Bio Events International Convention

# Coverage, Coding, and Reimbursement for Drugs, Devices, Diagnostics and Procedures

June 12, 2021

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# Coverage, Coding, and Reimbursement for Drugs, Devices, Diagnostics, and Procedures

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June 12, 2022

# Today's Agenda:
# Basic Concepts for Commercialization

Coverage


Coding

Payment

# From Bench to Bedside

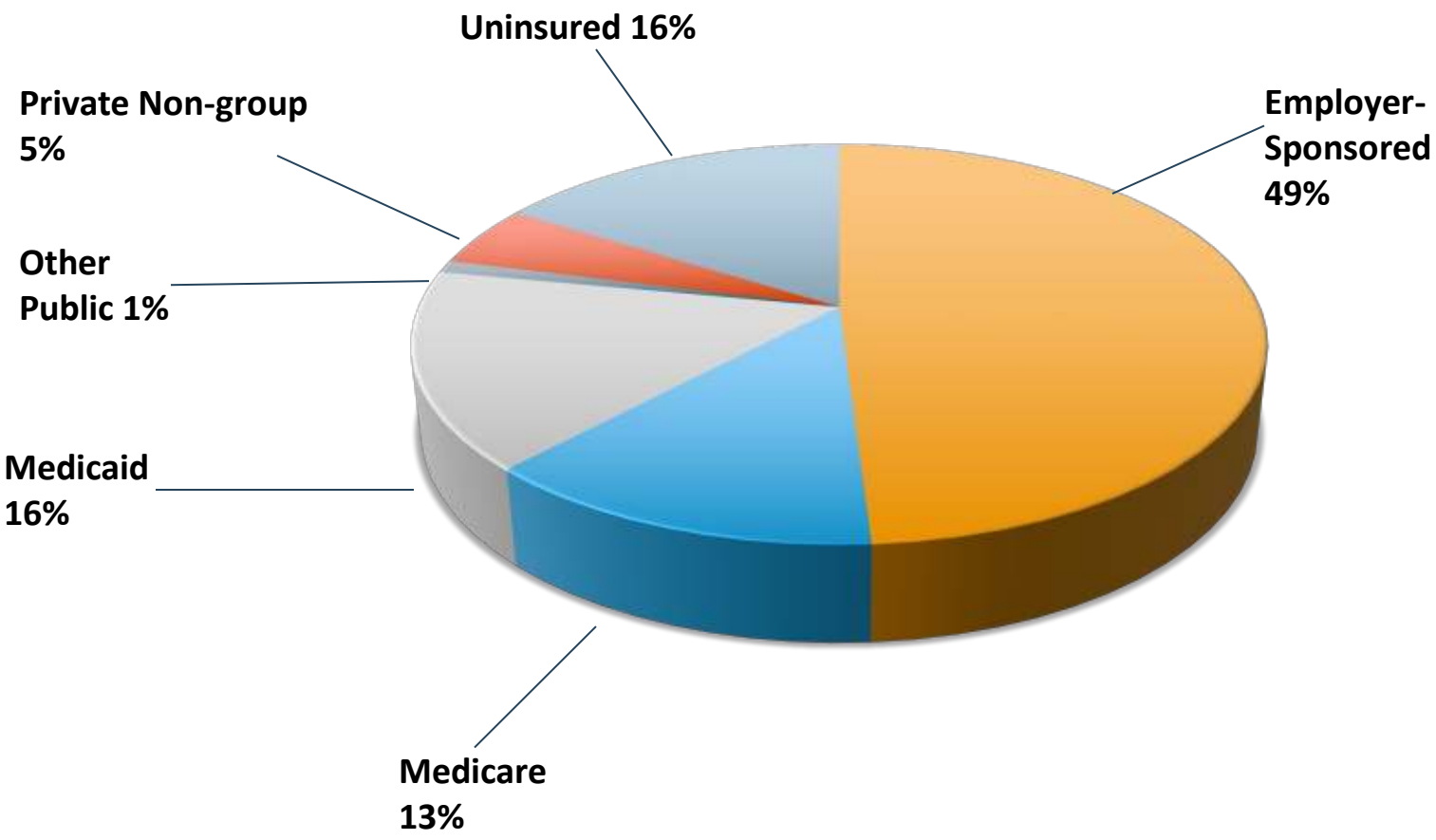
## Putting Coverage, Coding, and Payment Into Context

"Because of the pressures exerted by the costs of these new medicines on the healthcare system, the industry's future will be substantially determined by whether policymakers, physicians, and patients believe that the costly new medicines emerging from the industry provide enough value to be worth the continued investment in basic life sciences research"

D. Drakeman, L. Drakeman, N. Oraiopoulos, From Breakthrough to Blockbuster: The Business of Biotechnology at 12 (2022)

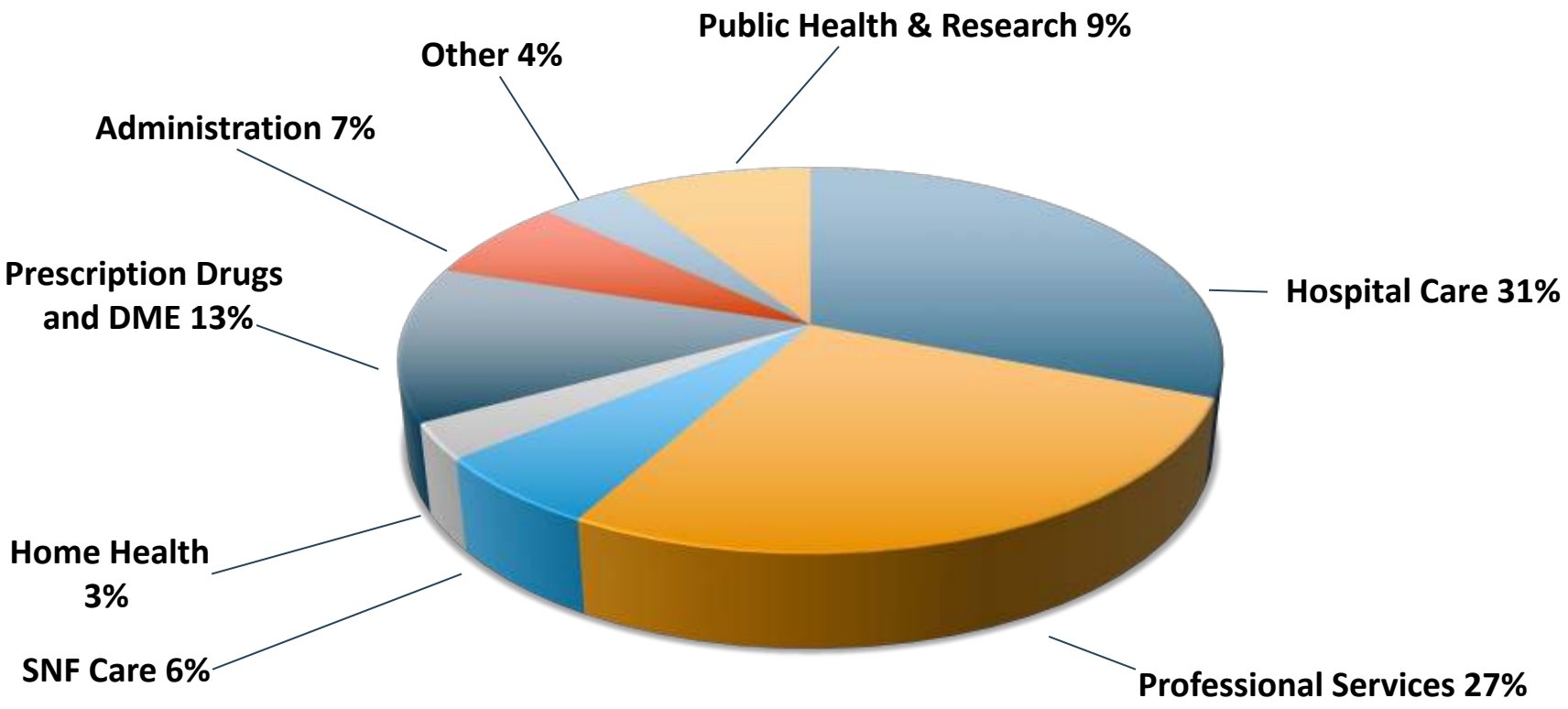
# U.S. Health Care Coverage

(Source: Centers for Medicare and Medicaid Services)



# U.S. Health Care Spending - $3.675 Billion

(Source: Centers for Medicare and Medicaid Services)



# In An Ideal World . . . .


*"The F.D.A. is nuts about it."*

# In Practice, Things Can Be Different

**"We do not see why the Secretary [of Health and Human Services] would be bound . . . by any earlier acceptance of MRI by the Food and Drug Administration"**

***Goodman v. Sullivan,* 891 F.2d 449, 451 (2d Cir. 1989)**

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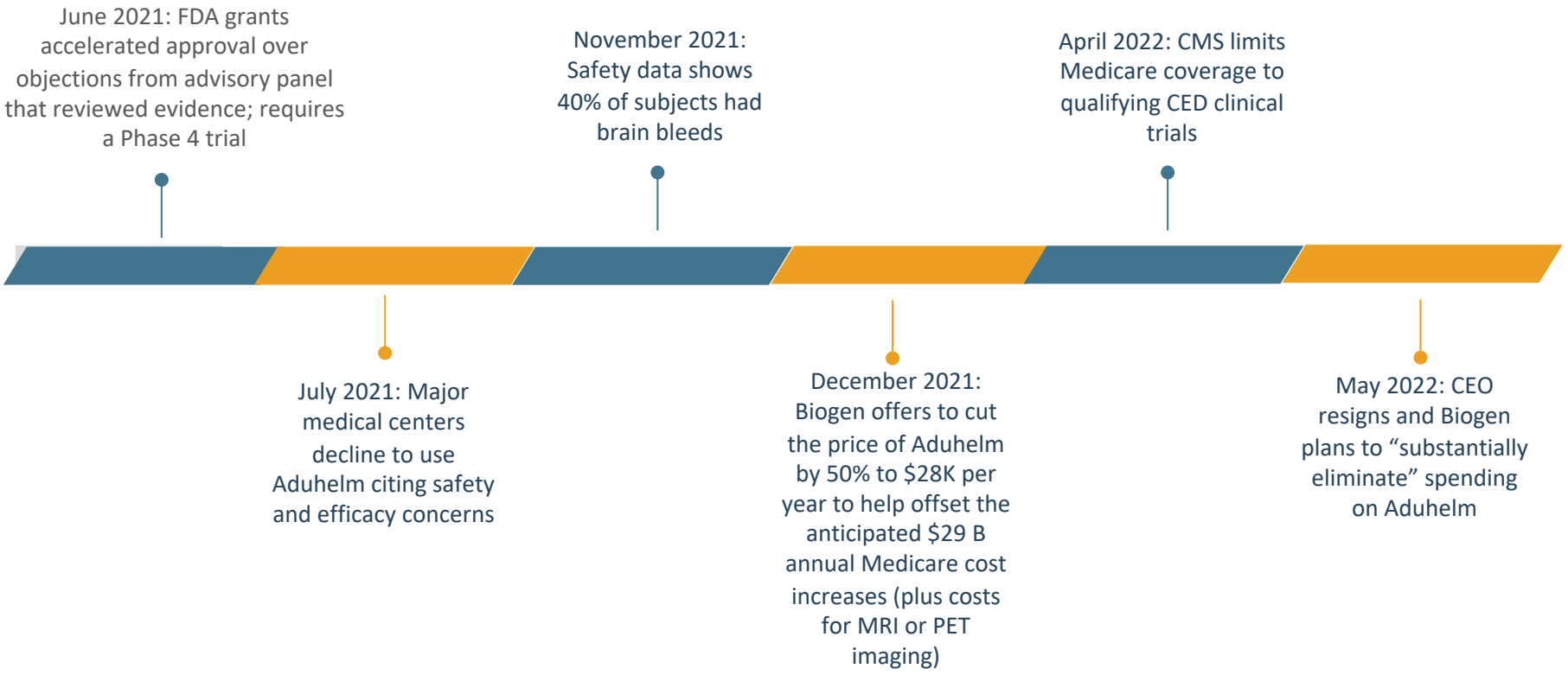
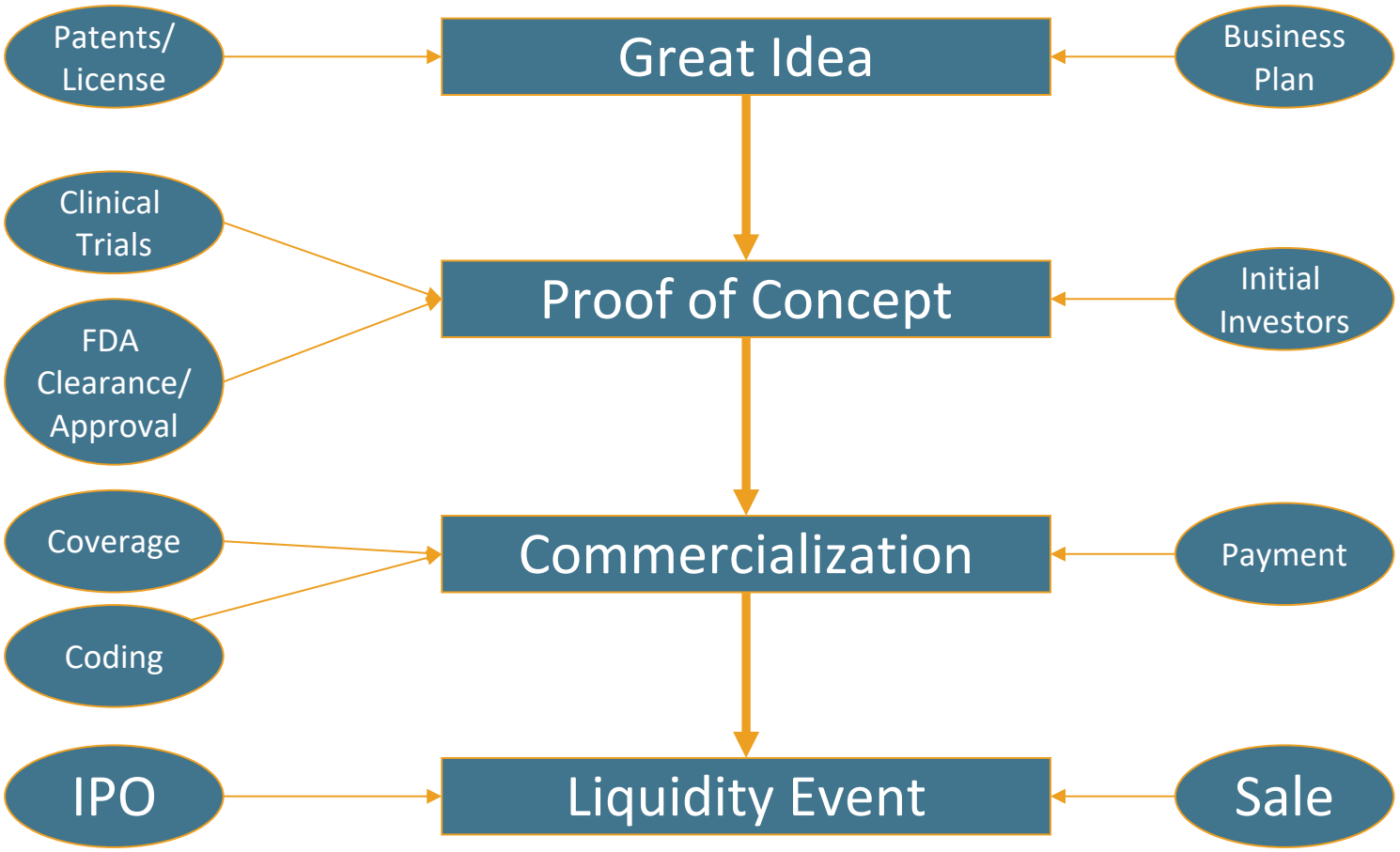
# A Story of How FDA Labeling Created An Initial Barrier To Successful Coverage

# The Aduhelm Experience

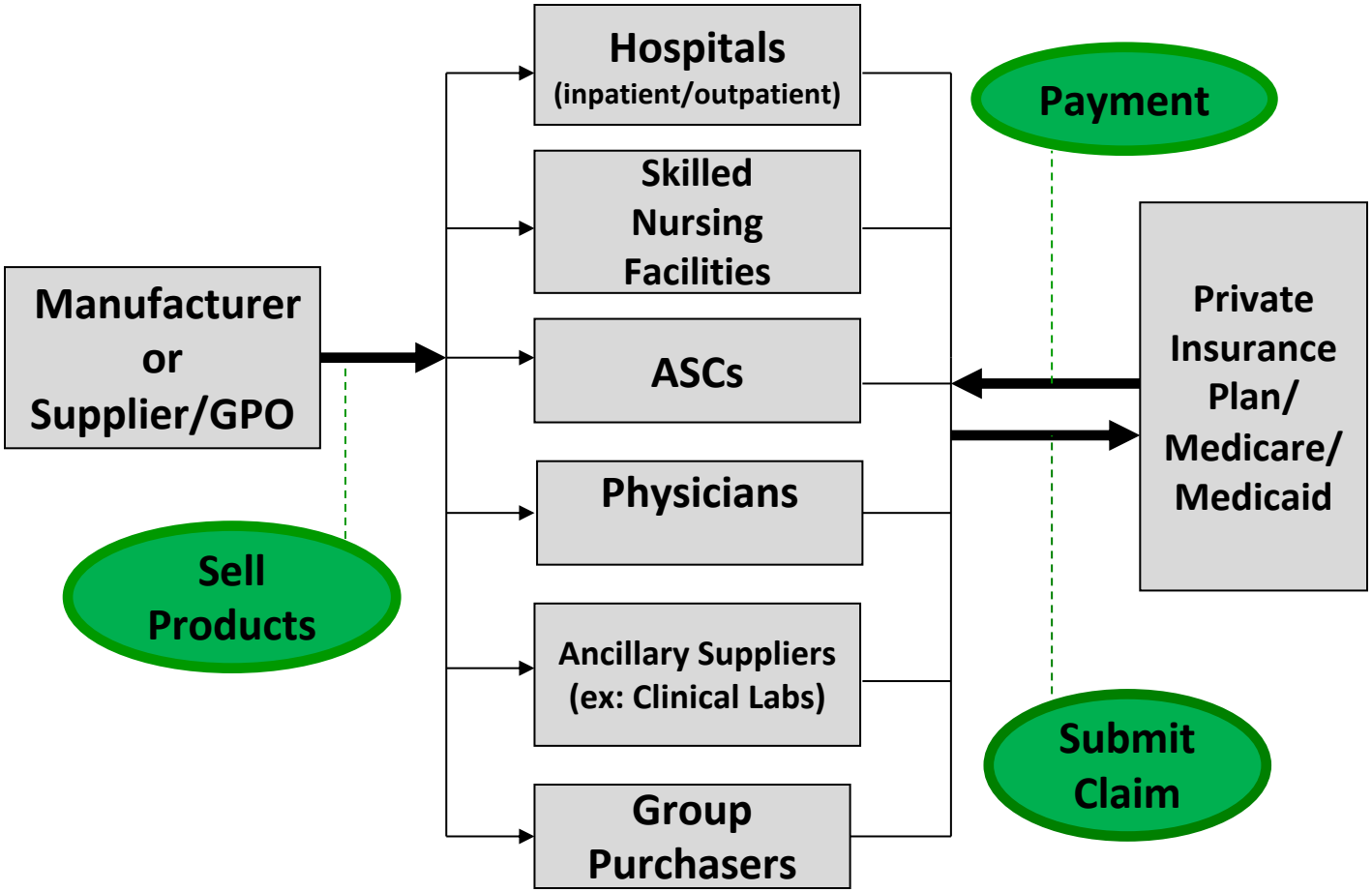
## The FDA Is the End of the Beginning



# Critical Milestones In Development



# How Does A New Item or Service Fit Into The U.S. Health Care System?



# Prescription Drug Distribution Channels

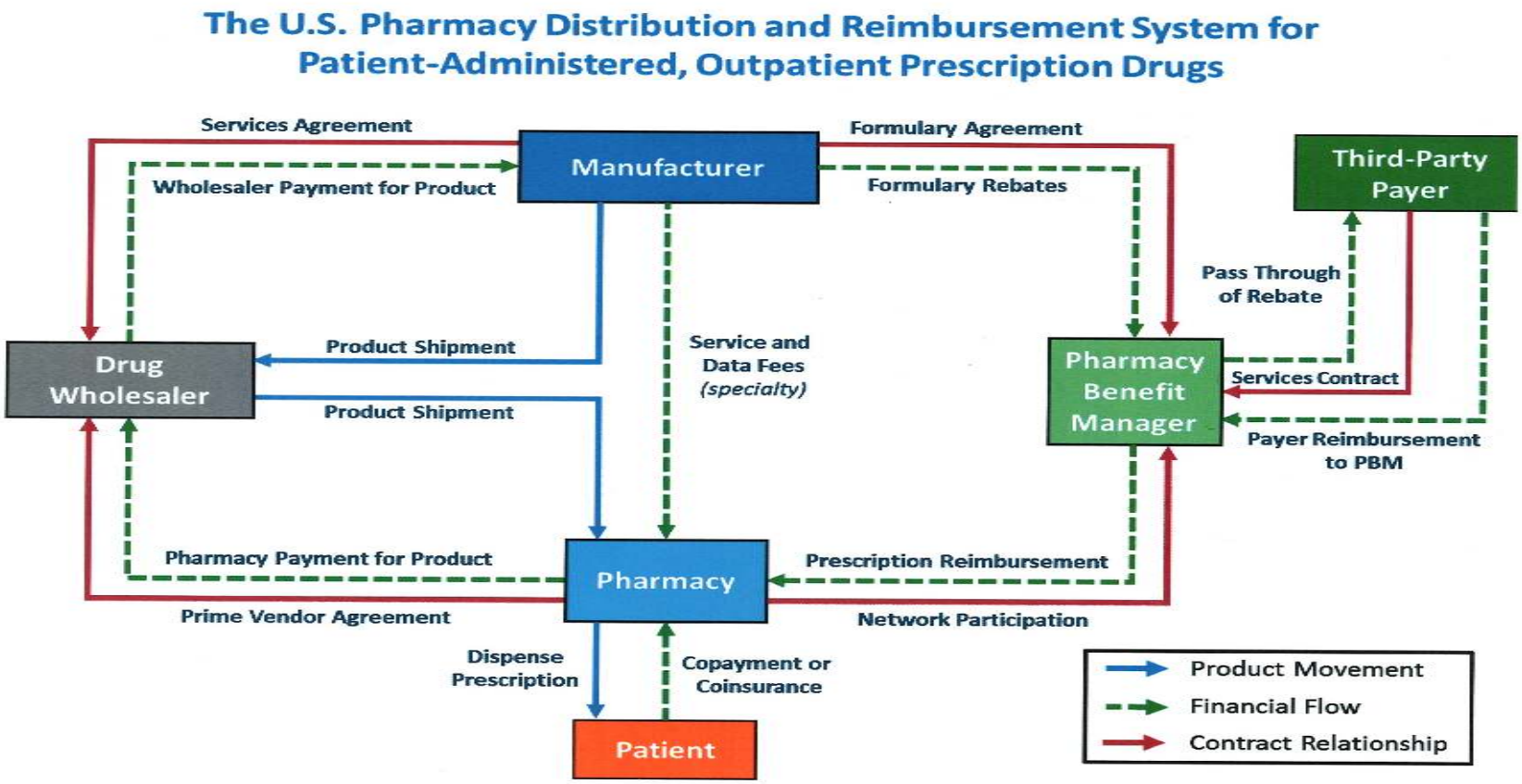



Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.

2

# Health Care Is A Highly Regulated Business

## Government Entities

- FDA (Approval/Clearance)
- OHRP/ORI (Federally-funded research compliance)
- CMS/State Medicaid Plans (Coverage and Reimbursement)
- SEC (Access to Public Funding)
- DOJ and OIG (Fraud and Abuse)
- States (Fraud and abuse)

## Private and Quasi-Public Entities

- IRBs (Research compliance)
- CPT Editorial Panel/HCPCS Workgroup (Coding)
- Health Plans (Coverage and Reimbursement)
- Investors
- Research Subjects

# Three Basic and Distinct Concepts

## Coverage

Terms and conditions for payment

## Coding

Unique identifiers for diagnoses, procedures, devices & diagnostics, inpatient services, and outpatient services

## Payment

Remuneration by health insurance plans, government-funded programs

**ALL THREE COMPONENTS ARE AN ESSENTIAL PART OF A SUCCESSFUL MARKET ENTRY**

# How Are These Concepts Different?

## Coverage

- Is not guaranteed when you receive FDA approval/clearance
- Does not guarantee a new or favorable billing code
- Does not guarantee favorable payment


## Payment

- Function of coverage and coding
- May be subject to limits
- May be stand-alone or bundled
- May be driven by breakthrough or existing technologies

## Coding

- Links coverage and payment with unique identifiers that can be used for electronic claims processing and health research
- Does not guarantee coverage
- Does not guarantee favorable payment

**ALL THREE COMPONENTS ARE AN ESSENTIAL PART OF A SUCCESSFUL MARKET ENTRY**

# Even CMS Gets Confused

**As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all. Nothing in the statute authorizes the least costly alternative policy.**

***Hays v. Sebelius,* 589 F.3d 1229 (D.C. Cir. 2009)**

# Coverage Strategy

Who will benefit most?

- Seniors, children, women, others?

What are the expected clinical outcomes?

Are there specific prerequisites or limits for coverage?

Key Coverage Issues

Where will the benefit be delivered?

- Institutions, outpatient, home care

Are there services that are comparable, but inferior or superior?

Immediate v. long-term benefits?

# Coverage Strategy

Process starts well in advance of product launch

- Thinking about coverage at all times beginning with the earliest product R & D discussions as well as when designing clinical trials
- Investors will demand a rigorous coverage and reimbursement strategy

Understanding realistic timeframes is critical

# Building a Team

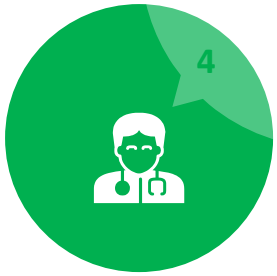
## Who Should Be Assisting a Biotech, Medical Device, Diagnostic, or Drug Manufacturer in Developing and Implementing a Commercialization Strategy?

A health lawyer with particular expertise in coverage, coding, and payment procedures for public and private U.S. payers



A coding consultant and, depending upon the circumstances, one or more certified coders

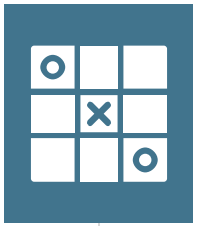
Physician consultants or advisors for assistance with presentations to the payers, to other physicians, or for CPT coding assistance





Health economists and disease management specialists to assist in clinical trial research design so that clinical research data contributes to the Medical Reimbursement Strategy – not just to the FDA Strategy.

# Coverage Strategy



## Coverage issues should be initiated with major stakeholders

- Professional organizations
  - ex: ACC for cardiovascular, AAOS for orthopedic
- Physician-advocates and thought leaders
  - Scientific advisory boards
- Hospitals, hospital systems, physicians
  - End-users of the items
  - Patient advocacy groups

## Build familiarity with the item

- Consult payers during the process
- Cultivate strong physician advocates, institutional and organizational support

# Special Coverage Challenges

- **Innovative breakthrough for patient health**
  - Fills a compelling unmet need
  - Does it replace a health care professional?
- **Replacing an existing test/technology**
  - Must have superior characteristics (ex: outcomes, speed, quality/quantity of performance or data)
  - Is it less expensive?
- **Additive to existing test/technology**
  - Fills an information or treatment gap
  - Is it more cost effective when you look at the total cost of the patient's treatment?

# Standards for Coverage

**Medicare: Section 1862(a)(1)(A) of the Social Security Act ("reasonable and necessary for the diagnosis or treatment of illness or injury.")**

- Improved outcomes; including return to regular ADLs
- Benefits outweigh risks
- Does the clinical evidence show outcomes in the relevant population?

**Private Plans (BCBS Technology Evaluation Center Criteria):**

1. The technology must have final approval from the appropriate governmental regulatory bodies
2. The scientific evidence must permit conclusions concerning the effect of health outcomes
3. The technology must improve net health outcomes
4. The technology must be as beneficial as any established alternatives
5. The improvement must be attainable outside of investigational settings

# Allies and Adversaries

Health benefit plans may not want to cover a new item or service if it would significantly increase costs without superior outcomes

Government programs often use a "budget neutrality" argument to avoid covering expensive new technologies

Hospitals or physicians may not adopt a new product or service if their bundled payment for the same or equivalent procedure is expected to drop if the new product or service is used, or the new technology increases their costs

Be cognizant of potential turf battles between physician specialty groups and among physician groups, ASCs, and hospitals

# Avoiding Pitfalls In The Coverage, Coding, and Payment Process

Section 510(k) clearance for devices makes it easier to get on the U.S. market, but more difficult to prove significant difference compared to the predicate device, unless specific indications justify it

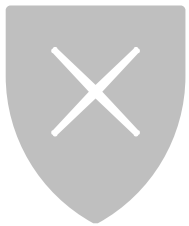
- Get articles published in peer-reviewed journals to demonstrate outcomes

Don’t argue that a new code is needed to get higher payment – base argument on

- Technological improvement
- Clinical improvement
- Higher and more complex resources

- Don’t go it alone - link arms with your allies

# Why is Coverage Denied?



- Experimental / investigational
- Not approved by the FDA
- Insufficient or inconclusive evidence
- Not within a defined benefit category
  (ex: some preventive services, some applications of AI)
- Reliable evidence not available for target population
  (ex: >65 for Medicare)
- Inconsistent with existing professional practice guidelines
- Humanitarian device
- Unproven services

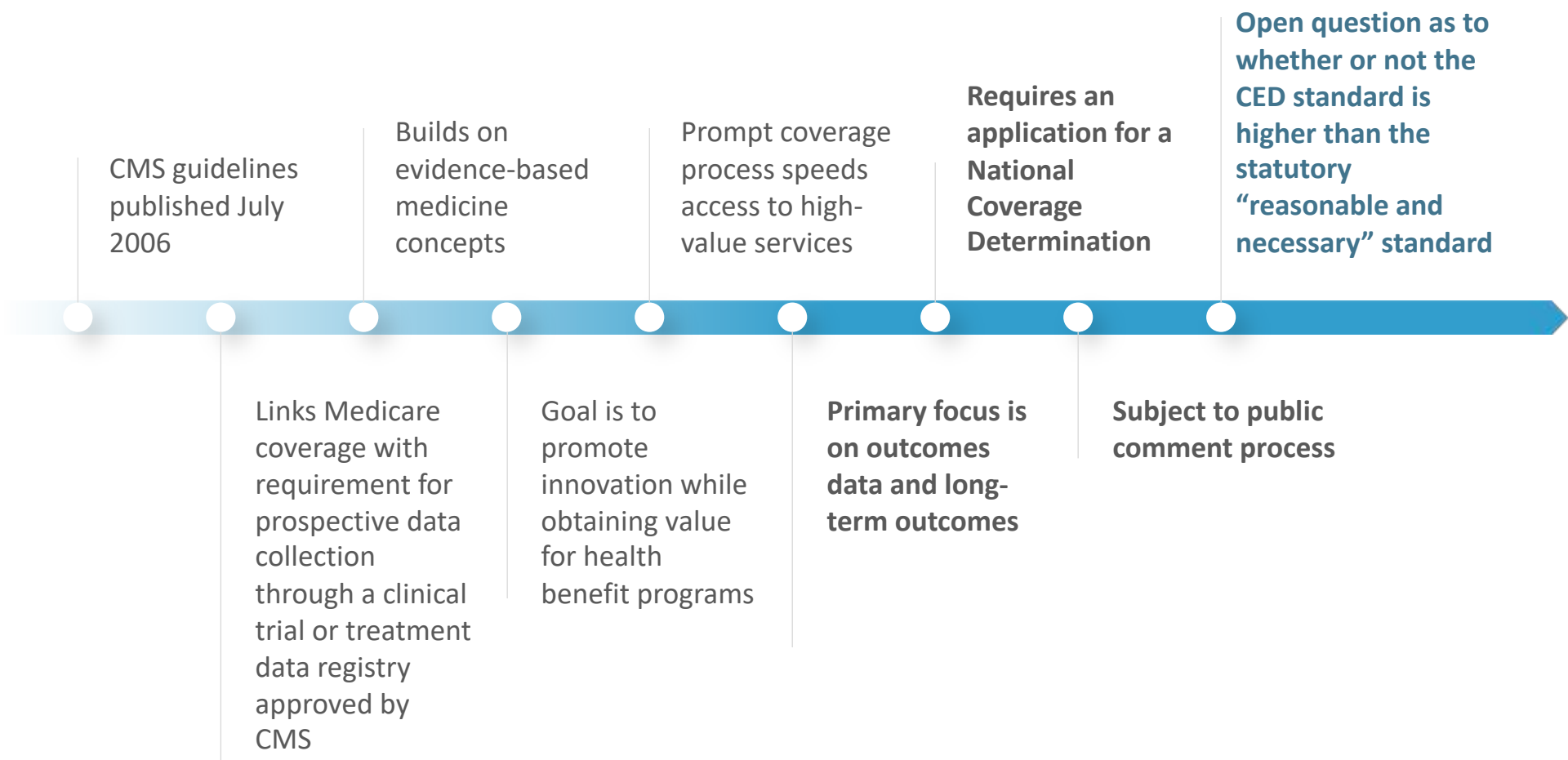
# Integrating Coverage Issues Into Clinical Trial Design

- Coverage is driven by evidence of improved outcomes, clinical efficiency, and cost effectiveness
- Does the study design match the target population (ex: Medicare)
- Study design should include gathering data comparing study item to existing treatments or technologies
- Consider factors relied on by the Agency for Healthcare Research and Quality in their evaluations (www.ahrq.com)

# What Kind of Evidence Is Needed?


- Meta-analysis of individual patient data
- Large, random, double-blind studies
- Meta-analysis of grouped data
- Small, single-site random clinical trials
- Cohort studies
- Non-U.S. studies
- Poorly controlled studies
- Anecdotal information

# Medicare Coverage With Evidence Development ("CED")



# Coding Basics: Types of Codes

**CPT:**
Procedures, Diagnostic Tests – HCPCS Level 1 – Approved by AMA

**HCPCS:**
Drugs, Devices, DMEPOS – HCPCS Level 2 – Approved by CMS Workgroup

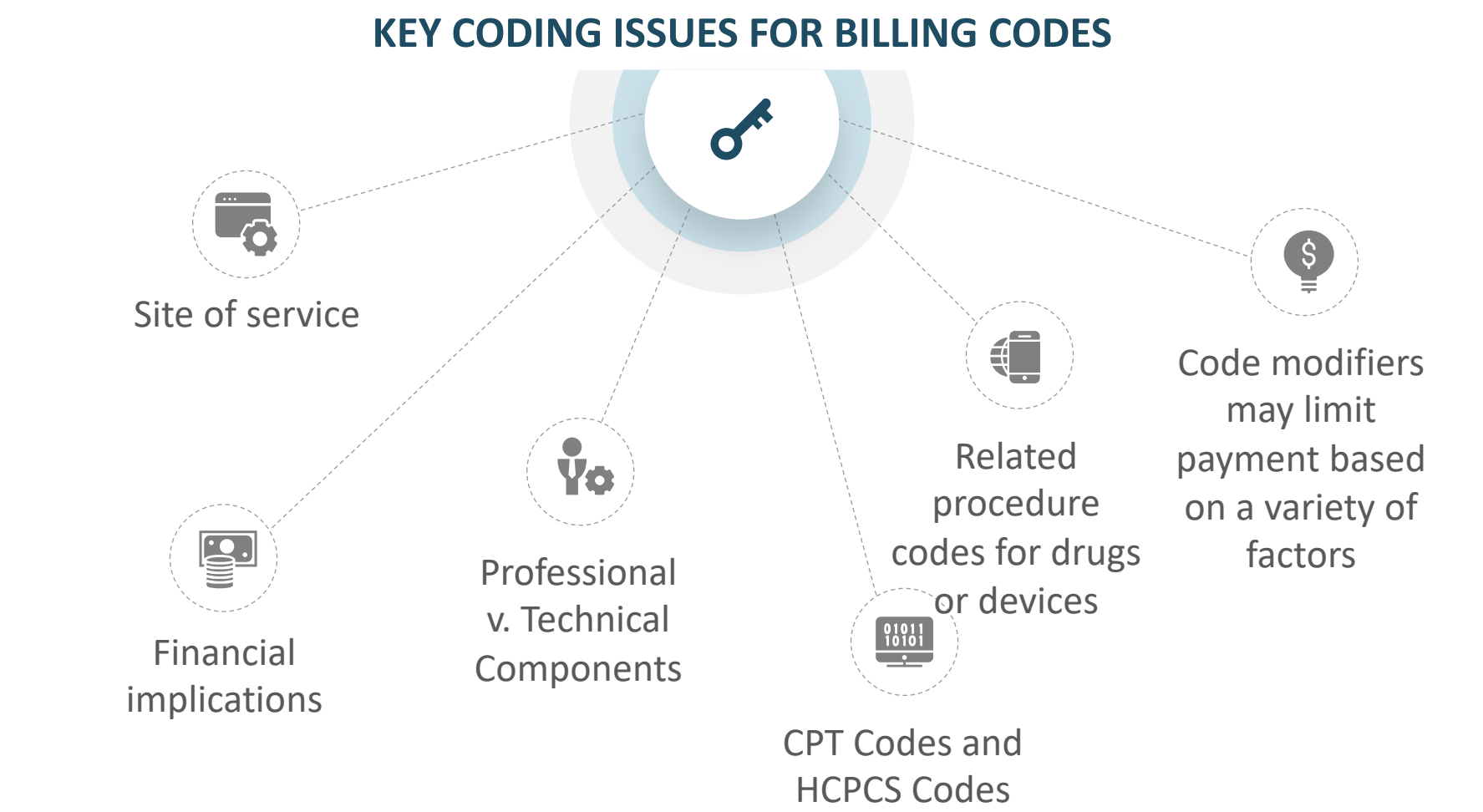
**ICD-10:**
Diagnoses & Inpatient Hospital Procedures



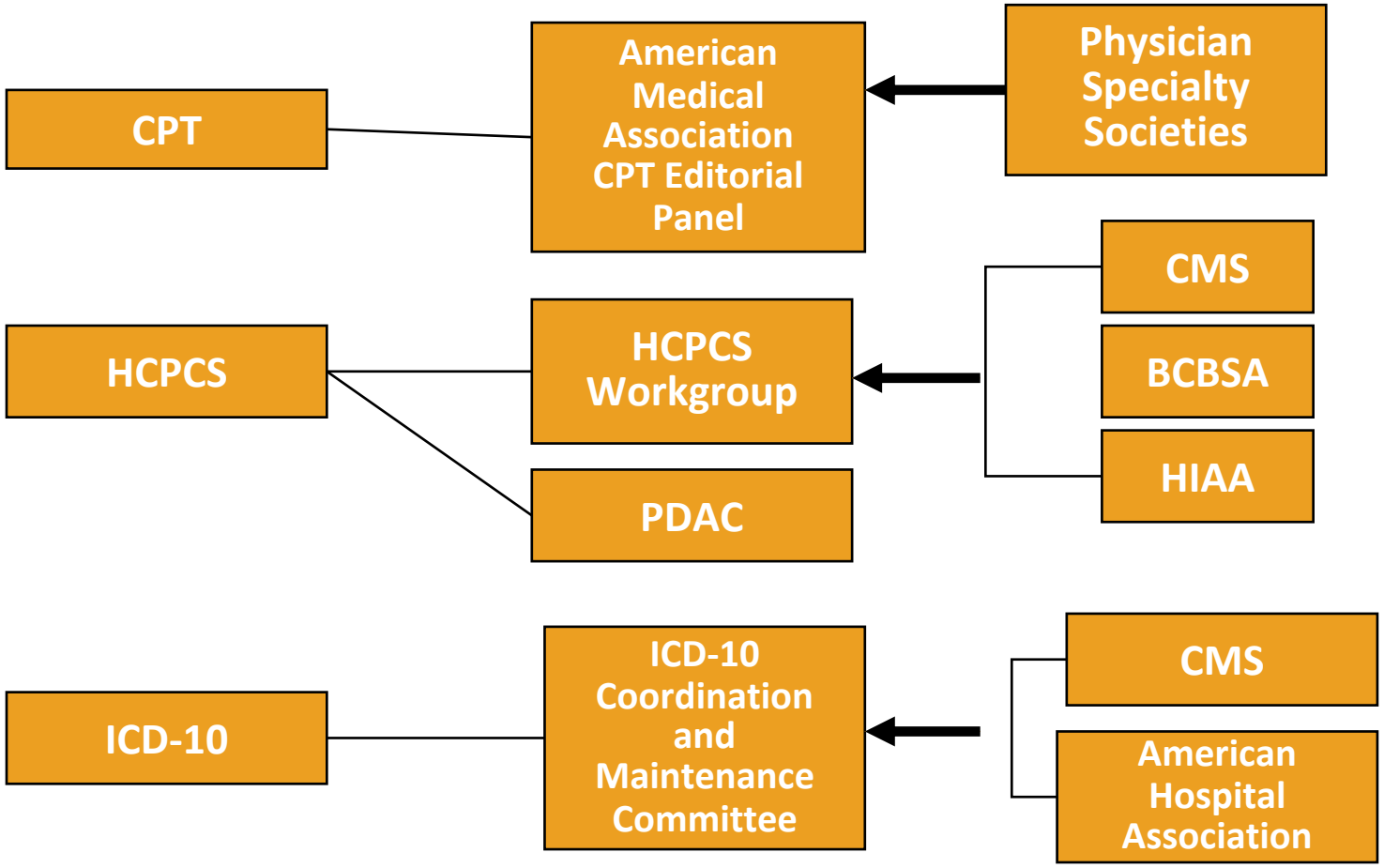

**Reimbursement codes that aggregate items and services in a particular setting:**

- DRG (inpatient hospital)
- APC (outpatient hospital/ASC)
- RUG (skilled nursing)

# Coding Basics



# How Are New Codes Established?

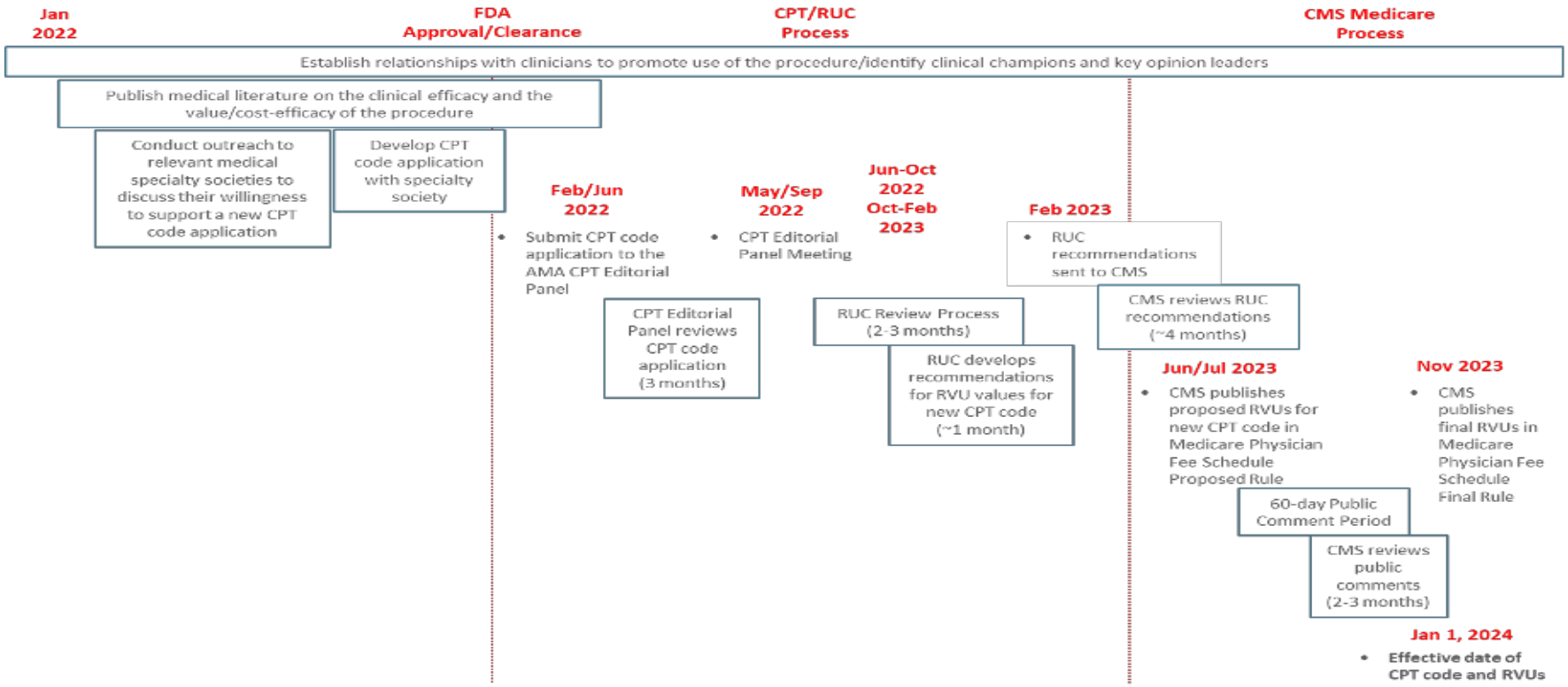


# Background on CPT Code Application Process

- The CPT application process is very political and mostly driven by medical specialty societies
  - New procedures/technologies rarely have sufficient claims data demonstrating ***widespread utilization*** as required by the AMA
  - New procedures/technologies rarely have the required ***clinical efficacy evidence*** of the service/procedure in the form of "several" U.S. peer-reviewed publications
  - A Category III CPT code may be granted in lieu of a Category I CPT Code, as a temporary code used to substantiate widespread usage and clinical efficacy of a new and emerging technology
  - However, payers often will not pay for Category III CPT codes, because they are viewed as "experimental or investigational"

**The support of physician specialty societies is a major factor in increasing the likelihood that a new CPT code will be adopted and that a favorable RUC survey will be conducted to determine the valuation of the new code**

# Timeline and Key Events in the CPT Category I Code Process



# Level of Evidence for New CPT Code

- CPT Code application for new technology must include up to 5 references
  - Of these, at least 2 articles must report different patient populations in addition to having different authors (no overlapping patient populations and no overlapping authors)
- Submitted references should represent the most informative and compelling peer-reviewed publications that directly support the application
  - Studies should be well-designed and executed, ethical in nature, and directly support the code change request
- Need to identify whether the literature was published in a U.S. based journal or a non-U.S. based journal, and whether the population studied is U.S., non-U.S., or both
- Need to identify the number of patients studied (total of all group[s] including controls) and whether the study is a prospective study

# AMA Level of Evidence Table

| Level of Evidence Table – LOE | |
|---|---|
| **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<br>***Randomized Controlled Trial(s):*** *An epidemiological experiment in which subjects in a population are randomly allocated into groups, usually called study and control groups, to receive or not receive an experimental preventive or therapeutic procedure, maneuver, or intervention. The results are assessed by rigorous comparison of rates of disease, death, recovery, or other appropriate outcome in the study and control groups.* |
| IIa | Evidence obtained from systematic review of cohort studies |
| IIb | Evidence obtained from an individual cohort study<br>***Cohort study(ies):*** *The analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels.* |
| IIIa | Evidence obtained from systematic review of case control studies |
| IIIb | Evidence obtained from a case control study<br>Case-control study(ies): The observational epidemiologic study of persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined by comparing the diseased and non-diseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups. |
| IV | Evidence obtained from case series<br>Case-series: A group or series of case reports involving patients who were given similar treatment. Reports of case series usually contain detailed information about the individual patients. This includes demographic information (for example, age, gender, ethnic origin) and information on diagnosis, treatment, response to treatment, and follow-up after treatment. |
| V | Evidence obtained from expert opinion without explicit critical appraisal |

Need at least 1 article that is considered Level Ia, Ib, or IIa for CPT code application

# Comparing the Code Sets

| CODE SET COMPARISON CHART | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Timing | | | Volume | Transparency | | |
| CODE SET | Application Deadline | Effective Date | Length of Cycle | Average Number of Applications in Cycle | Provide Detailed Application Summaries | Publish Preliminary Decisions | Public Input |
| HCPCS II | January 3 | January 1 of the following year | 12 months + Quarterly Updates | 150 | Yes – published at least 4 weeks prior to Public Meetings | Yes | Public Meetings Spring of each year |
| CPT | 3 months prior to May, October, or February meeting see www.ama-assn.org | Cat. I: codes released Fall, eff Jan 1<br>---<br>Cat I vaccine, MoPath, or III codes: Jan 1 or July 1<br>---<br>Cat II codes: Feb 15, Jun 15, or Oct 15 | 15 months + Quarterly Updates | 200<br>(Review is divided into committees and sub-committees, who report back to 1 group) | No | No | Public may attend voting meeting. Votes are silent. |
| CDT | November 1 | Jan 1 of second year following receipt of application | 14 to17 months | 120 | Yes | No | Public may attend voting meeting. Votes are known. |
| ICD-9 And ICD-10 | January (2 months prior to meeting) | October 1 of the following year | 7 months | CMS processes 10 – 25 procedure applications<br>NCVHS processes 25 diagnosis applications | Yes – provided at public meeting | No | Public Meeting March |
| | July (2 months prior to meeting) | October 1 of the following year (codes for New Tech can be implemented in following April) | 13 months | CMS processes 10 – 25 procedure applications<br>NCVHS processes 25- 35 diagnosis applications | Yes – provided at public meeting | No | Public Meetings September |

Source: CMS Innovators' Guide to Navigating Medicare, Version 3 2015, *available at*: https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf

# Overview of Payment Methodologies

### Hospitals

- Part A – inpatient – reasonable costs → DRGs
- Part B – outpatient – reasonable costs → APCs

### Other Part B Services

- Fee Schedules
- Average Wholesale Price "AWP"
- Average Sales Price "ASP"

### Skilled Nursing Facilities

- Reasonable costs → Resource Utilization Groups ("RUGs")

### Ambulatory Surgical Centers

- Nine payment groups → Multiple APCs

### Physicians – Part B

- Reasonable charges → RBRVS based on CPTs

# Payment Methodologies

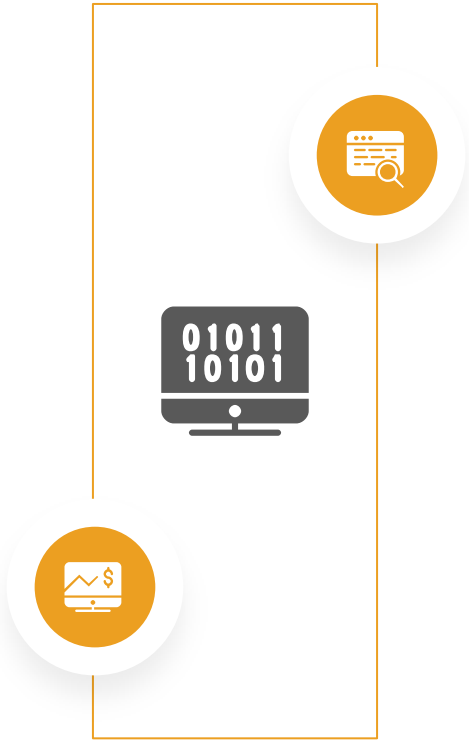
**GENERAL RULE:**

## Payment for Drugs, Devices, Diagnostics, and Procedures Will Turn On:

- Site of Service
- Enumerated Benefits
- Enumerated Exclusion
- Coverage determinations (nationally/locally)
- Bundled items and services, or stand-alone

# Coordinating Coverage With Coding & Payment

**Coverage determinations can have an impact on coding and payment**




**Analysis of competing or similar items in the same coding category:**

- What are the codes used for those items?
- What is the range of payment?
- Is the prevailing payment range acceptable?
- If not, what evidence justifies either a new code or higher payment?

*"It's always 'Sit,' 'Stay,' 'Heel'—never 'Think,' 'Innovate,' 'Be yourself.'"*

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# Questions?

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# Coverage, Coding & Payment Case Studies

# Case Study: Coverage for Virtual Colonoscopy ("VC")

- As of January 2009, VC covered by many private health plans in the U.S. for patients > 50 years old when there has been a failed traditional colonoscopy; two cover VC for screening in all patients > 50 years
- Medicare (CMS) focused on two questions:
  - Is the evidence sufficient to determine that CT colonography is a valuable screening test for colorectal cancer for average risk Medicare individuals compared to optical colonoscopy?
  - Is the evidence sufficient to conclude that the use of CT colonography improves health outcomes for colorectal cancer screening in average risk individuals compared to optical colonoscopy?

# Case Study: Coverage for Virtual Colonoscopy

- Published studies had a mean age of 57-58 years
- Studies found lower sensitivity and specificity for polyps < 6mm with VC compared to optical colonoscopy
- May 2009: CMS concluded that the current evidence is inadequate, and Medicare will not cover virtual colonoscopy
  - CMS found that no published study has focused on a population more representative of the Medicare population.
  - CMS could not determine if the published study results are generalizable to the Medicare target population (> 65 years).
  - CMS concluded that there is "insufficient [clinical trial] evidence to determine that CT colonography is a valuable screening test for colorectal cancer for average risk Medicare individuals compared to optical colonoscopy."

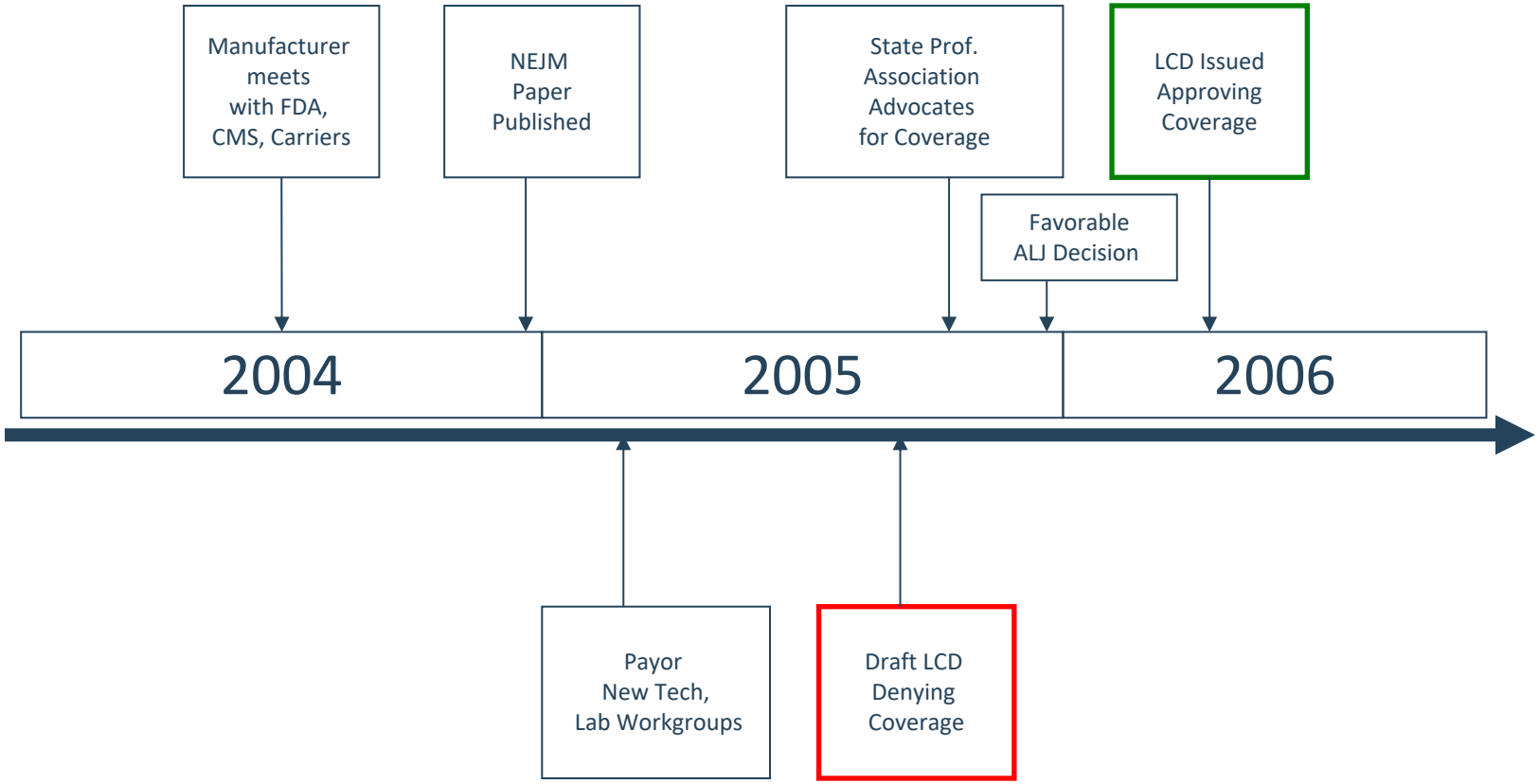
# Case Study: Artificial Disk Replacement

- October 2004: FDA approves artificial disk for sale, but requires that manufacturer provide data on long-term performance of the device
- July 2005: New York Times reports that several private insurers question clinical outcomes compared with spinal fusion
- February 2006: CMS proposes national noncoverage determination
- May 2006: CMS issues national coverage determination that artificial disk will be covered for beneficiaries under age 60 if local carrier medical director concurs.
- August 2007: CMS denies coverage for all artificial disk replacements
  - Agency explained that none of the clinical trial data submitted involved patients over age 60, and that as a result there was no basis on which CMS could conclude that the device is reasonable or necessary for the Medicare population

# Case Study: Oncotype DX

- Oncotype DX first marketed in 2004
- Diagnostic test uses RNA from paraffin-block tissues as an early predictor of the risk of breast cancer recurrence by measuring levels of specific genes
- Pivotal publication: 10-year retrospective study on 668 node-negative, estrogen receptor-positive patients.
  - Extremely high correlation with course of the malignancy
  - Correlation is higher than “traditional pathology”
- Results consistent with several large, independent patient cohorts
- Close collaboration with NSABP/NCI
- Professional association strongly recommended coverage upon December 2004 NEJM publication
- Draft Local Coverage Determination was unfavorable
- Final Local Coverage Determination was favorable, following ALJ decision and input of professional organizations

# Case Study: Oncotype DX



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# Appendix

# Comparing the Standards: FDA & CMS

| CMS Factors | FDA Factors | Comments |
|---|---|---|
| "Reasonable and Necessary" | "Safe and Effective" | No presumption of Medicare coverage; CMS focuses on outcomes and resumption of ADLs for the relevant population (≥ 65 y.o.) |
| Local standards | Equivalence to device, or new device | CMS emphasizes "standard of practice" |
| Published articles | Submitted data | CMS relies on peer-reviewed articles, systematic reviews, input from professional societies. It may do its own reviews |
| Expert consensus | Reasonable expectation of safety (risk/benefit) | CMS seeks to reflect professional consensus |
| Duration/Frequency | May be irrelevant to label (e.g., PET) | Critical for payors |
| Indication | May be broad or vague – "off-label" promotion prohibited | Potential for "off-label" use |
| Compare for available & appropriate alternative | FDA may be more focused on safety | CMS interested in outcomes and comparative effectiveness |

# Comparative Effectiveness Research

Research designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different options.

The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.


What are your “competing” treatments?


Comparative cost vs. clinical effectiveness

Potential ethical issues in designing trials

Strategy, approach, timing and engagement are critical

# Pathway for New Category I CPT Code

- Category I codes are permanent codes used to describe health care procedures or services
- A proposal for a new or revised **Category I code** must satisfy all of the following criteria:
  - All devices and drugs necessary for performance of the procedure of 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 United States
  - 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

# Pathway for New Category III CPT Code

- Category III codes are used for new and emerging technologies and are temporary codes
  - The purpose of these codes is to facilitate data collection and assess the new service and/or procedure
  - The data collected from these codes is used for the FDA approval process or to substantiate widespread use
- A proposal for a new **Category III code** does not require FDA clearance or approval, but the following should be demonstrated:
  - The procedure or service is currently or recently performed in humans ***AND***
  - At least one of the following additional criteria has been met:
    - The application is supported by at least 1 CPT or HCPAC Advisor representing practitioners who would use this procedure or service ***OR***
    - 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) ***OR***
    - There is:
      - At least 1 Institutional Review Board approved protocol of a study of the procedure or service being performed,
      - A description of a current and ongoing United States trial outlining the efficacy of the procedure or service, or
      - Other evidence of evolving clinical utilization