Coding Overview and Best Practices

Prepared for AdvaMed

Avalere Health | An Inovalon Company
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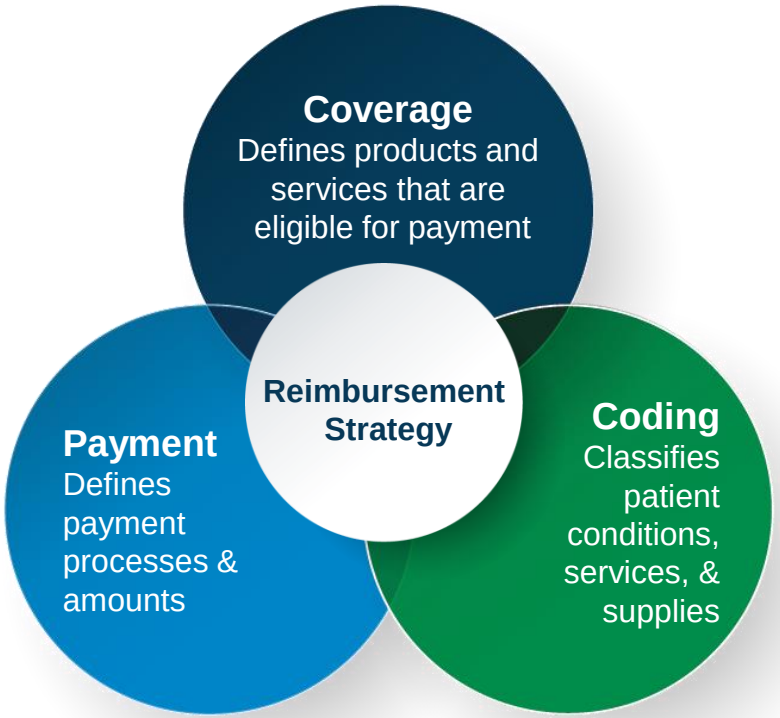
The Reimbursement Process Is Key to Product Success

- Reimbursement is the general term used to describe coverage, coding, and payment processes for medical services, devices, drugs, and supplies
- Gaining reimbursement for a product is vital once the new product is approved by the FDA*
- Adequate reimbursement helps ensure patient access to technologies
- Lack of coverage or inadequate payment may hinder adoption or lead to discontinued use of a medical device, drug, or service
- Different payment systems can create varying incentives and disincentives for providers to utilize certain devices, drugs, and procedures



Each aspect is a separate function, but all are required to establish reimbursement.

FDA: Food and Drug Administration
*Reimbursement for lab diagnostics does not always require FDA approval

A Successful Reimbursement Strategy Incorporates Multiple Elements

- Achieving optimal reimbursement is a long process that must begin well in advance of product launch
- Taking proactive steps prior, during, and post launch will help remove or mitigate the potential effect of coverage, coding, and payment barriers

Stakeholder Engagement

- Key opinion leaders (KOLs)
- Medical specialty societies
- Patient groups/coalitions
- Payers

Value Proposition

- Clinical data and supporting arguments
- Focus on evidence-based medicine
- Guideline/quality measure strategy

Investment & Support

- Appropriate investment to implement short and long-term strategies
- Organizational support
- Development of key materials
- Continued monitoring

Value messages should be tailored to address key issues for each stakeholder group.

Codes Facilitate Payment for Healthcare Services and Supplies

What are codes?	Standard systems to convey information between providers and payers
What do codes describe?	Medical services, procedures, devices, drugs, supplies, and patient conditions
Where are codes used?	In medical records and insurance claim forms
What do codes do?	Enable payers to process and pay claims for products, services, and procedures
What codes are necessary?	Depends on type of product, service or procedure, setting of care, and existing codes

What issues involving coding are critical to adoption and reimbursement?

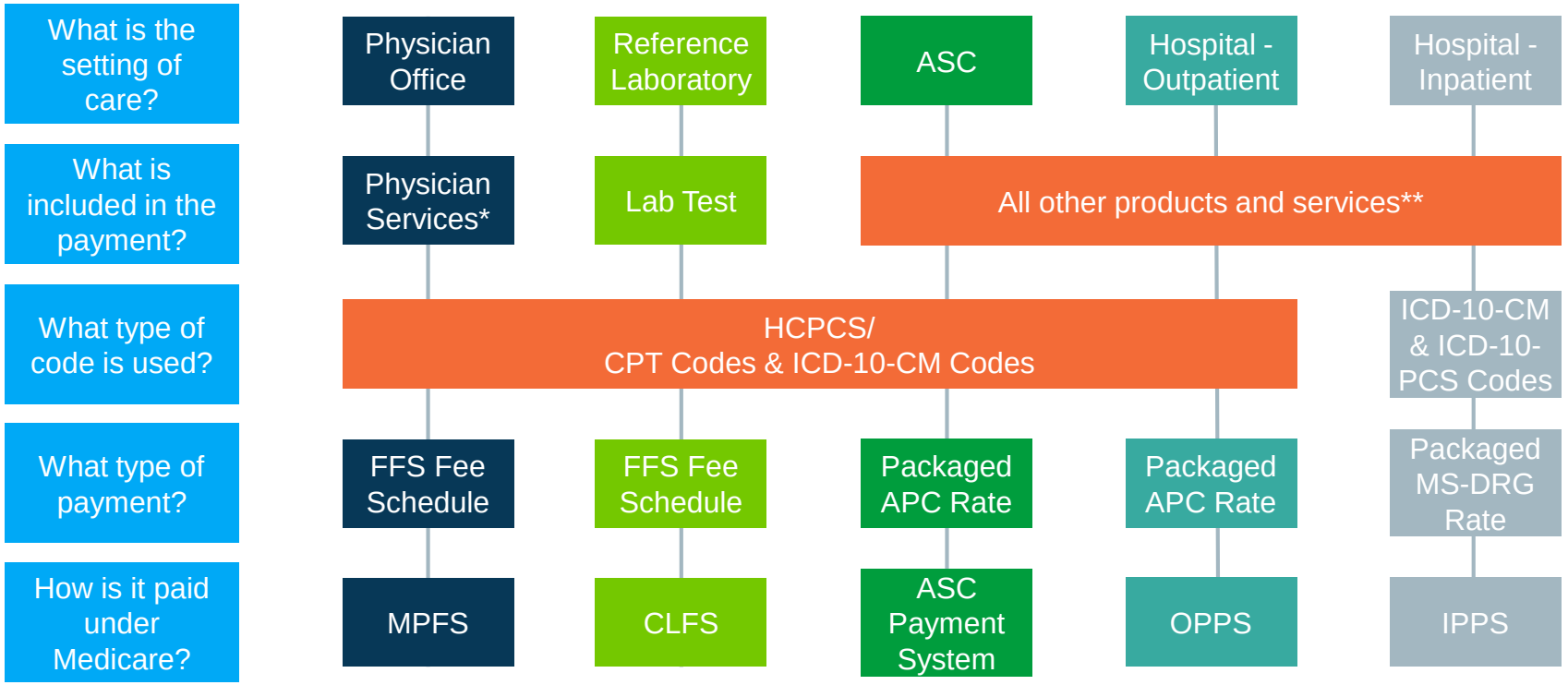
- Diagnosis codes: do the existing diagnosis codes support the indicated use for the product?
- Procedure codes: do existing codes describe the procedure that incorporates the device?
- Product codes: do you require a code to describe the product or type of technology?

A Wide Range of Coding Systems Are Used Across Settings of Care

Coding System	Maintained By	Uses / Settings
Level I HCPCS CPT Current Procedural Terminology	American Medical Association (AMA)	• Used in all settings of care to describe medical procedures and laboratory services • Used by most payers for medical procedures and laboratory payment • Used for Medicare hospital outpatient payment
Level II HCPCS Healthcare Common Procedure Coding System (HCPCS)	CMS	• Used to describe DMEPOS, drugs and biologicals, and services not described by CPT • Used to describe pass-through services in the Medicare hospital outpatient payment system
ICD-10-CM International Classification of Diseases, 10 Revision (ICD-10), Clinical Modification **ICD-10-PCS** International Classification of Diseases, 10 Revision (ICD-10), Procedure Coding System	Diagnosis Codes: NCHS Procedure Codes: CMS	• Diagnosis Codes: Used in all care settings to describe patient conditions • Procedure Codes: Used in hospital inpatient setting to describe procedures • Used for Medicare inpatient payment

DMEPOS = Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.
NCHS = National Center for Health Statistics.

Setting Dictates Code and Payment



ASC: Ambulatory Surgical Center
HCPCS: Healthcare Common Procedure Coding System
CPT: Current Procedural Terminology
ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-10-PCS: International Classification of Diseases, Tenth Revision, Procedure Classification System
FFS: Fee for service
APC: Ambulatory Payment Classification
MS-DRG: Medicare Severity-Diagnosis Related Group
MPFS: Medicare Physician Fee Schedule
CLFS: Clinical Laboratory Fee Schedule
OPPS: Hospital Outpatient Prospective Payment System
IPPS: Inpatient Prospective Payment Systems
CLFS: Clinical Laboratory Fee Schedule

*Physician service will encompass supplies as part of the practice expense
**Does not include services of physicians and other professionals not employed by the hospital who may bill separately. Some lab services are separately billable under the CLFS

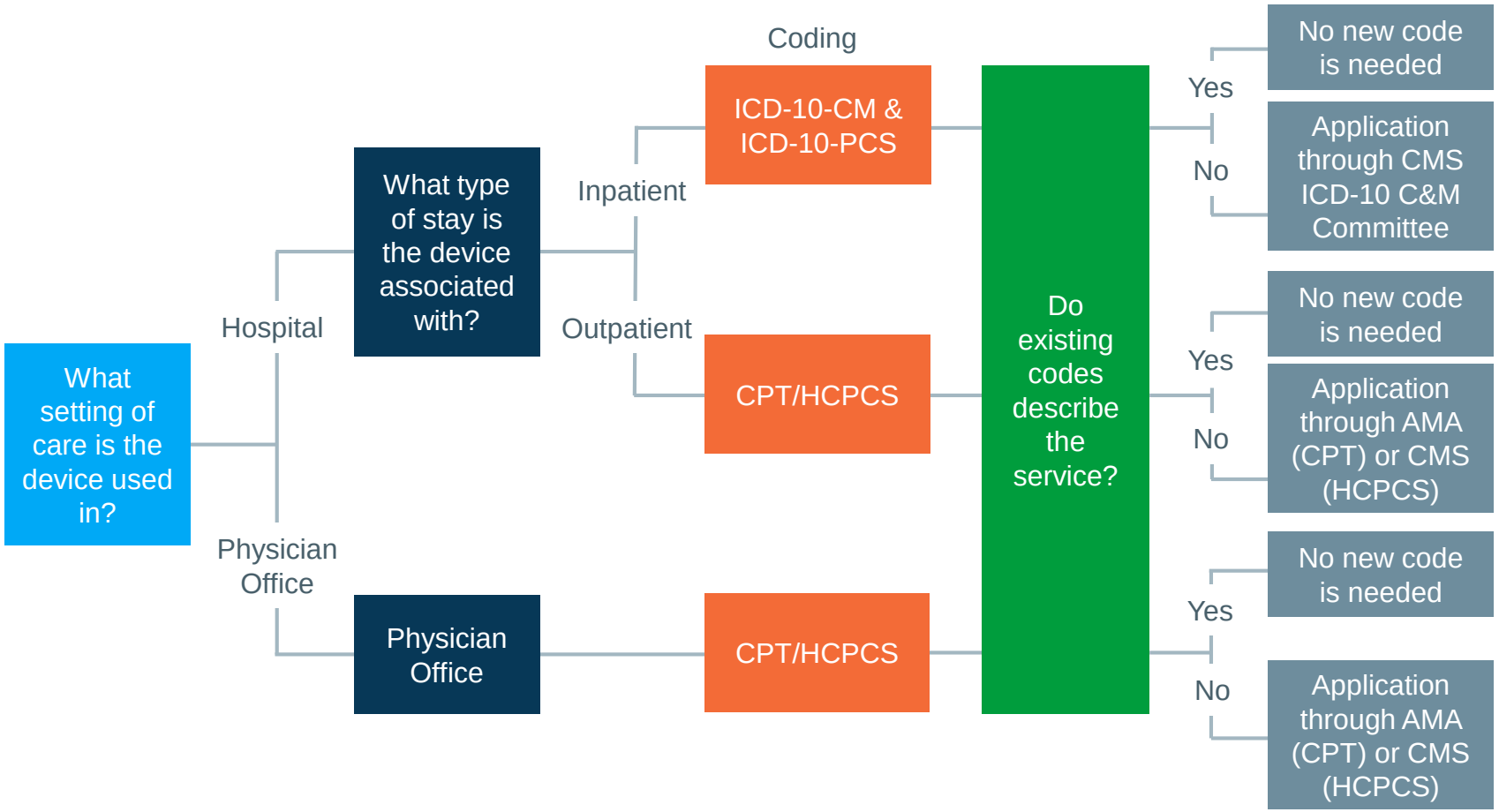
Payment for Healthcare Services Varies by Setting and by Payer*

- Medicare has standardized systems to pay for care
- Private insurer payment is highly variable depending on the health plan
- Medicaid payments vary by state
- In general, insurers make one payment to the facility and one to the physician
- Devices and drugs may be paid separately, or bundled with a larger group of services
  - In the facility, devices and drugs devices are likely to be bundled in with payment for other services
  - In the physician office, devices are often included in the practice expense input and drugs are often separately paid

Setting of Care	Payment Mechanism	Medicare	Medicaid	Private Insurers
Hospital Inpatient	DRGs	✓	✓	✓
	Percent of Charges		✓	✓
	Per Diems		✓	✓
Hospital Outpatient	Ambulatory Payment Classifications (APCs)	✓	✓	✓
	Fee Schedule		✓	✓
	Percent of Charges		✓	✓
	Per Diems		✓	✓
Physician Office	Fee Schedule	✓	✓	✓
	Percent of Charges		✓	✓
	Capitation	Contracted Medicare Advantage Plans	Contracted Managed Care Organizations	✓

*This payment summary provides a general overview of the payment methodologies applicable for *most* services provided in these settings, but many exceptions and special payment rules apply that are not addressed here.

Decision Tree – What Code is Appropriate?



In the hospital setting, physician work is reported with a CPT code and is separately paid at the MPFS facility rate.

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CPT Codes

Three Types of AMA-Managed CPT Codes Describe Healthcare Services

- CPT codes may not recognize all services and certain services may be considered bundled under existing codes
- Reimbursement is ultimately based on a payer's willingness to cover a service; billing of unique CPT codes does not guarantee payment

	Category I	Category II	Category III
Use	Permanent codes describe established healthcare procedures or services	Optional supplemental tracking codes used for performance measurement and to facilitate data collection on the quality of patient care	Temporary codes for emerging technology, services, and procedures to allow data collection on clinical efficacy, utilization, and outcomes
Evaluated for standard payment by AMA RUC	Yes*	No	No
Payment	Reimbursement/payment based on payer discretion to cover a service; most codes reimbursed	No reimbursement; for data collection purposes only	Reimbursement/payment at payer discretion (typically manually reviewed with variation across payers)

CPT codes are used by both public and private payers to identify physician services.

* Lab tests on the CLFS do not go through RUC process
AMA RUC=American Medical Association Relative Value Scale Update Committee

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The Process for Obtaining a New CPT Code is Time Consuming and Resource Intensive

- The CPT Editorial Panel meets three times a year according to a published schedule to review new code requests and modifications to existing codes
  - Panel meetings are open to the public
- The timeline for receiving a new Category III CPT code is quicker than Category I
  - Category III codes are effective six months after they are first posted on the AMA website*
  - Category I codes are updated on an annual basis
    - It takes at least 18 months from the application date for a Category I code to be implemented

Application Date	CPT Panel Meeting	Only Relevant for Category III Codes		Published in CPT Codebook
		Early Release on AMA Website	Implementation	
February 16, 2018	May 17 – 18, 2018	July 1, 2018	January 1, 2019	2020
June 25, 2018	Sept. 27 – 29, 2018	January 1, 2019	July 1, 2019	
November 7, 2018	February 7 – 9, 2019	July 1, 2019	January 1, 2020	2021
February 12, 2019	May 9 – 11, 2019	January 1, 2020	July 1, 2020	
June 25, 2019	September 26 – 28, 2019	July 1, 2020	January 1, 2021	

*Payers and providers can begin using Category III codes as soon as they are posted on the AMA's website (January and July of each year). The additional time can help payers to update their systems in advance of the implementation date/publication in the CPT Codebook (six months after AMA website posting).
Source: AMA, CPT Editorial Panel & RUC Meetings & Calendar https://www.ama-assn.org/practice-management/cpt%C2%AE-editorial-panel-process-amaspecialty-society-rvs-update-process

Key Information Requested on CPT Application Will Determine Likelihood of Success

The CPT application questions are related to the following:

FDA Approval*	Widespread Adoption by Providers Across the Nation	Clinical Efficacy
Clinical Vignette for Typical Patient	Experience to Date with Procedure	Existing Procedure Guidelines
Current Codes Used	Impact of New Code on Existing Codes	Literature Requirements

FDA approval, provider/specialty support, along with clinical and utilization data determine the strength of a CPT application.

*Reimbursement for lab diagnostics does not always require FDA approval
Source: AMA, CPT Code Applications: https://www.ama-assn.org/practice-management/applying-cpt-codes

Category I Requirements More Burdensome Than Category III

Category I

CPT Editorial Panel requires **ALL** of the following:

- 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
- The procedure or service is performed by many physicians or other qualified health care professionals across the U.S.
- The procedure or service is performed with frequency consistent with the intended clinical use (i.e., a service for a common condition should have high volume)
- The procedure or service is consistent with current medical practice
- The clinical efficacy of the procedure or service is documented in literature that meets the requirements set forth in the CPT code-change application

Category III

CPT Editorial Panel requires: The procedure or service is currently or recently performed in humans

AND AT LEAST ONE of the following:

- The application is supported by at least one CPT or HCPAC advisor representing practitioners who would use this procedure or service
- The actual or potential clinical efficacy of the specific procedure or service is supported by peer reviewed literature which is available in English for examination by the CPT Editorial Panel
- There is:
  - at least one IRB approved protocol of a study of the procedure or service being performed,
  - a description of a current and ongoing U.S. trial outlining the efficacy of the procedure or service, or
  - other evidence of evolving clinical utilization

A procedure unlikely to ever qualify for a Category I code is also unlikely to be issued a Category III code. Devices or services that are perceived to be unlikely to obtain FDA approval or to have low clinical utility may face additional scrutiny.

HCPAC: Healthcare Professionals Advisory Committee
IRB: Institutional review board
Source: AMA, Coding Change Application for Category I CPT Code(s) and Category III CPT Code(s) – Emerging Technology https://www.ama-assn.org/practice-management/criteria-cpt-category-i-and-category-iii-codes

The Literature Requirements for a Category I Code Are Demanding

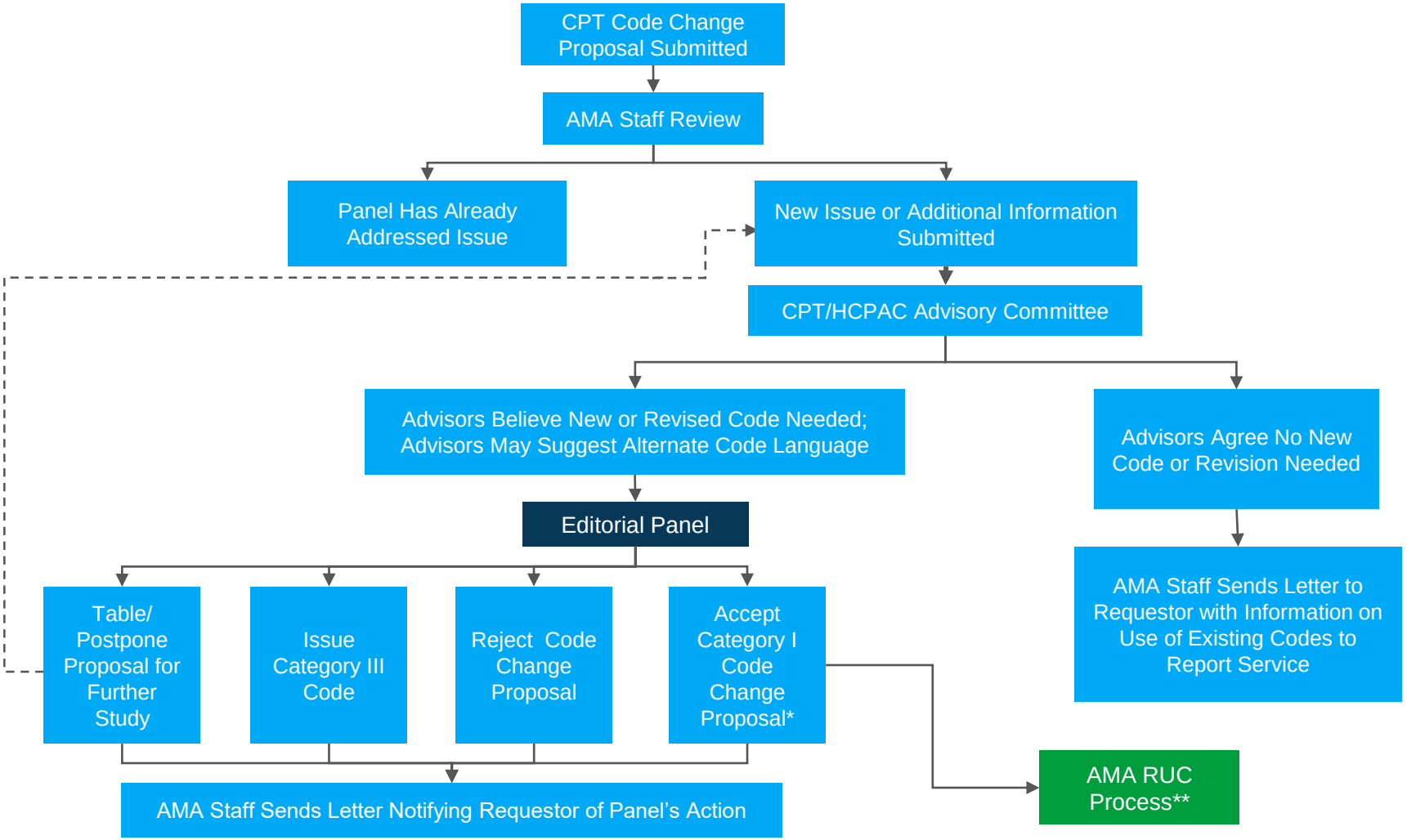
Category I Literature Requirements	Utilization	Typical	Typical	Limited, Specialized or Humanitarian	Limited, Specialized or Humanitarian
	Technology	New	Existing or Non-Contributory	New	Existing or Non-Contributory
# of Peer-Reviewed Publications:		5	5	5	3-5
Minimum # with U.S. Patient Populations:		3	3	2	1
Minimum # with Different Patient Populations:		2	2	1	1
Minimum Level of Evidence for at least One Article		IIa	IIIa/IIIb	IIb	IV

Level	Short Description (based on Oxford Centre 2009)
Ia	Evidence obtained from systematic review of randomized controlled trials
Ib	Evidence obtained from an individual randomized controlled trial
IIa	Evidence obtained from systematic review of cohort studies
IIb	Evidence obtained from an individual cohort study
IIIa	Evidence obtained from systematic review of case control studies
IIIb	Evidence obtained from a case control study
IV	Evidence obtained from case series
V	Evidence obtained from expert opinion without explicit critical appraisal

These literature requirements are subject to change based on recent AMA CPT Editorial Panel actions.

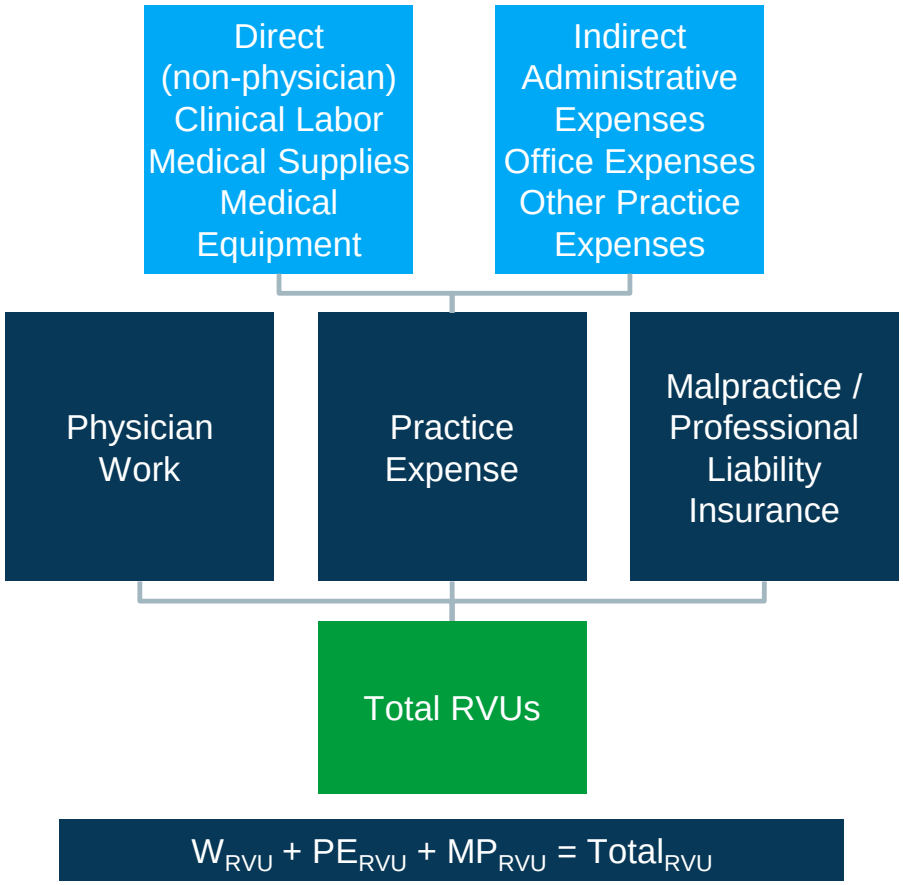
Source: AMA CPT, Coding Change Application for Category I CPT Code(s) and Category III CPT Code(s) – Emerging Technology

Overview of CPT Application Process



* Editorial changes, deletions, and Category III codes are not referred to the AMA RUC for valuation.
**Lab tests on the CLFS do not go through RUC process

Sum of RVU Components Create Total RVUs for a CPT Category I Code



- W_{RVU} measure of time, intensity, and skill required
- PE_{RVU} includes office expenses such as rent, wages, supplies, and equipment
- MP_{RVU} reflects local insurance cost

RVU: Relative Value Unit
Source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedcrephysFeeSchedfctsht.pdf

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HCPCS Codes

HCPCS Codes Are Used to Bill for Products and Certain Services Across Payers

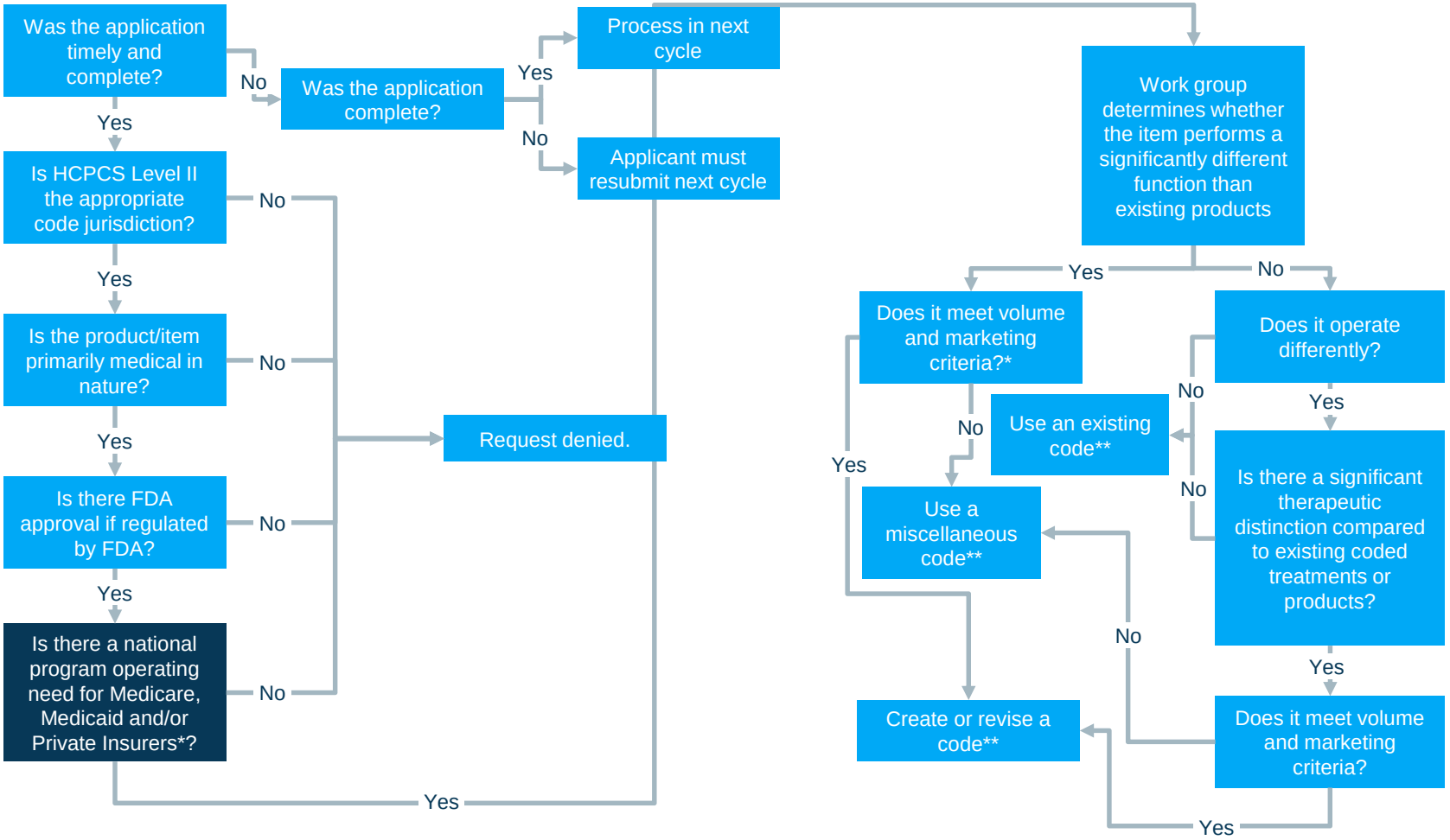
- HCPCS codes are issued and maintained by CMS
- HCPCS codes are standardized alpha-numeric codes that describe products and services on claim forms
  - Codes always begin with a letter and are followed by four numbers
  - Codes can be permanent or temporary and can be specific to setting of care

Code	General Use	Issued	Settings	Payers	Term of Use
A code	Miscellaneous medical and surgical supplies including dressings, ostomy and urinary supplies, DME supplies, and radiopharmaceutical diagnostic agents		All medical benefit settings (physician office, HOPD)		Permanent
C code	Describe certain devices in the HOPD and drugs that have Medicare pass-through payment		New products in Medicare HOPD		Temporary
E code	Durable medical equipment		All medical benefit settings (physician office, HOPD)		Permanent
G code	Typically describe services not identified by CPT codes. Tracks utilization of a product prior to issuing a coverage restriction or altering payment				Temporary
J code	Physician administered drugs including chemotherapy, immunosuppressive drugs and inhalation solutions, and some orally administered drugs		All medical benefit settings (physician office, HOPD)		Permanent
Q code	Typically used to identify drugs for which Medicare wants to track and monitor more closely		All medical benefit settings (physician office, HOPD)		No definitive end
S code	Products and services used by private payers and/or Medicaid		Various		No definitive end

 Yearly  Quarterly  Medicare  Medicaid  Private Payer

HOPD: Hospital Outpatient Department

CMS Has Established Stringent Requirements for the Creation of New HCPCS Codes



Note: There is no specific application for G codes; CMS can issue G codes as they deem appropriate

*At least one insurance sector, public (Medicare or Medicaid) or private (commercial insurers) identified a program operating need to separately identify the item and that need is common across the sector, (i.e., nationally, as opposed to one or a handful of individual insurers or states). Does not apply if item identification is statutorily required.

**Subject to national program operating need

Source: CMS, HCPCS Decision Tree and Definitions

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ICD-10 CM & ICD-10-PCS Codes

Overview of ICD Code Use in the United States

- ICD-10-CM is the standardized classification system used in the U.S. by providers and payers to accurately report and track the occurrence of diseases, injuries, and clinical procedures
  - ICD-10-CM diagnosis codes are used **across all healthcare settings**
  - ICD-10-PCS procedure codes are used only in the **inpatient hospital setting**
- The reporting of ICD-10* codes on claim forms is a key component in establishing medical necessity and determining payment rates in the inpatient setting under Medicare
- The ICD-10 Coordination and Maintenance (C&M) Committee oversees implementation of new codes and is co-chaired by NCHS and CMS
- CMS made the transition from the ninth version of ICD to the tenth version in October 1, 2015**

Coding System	Maintained By	Uses / Settings
ICD-10-CM** International Classification of Diseases, Tenth Revision, Clinical Modification	Diagnosis Codes: National Center for Health Statistics (NCHS)	• Diagnosis Codes: Used in all care settings to describe patient conditions • Used for Medicare inpatient payment
ICD-10-PCS** International Classification of Diseases, Tenth Revision, Procedure Coding System	Procedure Codes: Center for Medicare & Medicaid Services (CMS)	• Procedure Codes: Used in hospital inpatient setting to describe procedures • Used for Medicare inpatient payment

*When the term ICD-10 is used, it incorporates both the diagnosis codes and procedures codes in ICD-10-CM and ICD-10-PCS
** ICD-10 implemented on October 1, 2015. Prior to this date, ICD-9-CM was used
NCHS: National Center for Health Statistics (A division of the Centers for Disease Control and Prevention [CDC])
ICD-9-CM: International Classification of Disease, Ninth Revision, Clinical Modification

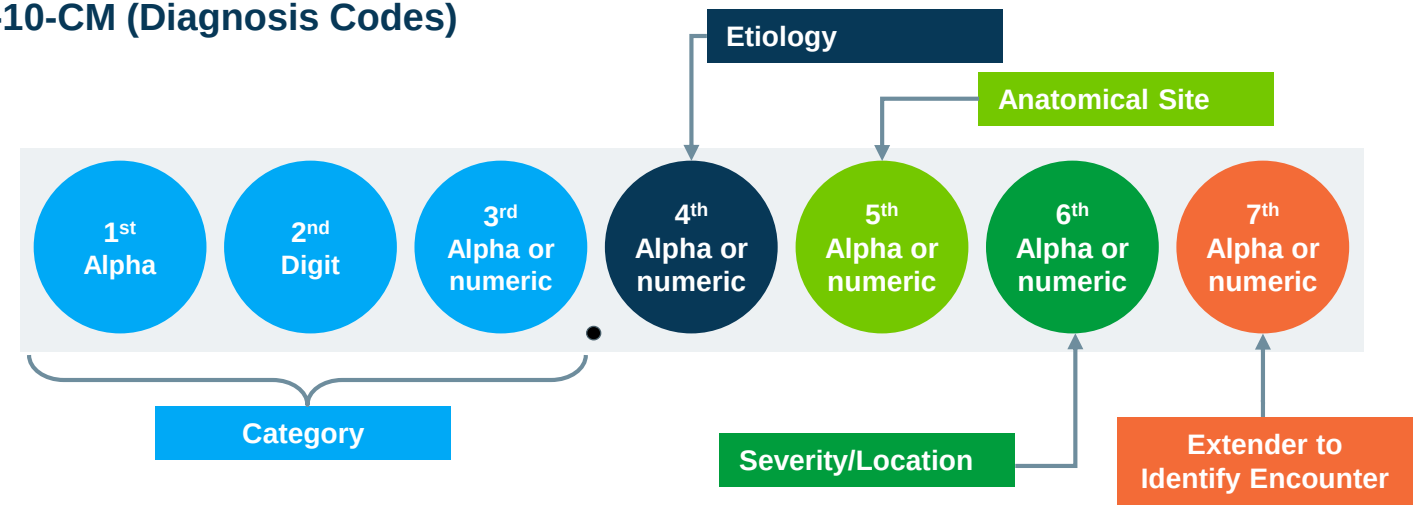
ICD-10 Has Widespread Impact Across U.S. Healthcare System

Coverage & Payment	• Better understand incidence of procedures and associated costs, allowing increased specificity in payment decisions • Advance value-based coverage decisions
Quality	• More specific and accurate data for quality data collection and measurement • Improve clinical specificity to yield improvements to patient safety and quality of care
Population Health & Monitoring	• Improve understanding of disease states • Enhance participation of United States in international disease surveillance • Increase responsiveness to emergent diseases and their detection
Research	• Enable more robust evidence-based development and trends analysis • Better understand value of new procedures • Support quality metrics and reporting
Information Technology	• Facilitate interoperability across EHRs • Promote and expand analytic tools and decision support with more robust and precise data
Medical Practice & Documentation	• Reduce number of miscoded, rejected, and improper claims • Inform clinical decision support to better enable evidence-based medicine • More precise oversight and monitoring of practices and procedures

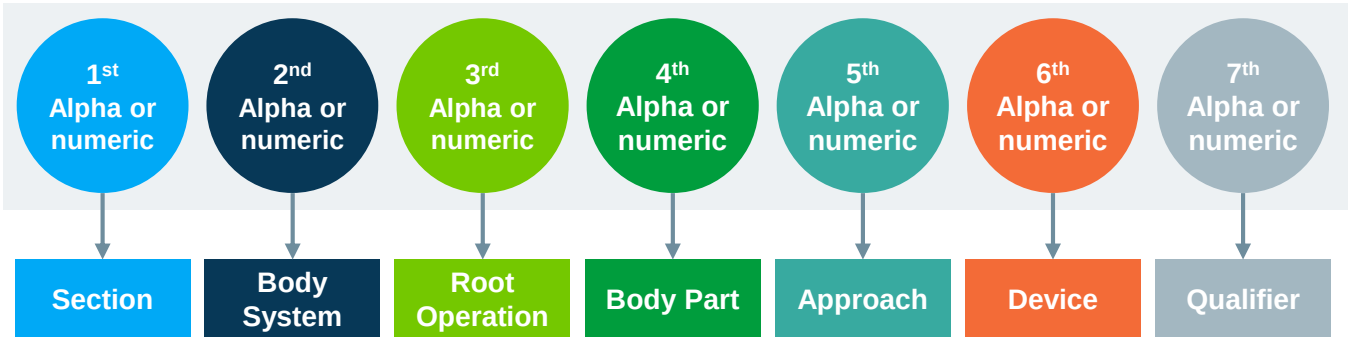
EHR: Electronic Health Record

ICD-10-CM & PCS Code Format Allows for Greater Detail by Accommodating Additional Characters

ICD-10-CM (Diagnosis Codes)



ICD-10-PCS (Procedure Codes)



Coding Considerations

After identifying the appropriate type of code for their device, manufacturers must assess early on in trials and design if they will meet criteria for a new code **and** understand how payment for providers works.

- Do existing codes adequately describe the device or procedure?
- What type of evidence is required for the necessary code(s)?
- Do you meet the requirements of the coding application?
- Do you have the support of relevant specialty societies?
- Have you considered the implications of coding on payment?

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Case Studies: Cologuard and TAVR

Cologuard: Technology Overview

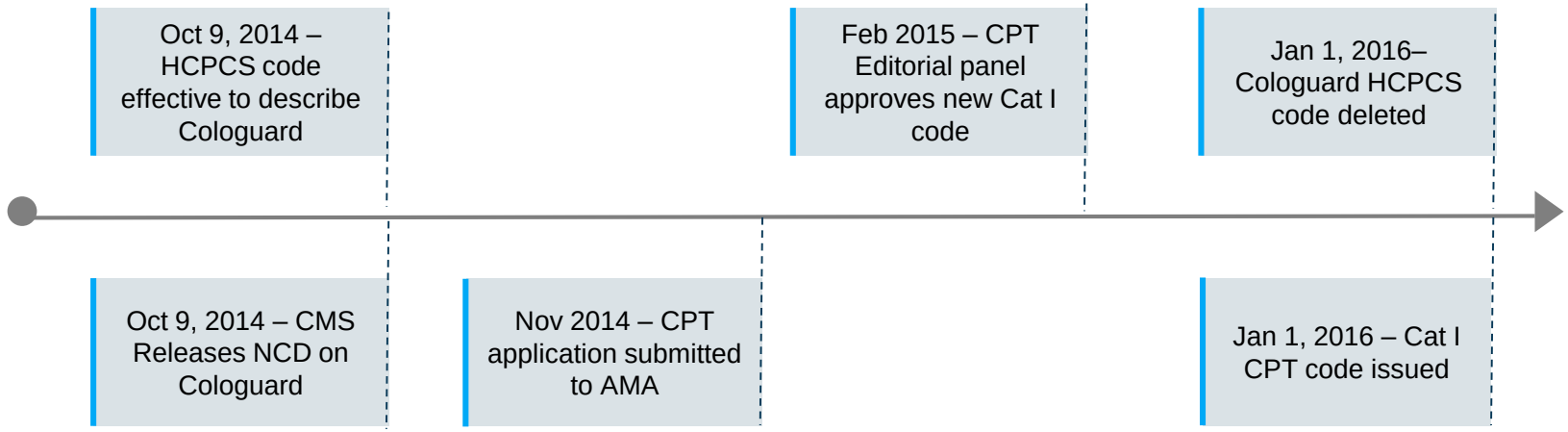
Cologuard is a qualitative non-invasive screening test indicated for the detection of colorectal cancer or advanced adenoma

Exact Sciences received Premarket Approval from the FDA for Cologuard on August 11, 2014. Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for colorectal cancer

Cologuard was the first noninvasive screening test for colorectal cancer that analyzes both stool DNA and blood biomarkers

Cologuard: Coding Timeline

COLOGUARD CODING TIMELINE



Initial HCPCS Code issued by CMS October 9, 2014, Deleted January 1, 2016

- G0464: Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)

Subsequent CPT Category I Code Issued by AMA January 1, 2016

- 81528: Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result

Cologuard: Key Coding Learnings

Strategy and Perceptions

- Exact Science worked with CMS through the NCD process to issue a temporary HCPCS code until a permanent CPT code became available
- Pivotal trial data released in April 2014 and published in the NEJM, before CPT code application submitted
  - However, there was no new clinical data between the NCD release and the CPT application

Stakeholder Engagement

- **Specialty Societies**: Exact Sciences led the process for their CPT code application and engaged with specialty societies (AGA, ACG) for their support

Impact

- **CMS**: Having a unique code was instrumental in implementing the NCD
- **Commercial Payers**: The Cologuard CPT code is located in the genetic testing section of the CPT codebook, which has generated some coverage and billing issues with commercial payers who have broad non-coverage policies for genetic testing

NEJM: New England Journal of Medicine
AGA: American Gastroenterological Association
ACG: American College of Gastroenterology

TAVR: Technology Overview

TAVR is a minimally invasive surgical procedure that replaces a damaged heart valve with a fully collapsible replacement valve through a catheter

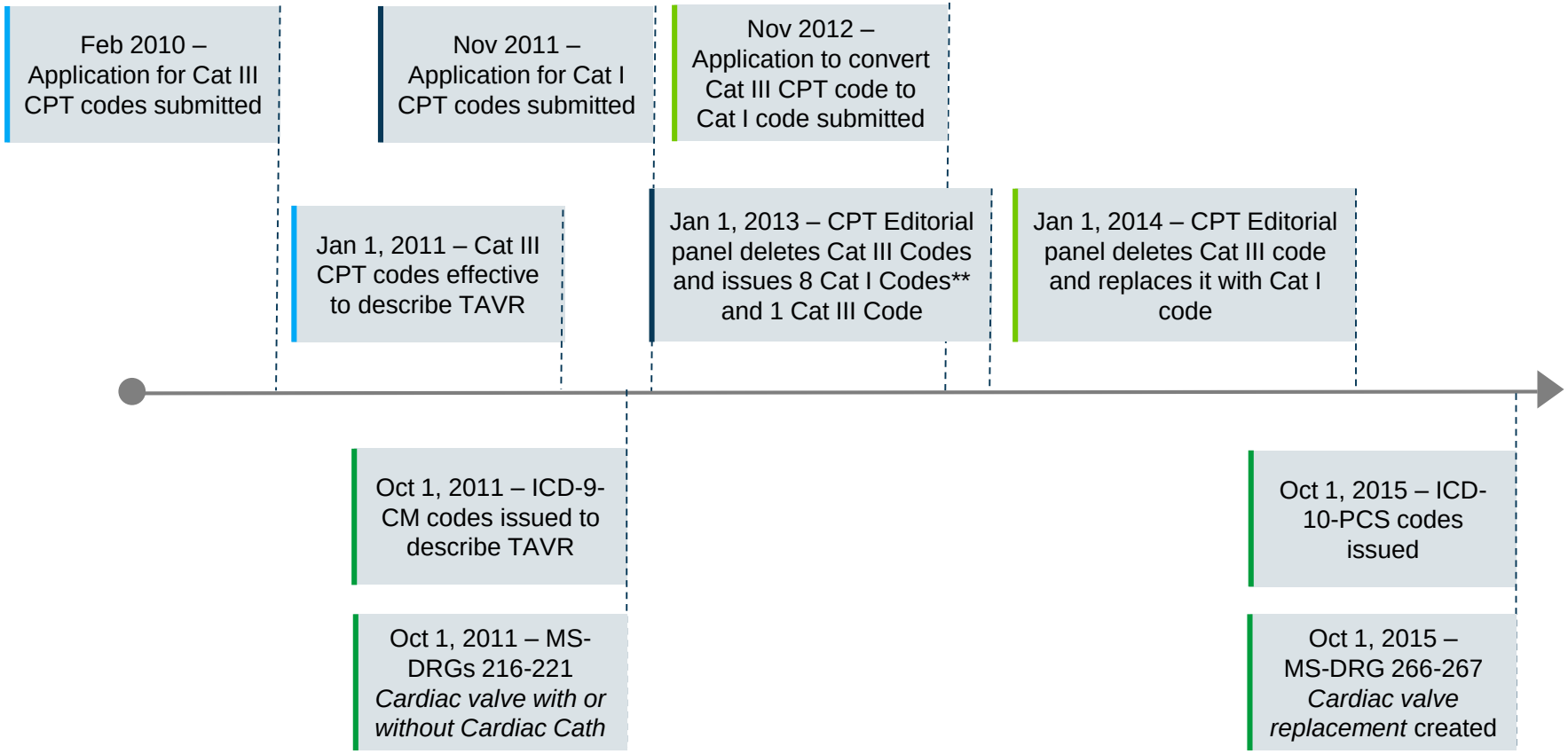
Edwards Lifesciences gained premarket approval from the FDA on October 19, 2012 for their SAPIEN device. The SAPIEN is approved for patients with symptomatic aortic stenosis who are considered an intermediate or high risk patient for standard valve replacement surgery

The TAVR procedure was revolutionary in that it permitted valve replacement to occur without a sternotomy

TAVR: Transcatheter aortic valve replacement

TAVR: Coding Timeline

TAVR CODING TIMELINE



*CMS NCD for TAVR became effective May 1, 2012
**5 base codes and 3 add-on codes

TAVR: CPT Coding

Jan 1, 2011 - AMA issues Category III CPT codes to describe TAVR procedure

- 0256T:Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach
- 0257T: Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (eg, transapical, transventricular)
- 0258T:Transthoracic cardiac exposure (eg, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass
- 0259T: Transthoracic cardiac exposure (eg, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; with cardiopulmonary bypass

Effective Jan 1, 2013, AMA replaces Cat II codes with 5 Cat I and 1 Cat III codes and issues 3 Cat I add-on codes

- 33361: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
- 33362: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
- 33363: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
- 33364: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
- 33365: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
- 0318T: Implantation of catheter-delivered prosthetic aortic heart valve, open thoracic approach, (eg, transapical, other than transaortic)
- 33367: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels)
- 33368: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels)
- 33369: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery)

Effective January 1, 2014, AMA replaced Cat III code with Cat I code

- 33366: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)

Indicates Category III code
Indicates Category I code

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TAVR: Key CPT Coding Learnings

Strategy and Perceptions

- New CPT coding was necessary because of the transformative nature of the procedure. Existing codes did not adequately describe the procedure
- Edwards believed a Cat III code would help facilitate the pathway to a Cat I code
- Edwards did not release any new clinical data between the Cat III and Cat I applications, but ensured all data previously presented was published in peer reviewed journals

Stakeholder Engagement

- **Specialty Societies**: ACC, STS, and SCAI drove the CPT coding process and made the formal request to AMA. Edwards worked with societies to provide information as needed in support of the request
- **Industry**: Edwards partnered with Medtronic, the manufacturer of another TAVR device, during CPT coding efforts

Impact

- Edwards supported an early Cat III code application and received coding before FDA approval of SAPIEN. The CPT Editorial Panel agreed with the need for codes because of the transformative nature of the technology
- CPT codes allowed for physician payment for the TAVR procedure

STS: Society of Thoracic Surgeons
ACC: American College of Cardiology
SCAI: Society for Cardiovascular Angiography and Interventions

TAVR: ICD-9-CM and ICD-10-PCS Coding

ICD-9-CM Code	ICD-9-CM Description	ICD-10-PCS Code	ICD-10-PCS Description
35.05	Endovascular replacement of aortic valve	02RF37Z	Replacement of Aortic Valve with Autologous Tissue Substitute, Percutaneous Approach
		02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
		02RF3JZ	Replacement of Aortic Valve with Synthetic Substitute, Percutaneous Approach
		02RF3KZ	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Approach
35.06	Transapical replacement of aortic valve	02RF37H	Replacement of Aortic Valve with Autologous Tissue Substitute, Transapical, Percutaneous Approach
		02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach
		02RF3JH	Replacement of Aortic Valve with Synthetic Substitute, Transapical, Percutaneous Approach
		02RF3KH	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Transapical, Percutaneous Approach

Above is the mapping from ICD-9-CM to ICD-10-PCS for the TAVR procedure. In ICD-10-PCS, the TAVR procedure is more explicit regarding the type of valve placed. Specifically, CMS created a device key to help identify technologies used with the procedure. For TAVR CMS states it should be coded as "zooplastic tissue in heart of great vessels". ICD-10-PCS codes map directly to the MS-DRGs that determine payment rates for surgical procedures such as TAVR

TAVR: Key ICD-9-CM and ICD-10-PCS Coding Learnings

Strategy and Perceptions

- Edwards carefully studied the experiences of other cardiovascular devices and used this information to inform their ICD strategy
- Physicians brought TAVR coding issues to specialty society coding clinics, which were unable to resolve these issues; Edwards then determined to pursue new ICD codes

Stakeholder Engagement

- **CMS**: Edwards engaged CMS early and frequently, and provided them with cost and clinical information that helped inform MS-DRG assignment
- **Specialty Societies**: Edwards partnered with specialty societies during their engagement with CMS. The societies did not have ownership of the request, but instead provided the perspective of the provider and patient
- **KOLs**: Edwards engaged with KOLs to present before the ICD C&M Committee

Impact

- Edwards carefully evaluated the coding environment and MS-DRG assignments and requested an MS-DRG assignment based on cost and clinical data
- ICD coding had a greater impact on TAVR uptake than CPT coding because MS-DRG assignment directly ties to hospital payment

STS: Society of Thoracic Surgeons
ACC: American College of Cardiology
SCAI: Society for Cardiovascular Angiography and Interventions

Coding Learnings: Exact Sciences and Edwards

Key lessons from the case studies include:

- Advance planning, including reimbursement landscape assessments, shaped the companies' coding strategy and was a key element to successful market access
- Engaging with coding experts was vital to the companies' coding strategies and outcomes
- Securing the support of specialty societies was necessary for CPT applications and helped with favorable ICD coding
- Publishing clinical data in peer-reviewed journals ensured the companies met the requirements for code applications