

Coverage, Coding, and Payment for Procedures, Devices, Drugs, and Diagnostics or (If you build it, will they buy it?)

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Today's Agenda:

Basic Concepts for Commercialization



Coverage



Coding



Payment

In An Ideal World



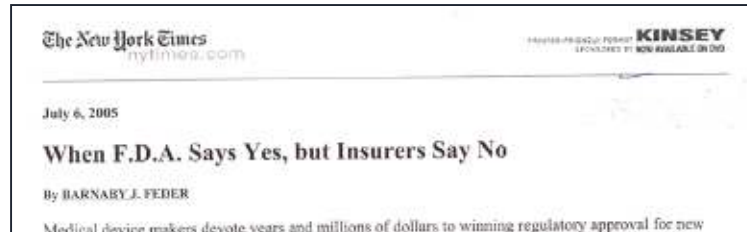
"The F.D.A. is nuts about it."

In Practice, Things Can Be Different



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

In Practice, Things Can Be Different



Medical device manufacturers devote years and millions of dollars to winning regulatory approval for new products. But all that work does not necessarily produce the kind of data that persuades insurers to pay for the products once they hit the market.

how it will wear over decades and the health impact on patients when it fails.

Laboratory tests submitted to the F.D.A. suggested that the disk can last 80 years. But critics say that conclusion does not square with the condition of some disks retrieved from ailing European patients or with X-rays showing relatively rapid deterioration of the disks in some patients.

"The lab tests do not represent what happens in the body," said Dr. Steven Kurtz, a biomechanics expert who has analyzed wear and tear in five failed Charité disks for Exponent, a consulting firm. "Some patients might go 20 years or more with no problems but I wouldn't advise anyone to count on more than 10. And some could be less."

Johnson and supporters of the disk say that nearly all the problems to date have been in cases where the wrong size disk was used or the disk was not properly centered.

The F.D.A. required Johnson to show that the Charité matched spinal fusion in terms of safety and

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

Introduction



Private Payers

- Employers
 - Self-funded or not
- Unions
- Health Plans
 - Blue Cross/Blue Shield Plans
 - UnitedHealthcare
 - Aetna
 - Anthem
 - Kaiser
 - Others

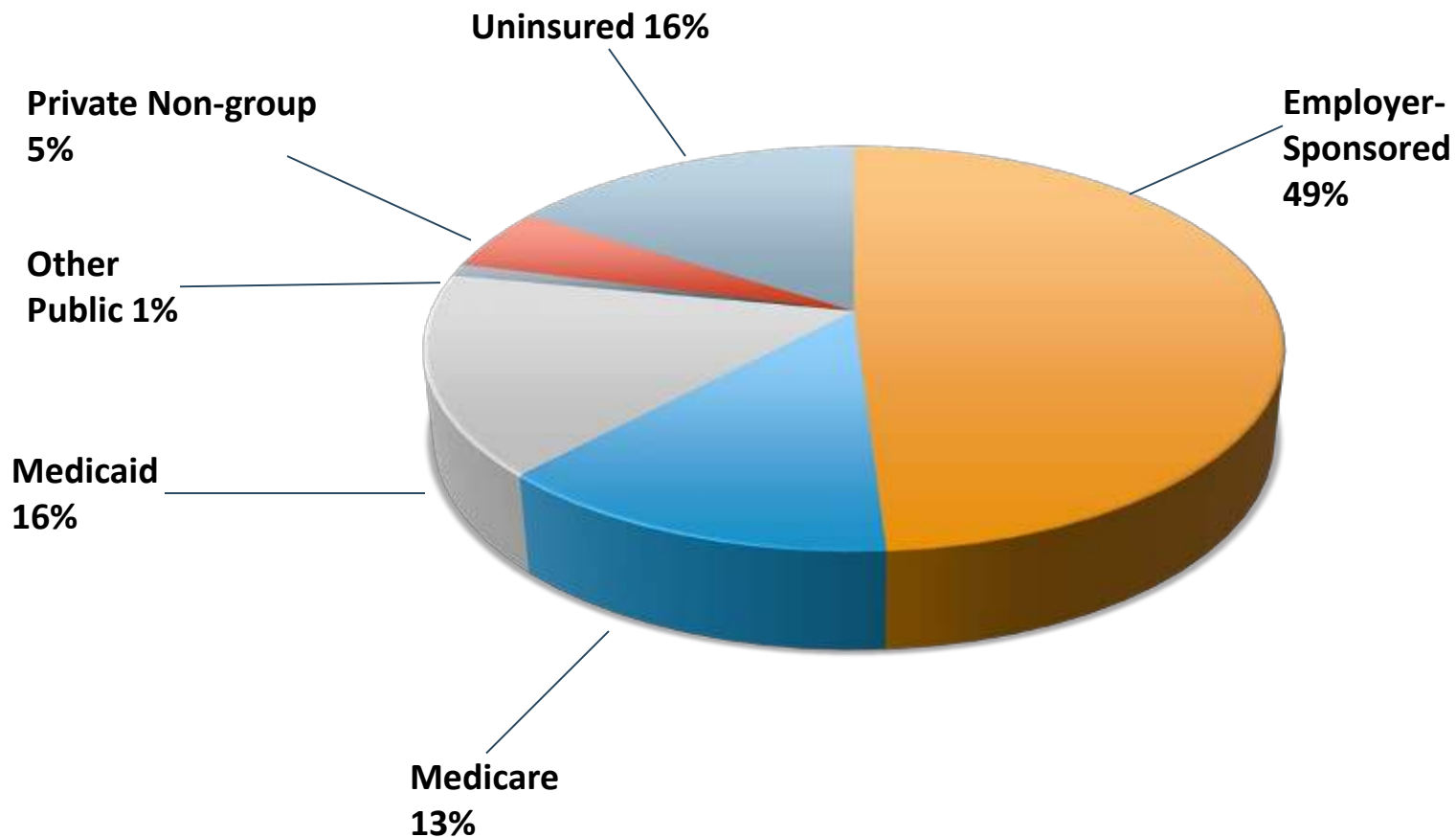


Public Payers

- Medicare
 - Federal
 - Seniors, disabled, ESRD
- Medicaid
 - Federal/state
 - Indigent, women, children, indigent seniors, chronically ill
- TriCare
- Federal
 - military dependents
- SCHIP
 - Federal/state
 - Children
- Others

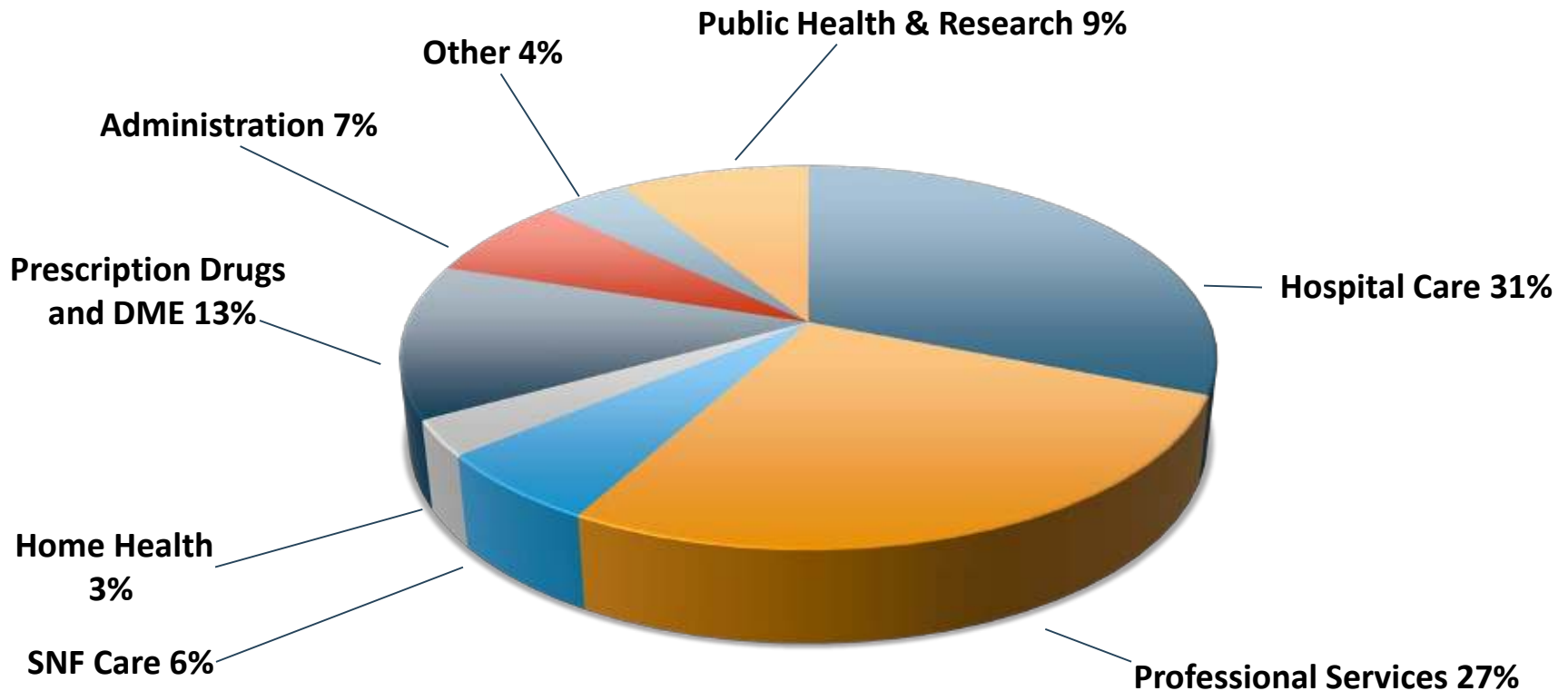
U.S. Health Care Coverage

(Source: Centers for Medicare and Medicaid Services)

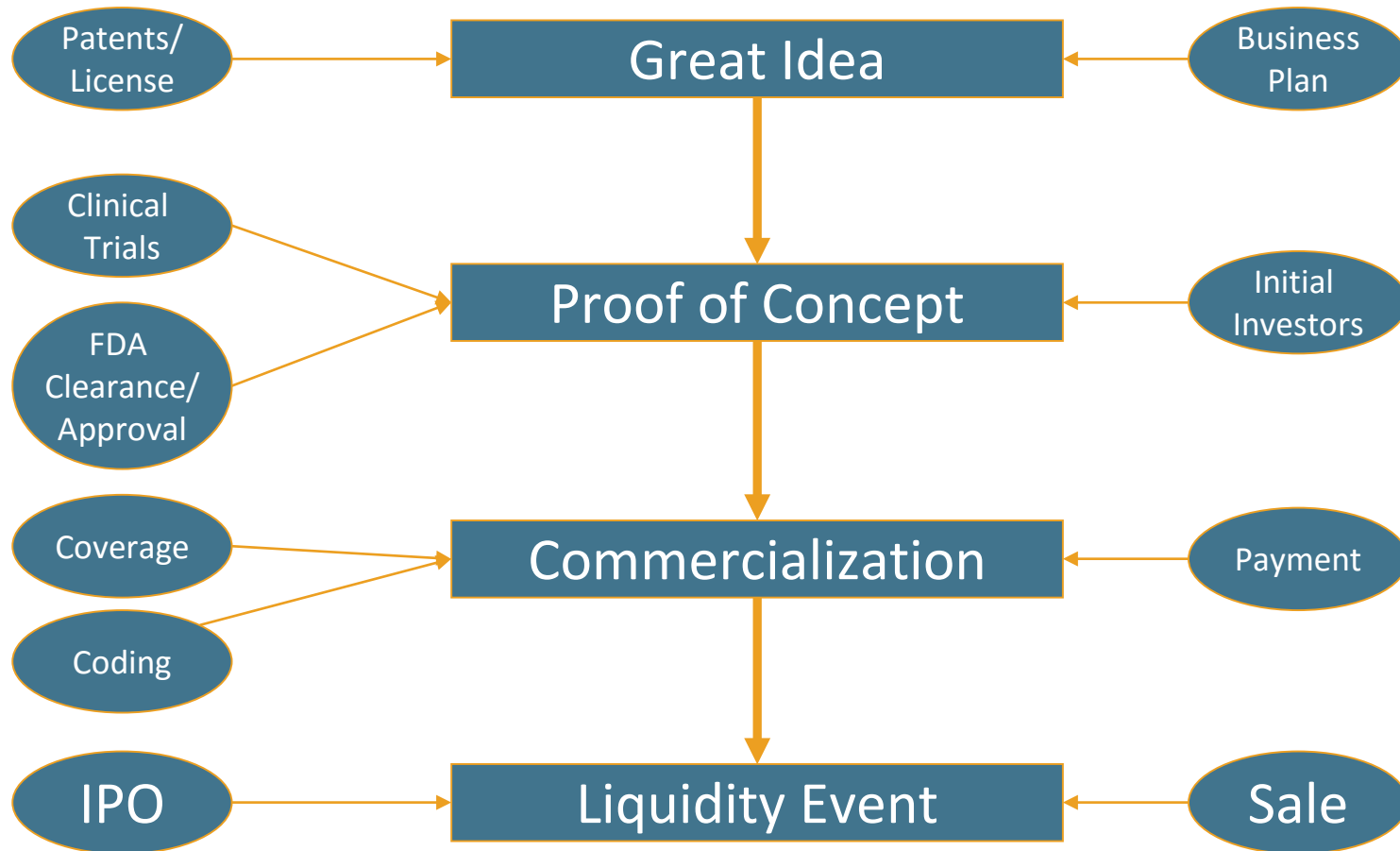


U.S. Health Care Spending

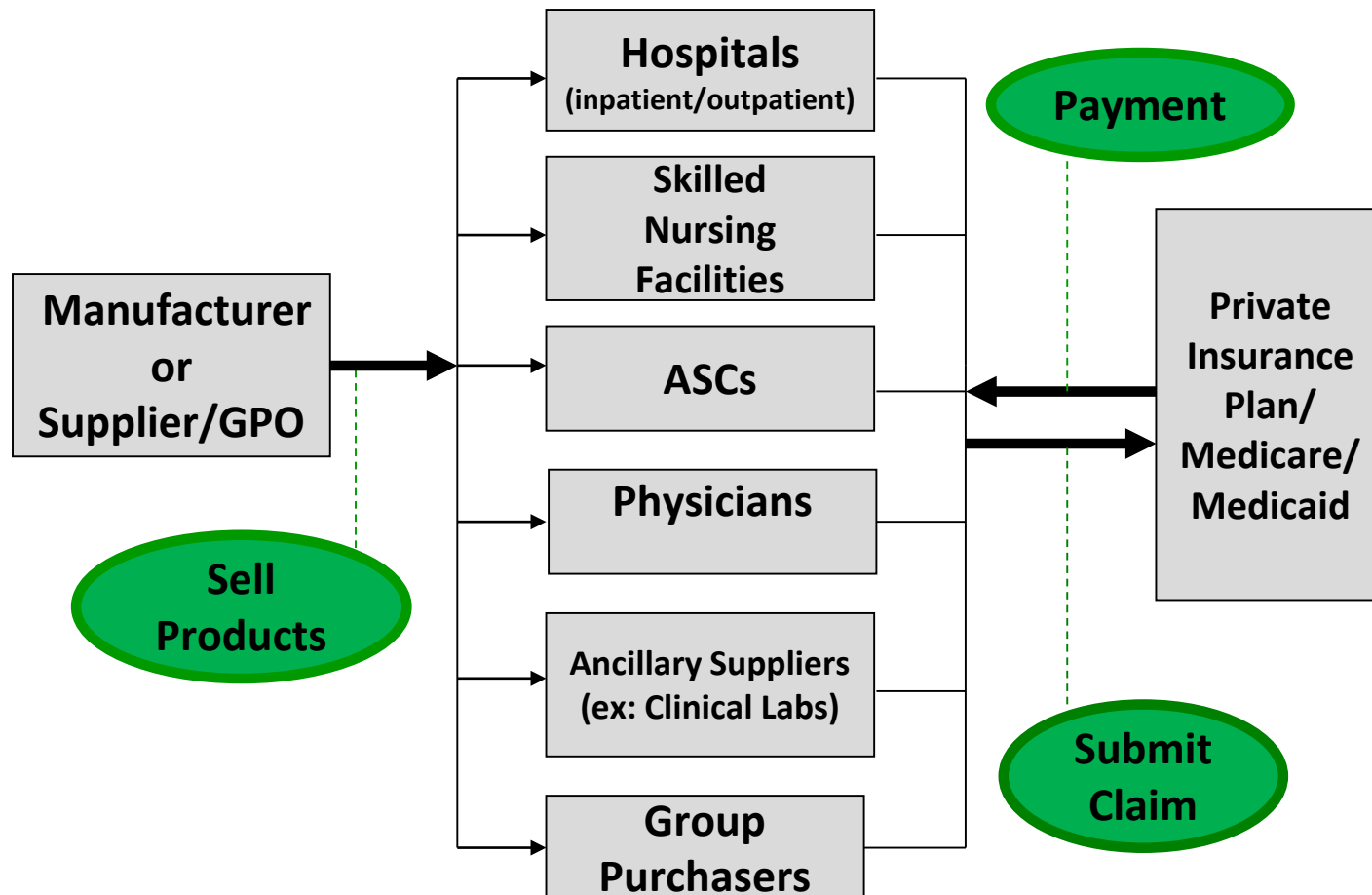
(Source: Centers for Medicare and Medicaid Services)



Critical Milestones In Development



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





*“If there’s anything more we can do for you, don’t
hesitate to fill out the proper forms.”*

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)



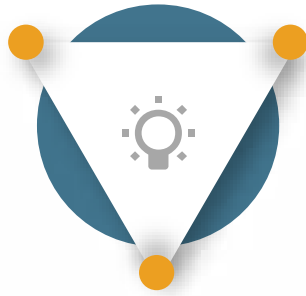
Private and Quasi-Public Entities

- 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 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 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?



What is the expected financial impact for the payer/consumer?



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 may demand a rigorous coverage and reimbursement strategy



Understanding realistic timeframes is critical

Building a Team

Who Should Be Assisting a 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



Specific Controls for
New Drugs or
Medical Devices



Limit coverage

- Certain locations, clinical conditions, prior actions (ex: new technology may not be covered unless treatment with existing method tried but failed)



Payers employ Medical Directors who oversee a staff of health professionals and others – both employees and consultants – to help with these decisions.



Medical Directors have diverse backgrounds; they may need additional education on specific technologies

Coverage Strategy



Coverage process can range from six months to several years

Coverage is distinct from FDA approval/clearance

Must take into account the various coverage standards established for government and private players in the U.S. health system

Must address indications for “medical necessity”

May also address coverage limits, such as required site of service as a condition of coverage or frequency of tests (may have a payment impact as well)

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 devices
 - Patient advocacy groups

Build familiarity with the item

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

Special Coverage Challenges



- Payers may classify devices or tests as:
- Innovative breakthrough for patient health
 - Fills a compelling unmet need
- 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

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
Expert consensus	Reasonable expectation of safety (risk/benefit)	Disputes over what constitutes expertise and expert opinion; 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 comparative effectiveness

Allies and Adversaries



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



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



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



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 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

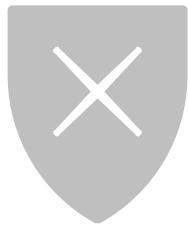
Get articles published in peer-reviewed journals to demonstrate outcomes

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)
- 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

Clinical trial design should incorporate these factors

Study design should include gathering data comparing study device to existing treatments or technologies

Consider factors relied on by the Agency for Healthcare Research and Quality in their evaluations (www.ahrq.com)

Evidence-Based Medicine (“EBM”)



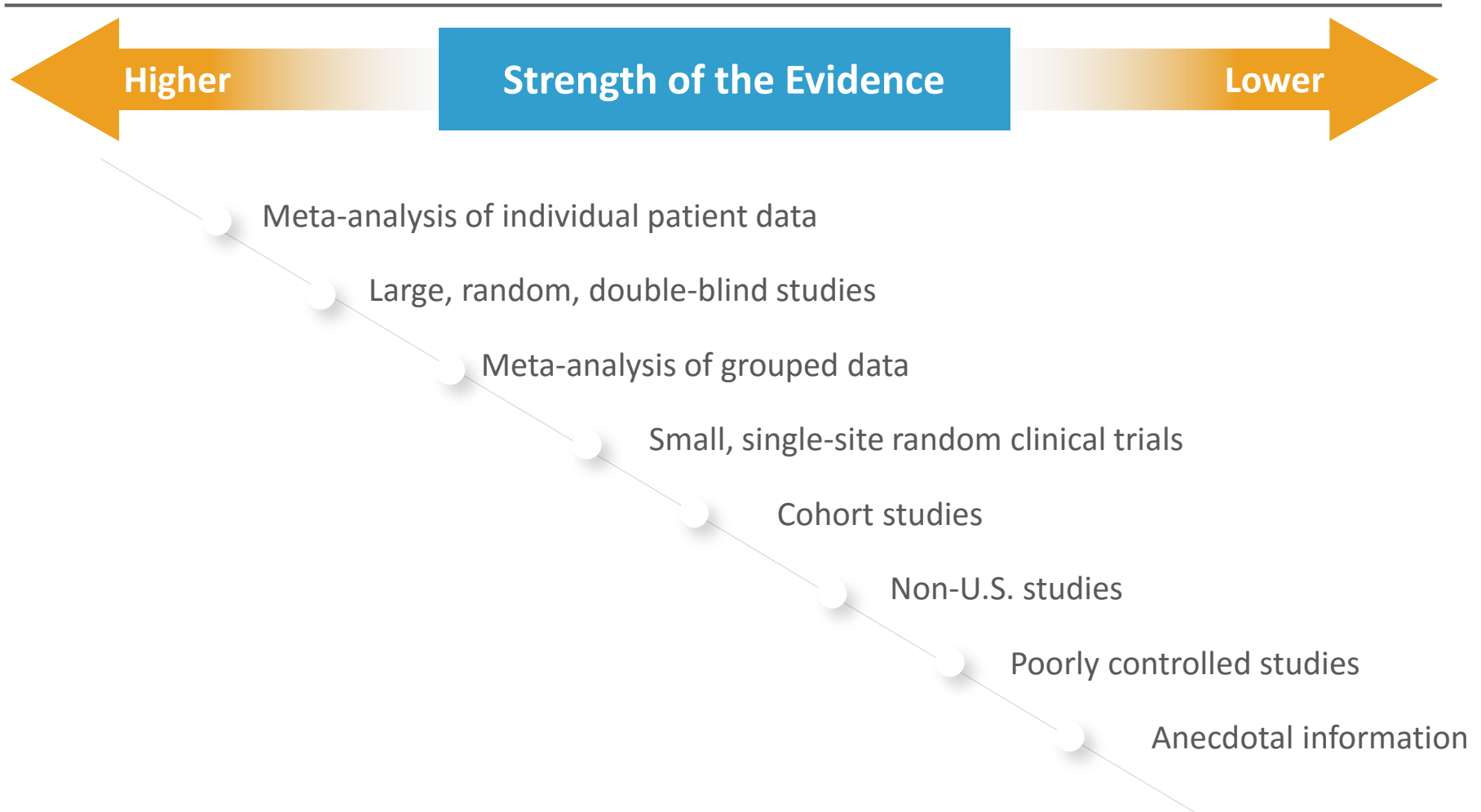
Relies on published and unpublished studies, expert opinions, technology assessments, opinions of professional societies, recommendations from Medicare Coverage Advisory Committee (“MCAC”)



Key areas of focus include:

- Study design, implementation, analysis
- Applicable to Medicare population
- Assessment of risks and benefits
- Does the item add value (lower costs, improved outcomes, less follow-up, etc.)

What Kind of Evidence Is Needed?



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

Comparative Effectiveness Research



PPACA – Health Reform Law



Not to be construed as “authorizing the Secretary to deny coverage ... solely on the basis of comparative clinical effectiveness research”



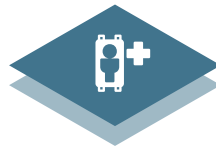
Establishes Patient-Centered Outcomes Research Institute



“not use ... in a manner that treats extending the life of [the] elderly ... as of lower value”



“Iterative and transparent process”



“not use ... with the intent to discourage ... treatment ... based on how the individual values ... length of their life and the risk of disability”

“LIMITATIONS ON CERTAIN USES OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

“SEC. 1182. (a) The Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

“(b) Nothing in section 1181 shall be construed as—

“(1) superseding or modifying the coverage of items or services under title XVIII that the Secretary determines are reasonable and necessary under section 1862(D)(1); or

“(2) authorizing the Secretary to deny coverage of items or services under such title solely on the basis of comparative clinical effectiveness research.

“(c)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

“(2) Paragraph (1) shall not be construed as preventing the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under title XVIII based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual’s life due to the individual’s age, disability, or terminal illness.

“(d)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.

“(2)(A) Paragraph (1) shall not be construed to—

H. R. 3590—623

“(i) limit the application of differential copayments under title XVIII based on factors such as cost or type of service; or

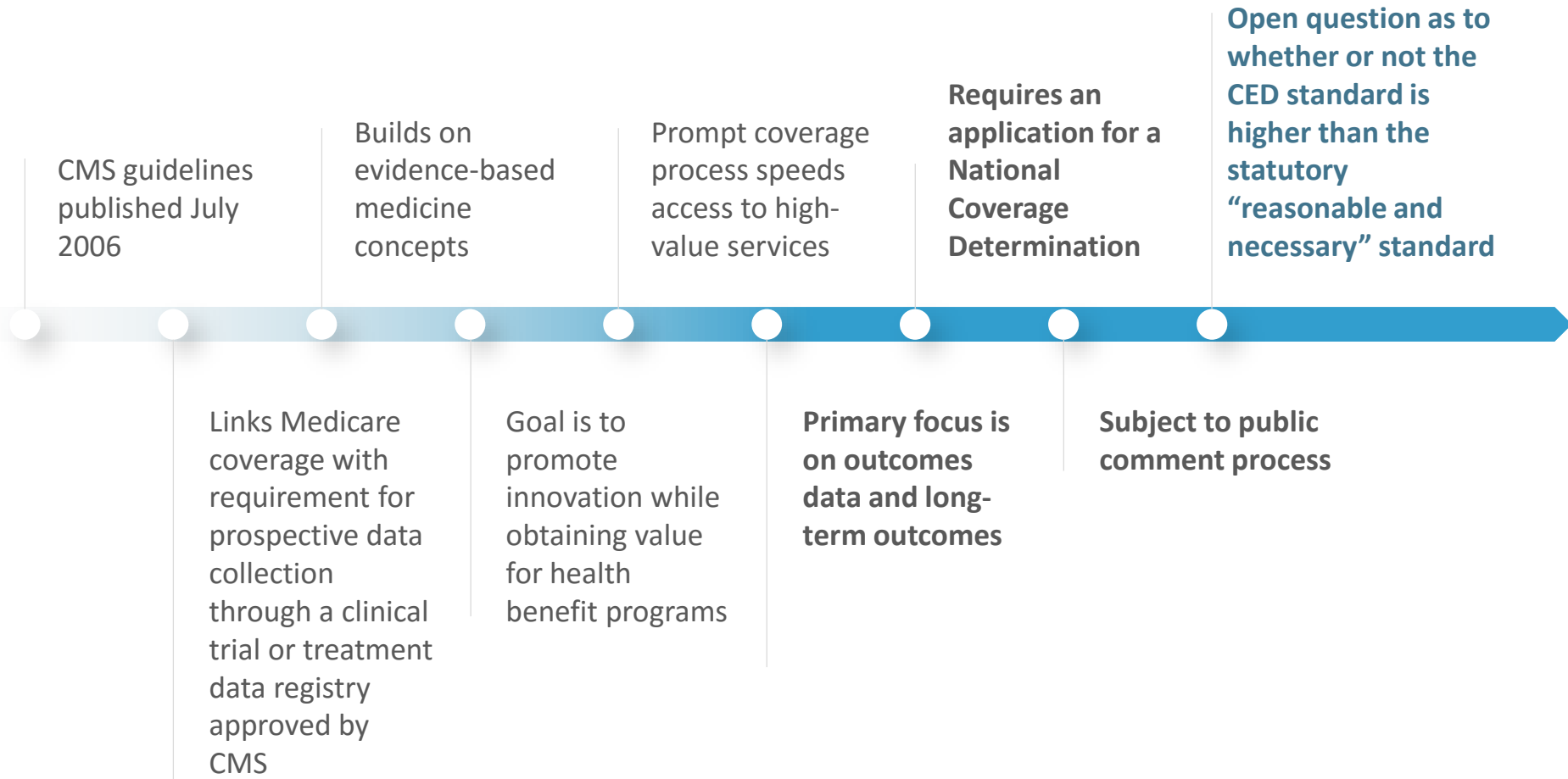
“(ii) prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual’s life due to that individual’s age, disability, or terminal illness.

“(3) Nothing in the provisions of, or amendments made by the Patient Protection and Affordable Care Act, shall be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

“(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollar-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”

(d) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a) and amended by subsection (c), is amended by adding at the end the following new section:

Medicare Coverage With Evidence Development (“CED”)



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CED Case Study: Autologous Platelet-Rich Plasma For Chronic Wounds

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:**

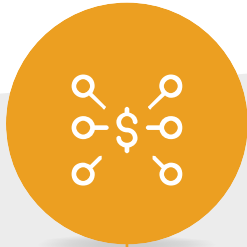
- DRG (inpatient hospital)
- APC (outpatient hospital/ASC)
- RUG (skilled nursing)



Coding Basics



• Coding is an identifier for a diagnosis, drug, device, or procedure



• Coding connects coverage and payment



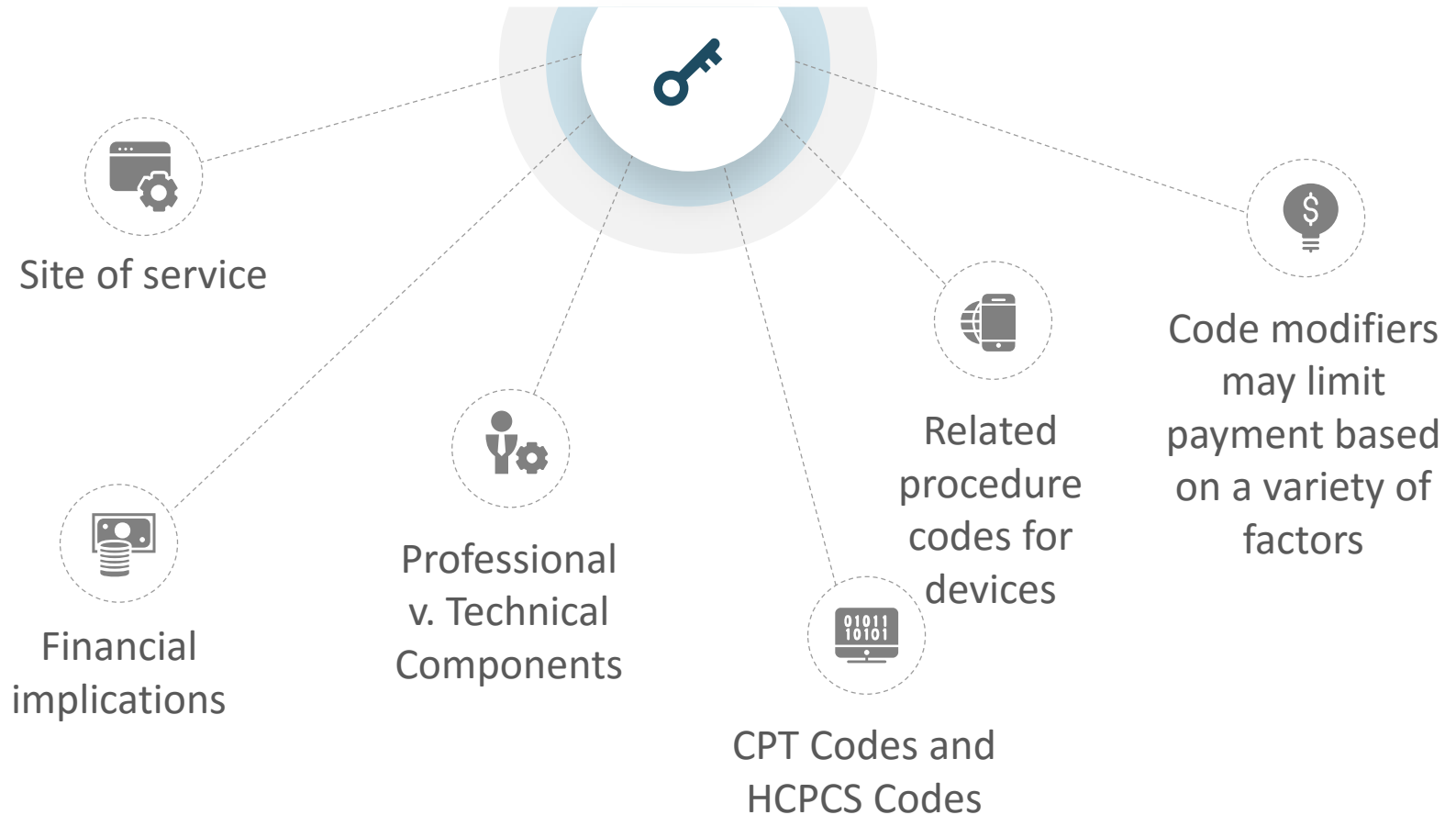
• Codes allow for rapid claims processing and health policy research



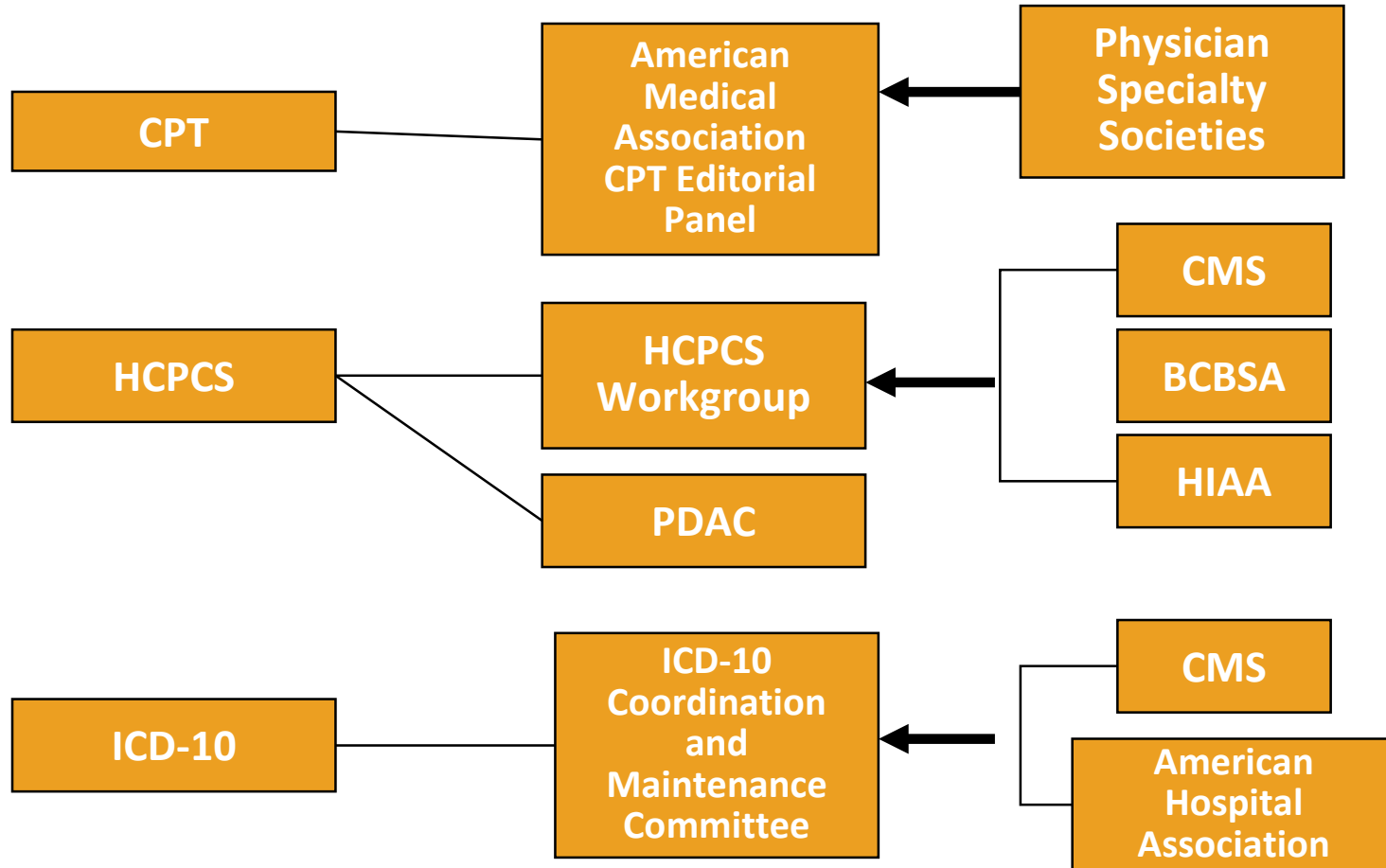
• Coding systems have different timetables for updates and revisions

Coding Basics

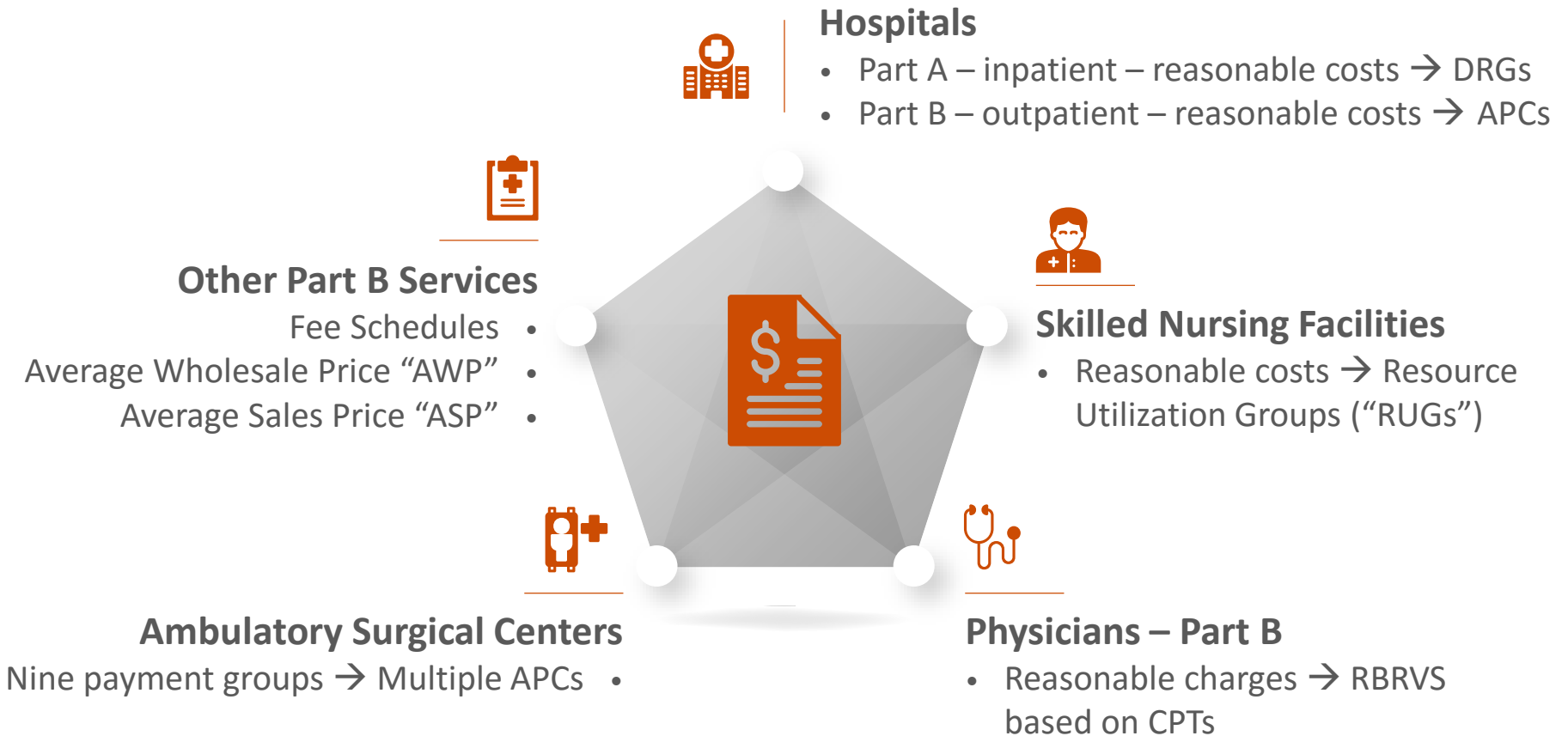
KEY CODING ISSUES FOR BILLING CODES



How Are New Codes Established?



Overview of Payment Methodologies



Payment Methodologies

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



GENERAL RULE:

- 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 devices in the same coding category:

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



"Never, ever, think outside the box."

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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.”

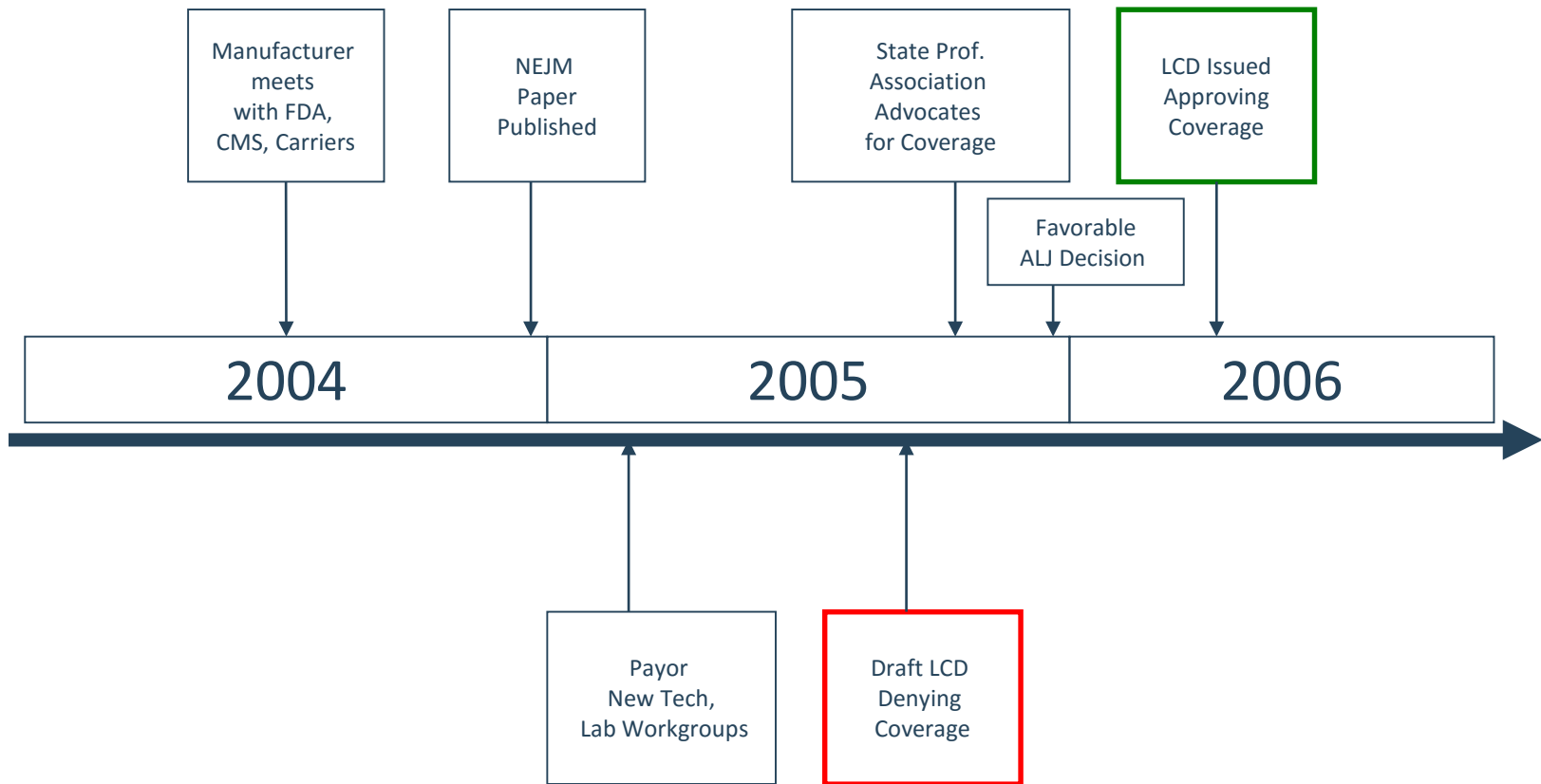
Case Study: Artificial Disk Replacement

- 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



Case Study: Coverage of MTWA

- Microvolt T-Wave Alternans (“MTWA”) is a non-invasive diagnostic test for identifying patients who are at risk of sudden cardiac death from arrhythmia
- MTWA was covered by a few Medicare carriers
- Manufacturer met with CMS to request a national coverage decision

Case Study: Coverage of MTWA

- CMS reviewed peer-reviewed literature and conducted its own technology assessment
- Focused on 12 of 1028 citations in support of MTWA
- CMS conducted its own literature review
- March 2006: NCD approved coverage for MTWA

Case Study: Coverage of MTWA

- BCBS TEC had previously concluded that MTWA did not meet its criteria for coverage
- CMS focused on the Medicare-eligible population
- Only spectral analytic method is covered – not all methods
- Aetna, a large commercial health insurer, followed CMS's policy

Case Study: Natrecor[®]

- Natrecor[®] was approved by the FDA in 2001 for treatment of acutely decompensated heart failure (ADHF) in patients who have dyspnea at rest or with minimal activity
- Risks include renal complications, hypotension, increased mortality
- FDA approval followed concerns about safety
- Drug typically used in the inpatient setting
- Medicare accounts for approximately 85% of the market

Case Study: Natrecor®

- Manufacturer had its scientific advisory board study safety issues regarding use of the drug in outpatient settings
- Questions about safety appeared in newspaper articles and in medical journals
- TrailBlazer Health Enterprises, a large Medicare carrier, requested a national coverage determination review in May 2005

Case Study: Natrecor[®]

- Utilization data showed a rapid increase in number of services allowed and dollars paid by Medicare Part B contractors
- Trailblazer attributed increased volume to off-label use in the outpatient setting
- The NCD request also referenced reports indicating serious adverse consequences associated with Natrecor[®]

Case Study: Natrecor[®]

- CMS review resulted in a revised national coverage determination in March 2006 that Natrecor would not be covered for “Chronic” CHF
- CMS acknowledged that some studies suggested Natrecor may reduce days of hospitalization and improve symptoms of chronic CHF
 - However, CMS found that this was not a consistent finding in the clinical literature
- CMS weighed the weaknesses of the literature against “substantial” safety concerns
 - Determined that the benefits of Natrecor for the treatment of chronic CHF benefits do not outweigh the risks in the Medicare population
- CMS’ decision applies only to off-label use of Natrecor as a treatment for chronic CHF
 - Does not address current FDA indication of ADHF

Case Study: Natrecor®

- Trailblazer Health Enterprises issued a Local Coverage Determination (“LCD”) to define coverage further in its jurisdiction
- The LCD defines the five ICD-9-CM diagnosis codes for which Natrecor will be covered as reasonable and necessary:
 - 428.0 – congestive heart failure unspecified
 - 428.21 – acute systolic heart failure
 - 428.23 – acute on chronic systolic heart failure
 - 428.41 – acute combined systolic and diastolic heart failure
 - 428.43 – acute on chronic combined systolic and diastolic heart failure
- If one of the above ICD-9-CM diagnosis codes does not appear on the claim form, Natrecor will not be covered