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Innovation Organization

Become a Biotech or MedTech Entrepreneur

Navigating Coding Systems and Optimizing Pricing and Reimbursement

Presented by:
Robert Wanerman, J.D., M.P.H.

June 1, 2024

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Coverage, Coding, and Reimbursement for Innovators

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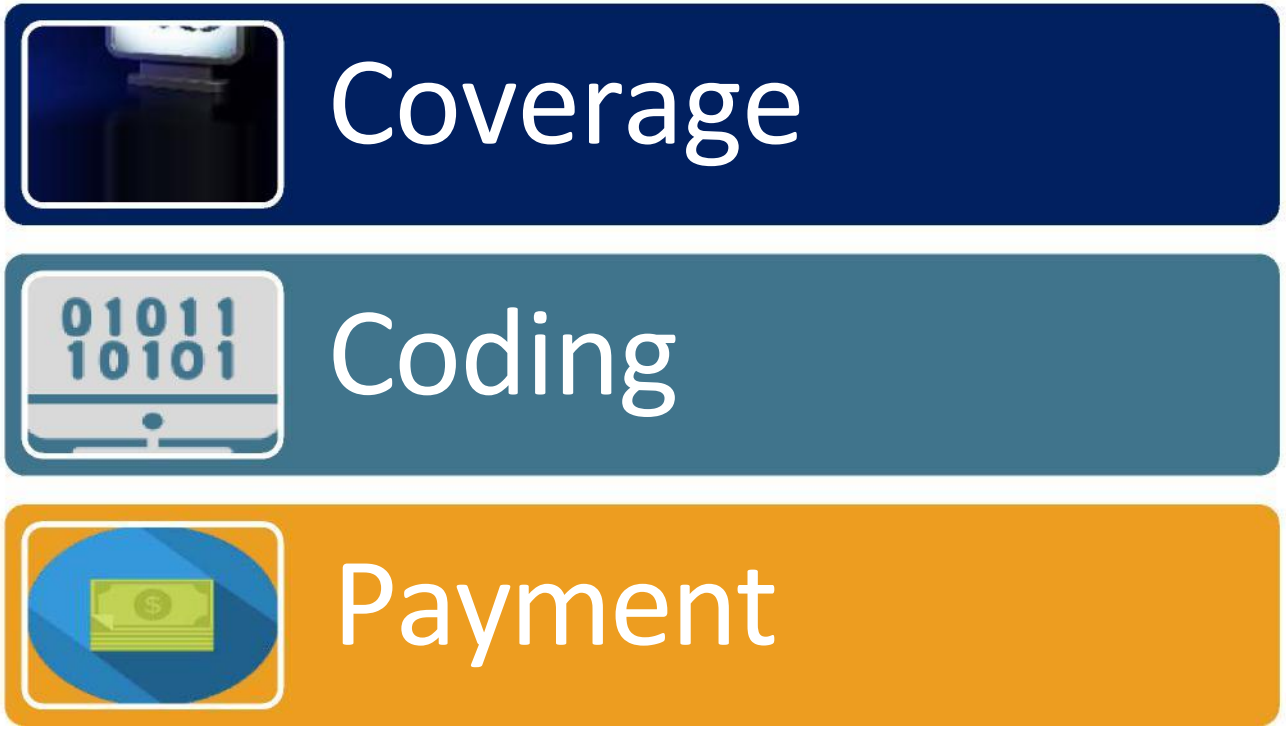
June 1, 2024

Today's Agenda

Basic Concepts for Commercialization



Setting The Table

Putting Coverage, Coding, and Reimbursement Into Context

- Who is really interested in your strategy?
  - Thoughtful investors
  - Regulators
  - Clinicians and Other Providers
  - Health Plans

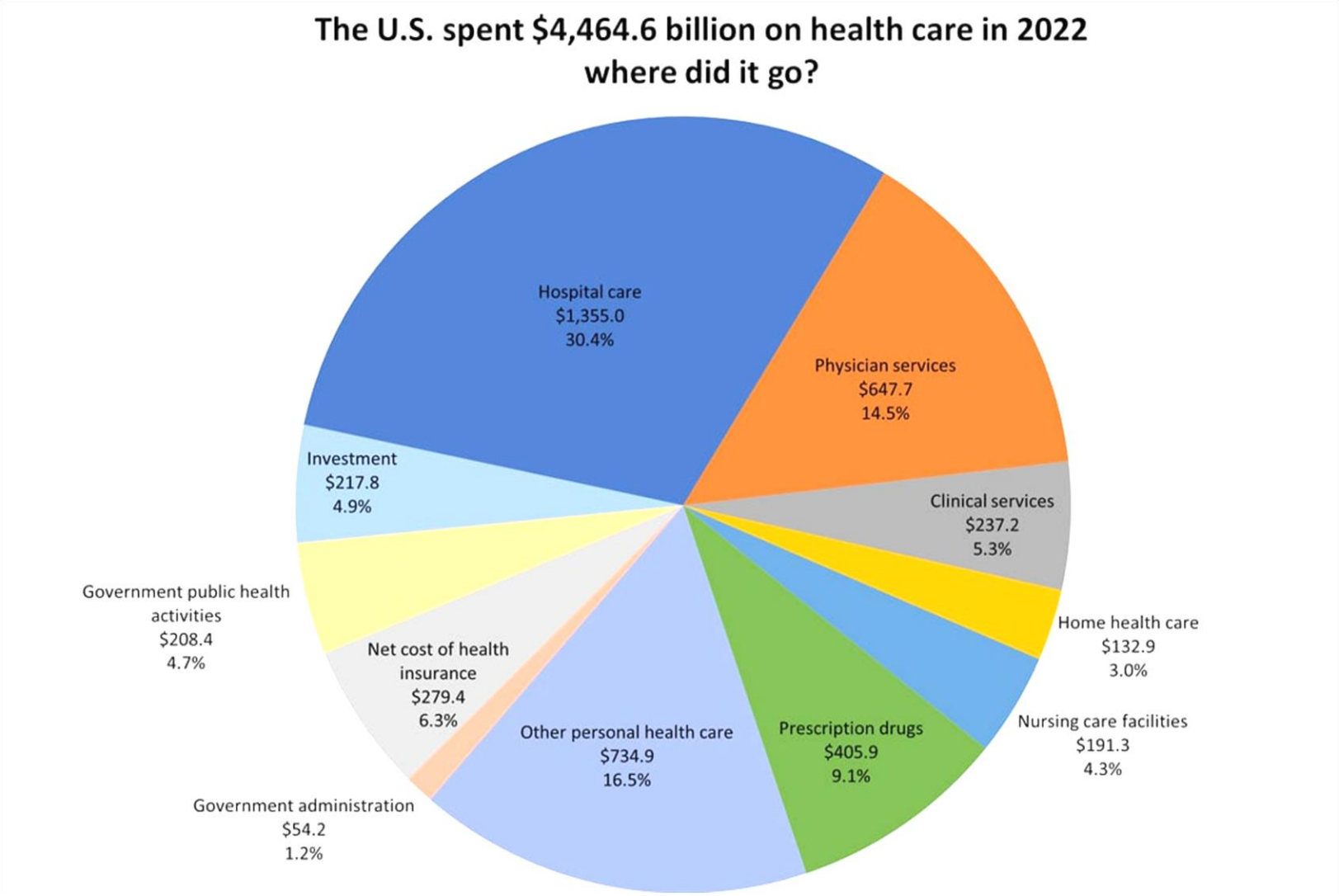
From Bench to Bedside

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."

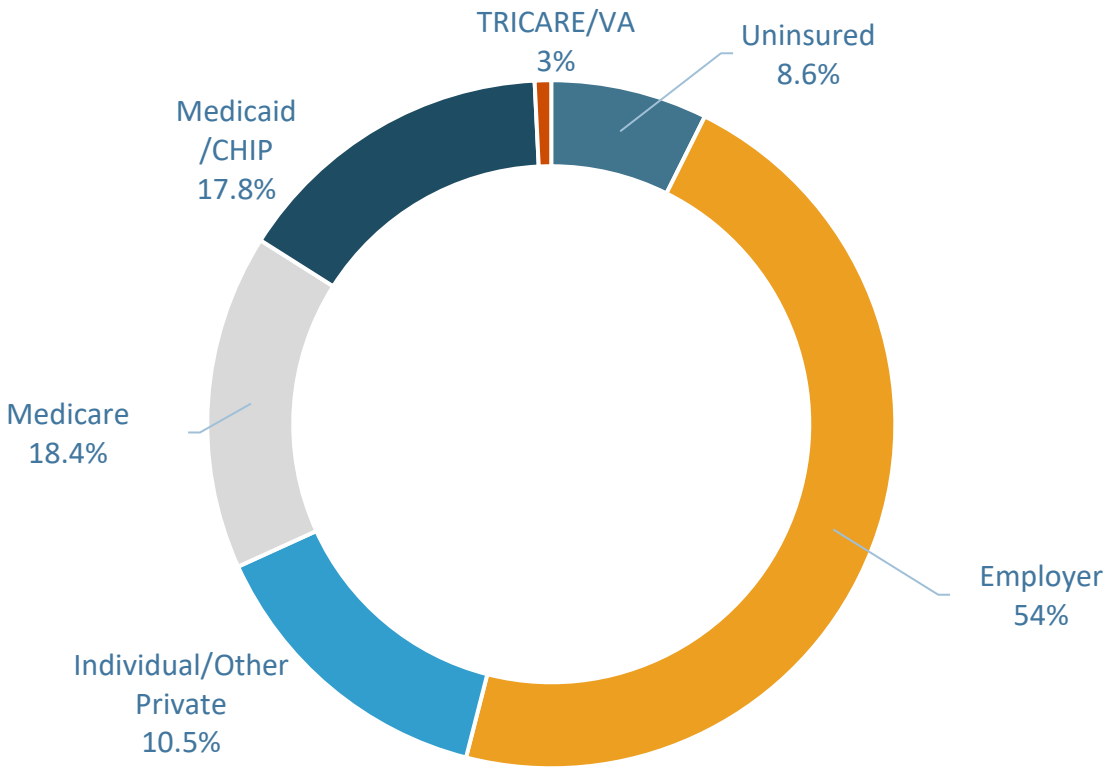
D. Drakeman, L. Drakeman, N. Oraiopoulos, From Breakthrough to Blockbuster: The Business of Biotechnology at 12 (2022)

Components of Total US National Health Expenditures: $4.5 Trillion in 2022



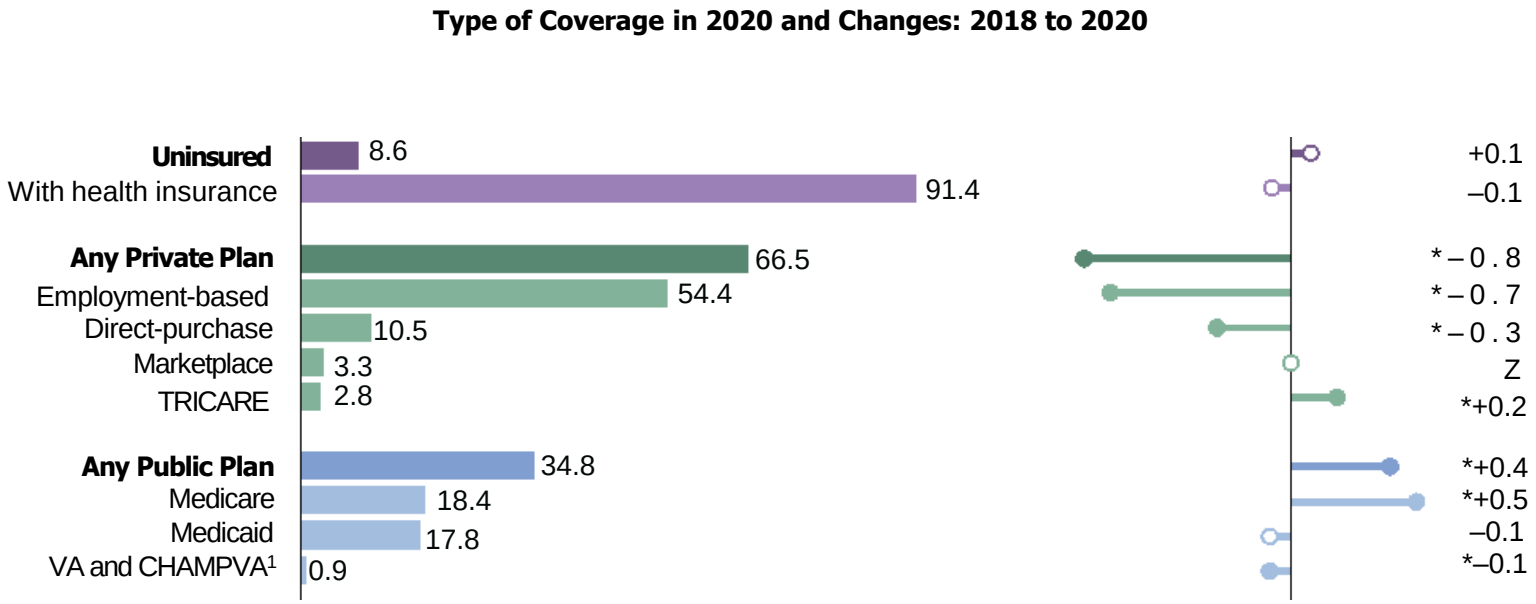
Hartman, M., Martin, A., Whittle, L. and Catlin, A. National Health Care Spending in 2022: Growth Similar to Prepandemic Rates. Health Aff 2024 January; 43(1)

Government Programs Account for Approximately 40% of US Health Care Coverage



Source: US Census Bureau, Table HHI-02, Current Population Survey Annual Social and Economic Supplement, October 2021

Health Insurance Coverage in the United States



* Denotes a statistically significant change between 2018 and 2020 at the 90 percent confidence level.

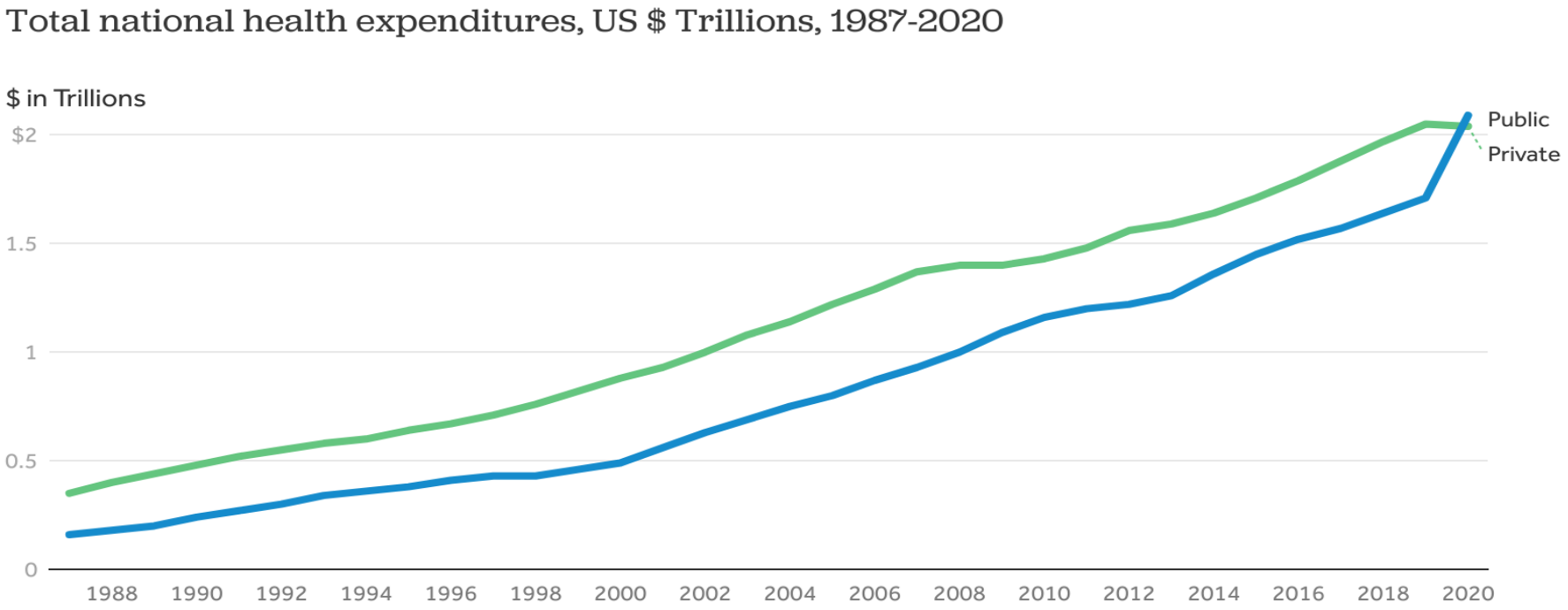
Z Rounds to zero.

[1] Includes CHAMPVA (Civilian Health Medical Program of the Department of Veterans Affairs), as well as care provided by the Department of Veterans Affairs (VA) and the military.

Note: The estimates by type of coverage are not mutually exclusive: people can be covered by more than one type of health insurance during the year. Information on confidentiality protection, sampling error, nonsampling error, and definitions in the Current Population Survey is available at <https://www2.census.gov/programs-surveys/cps/techdocs/cpsmar21.pdf>.

Source: U.S. Census Bureau, Current Population Survey, 2019 and 2021 Annual Social and Economic Supplement (CPS ASEC).

Total National Health Expenditures, US $ Trillions, 1987-2020



Source: KFF analysis of National Health Expenditure (NHE) data

Peterson-KFF Health System Tracker

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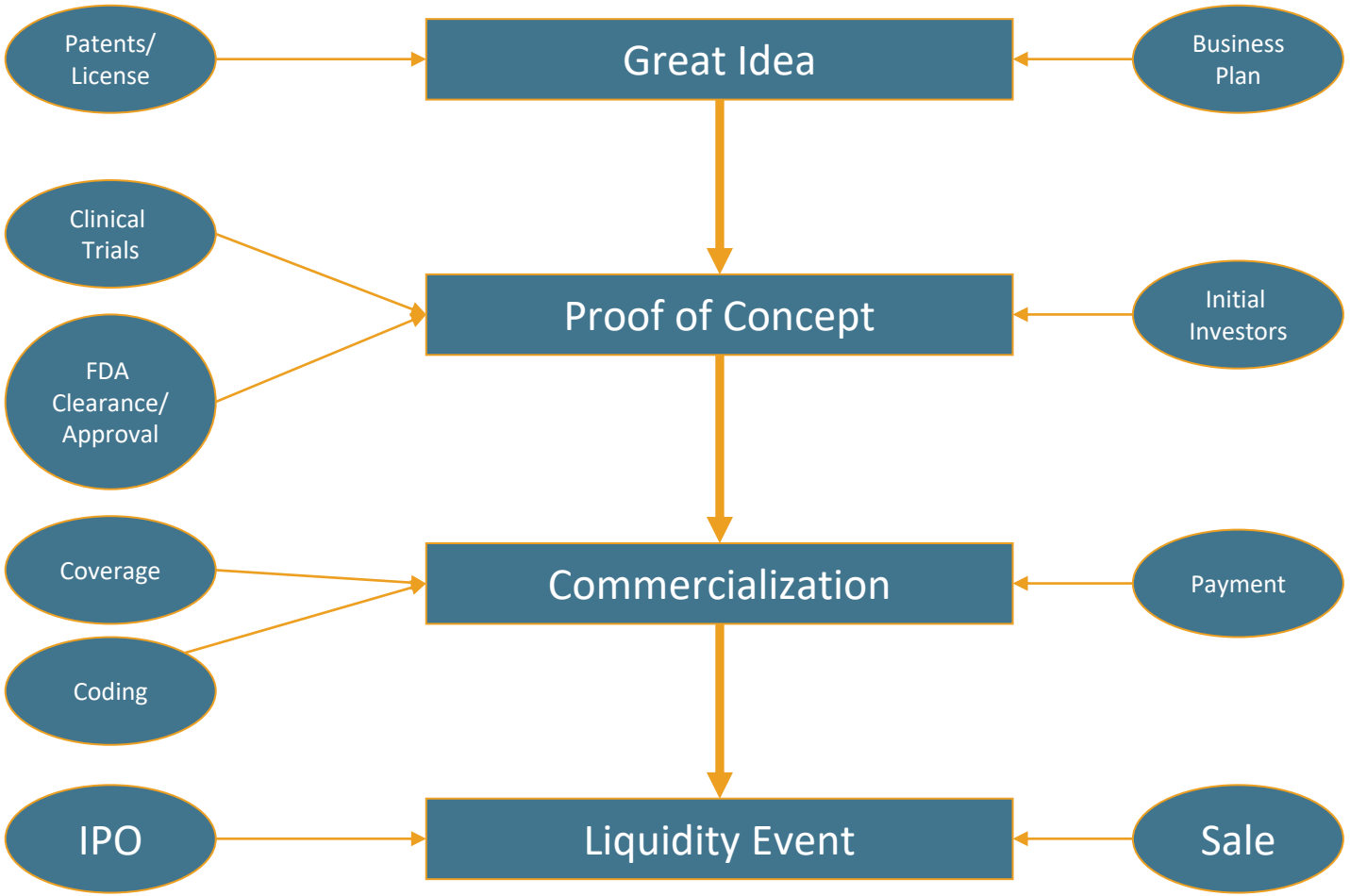
A Story of How FDA Labeling Created An Initial Barrier To Successful Coverage

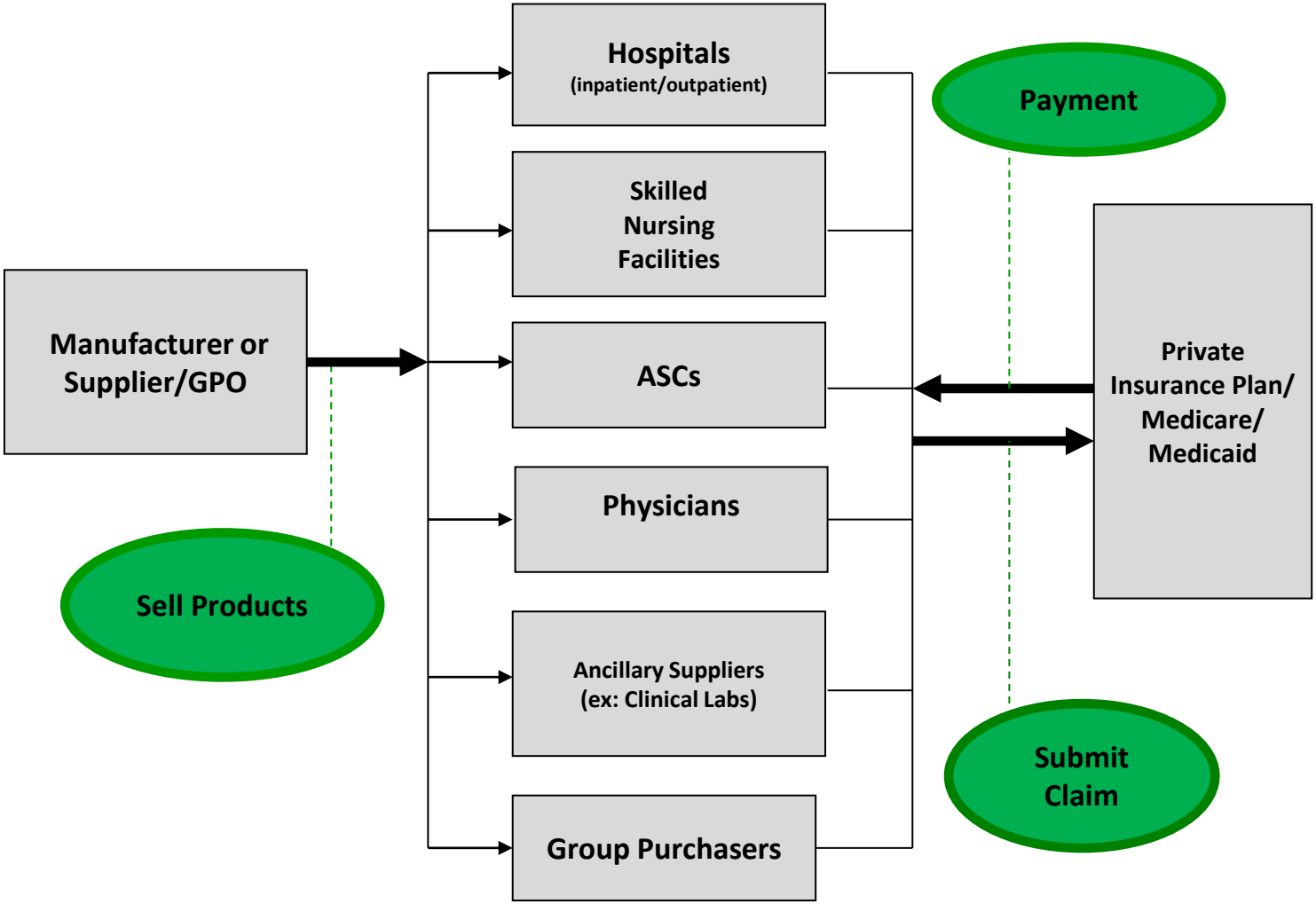
In Practice, Things Are Different: The Aduhelm Experience

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

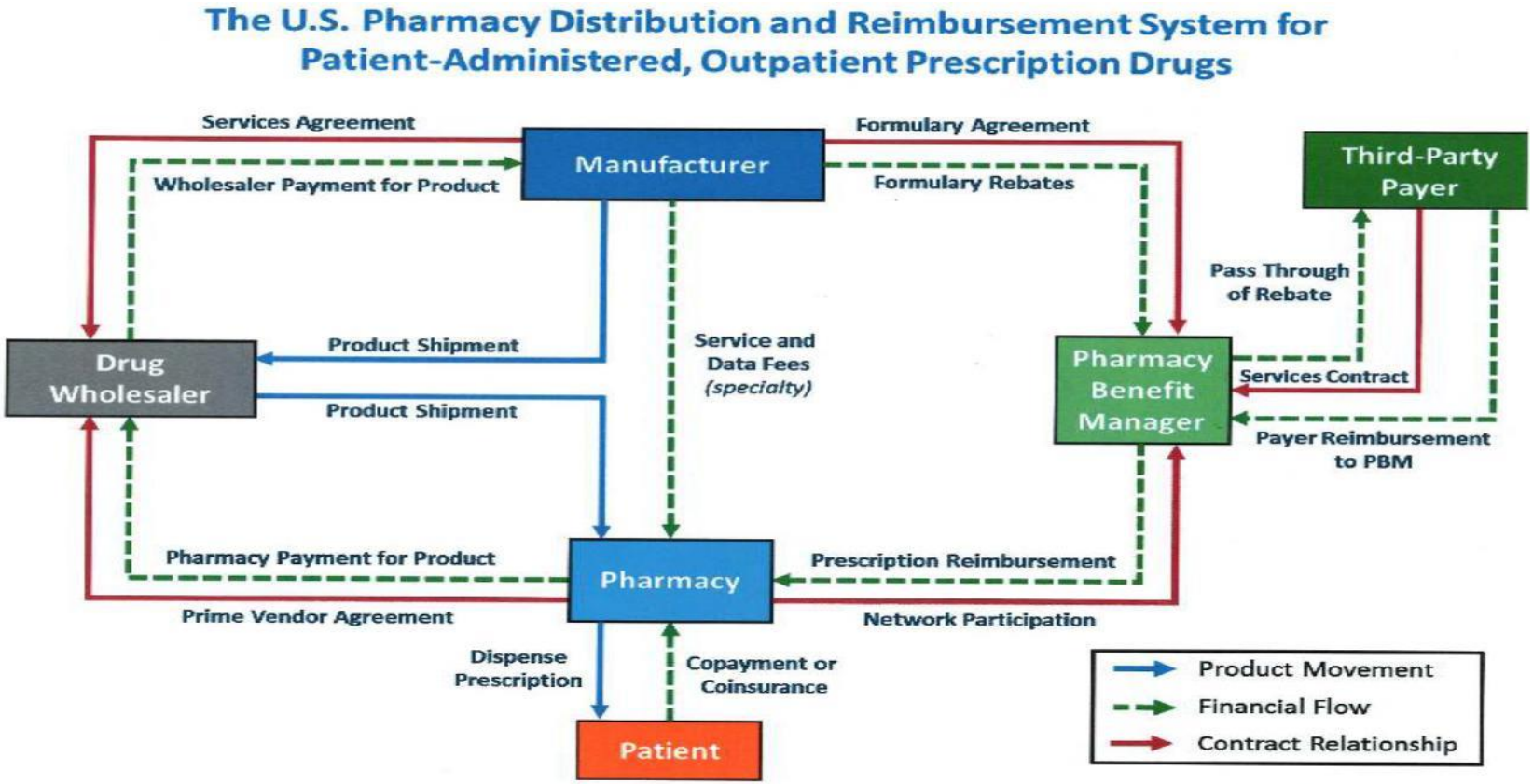


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report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

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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,drugs, 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

Key Coverage Issues

- Who will benefit most?
  - Seniors, children, women, others?

- What are the expected clinical outcomes?

- Are there specific prerequisites or limits for coverage?

- 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?

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

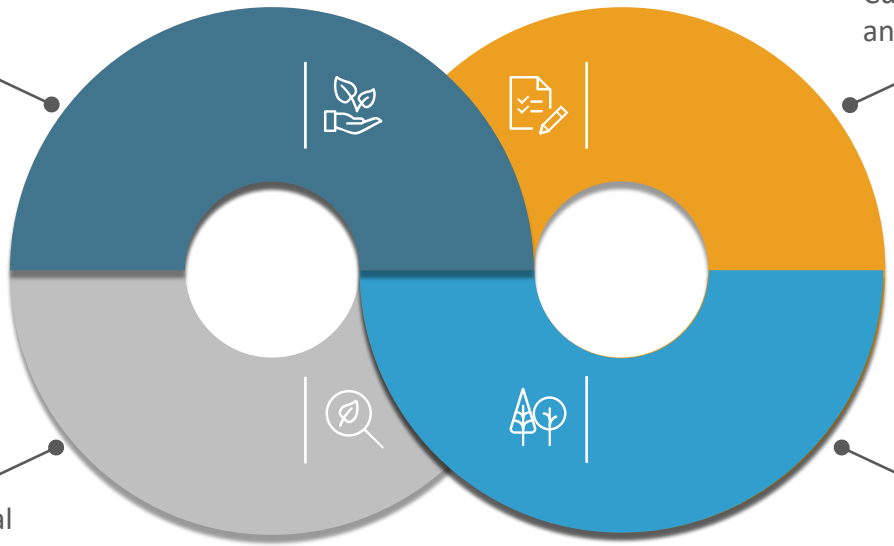
Physician consultants or advisors for assistance with presentations to the payers, to other physicians, or for CPT coding assistance

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 – Build Familiarity With The Innovation

Process begins well in advance of product launch; build coverage issues into the clinical trial protocol(s)

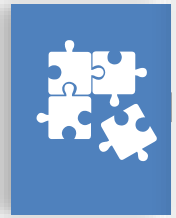
Cultivate physician thought leaders and institutional advocates



Build familiarity with professional organizations and end-users

Investors will demand a rigorous coverage and reimbursement strategy

Special Coverage Challenges



- **Innovative breakthrough for patient health**
  - Fills a compelling unmet need
  - Does it replace a health care professional?

Replacing an existing technology or treatment

- Must have superior characteristics (ex: outcomes, speed, quality/quantity of performance or data)
- Is it less expensive?

Additive to existing technology or treatment

- 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

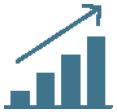
Medicare: Section 1862(a)(1)(A) of the Social Security Act ("reasonable and necessary for the diagnosis or treatment of illness or injury.")

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

Private Plans (Former BCBS Evidence Street):

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

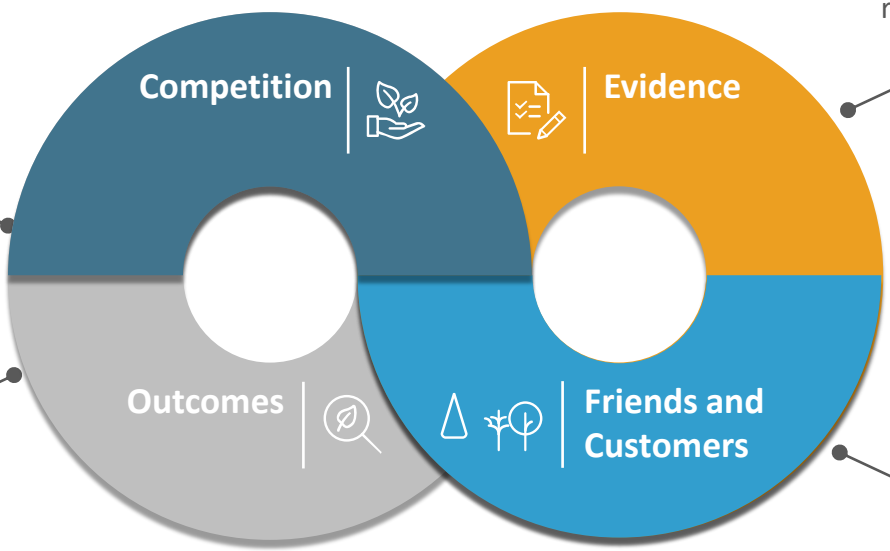
Hospitals or physicians may not adopt a new product or service if their bundled payment for the same or equivalent procedure is expected to drop if the new product or service is used, or the new technology increases their costs

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

Predicates make it easier to get on the U.S. market, but more difficult to prove significant difference compared to the predicate, unless specific indications justify it

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



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

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

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

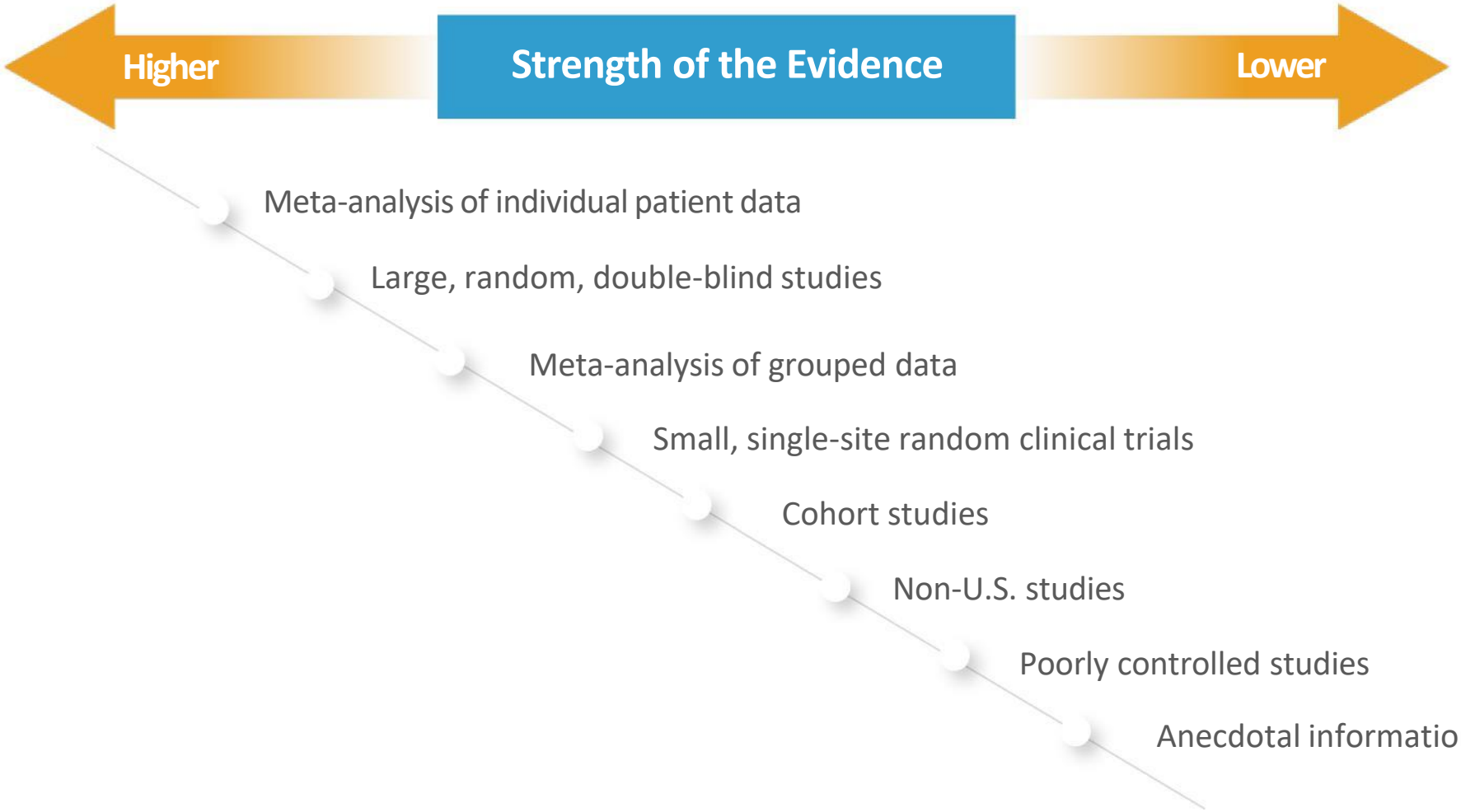
Why Is Coverage Denied?

- 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)

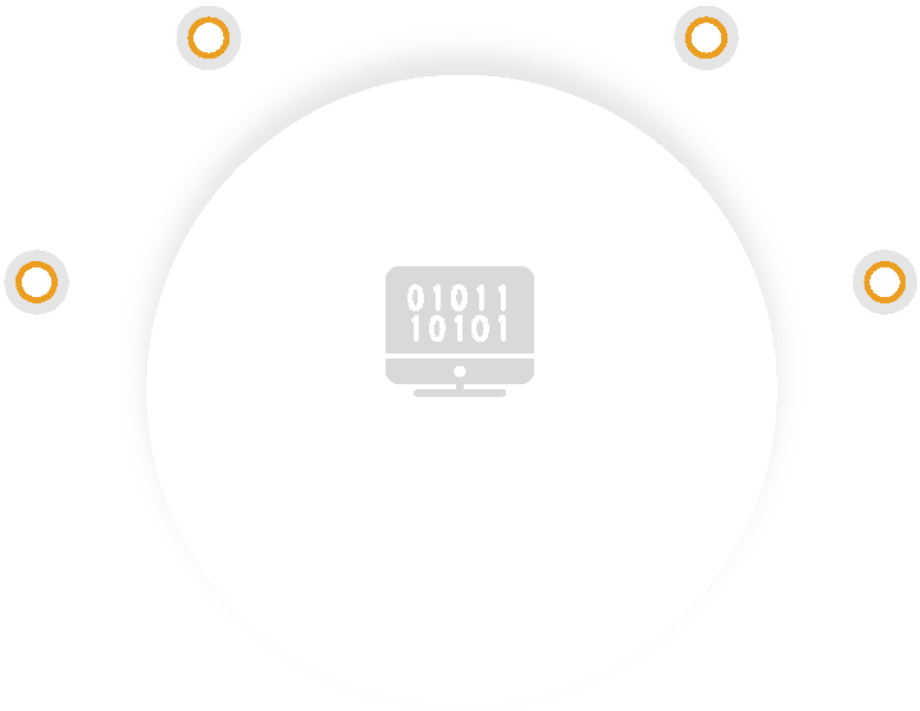
What Kind of Evidence Is Needed?



Coding Basics: Types of Codes

CPT: HCPCS:
Procedures, Diagnostic Tests – Drugs, Devices, DMEPOS – HCPCS
HCPCS Level 1 – Approved by AMA Level 2 – Approved by CMS Workgroup

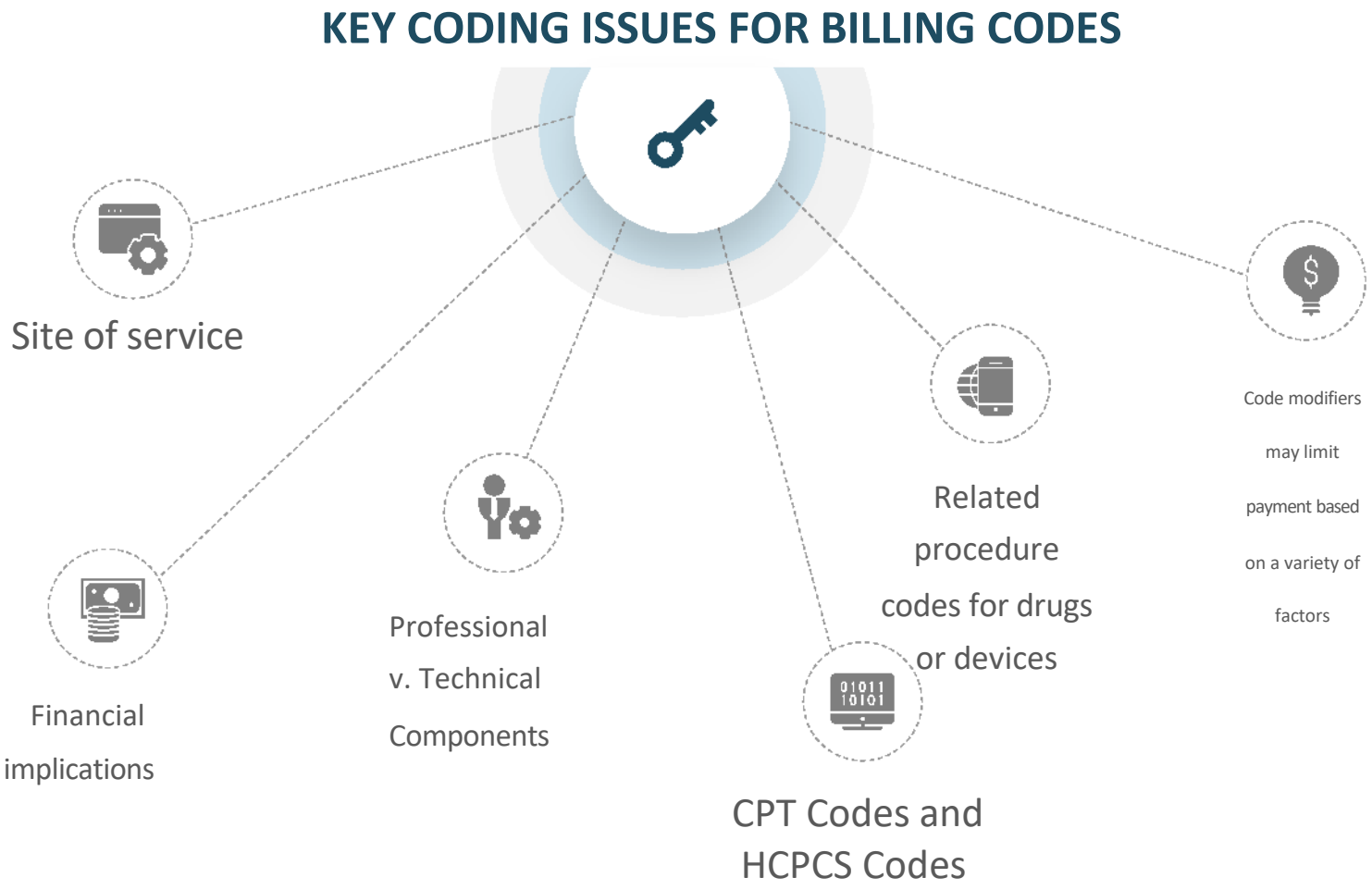
ICD-10:
Diagnoses & Inpatient Hospital Procedures



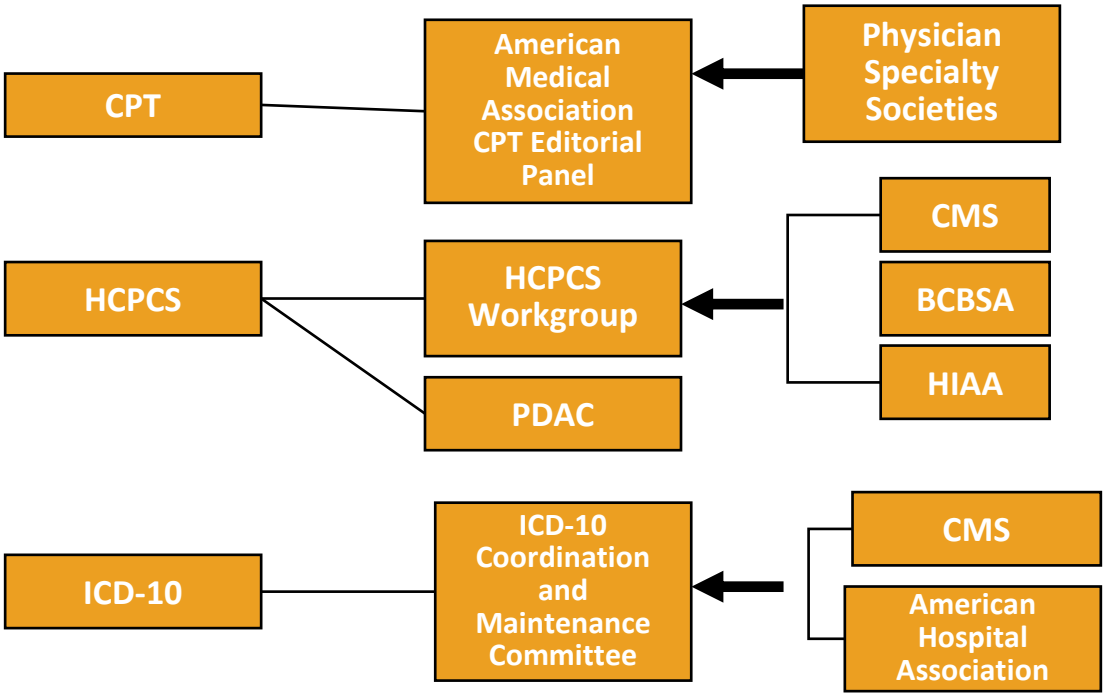
Reimbursement codes that aggregate items and services in a particular setting:

- 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

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

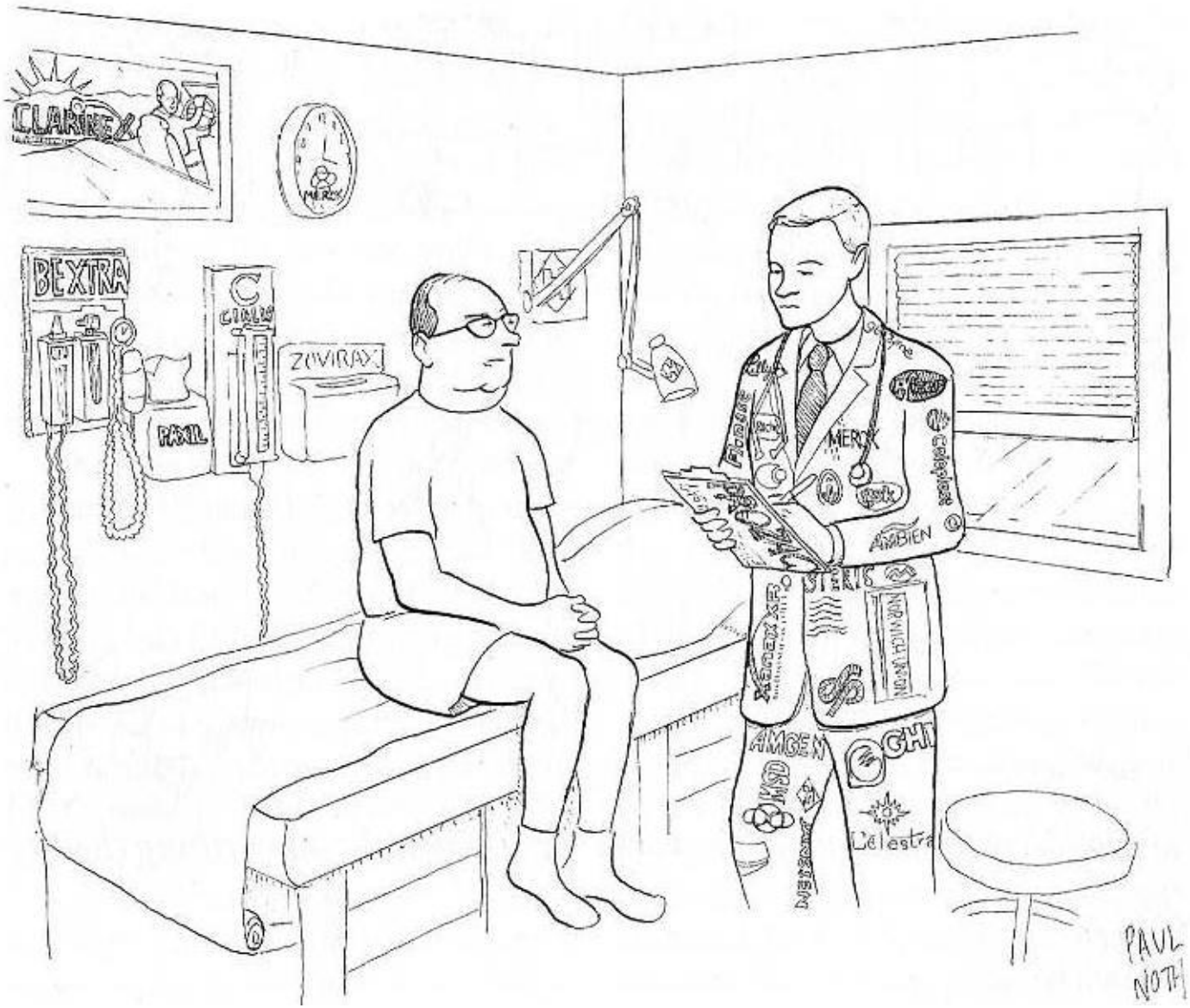
GENERAL RULE:

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

- Site of Service
- Enumerated Benefits
- Enumerated Exclusion
- Coverage determinations (*national/local/none*)
- Bundled items and services, or stand-alone

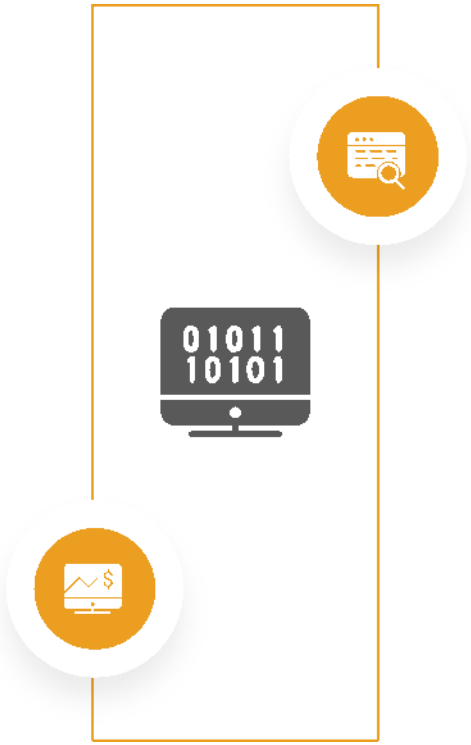
Payment Methodologies – The Ecosystem

- **Cross-walking Potential**:
  - If the new item or procedure is comparable to an existing item or procedure, it can be "crosswalked" an item or procedure described in an existing code, and the reimbursement is the same as the reimbursement for that existing code.
    - Predictable reimbursement
    - Reimbursement may not be ideal
- **Gap-filling Potential**:
  - If the payor determines that the applicable fee schedule includes no sufficiently comparable item or procedure to permit crosswalking, it may "gap-fill" the payment amount for the new code. Gap-filling is the term for setting a reimbursement rate based on external sources that can include:
    - charges net of any discounts or rebates
    - resources required to perform a procedure
    - payment amounts determined by other payers
    - charges, payment amounts, and resources required for other items or procedures in the same part of the code set



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."

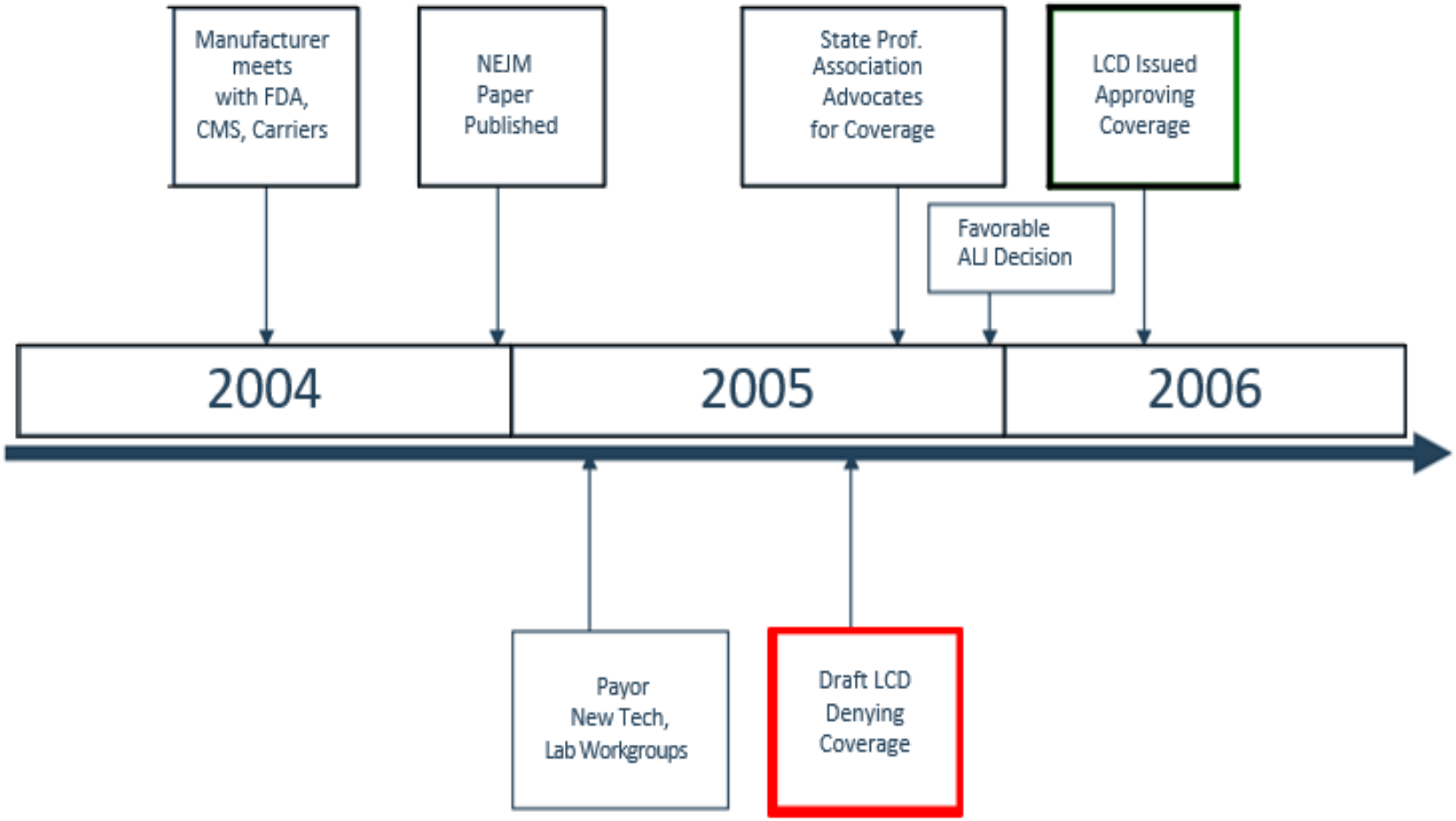
Case Study: Artificial Disk Replacement

- 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