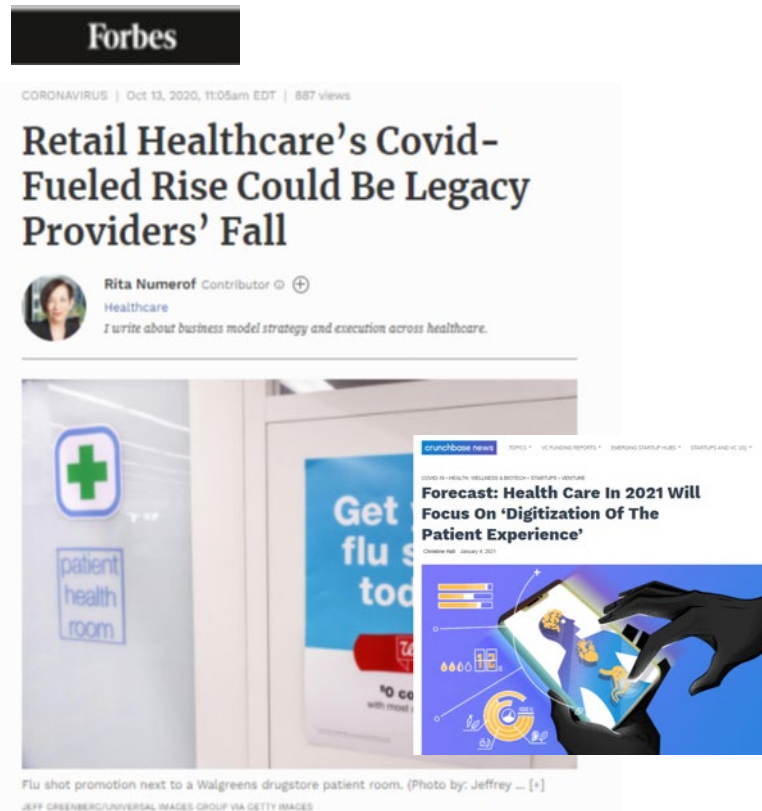
Resources

AMA: The physicians' powerful ally in patient care



Disruption of health care has already begun...

- **Retail and direct-to-consumer (DTC) growth:**
 - Increase in physicians going to work for new models
 - Increase in patient use of new models
 - *Millions have lost employer-provided healthcare coverage making \$40 doctor visits at care clinics increasingly tempting*
- **Patients and physicians want virtual care to continue:**
 - 68% of clinician respondents are motivated to increase telehealth; 75% of clinicians indicated that telehealth enabled them to provide quality care (*COVID 19 Coalition Telehealth Impact Survey*)
 - Patient satisfaction score for telehealth is 860/1000 – highest of all healthcare, insurance and financial services (*JD Power*)
- **Record digital health investments in 2020:**
 - \$20 billion globally
 - Similar investments expected in 2021 focused on interoperability, mental health and personalized care (Rock Health)
- **AI, genomics, precision medicine, health at home...**



New care delivery models already at work

Tech-enabled healthcare services

Companies that provide healthcare through technology

Characteristics

- Clinical staff typically employed as 1099's
- No brick-and-mortar footprint
- Bundled services into a recurring fee, such as PMPM, or per unit (e.g. per query if a data services business).
- 50-75%+ gross margin

<p>Employer-facing</p>	<p>Payer-facing</p>
<p>Pharma-facing</p>	<p>Consumer-facing</p>

"Pure-play" healthcare services

Companies that offer healthcare in-person

Characteristics

- Primarily utilize technology for practice management, electronic medical record keeping, billing and coding, scheduling, and patient communication
- Typically bill through claims or are cash pay
- Either fee-for-service or fee-for-value
- Typically, clinical staff are employed as full-time employees
- 30-60% gross margin depending on whether there is a B&M footprint.

<p>Brick & Mortar</p>	
	<p>Non-B&M</p>

Melting margins and hospital closures



'Tumultuous' year for hospitals results in 55% drop in median operating margin, Kaufman Hall finds

Alia Paavola - Monday, January 25th, 2021 Print | Email

BECKER'S Hospital CFO Report

Negative operating margins likely for 39% of hospitals this year: Kaufman Hall

Alia Paavola - yesterday Print | Email

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Even under an optimistic pandemic recovery scenario, 39 percent of hospitals may have negative operating margins this year, according to a [new report](#) from healthcare consulting firm Kaufman Hall.

In a pessimistic scenario, nearly half of U.S. hospitals may have negative operating margins, according to the report. Prior to the pandemic, 25 percent of hospitals had a negative operating margin.

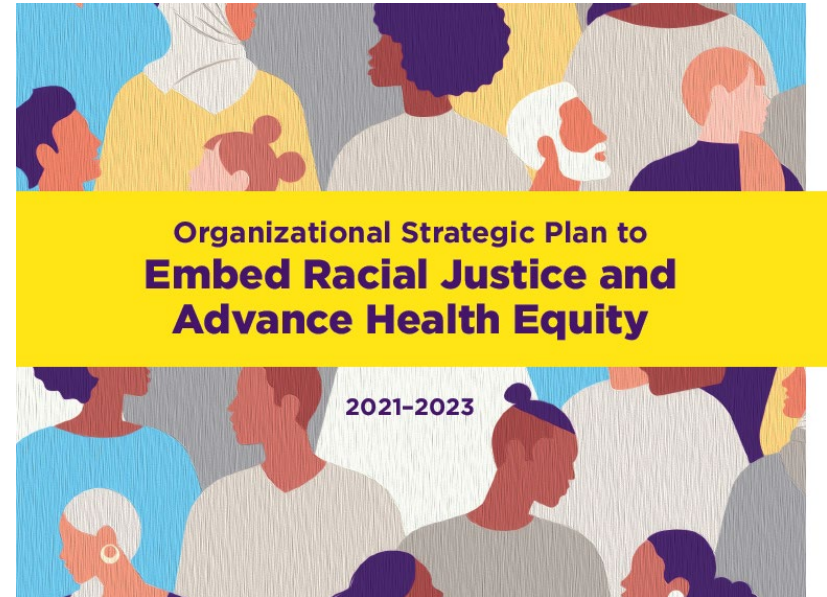
Medicine's next frontier – Health2047

- Silicon Valley-based business development company **founded by the AMA in 2017**.
- Integrates physician experience and expertise into the design and commercialization of new health care technologies.
- Work focused in four areas:
 - Enable data liquidity
 - Realign systems to better manage chronic care
 - Enhance productivity at all levels
 - Facilitate value-based payments



AMA's commitment to equity and justice

- Three-year plan to address racial justice and health equity in medicine launched in May 2021
- AMA seeks to:
 - **Embed equity and racial justice throughout the AMA**
 - **Build alliances with marginalized physicians and other stakeholders**
 - **Push upstream to address determinants of health and root causes of inequities**
 - **Ensure equitable structures and opportunities in innovation**
 - **Foster pathways for truth, racial healing, reconciliation and transformation for AMA's past**



AMA Equity Strategy and Innovation

To push upstream, AMA is working to “...equip physicians and health systems to improve services, technology, partnerships and payment models that advance public health and health equity.”

- Accelerate and support the formation of cross-sector coordination, use of technology, adoption of national equity standards, and payment models that support integrated social needs and community-based social determinants of health approaches.

AMA is working to insure equitable structures and opportunities in innovation.

- AMA is collaborating with stakeholders to embed social justice and health equity into existing innovation strategies, processes, products and policies—including our digital health, telemedicine, AI, precision medicine, data and interoperability initiatives.



What CPT Is

(and why you should care)

Level Set Your CPT Knowledge: A Poll

What are Current Procedural Terminology (CPT®) codes?

A uniform language of descriptive terms and identifying codes

Accurately describes medical, surgical, and diagnostic services

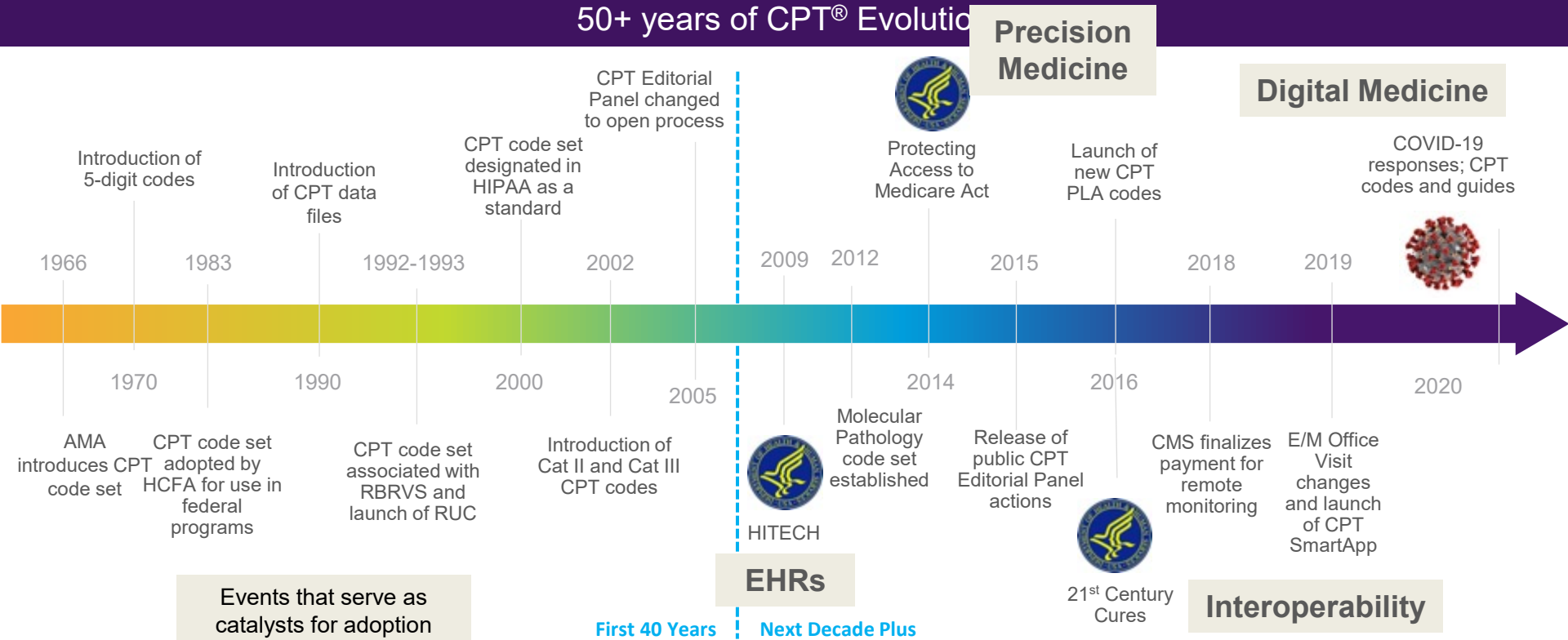
Effective, reliable nationwide communication among:

- Physicians and other qualified health care professionals
 - Patients
 - Third parties (eg, insurers)

CPT code set history



50+ years of CPT® Evolution



Events that serve as catalysts for adoption

First 40 Years

EHRs

Next Decade Plus

Precision Medicine

Digital Medicine

21st Century Cures

Interoperability

Why learn about CPT[®] codes?

Your innovation could provide better care for patients.
A CPT code could help. How?

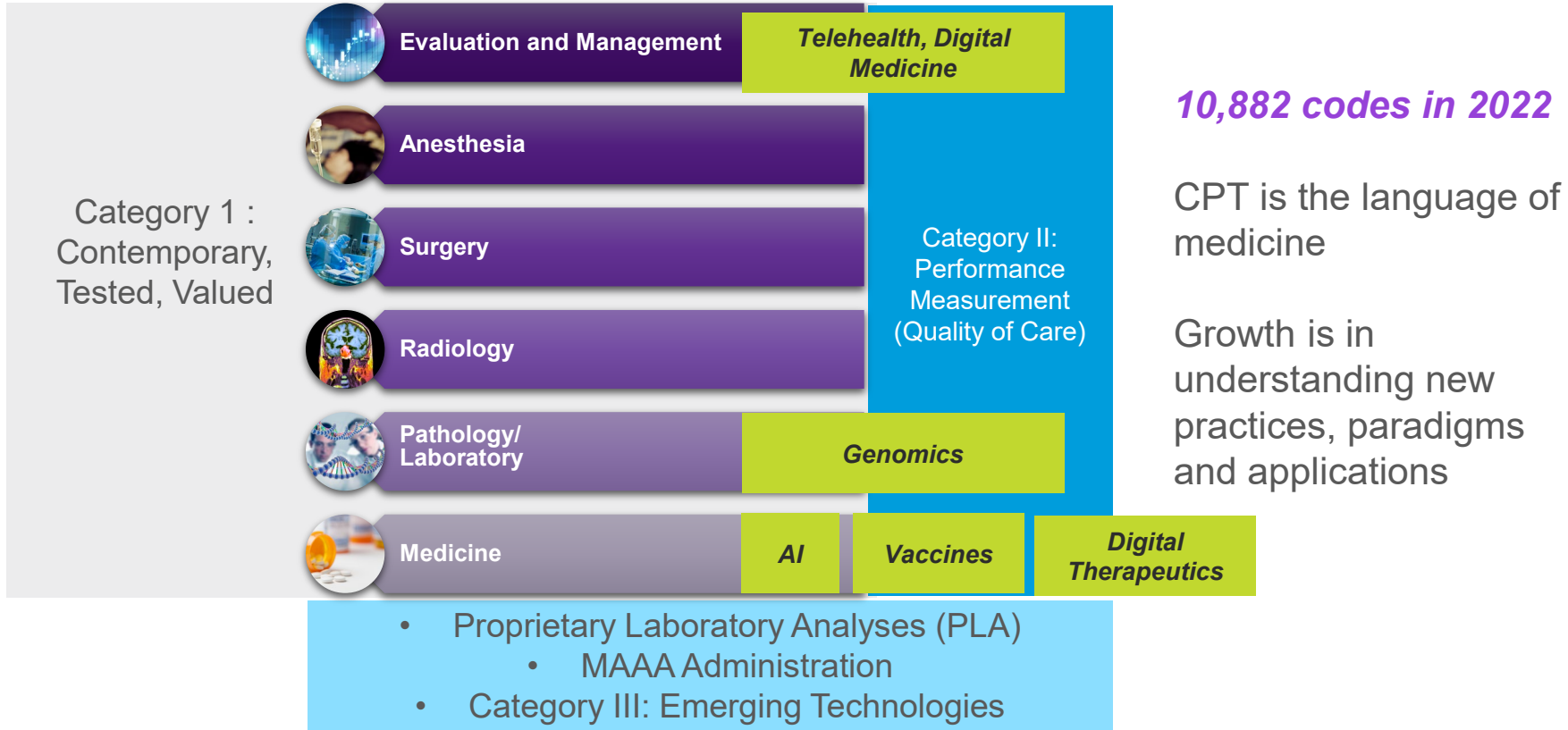
Credibility – CPT codes are the language of medicine. Care provided by physicians is captured by CPT codes.

Coverage – Insurance companies also use CPT codes to describe what procedures are covered. Nearly \$1trillion of healthcare is covered every year.

Adoption – One of the key questions that physicians ask with a new tool or procedure is whether they will be reimbursed for using it.

CPT codes are a key step on the path to **reimbursement**.

CPT code set moves at the pace of medicine



CPT codes are a common language

Patient Says:



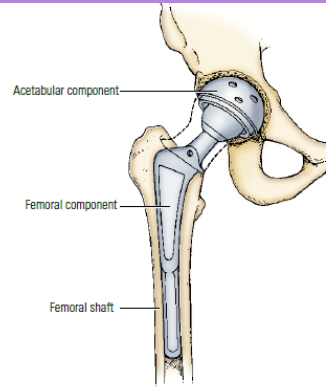
I got a new hip!

Patient Sees:

Consumer Descriptors

27130 Replacement of thigh bone and hip joint with prosthesis

CPT codes see:



Total Hip Replacement

27130

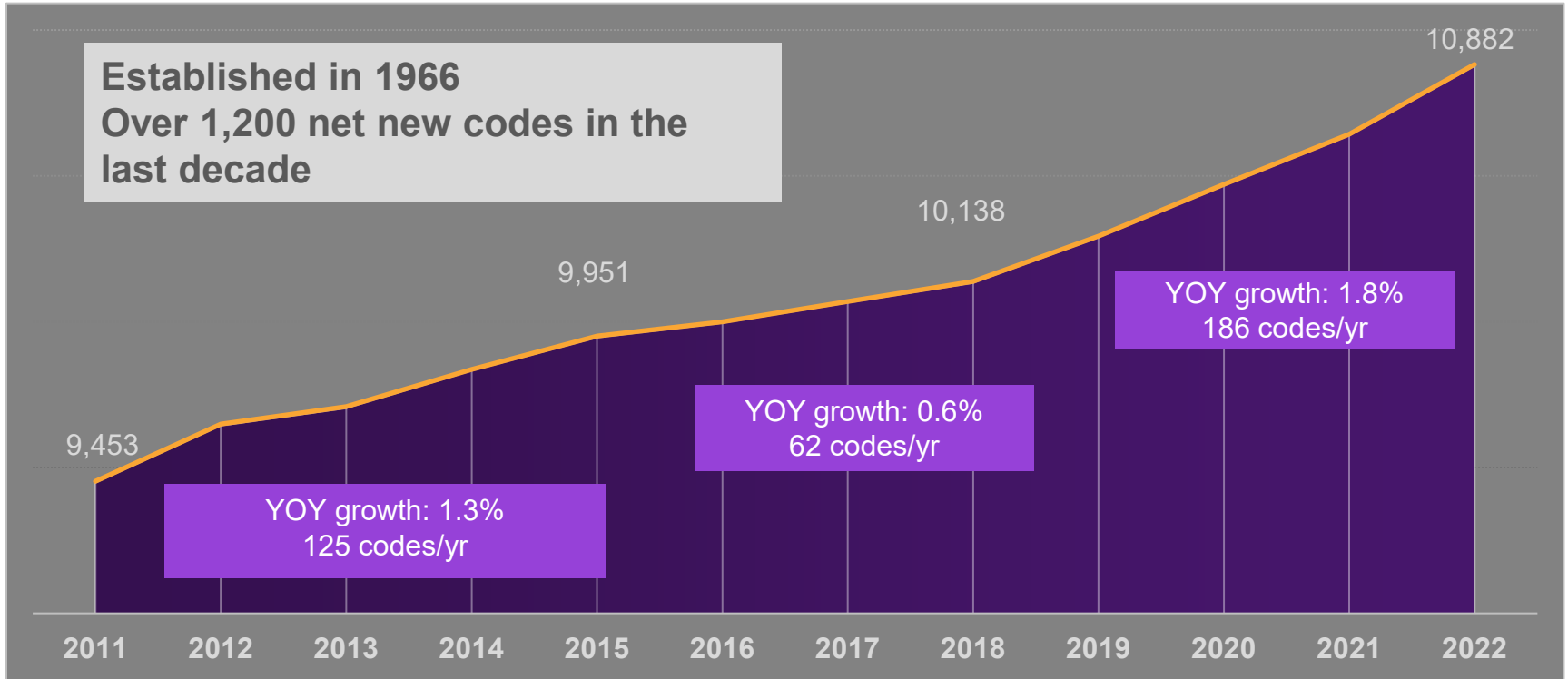
The femoral head is excised, osteophytes are removed, and acetabulum is reamed out before replacement is inserted in the femoral shaft.

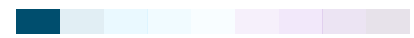
CPT codes say:

27130 Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft

Data liquidity – Interoperability

The pace of CPT code growth is increasing

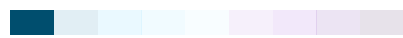




Why Health Equity Matters in CPT

- Equity and innovation intersect to influence population level health outcomes (e.g., Differential *access* to technologies, variations in *adoption* and *use*).
- Health equity issues are catalysts for the development of innovative solutions and technologies that reduce social inequalities.
 - COVID-19 pandemic: telehealth and remote care technologies have been critical
- Bringing innovations to CPT with a health equity lens enhances adoption and increases value across health serving industries.

Weiss D, Rydland HT, Øversveen E, Jensen MR, Solhaug S, Krokstad S. Innovative technologies and social inequalities in health: A scoping review of the literature. *PLoS One*. 2018;13(4):e0195447. Published 2018 Apr 3. doi:10.1371/journal.pone.0195447



Inequities in health tech: who is left out?

Advancements in digital health and telemedicine are **not** reaching nor improving health in all communities equally - **Black, Brown, and low-income populations are left behind the most.**

Patient Portals

- Despite nearly universal provision of patient portals, only about a third of patients are using them.
- Black and older patients are less likely to use portals.
- Even when digital devices are provided, there are still persistent gaps in usage.

Mobile Health

- There are a wide variety of telehealth apps in the marketplace, but few apps address the needs of the patients who could benefit the most.
- Many do not have clinical utility or properly ensure crisis management for high-need populations with chronic conditions.

Telehealth

- At least 1 in 4 Americans may not have digital literacy skills or access to Internet-enabled digital devices to engage in video visits.
- Medicaid, low-income, and rural populations do not use live video communication as widely as other groups.

Innovators are the key to bridging the gap

References:

- <https://www.liebertpub.com/doi/10.1089/tmj.2019.0065>
- <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.0578>
- <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0123#r10>





The Who

Key CPT Groups

CPT Editorial Panel Video

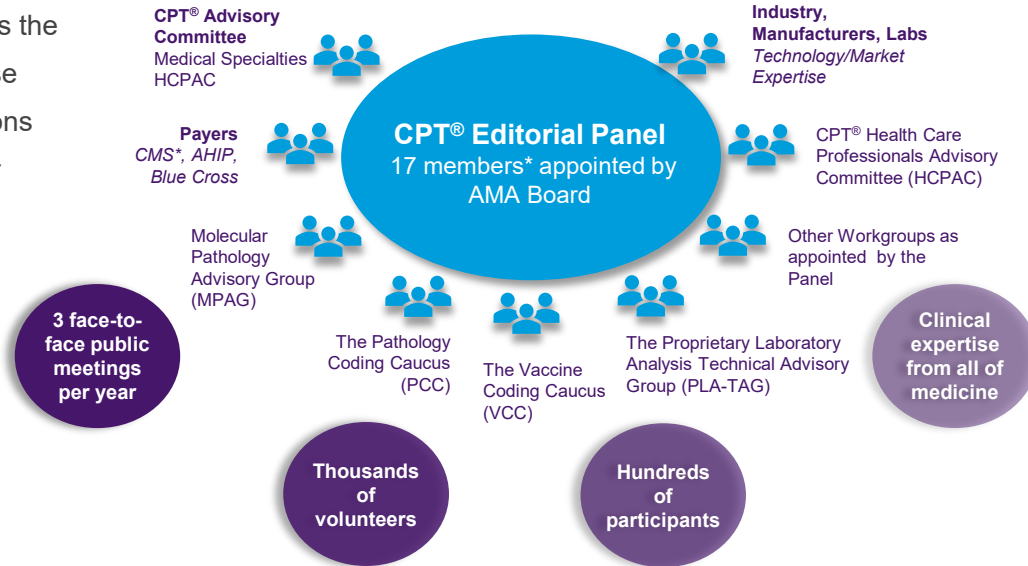


The CPT® Editorial Panel



The CPT® Editorial Panel has the sole authority to create, revise and update codes, descriptions and applicable guidelines for appropriate CPT® coding.

**CMS has observer status*



CPT® Editorial Panel members do not advocate for their specialty or organization once named to the Panel.

CPT Editorial Panel - Expansion

- At the recent April 2021 AMA BoT meeting, four additional seats were added to the CPT Editorial Panel



- Call for nominations held this summer
- The Panel supports diversity, equity, and inclusion in its members and its policies
- The AMA encourages qualified candidates of all backgrounds that meet the criteria outlined for Panel membership to apply for these positions

Who are CPT Advisors?

CPT Advisory Committee

Over 100 Medical
Specialty Societies with
membership in the AMA
House of Delegates

Organizations
representing non-
physician healthcare
professionals

CPT Health Care Professionals Advisory
Committee (HCPAC)

The CPT[®] Assistant Editorial Board

CPT Assistant is the Official Source for CPT Coding Guidance

Organizational Board Members (5)

American Hospital Association

CMS

AMA Specialty Society
RVS Update Cmte

Blue Cross Blue Shield Association

AHIP



Elected Board Members (6)

Contract Medical Director

Current/former HCPAC Member

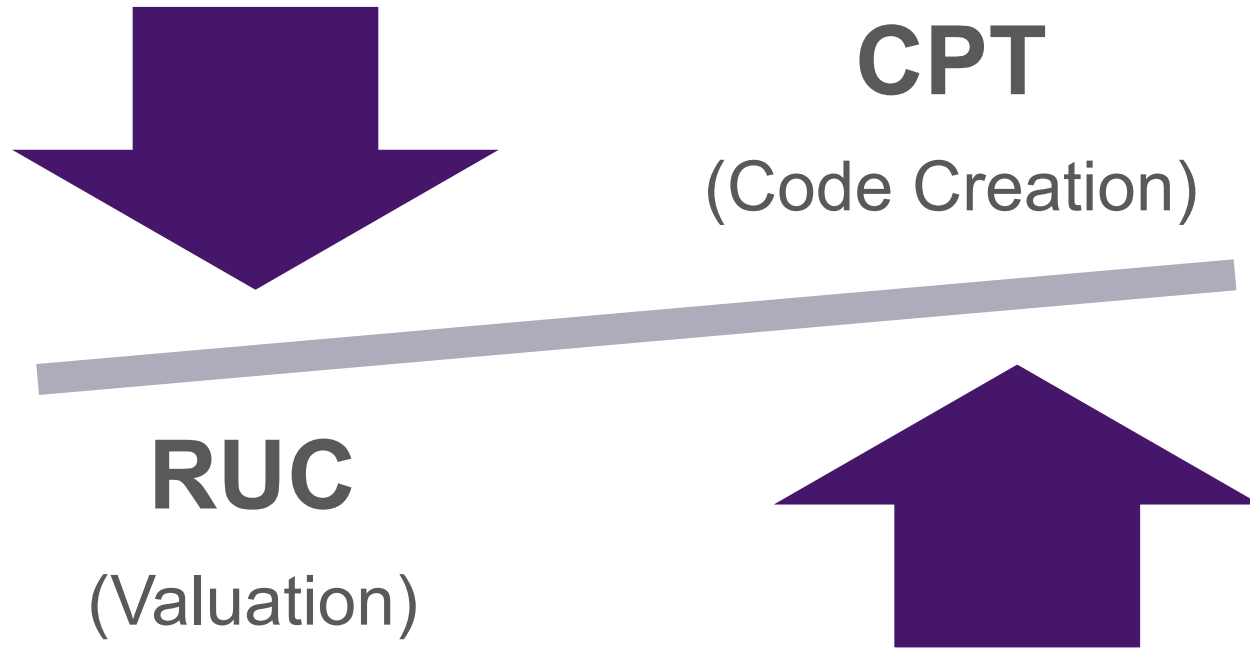
CPT Advisory Committee member – Non-surgical

CPT Advisory Committee member – Surgical

Current/Former CPT Editorial Panel – Non-surgical

Current/Former CPT Editorial Panel member - Surgical

The CPT code set & the AMA/Specialty Society RVS Update Committee (RUC) – One Story

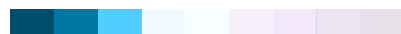




The What

The Payer Landscape

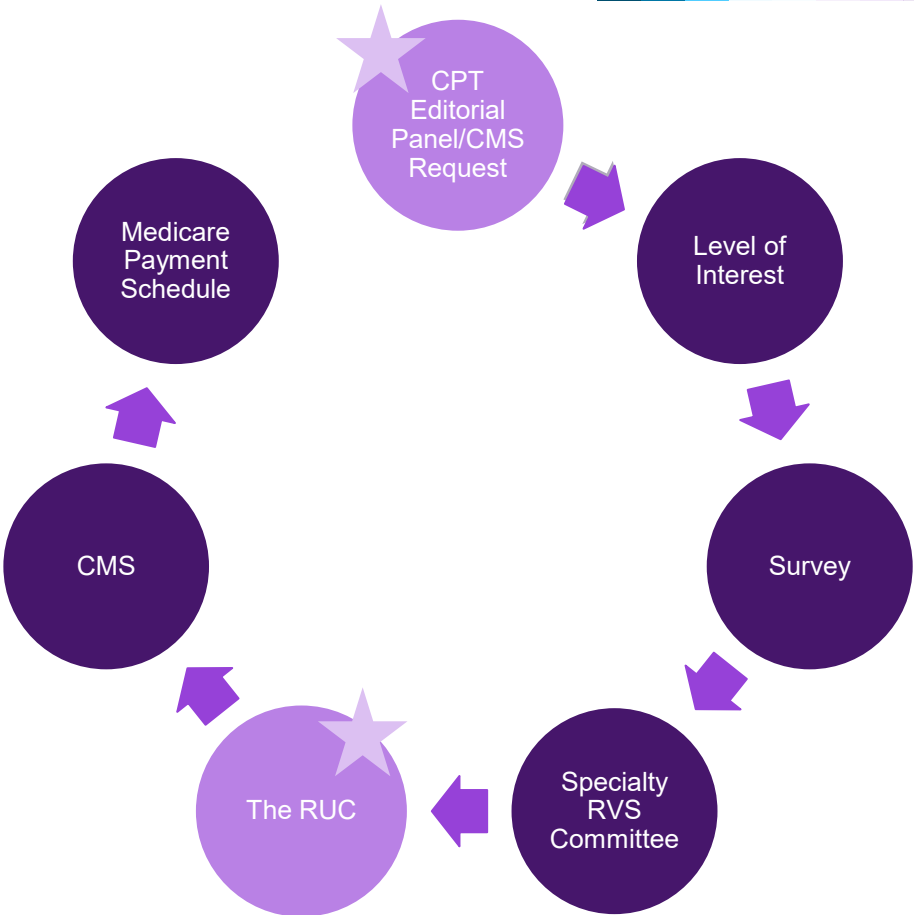
How CPT Enhancements Embrace Innovation



CPT & RUC

Additional Reimbursement mechanisms

- PLA
- Clinical Lab Fee Schedule (CLFS)
- Category III



The Payer Landscape

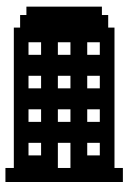
CMS

59 Million enrollees
(18% of U.S. Population;
28% of adult population)



Largest single purchaser of personal health care
(22% of \$3 *Trillion* spend)

Roles:



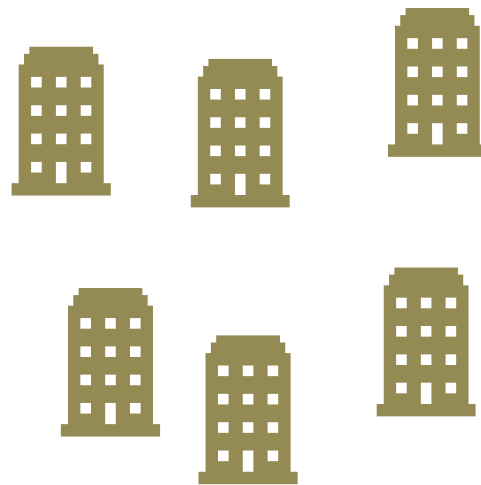
Payer

and



Regulator

Other Payers



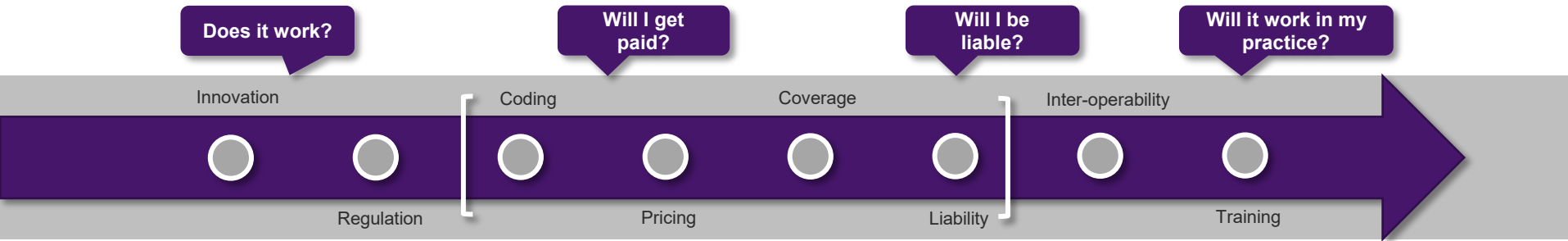
CMS' policies significantly influence other payers

CPT Codes - not limited to fee-for-service

All benefit from CPT common language

- Consumer driven health care
- Cash pay models
- Freemium model
- Diagnostic coding

CPT Focus on Digital Health: The AMA-Convened Digital Medicine Payment Advisory Group (DMPAG)



Aggregate evidence base

Address gaps in coding

Propagate widespread coverage

- ✔ Remote physiologic monitoring and Internet consultation codes
- ✔ Gain broader coverage of remote monitoring services with payers like CMS
- ✔ DMPAG created use cases and consolidated evidence from hundreds of studies

13 nationally recognized advisors engages a diverse cross-section of nationally recognized experts Panel and RUC members.

DMPAG Focus Areas

Coding/Payment

Create a taxonomy in coding for digital health

Review face to face service definitions in the age of digital medicine

Artificial Intelligence

Development of payment pathways for AI and related services such as digital therapeutics

Advocacy

Focus on geographic and originating site digital medicine restrictions

Continued dissemination of data on effectiveness of digital medicine

CPT® Coding for Digital Medicine: 2019–2022

Remote Physiologic Monitoring



Between 2019 and 2020, the Panel created four new codes to allow physicians and other qualified healthcare professionals the ability to report **remote monitoring** of conditions not currently covered by existing CPT codes. The Panel considered the typical patient to be an individual needing management of heart failure.

99446 | 99447 | 99448 | 99449 | 99451 | 99452

Remote Therapeutic Monitoring



For the 2022 code set, the Panel created five new codes to allow report **remote therapeutic monitoring** services. The Panel's goal in creating these services were two-fold: 1). Creating a reporting pathway for remote monitoring of "non-physiologic" parameters and 2). Placing the codes in the general Medicine section of the CPT code set to provider greater opportunities for QHPs to report.

98975 | 98976 | 98977 | 98980 | 98981

Pulmonary Artery Pressure Sensor Remote Monitoring



In 2019, the Panel created a new code to describe **remote monitoring of pulmonary artery pressure sensors**. This code was needed in addition to the established Remote Physiologic Monitoring codes (99457, 99458) because the typical patient for this service has congestive heart failure and requires additional time and complexity.

93264

Online Digital Evaluation Service (E-Visit)

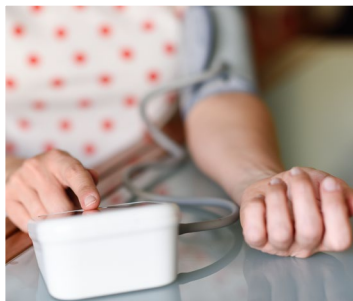


In 2020, the Panel created six new codes to describe novel digital communication tools, such as **patient portals**, that allow health care professionals to more efficiently **connect with patients** at home and exchange information.

99421 | 99422 | 99423 | 98970 | 98971 | 98972

CPT[®] Coding for Digital Medicine: 2019–2022

Self-Measured Blood Pressure Monitoring



For 2020, the Panel created two new codes to better support home blood pressure monitoring that aligns with current clinical practice. While not solely digital services, the goal of these codes is to **expand reporting pathways** for physicians across the country who take care of a **diverse** set of **patients** that have varying degrees of **access** to care.

99473 | 99474

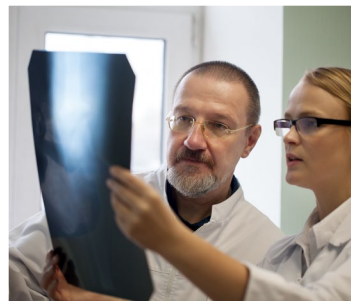
Remote Retinal Imaging



For the CY 2021 CPT code set, the Panel created a new code 92229, which describes technology that identifies diabetic retinopathy through **automated AI**, which set a foundation for the first truly automated AI service in the CPT code set.

92227 | 92228 | 92229

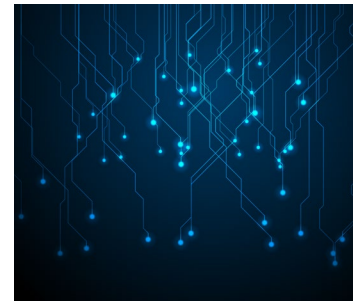
Remote Optical Coherence Tomography



For 2021, the Panel created several codes to report patient-initiated remote retinal OCT **utilizing AI** to analyze the patient generated data and then create a report that is reviewed by a physician/QHP.

0604T | 0605T | 0606T

Digital Taxonomy



For 2022, the Panel created a **taxonomy** that visually communicates all of the CPT codes that correspond to **digital medicine** and how the associated work is either distinct or overlaps. This new reference source will be a helpful visual for users to both better understand which codes apply to digital medicine and what coding gaps may still remain for emerging services.

Proprietary Laboratory Analyses (PLA) Codes Deliver Laboratory Innovation

- Specific to labs or manufacturers that wish to uniquely identify their laboratory test
- Code criteria -
 - The test must be commercially available in the US for use on human specimens
 - The clinical laboratory or manufacturer that offers the test must request the code
- Over 150 codes issued since 2016
- Constant innovation: codes updated four times per year





Category III Codes Fuel the Range of Innovation

Temporary alphanumeric new and emerging technology, procedures and services

- Created for data collection and assessment of new services and procedures
- One of the most visible areas of change
- Codes are temporary: many convert to Category I
- Rapid expansion: code volumes have increased **246 percent** since 2011

CPT[®] Meets the Challenge of Rapid Innovation: Telemedicine implementation and COVID-19

Expectation



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Vs.

Reality



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The When and The How

Innovation Lifecycles and the CPT Process

How Innovators Interact

Let's talk about... Processes

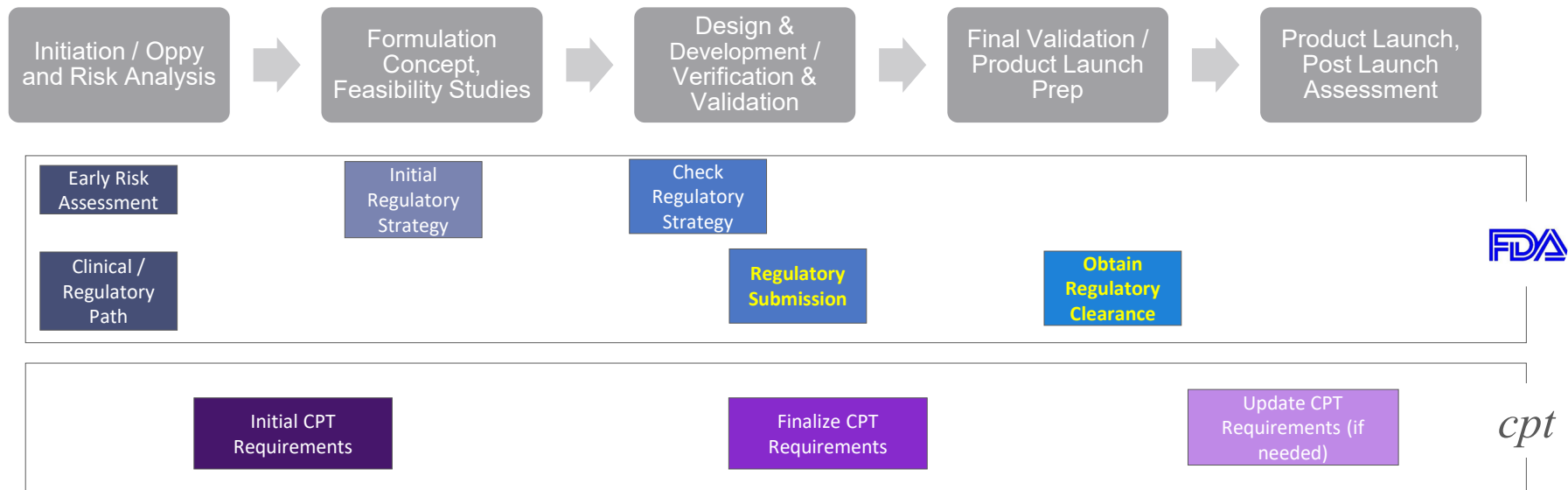
CPT

FDA

Device Development

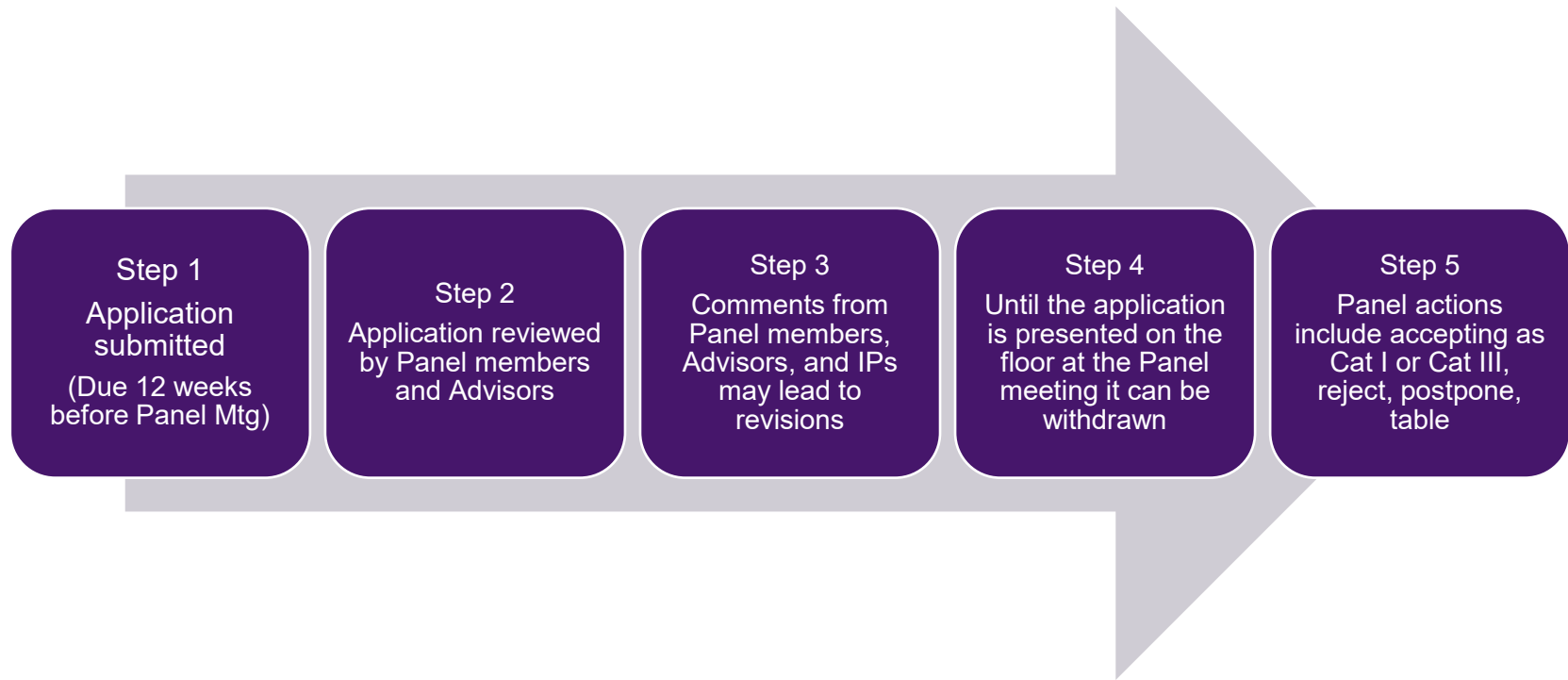
Put it Together: CPT, FDA and Device Development

Timeframe: Historically 3 – 7 Years (or more...) Today: Less



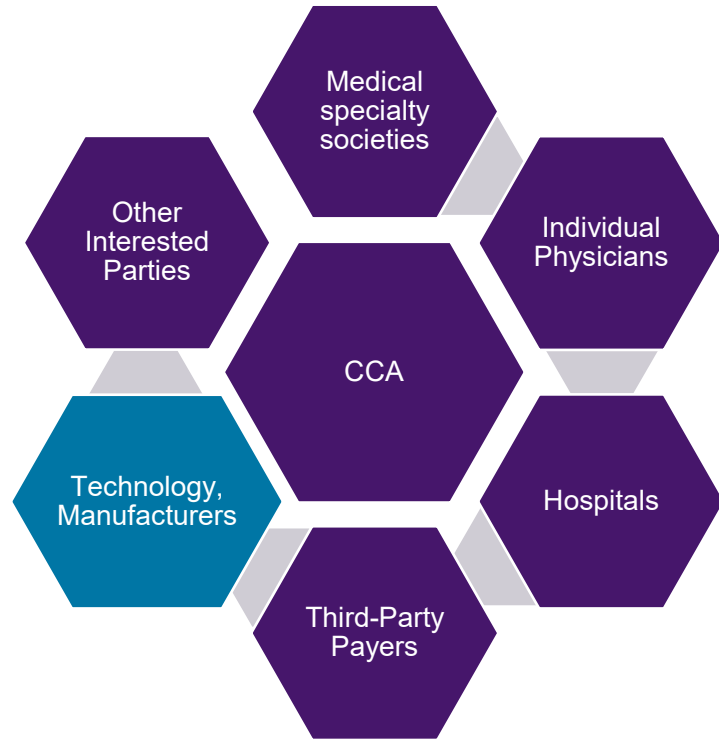
Consider CPT requirements throughout your development process

The CPT Code Change Application (CCA) Process – Key Steps



CPT process step 1: Code Change Application (CCA)

- Used to request CPT revisions: adding and deleting codes, modifying existing nomenclature
- CCAs can originate from many groups



CPT Process Step 1: Code Change Application - Key Components (Category I and III)

FDA Status

Rationale

Proposed New Code descriptor, parentheses, guidelines

Current CPT codes in use, differences from other established codes

Who Typically Provides the Service?* (*Digital options included*)

Conditions to treat

Utilization Data

Studies / Literature

Known Guidelines / Policy

Clinical Vignette and Description of Service

CPT process step 2: CPT Panel review

The CPT Panel uses a set of objective criteria to determine the appropriateness of code requests



Each Panel member reviews each application and votes based upon that review, using their own clinical judgment



CPT Category I and III: General Criteria Highlights*

- Descriptor is **unique, well-defined**; describes a procedure or service which is **clearly identified and distinguished from existing procedures and services**
- **Consistent with current Editorial Panel standards**
- **Neither a fragmentation of an existing procedure or service, nor currently reportable as a complete service by one or more existing codes** (with the exclusion of unlisted codes). However, procedures and services frequently performed together may require new or revised codes
- Proposed descriptor **accurately reflects the procedure or service as typically performed**
- **Not proposed as a means to report extraordinary circumstances** related to the performance of a procedure or service already described in the CPT code set
- **Satisfies the category-specific criteria.**

** Abbreviated for presentation purposes only*



CPT Category I Criteria*

- All devices and drugs necessary for performance of the procedure or service **have received FDA clearance or approval** when such is required for performance of the procedure or service;
- Performed by many physicians or other qualified health care professionals **across the United States**
- **Performed with frequency consistent with the intended clinical use** (i.e., a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume);
- **Consistent with current medical practice**;
- **Clinical efficacy is documented in literature** that meets CPT code change application requirements

** Abbreviated for presentation purposes only*

CPT Category III Criteria*

- **Currently or recently performed in humans, AND**

At least one of the following additional criteria :

- **Supported by at least one CPT or HCPAC advisor representing practitioners** who would use this procedure or service; **OR**
- **Actual or potential clinical efficacy is supported by peer reviewed literature; OR**
- There is a) at least one Institutional Review Board approved protocol of a study of the procedure or service being performed, b) a description of a current and ongoing United States trial outlining the efficacy of the procedure or service, or c) other **evidence of evolving clinical utilization.**

** Abbreviated for presentation purposes only*



CPT process steps 3 and 4: Comment Period, Withdrawals

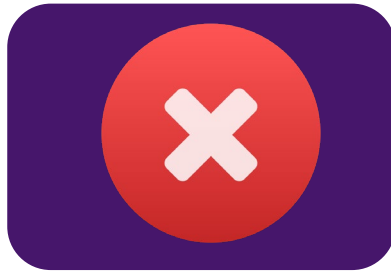
- Applications reviewed by AMA staff
- Comments are compiled from CPT Advisors, Panel and Interested Parties (IPs)
- Agenda publicly posted 30 days in advance
- Until the application is presented on the floor at the Panel meeting it can be withdrawn

CPT process step 5: at the CPT Editorial Panel meeting

- Applicants attend, answer questions from Panel and reviewers
- Opportunity for input from the General Audience
- Panel members vote anonymously
- Possible actions:



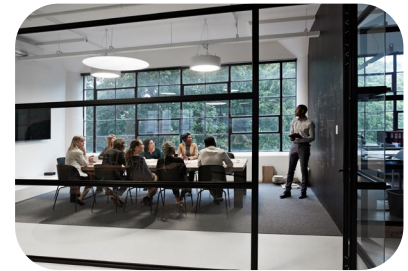
Accept



Reject



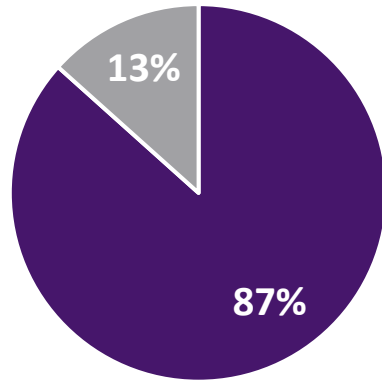
Postpone



Table

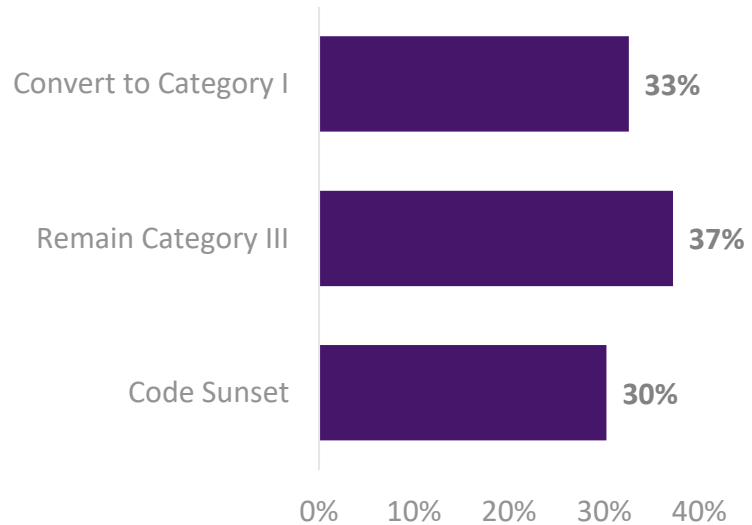
Category III: Experience over time

Cat III applications,
2008-2019 (n=187)



■ Approval ■ Rejection

Category III Code Status: 5+
years forward



Based on 86 Category III applications approved between 2008 and 2014; status as of 2019



Category III: Areas for Application Improvement

- While the criteria for Category III codes is, relative to Category I codes, less intensive, there are still critical issues to address before your submission
- Commonly seen reason with rejections: Ensuring that an existing CPT code(s) doesn't already address some or part of your service/procedure
- General CPT criteria:
 - *The proposed descriptor for the procedure or service is neither a fragmentation of an existing procedure or service nor currently reportable as a complete service by 1 or more existing codes (with the exclusion of unlisted codes). However, procedures and services frequently performed together may require new or revised codes*



Category III: Consider Importance to your coding pathway

Ensure that your desired coding pathway is well researched; for both timing and coverage concerns

- An Example:
 - Company with new innovation opts to use a rarely used Category I CPT code (versus applying for a Category III code)
 - Utilization of CPT code is driven up; catalyst for re-evaluation by the RUC, or referral to the CPT Editorial Panel
 - CPT code is evaluated based on *Category I* criteria
 - Innovation is carved out into a separate Category III code, due to lack of specified widespread volume and potentially clinical efficacy defined in the literature.
 - CPT Network is a resource to obtain official AMA guidance on coding for your specific service/procedure.

FDA - 510(k) Submission: parallels with CPT CCA

Device Class	Code Category (I / III)
Section 514 (performance standards compliance requirements)	
Proposed labels, labeling, and advertisements (describe device, intended use, directions)	Proposed New Code descriptor, parentheticals, guidelines Clinical Vignette and Description of Service
Statement: device is similar to and/or different from other products of comparable type	Current CPT codes in use, differences from other established codes
510(k) summary	
Financial certification/disclosure statement	
Investigational data: US (Part 50; Part 56 (IRB), Part 812) or Outside US (GCP, §812.28)	Utilization Data, Literature
Search of all information / available about the device and other similar legally marketed devices	Known Guidelines / Policy
'Truthful and Accurate' Statement	

FDA - PMA Submission: parallels with CPT CCA

Name/Address

Name / Address

Table of Contents

Application Summary

Conditions to Treat, Current CPT Codes in use & differences from other established codes, Clinical Vignette

Complete Device Description

Proposed New Code descriptor, parentheses, guidelines, Description of Service, Who Typically Provides the Service

Performance Standard Reference (Section 514)

Data: Nonclinical Laboratory Studies and Clinical Investigations

Utilization Data, Studies

Bibliography

Studies / Literature

Device Sample

Proposed Labeling

Mfr. Product Insert (Labs)

Environmental assessment

Financial Certification

Use in Pediatric Patients

Literature

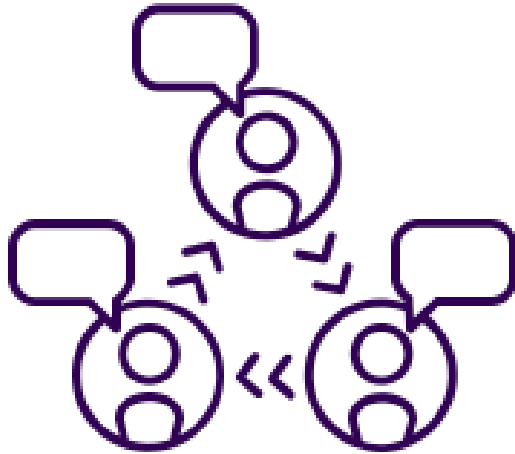
Enhancing the CPT® Process: Simpler Requirements



Literature Standards Update

- Assist applicants with the code application process
- Clarify the impact and use of literature on the outcome of CPT Editorial Panel consideration
- Increase focus on identifying and documenting papers that have overlapping authors and/or patient populations
- Literature submitted no longer requires a U.S. patient population
- Help applicants better select the most appropriate level of evidence

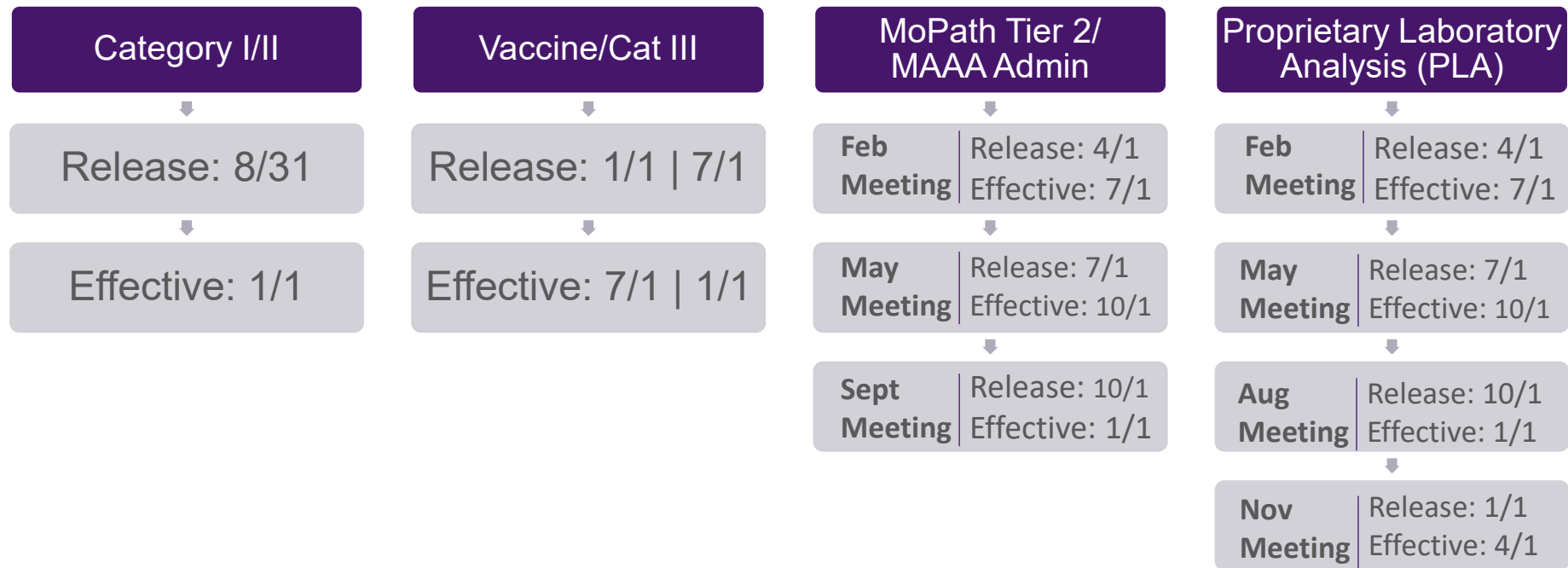
Enhancing the CPT® Process: Open Collaboration



Interested Party Process

- “Interested party” = Open opportunity for anyone to review/comment code change submissions
- Stakeholders *not* represented by advisors can review and comment on agenda items coming before the CPT Editorial Panel
 - Within deadlines for submitting written comments
- Additional verbal comments can be provided in person, at any CPT Editorial Panel meeting
 - Acceptance of a statement of conflict of interest
- Interested party requests are processed within 5 days of form receipt

Current Annual Code Release Schedule

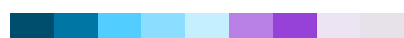




Debunking

Q&A

Resources



CPT process evolution: the importance of feedback

- CPT process continues to move with medicine
- Utilizing the CPT code set for all types of procedures and services used by physicians involved in healthcare delivery helps to maximize efficiency and improve patient care; CPT Advances AMA's mission
- Hearing from stakeholders helps ensure that CPT processes understand industry needs, facilitate active participation
- Feedback also ensures that CPT remains a uniform, up to date language by which medical professionals can communicate regarding medical services.

CPT Myths... Debunked

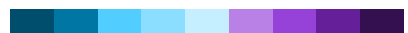
Myth

- Submittal process takes forever to complete
- Lack of transparency
- Little help for new submitters
- Complexity works against the applicant
- Category III Codes don't get reimbursed

Debunked

- NEW “CPT Code Change Application Tool (CCAT)” for code change submissions reduces administrative issues related to paper-based form
- Open Panel process since 2005
- 2019 Part B fee for service payments for Category III codes: \$212 million

Q&A



CPT Resources – For More Information

Visit the CPT code set quick reference guide page to learn more about AMA and CPT resources on:

- The CPT Editorial Panel Process, including code change application details and the Editorial Panel meetings calendar
- CPT News, for the latest in CPT Codes and Content
- Innovation and Technology
- Medical Practice Management
- Health Equity

And... sending in your questions!

<https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-set-quick-reference-guide>



Physicians' powerful ally in patient care