Connecting the Dots: From FDA Regulation to CPT® Coding :

PRESENTED BY
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Dec. 7, 2023

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AMA: The Physicians' Powerful Ally in Patient Care

Making Technology an Asset in the Delivery of Care

AMA research, resources and authoritative guidance

AMA DIGITAL HEALTH RESEARCH
(2016, 2019, 2022)

AUGMENTED INTELLIGENCE (AI) PRINCIPLES

AMA DIGITAL HEALTH PLAYBOOK SERIES
(RPM, TELEHEALTH, HAH, AI)

AMA FUTURE OF HEALTH
(IMMERSION PROGRAM)

CPT® coding resources

AMA DIGITAL MEDICINE PAYMENT ADVISORY GROUP (DMPAG)

CPT® APPENDIX S: AI TAXONOMY FOR MEDICAL SERVICES & PROCEDURES

Collaborations across the health care innovation ecosystem

HEALTH2047

PHYSICIAN INNOVATION NETWORK (PIN)

CPT DEVELOPER PROGRAM

DATA STANDARDS & INTEROPERABILITY INITIATIVES

ENSURING EQUITY IN INNOVATION

Understanding the CPT® Code Set, the Language of Medicine Today

Internal Panel Process Support

External Panel Process Support

The CPT Editorial Panel (the Panel) is responsible for ***creating, revising, and updating codes, descriptions and applicable guidelines*** for appropriate CPT coding.

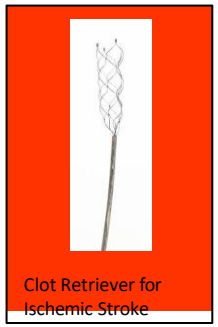
FDA's Role in Medical Device Regulation

Douglas E. Kelly, MD
Deputy Center Director for Science
Office of the Center Director, CDRH, US FDA
CPT Webinar
December, 2023

FDA Mission:
Historical Basis

- Protect the public from unsafe products

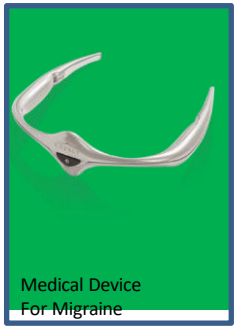
FDA also catalyzes innovation and moves Medical Devices from **Bench to Market**


Clot Retriever for Ischemic Stroke


Ablation Therapy


Cognitive Function following concussion


Prosthetic Arm


Medical Device For Migraine


Microcatheters for the neurovasculature

FDA's Public Health Mission: *Timely* patient access to *safe* and *effective* medical devices

The Office

FDA Regulatory Review of Medical Devices and Clinical Investigations

Discussion Topics

- Intro to the FDA's Review of Medical Devices
- Regulatory Paths to Market
- Marketing Applications
- Investigational Device Exemptions (IDE studies)
- Special Programs and evolution of TAP

Medical Device Definition

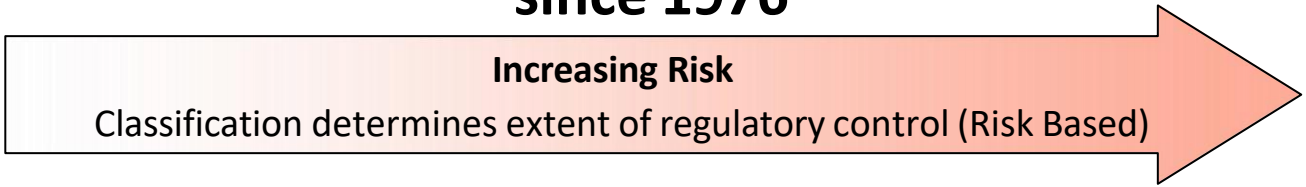
- Definition of a medical device is specified in section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) *
- Section 201(h) states in part:
  - The term “device”…means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…”
  - “…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…” or
  - “…intended to affect the structure or any function of the body of man and which does not achieve any of its primary intended purposes through chemical action….”

A Few Medical Device Regulatory Concepts

- Device classification is based on risk
- Use **valid scientific evidence**
- **Weigh benefit vs. risk** to determine safety and effectiveness
- Provide "**reasonable assurance**" of safety and effectiveness
- Assess based on the **indication for use**
- **Least burdensome rule**

1976 Medical Device Act

A Risk Based Approach for Medical Devices since 1976



Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Performance testing, such as biocompatibility, engineering, animal, etc.
- Special Labeling

Types of Marketing Submissions

Regulatory Pathways and Processes

- Premarket Application (PMA)
- 510k Premarket Notification (510k)
- De Novo (DEN)
- Humanitarian Device Exemption (HDE)

Classifications & Regulatory Pathways

- Class III: generally PMA (Premarket Approval)
- Class II: 510(k) (or premarket notification), if the intended use and technology are similar to something already classified
- De Novo: devices that aren't comparable enough to something on the market. This generates a new device regulation, and will typically (but not always) be Class II
- Class I: lowest risk; typically exempt from a regulatory submission; subject to registration and listing

Premarket Approval (PMA)

- Used for approval of **Class III devices (highest risk)**
- Majority of PMA applications are **supported by clinical data generated under an Investigational Device Exemption (IDE)**
- May (or may not) go to an **FDA Advisory Panel meeting**
- Subject to **annual reporting** after approval
- Subject to notification of manufacturing process changes if the change can affect the safety and effectiveness of the finished device through 30-Day Notices
- May be subject to **post-approval studies (PAS)** as a condition of approval
- Requires concurrent **Manufacturing/GMP and Bioresearch Monitoring Inspections Prior to Approval**

Premarket Notification [510(k)] Program

- New guidance document issued July 28, 2014 ("The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"

- Establishes **substantial equivalence (SE) to a legally marketed primary predicate device.**
  - The same intended use and the same technological characteristics as the primary predicate device.

    OR

  - The same intended use and different technological characteristics, but the different technological characteristics:
    - Does not raise different questions of safety and effectiveness, and
    - Performance data is available to demonstrate that the new device has a similar safety and effectiveness profile as the primary predicate.

De Novo

- Appropriate for **low to moderate risk devices that do not fall within any classification regulation**, based on:
  - A **Not Substantially Equivalent (NSE) decision** to a legally-marketed predicate device through the 510(k) process, or
  - Direct submission because the device is believed to be **appropriate for classification into Class I or II, and there is no legally marketed predicate device.**
- **General controls or general and special controls** that can be written to provide reasonable assurance of the safety and effectiveness of the device, and address all of the known risks.
- **Generates a new device regulation**.

When is Clinical Data Needed?

- PMA: typically needed
- 510(k): typically not needed
- De novo: typically needed, but not always

Applicants can request feedback on any protocols through a Q-sub, preferably before starting the study.

Investigational Device Exemptions (IDEs)

- **An IDE is a regulatory submission that permits clinical investigation of devices.**

- 21 CFR 812.1:

*"An approved **investigational device exemption (IDE)** permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be **shipped lawfully** for the purpose of **conducting investigations** of that device."*

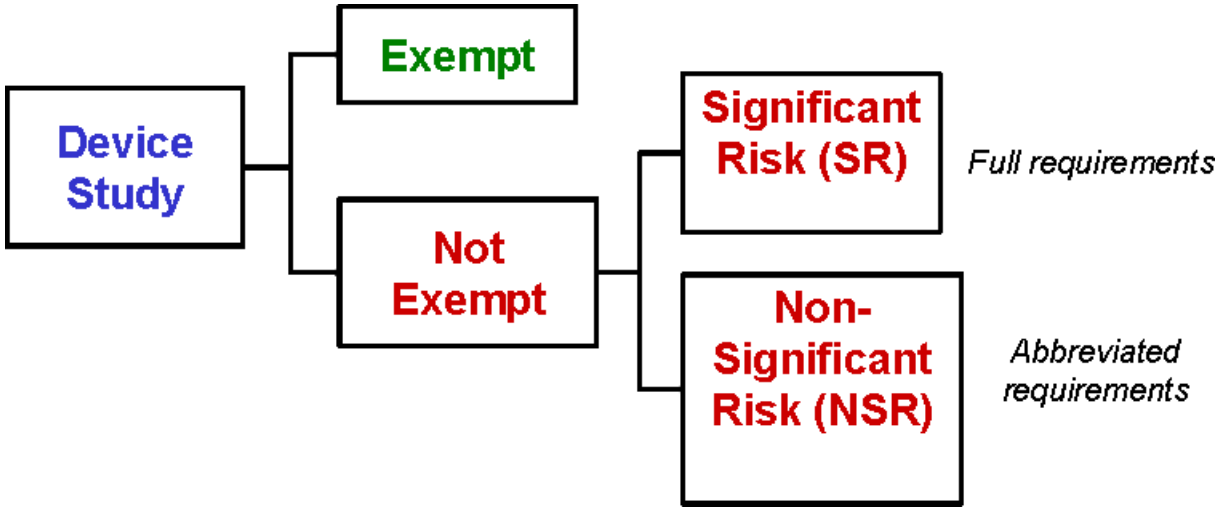
IDE Study Types

- **Pivotal Study**
  - Designed to collect definitive evidence on safety and effectiveness for a specified intended use, typically in a statistically justified number of subjects
- **Sponsor-Investigator Studies**
  - Not intended to support a marketing application
  - Typically only for research purposes
- **Traditional Feasibility Study**
  - Capture preliminary safety and effectiveness data typically in a small number of subjects (typically to inform pivotal study)
  - Typically 20-30 subjects
  - Near final or final device design

IDE Study Types (Cont…)

- **Early Feasibility Study (EFS)**
  - Small number of subjects (generally < 10 subjects)
  - Device may be early in development, before final device design
  - Approval may be based on less nonclinical data than would be needed to support the initiation of a larger clinical study on a more final device design
    - EFS is only appropriate when additional nonclinical testing would not provide the information needed to advance the device design validation, verification, and development process.
  - For example, EFS can be utilized to gain initial clinical user experience
  - Guidance ***"Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies"***

You want to study a device…
When is an IDE Needed?



Exempt Device Study

- Studies for Basic Physiologic Research
- Many In-Vitro Diagnostic Studies
- Studies of Marketed Devices Used On-Label
  - Studies of Off-Label Use of Marketed Devices is **NOT** Exempt (e.g., general cleared tool indications vs. treatment for a specific patient population that can affect clinical outcomes)

Non-Exempt Studies

- **Non-Significant Risk** – no IDE submission to FDA needed
  - Abbreviated requirements (labeling, IRB, consent, monitoring, reporting, prohibition on promotion)
  - IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies.
  - An NSR device study may start at the institution as soon as the IRB reviews and approves the study

- **Significant Risk** –Study can not begin until IDE is approved by FDA

Significant Risk (SR) Study

- Presents a **potential for serious risk to the health, safety, and welfare of a subject** and is:
  - an implant; or
  - used in supporting or sustaining human life; or
  - of substantial importance in diagnosing, curing, mitigating, or treating disease or preventing impairment of human health
  - otherwise poses a risk

See 21 CFR 812.3(m)

Risk Determination

- **Sponsor** makes initial determination

- **IRB (Institutional Review Board) reviews** the sponsor's determination
  - Information provided by the sponsor includes device description, prior investigations, investigational plan, subject selection, risk assessment and rationale used in making its SR or NSR determination

- If the IRB disagrees with a sponsor's NSR assessment, the IRB must inform the clinical investigator, and where appropriate, the sponsor. (21 CFR 812.66)

Study Risk Determinations Inquiries to FDA

- FDA is available to help in making the risk determination
- Sponsor submits **"Study Risk Determination" Q-Submission**
- FDA issues letter indicating if study is
  - Basic physiological research
  - Exempt
  - Not exempt: SR or NSR

"The Pre-submission Program and Meetings with FDA Staff"

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

- FDA (not the investigator or IRB) is final arbiter

Ready to Submit an IDE – Basic Elements

(21 CFR Part 812)

- Name and address of sponsor
- Background of medical issue, the study goals, and why this study will further the science
- Detailed description of the device under study
- Report of prior investigations
  - Preclinical laboratory, in vivo animal, computational modeling studies
  - Prior clinical experience and/or published scientific literature
  - Executive summary of each available study and how the evidence supports the safety of the study/device
  - Full test protocol and report, if available

Basic Elements of an IDE (Cont…)

- Risk Analysis
  - What are the potential risks to the patient?
  - Does the study mitigate the risks where possible?
  - Are the risks outweighed by the potential for benefit and/or value of the study
- Investigational Plan and Clinical Protocol (21 CFR 812.25)
  - Inclusion and exclusion criteria
  - Study objectives or endpoints
  - Patient monitoring procedures (e.g., data monitoring committee (DMC) and charter, stopping rules)
  - Follow-up plan
  - Sample size and number of investigational centers, with justification

Basic Elements of an IDE (Cont…)

- Informed Consent Document (21 CFR Part 50)
  - A statement that the study involves research, purposes of the research, subject's expected duration for participation, description of procedures, and identification of procedures are that experimental
  - Description of risks and discomforts
  - Description of potential benefits
  - Disclosure of alternative treatments
  - Disclosure of patient confidentiality and records
  - Disclosure of cost, compensation, procedures in the event of subject injury or for participation in the study
  - Contact information
  - Statement that participation is voluntary

Basic Elements of an IDE (Cont…)

- Investigator Agreement
- List of the Name, Address, and Chairperson of each IRB
- Charge for Device
- Environmental Assessment
- Labeling
  - "CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use."

FDA Decisions on IDEs

Three Outcomes

- **Approval**
  - Approves the trial for specified number of sites and subjects
  - Enrollment can begin once IRB approval is obtained

- **Approval with conditions**
  - Approves the trial for specified number of sites and subjects provided conditions (deficiencies) are addressed within 45 days
  - Enrollment can begin once IRB approval is obtained

- **Disapproval**
  - Study may not begin; sponsor must address deficiencies and obtain FDA approval to start study

FDA Additional Comments on IDEs

- **Study Design Considerations**
  - Recommendations (but not requirements) regarding study design to help study achieve its goals
- **Future Considerations**
  - Issues relevant for future submissions (e.g. future marketing application)
- Sponsors are not required to respond to these elements although most do respond to ensure they have an adequate study design.

Challenges we face in review of Medical Devices

- What is the Regulatory Path?
  - 510(k), HDE, PMA, de novo
- When is Clinical Data Needed?
  - Expansion of Indications
  - General to Specific Indications (e.g., Tool vs. Treatment Claim)
  - New Device
  - Significant Change to Device Technology

FDA Advisory Committees

To assist in its mission to protect and promote the public health, the FDA uses 50 committees and panels to obtain expert advice on scientific, technical and policy matters.

- Neurological Devices Panel of the Medical Devices Advisory Committee
- Apply for Membership

https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/default.htm

SPECIAL PROGRAMS

Device Access

FDA-Payer Parallel Review

- We are not involved with reimbursement activities but we do have an initiative to help coordinate early interaction with public and private payers
- We are available to discuss outcome measures of interest in your study which would address both FDA and payer concerns.

Resources available (please contact these channels directly)

- Payer Communication Task Force (PCTF) (https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm)
- FDA and Payer Parallel Review (with a pre-submission)
- Please review the website above and contact the CDRHPayerCommunications@fda.hhs.gov for questions

CDRH's Early Payor Feedback Program

CDRH has a voluntary program that introduces sponsors to payors to learn what data the payors may need to make a positive coverage decision

- Can invite the payor to an upcoming CDRH pre-submission meeting or meet with the payors independent of CDRH meetings
- As of January 2023, resulted in successfully matching 90 device innovator requests with payors
- Participating payors and how to apply can be found at https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force

*Slide current as of 1/10/23

What Is a Collaborative Community?

Collaborative communities are continuing forums where public and private sector members proactively work together to:

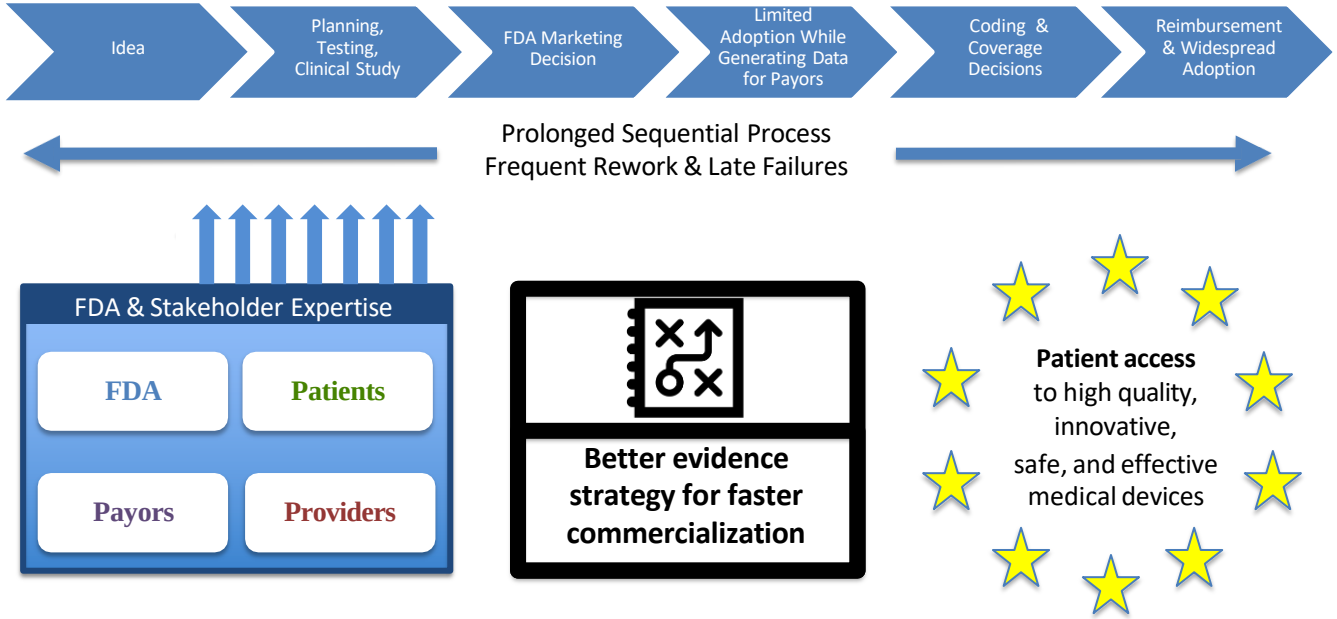
- Achieve common objectives and outcomes
- Solve shared challenges
- Leverage collective opportunities in an environment of trust, respect, empathy and openness.

Please visit CDRH website (https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together) for a Collaborative Communities Toolkit.

Breakthrough Devices Program

- Intended to help patients have more timely access to certain medical devices and device-led combination products that **provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions** by expediting their development and prioritizing their review
  - Voluntary program
  - Access to Breakthrough Interactions (Sprints, etc…)
  - Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download

Total Product Lifecycle Advisory Program (TAP)

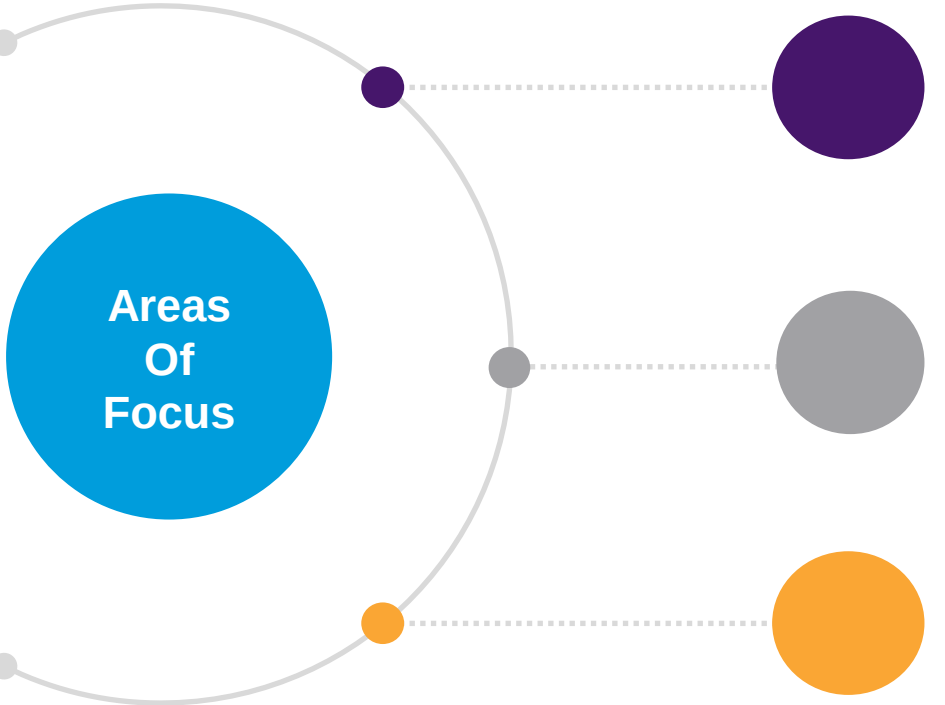


Significance of FDA Medical Device Regulation on CPT® Coding

Robert Jarrin, JD

Member

Digital Medicine Payment Advisory Group



FDA

Marketing authorization

CPT®

Description, Clinical effectiveness, Widespread use

CMS

Reasonable and necessary (LCD, NCD, CED)

CPT® – Areas of Focus

L

Language

- Accurate clinical description
- Not proprietary products or services
- Alignment with CPT code set

U

Use

- Widespread use across the U.S.
- Number depends on patient population

E

Evidence

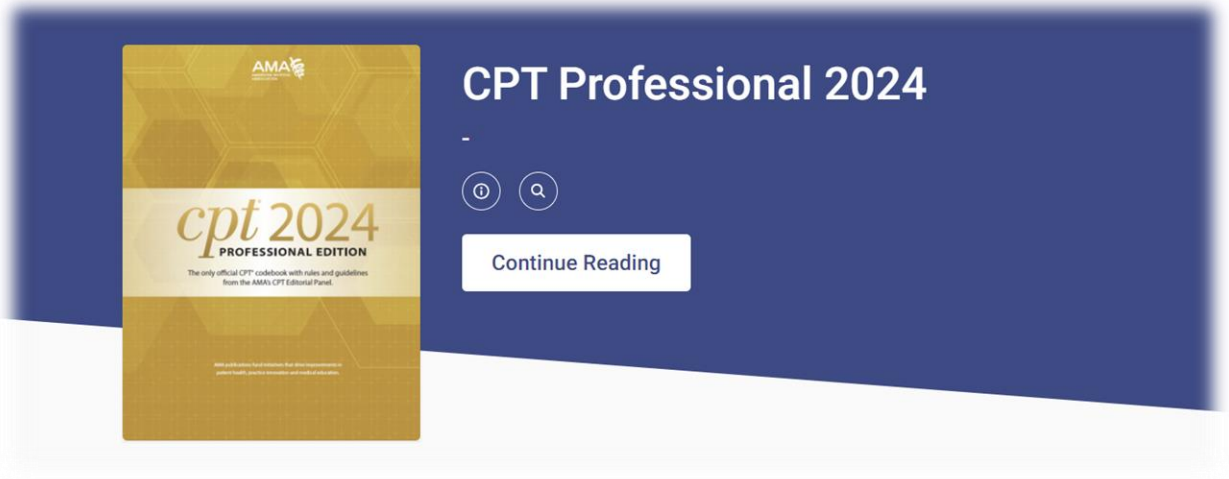
- Evidence of clinical effectiveness (peer reviewed literature)
- Specific criteria must be met

CPT® Process – Key Components of Code Creation

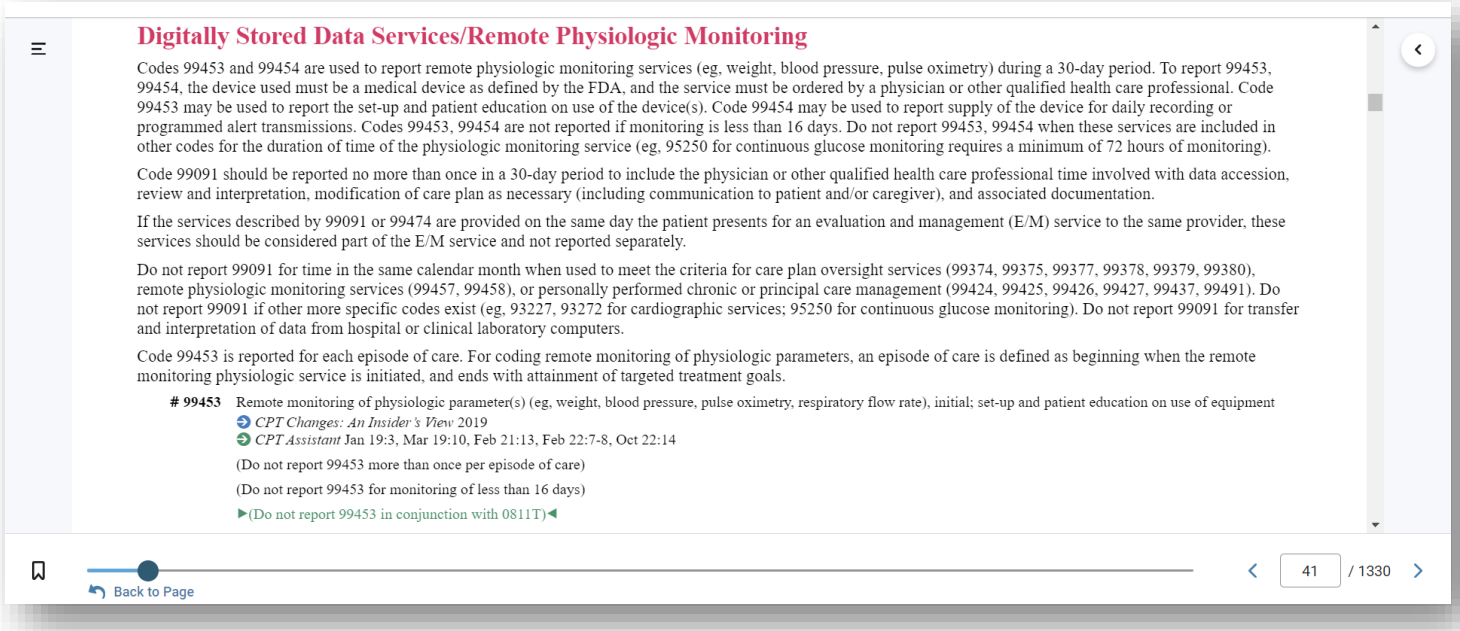
Both Category I and Category III

FDA Status	Rationale	Proposed New Code descriptor, parentheticals, 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	

AMA CPT® 2024 Professional Edition



CPT® Code Guidelines (e.g., RPM)



Digitally Stored Data Services/Remote Physiologic Monitoring

Codes 99453 and 99454 are used to report remote physiologic monitoring services (eg, weight, blood pressure, pulse oximetry) during a 30-day period. To report 99453, 99454, the device used must be a medical device as defined by the FDA, and the service must be ordered by a physician or other qualified health care professional. Code 99453 may be used to report the set-up and patient education on use of the device(s). Code 99454 may be used to report supply of the device for daily recording or programmed alert transmissions. Codes 99453, 99454 are not reported if monitoring is less than 16 days. Do not report 99453, 99454 when these services are included in other codes for the duration of time of the physiologic monitoring service (eg, 95250 for continuous glucose monitoring requires a minimum of 72 hours of monitoring).

Code 99091 should be reported no more than once in a 30-day period to include the physician or other qualified health care professional time involved with data accession, review and interpretation, modification of care plan as necessary (including communication to patient and/or caregiver), and associated documentation.

If the services described by 99091 or 99474 are provided on the same day the patient presents for an evaluation and management (E/M) service to the same provider, these services should be considered part of the E/M service and not reported separately.

Do not report 99091 for time in the same calendar month when used to meet the criteria for care plan oversight services (99374, 99375, 99377, 99378, 99379, 99380), remote physiologic monitoring services (99457, 99458), or personally performed chronic or principal care management (99424, 99425, 99426, 99427, 99437, 99491). Do not report 99091 if other more specific codes exist (eg, 93227, 93272 for cardiographic services; 95250 for continuous glucose monitoring). Do not report 99091 for transfer and interpretation of data from hospital or clinical laboratory computers.

Code 99453 is reported for each episode of care. For coding remote monitoring of physiologic parameters, an episode of care is defined as beginning when the remote monitoring physiologic service is initiated, and ends with attainment of targeted treatment goals.

 # 99453 Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment

- *CPT Changes: An Insider's View* 2019
- *CPT Assistant* Jan 19:3, Mar 19:10, Feb 21:13, Feb 22:7-8, Oct 22:14

(Do not report 99453 more than once per episode of care)

(Do not report 99453 for monitoring of less than 16 days)

►(Do not report 99453 in conjunction with 0811T)◄

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A Closer Look: Medical Device Guidelines RPM / RPM-TMS

- **Remote Physiologic Monitoring (99453/99454)**

  To report 99453, 99454, the device used must be a medical device as defined by the FDA, and the service must be ordered by a physician or other qualified health care professional.

- **Remote Physiologic Monitoring Treatment Management Services (99457/99458)**

  To report remote physiological monitoring, the device used must be a medical device as defined by the FDA, and the service must be ordered by a physician or other qualified health care professional.

A Closer Look: Medical Device Guidelines RTM / RTM-TMS

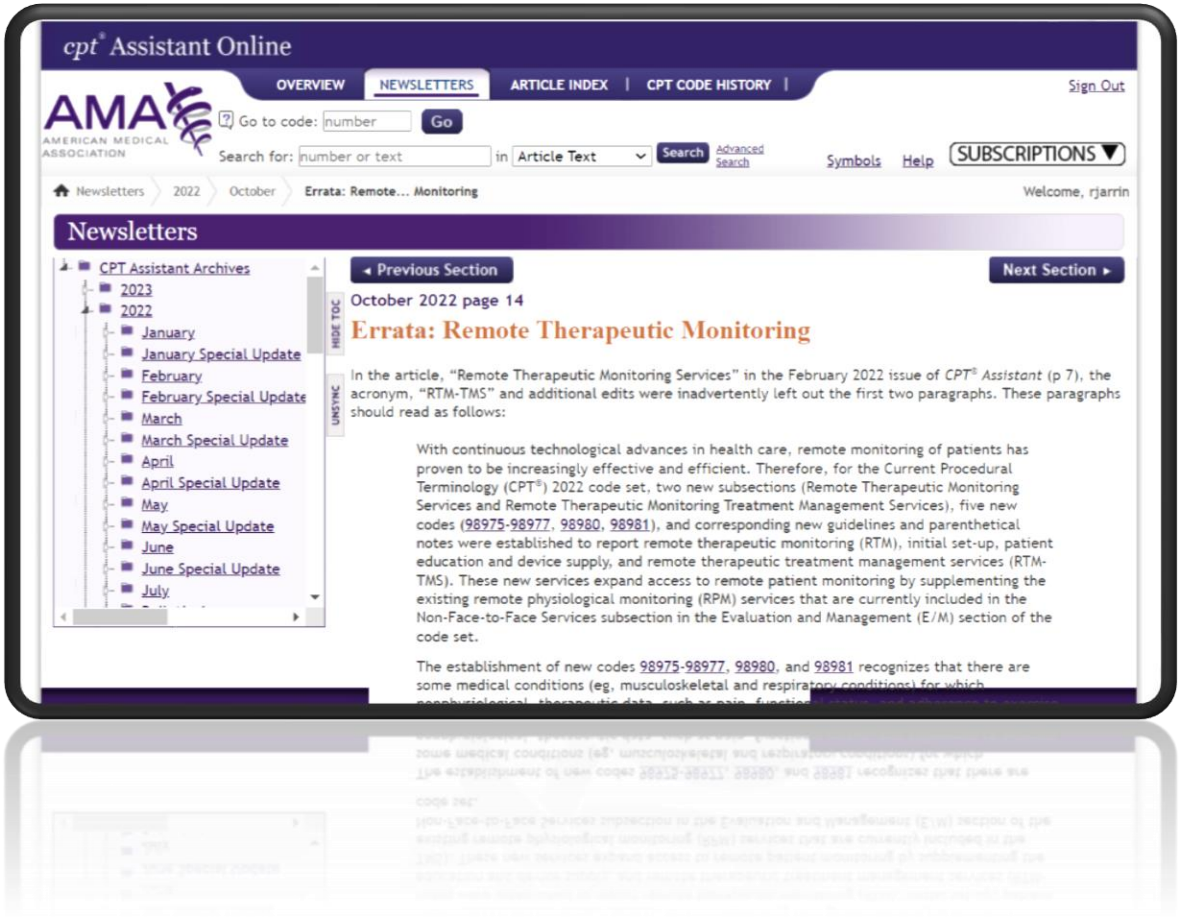
- **Remote Therapeutic Monitoring Services (98975, 98976, 98977, 98978)**

  To report 98975, 98976, 98977, 98978, the device used must be a medical device as defined by the FDA.

- **Remote Therapeutic Monitoring Treatment Management Services (98980, 98981)**

  To report 98980, 98981, any device used must be a medical device as defined by the FDA.

Trusted Source: *CPT® Assistant* Online



From Various *CPT® Assistant* Online

- The RPM codes are used to report the monitoring of physiologic parameters (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate, etc). *CPT Assistant*, February 2022, pg. 7
- RTM codes were created to be analogous, but not identical, to RPM codes 99453, 99454, 99457, and 99458. One of the main distinctions between these two code families is the data parameters being monitored and reviewed. *CPT Assistant*, February 2022, pg. 7
- To report codes 98975-98977, the device used must be a medical device as defined by the US Food and Drug Administration (FDA). RTM addresses the monitoring of signs, symptoms, therapy adherence, and response, ie, parameters not included in the RPM family *CPT Assistant*, October 2022, pg. 14
- The RTM codes (98975-98977) and the RTM-TMS codes (98980, 98981) are used to report the reviewing and monitoring of data related to signs, symptoms, and functions of a therapeutic response (e.g., musculoskeletal system status, respiratory system status, therapy adherence, therapy response) that are not otherwise addressed by remote physiologic monitoring. *CPT Assistant*, October 2022, pg. 14
- For 2023, codes 98975-98977 were revised and code 98978 was added to report supplying a device(s) to monitor cognitive behavioral therapy (CBT). *CPT Assistant*, February 2023, pg. 3

Device Regulation – Coding – Coverage / Payment

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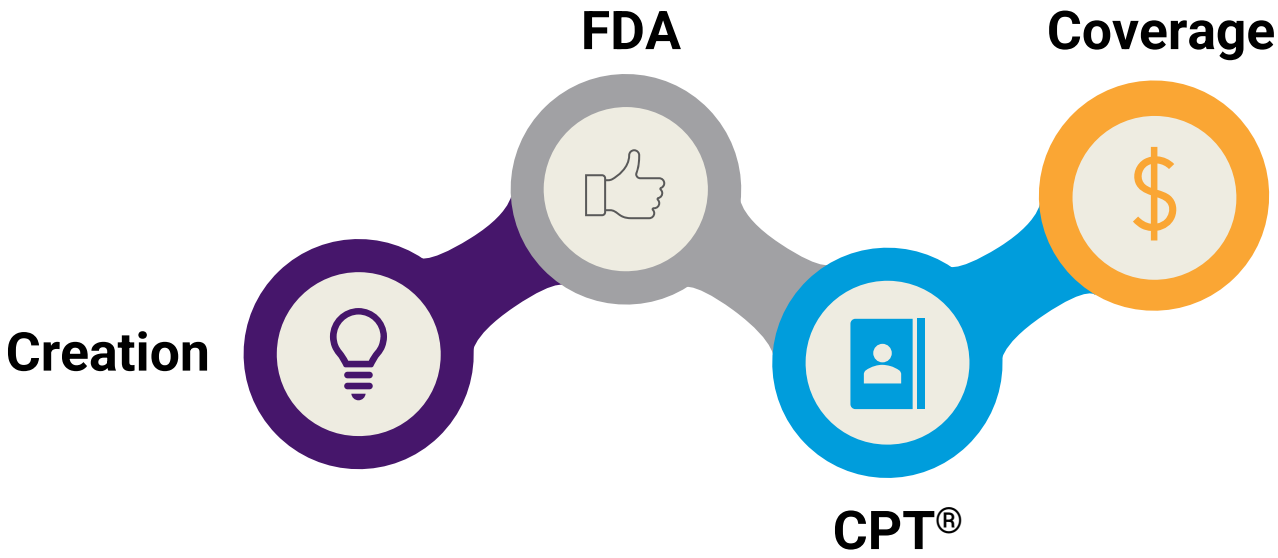
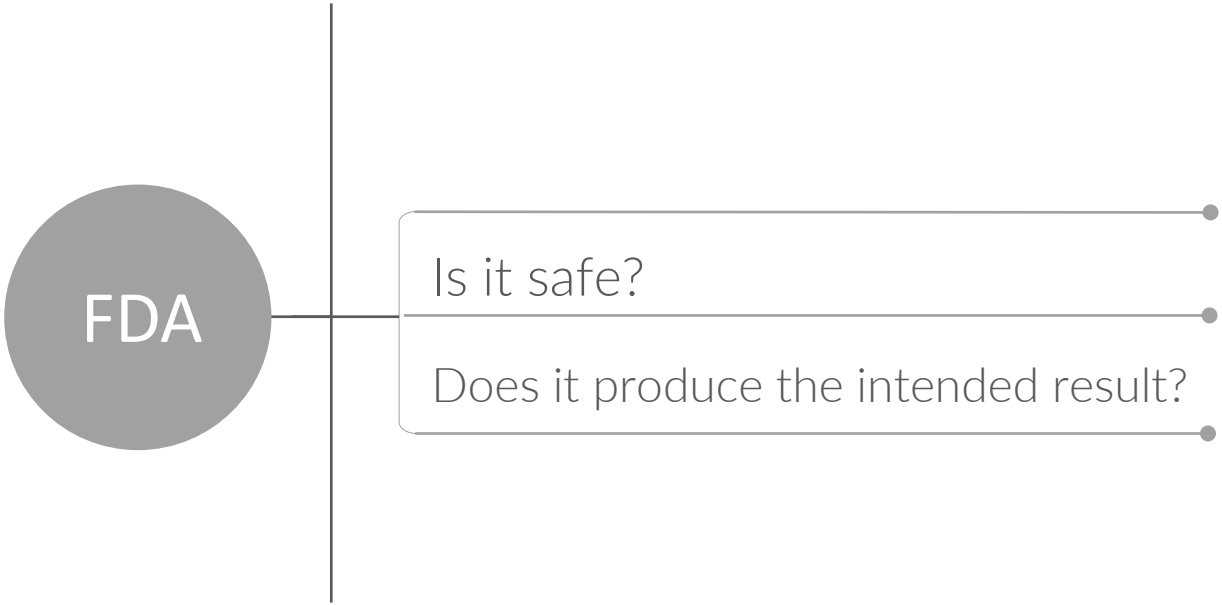
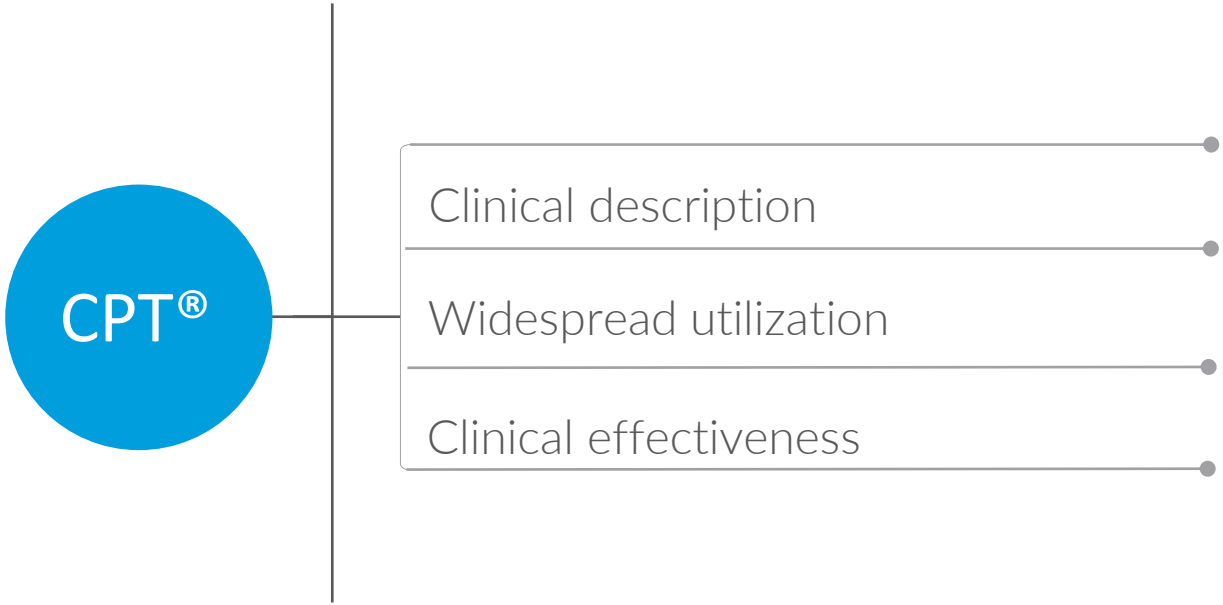
Coding, Coverage & Payment Lifecycle



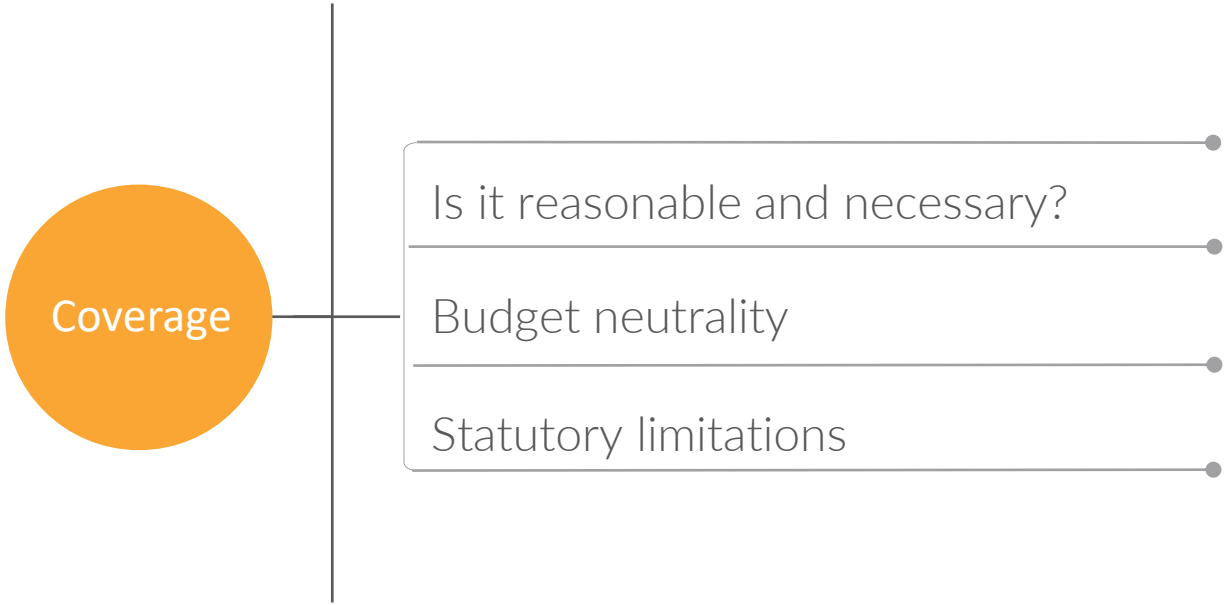
Coding, Payment & Coverage Lifecycle



Coding, Payment & Coverage Lifecycle



Coding, Payment & Coverage Lifecycle



Significance of FDA Device Regulation on CPT® Coding, as well as Coverage and Payment

- In the past, CMS has attempted to describe the types of medical devices used for RPM
- For RPM/TMS a medical device as defined by Section 201(h) of the FD&C Act
  - Used to collect and transmit "*reliable and valid*" physiologic data
  - In order to understand a patient's health status and "*develop and manage a plan of treatment*"
  - The medical device should digitally ("*that is, automatically*") upload patient physiologic data – not patient self-recorded and/or self-reported

Source: https://www.federalregister.gov/d/2020-26815/p-632

Significance of FDA Device Regulation on CPT® Coding, as well as Coverage and Payment (con'd)

- In the past, CMS has attempted to describe how medical device data may be collected (particularly with regards to CPT codes 99453* and 99454):
  - Only once per patient
  - Billed by only one practitioner (even when multiple medical devices are provided)
  - Reported only once during a 30-day period
  - And only when at least 16 days of data have been collected
  - The "services must be reasonable and necessary"
  - (*CPT code 99453 may only be billed once per episode of care)

Source: https://www.federalregister.gov/d/2020-26815/p-632

February 2024 CPT® Editorial Panel Meeting Public Agenda

AMA AMERICAN MEDICAL ASSOCIATION

Proposed Panel Agenda
February 2024 CPT® Editorial Panel Meeting

Tab #	Name	Code #	Request-Description
49	Digital Cognitive Behavioral Therapy	---------- ----------	Request to restore the language of CPT codes 98975, 98976, 98977, 98978 and the guidelines of the Remote Therapeutic Monitoring Services and Remote Therapeutic Monitoring Treatment Management Services to the current language included in the 2024 code set.
50	Remote Monitoring	●9XX0X ●9XX1X D99453 D99454 D99457 D99458 ▲98975 D98976 D98977 D98978 ▲98980 ▲98981	Establish codes 9XX0X, 9XX1X for device supply with daily recordings; delete the Digitally Stored Data Services/Remote Physiologic Monitoring subsection guidelines and delete codes 99453, 99454, 99457, 99458; relocate codes 99091, 99473, 99474 to the Medicine section in the Non-Face-to-Face Nonphysician Services subsection; revise the Medicine Non-Face-to-Face Nonphysician Services and Remote Therapeutic Monitoring Services subsection headings and guidelines; revise code 98975 and delete codes 98976-98978; revise the Remote Therapeutic Monitoring Treatment Management Services guidelines; and revise codes 98980,98981.

View the full proposed Panel agenda: ama-assn.org/system/files/cpt-panel-february-2024-agenda.pdf

Together we discussed:

- Making technology an asset in the delivery of care
- FDA's role in medical device regulation
- Significance of FDA medical device regulation on CPT® coding

Questions?

Get involved!

Attend a CPT® Editorial Panel Meeting in 2024

- Feb. 1-3 (San Diego, Calif. & Virtual)
- May 9-11 (Chicago, Ill. & Virtual)
- Sept. 19-21 (Albuquerque, NM & Virtual)

Register today for the February Panel Meeting!

Apply for a CPT Code

Help the CPT Editorial Panel and the AMA build the foundation for how health care procedures are tracked, reimbursed, and studied.

Submit code change applications online via the CPT Smart App.

CPT® Smart App: Simplified CPT Code Change Application Submission Process

All code change applications are to be submitted online via the CPT Smart App.

- ✓ Stay updated on your application.
- ✓ Manage applications smoothly with user-friendly tools like quick access to the latest CPT code set.
- ✓ Intuitive question flow and integrated help prompts aid in application completion.
- ✓ Easy reference and citation uploading.
- ✓ Consolidated application management.
- ✓ In-line assistance including video tutorials on how the code change process works.

Applications that require electronic submissions:

- Category I Codes
- Category III Codes
- Category I "Short Form" Codes
- Pathology/Laboratory (including Molecular Pathology (MoPath) / Genomic Sequencing Procedures (GSP) / Multianalyte Assays with Algorithmic Analyses (MAAA))

Visit cptsmartapp.ama-assn.org and start your CPT code change application today!

We want to hear from you!

When you see the **poll** appear in the slide window, click on the **answer**, then click **SUBMIT**.

Poll

Finish this sentence by selecting your top three topics:

Next year, I would like to learn more about CPT coding for…

- AI
- Digital medicine
- RPM/RTM
- New Category III Codes
- Telemedicine
- E/M

Results of Poll

This poll was a function of the live webinar. To view results, please watch the recorded webinar.

Stay informed with additional AMA resources

NEW!

The **AMA Principles for Augmented Intelligence Development, Deployment and Use** address the development, deployment and use of health care AI, with particular emphasis on:

- Health care AI oversight
- When and what to disclose to advance AI transparency
- Generative AI policies and governance
- Physician liability for use of AI-enabled technologies
- AI data privacy and cybersecurity
- Payor use of AI and automated decision-making systems

ama-assn.org/ai

The **AMA Digital Medicine Payment Advisory Group** identifies barriers to digital medicine adoption and proposes comprehensive solutions on coding, payment, coverage and more.

ama-assn.org/dmpag

The CPT Editorial Panel has responded to the fast pace of digital health innovation with two taxonomies. **Appendix R,** a taxonomy for **digital medicine services**, and **Appendix S.** which provides guidance for classifying various **AI-powered medical service applications**, into one of three categories: assistive, augmentative, or autonomous.

ama-assn.org/cpt-ai-taxonomy

The ***In Full Health Learning & Action Community to Advance Equitable Health Innovation*** seeks to advance equitable opportunities in health innovation investment, solution development and purchasing.

InFullHealth.org

Designed to address the needs of developers and creators of health technology and services, the **CPT® Developer Program** offers access to AMA-published content from CPT during the crucial stages of development.

developer.ama-assn.org

The **Physician Innovation Network** connects physicians and entrepreneurs to collaborate on new digital health care solutions.

innovationmatch.ama-assn.org

The **Future of Health Report** was prepared by the AMA and Manatt Health, and builds on the AMA's Return on Health research to explore and define the disconnect between the transformative potential of digital health, and the reality of its impact today; offer a blueprint to optimize digitally enabled care; and share stakeholder opportunities to leverage digital care through case examples from various organizations.

ama-assn.org/future-health

Next Steps

Tell us what you think

Please complete our **post-webinar survey**.

Your feedback helps us deliver expert perspective on topics you want to learn more about.

Join us for more CPT® Webinars!

2024 is going to be an exciting year for CPT Webinars!

Watch your inbox for registration information.

Physicians' powerful ally in patient care