

Reimbursement for New Medical Technologies

Quorum Consulting®[®], Inc.

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What is reimbursement?

reimbursement

noun

compensation paid (to someone) for damages or losses or money already spent etc.; "he received reimbursement for his travel expenses"

Reimbursement – The bottom line

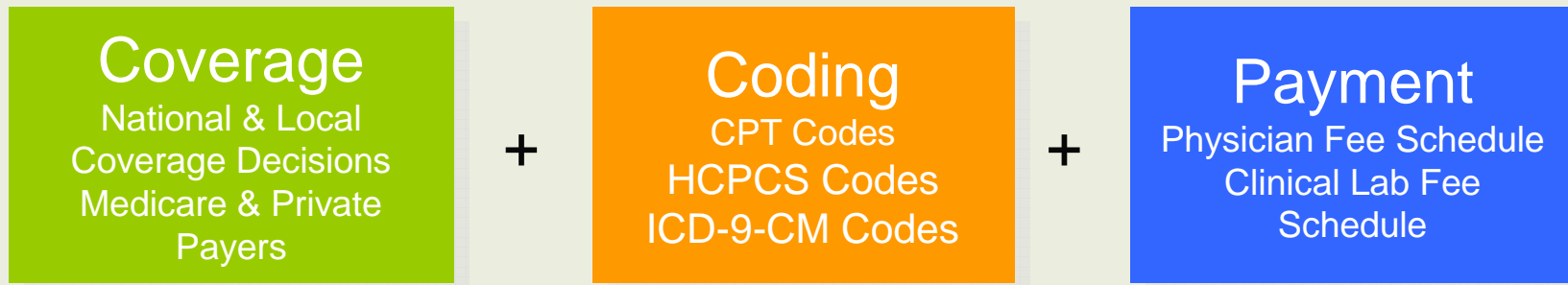
- For entrepreneurs, venture capitalists, and marketers, reimbursement for health care technologies is getting a third-party payer (e.g., Medicare, commercial payers) to:
 - Pay the end user of the technology
 - An amount at least equal to the manufacturer's price
 - And allows the provider/end user to stay in the business of patient care

FREAKONOMICS

A ROGUE ECONOMIST EXPLORES
THE HIDDEN SIDE OF EVERYTHING

- FDA approval does not equal reimbursement from third party payers
- Coding is not the answer, only part of the solution
- In the absence of outcomes data, physician and specialty society support is critical to drive reimbursement

Sound Clinical Foundation + Reimbursement Fundamentals = Reimbursement Success



Peer Review Publications of Randomized Controlled Trials

Clinical Enthusiasm & Physician Specialty Society Support



Case Study A – Medical Device

- April 2003 PMA Approval by FDA
- Randomized clinical trials involving 1058 patients
- Medicare policy (April 2003)

“CMS recognizes the importance of the new technology and will provide accelerated incremental reimbursement to hospitals under newly established Diagnostic Related Groups (DRGs). In order to ensure access to this technology for patients as rapidly as possible, CMS has taken the unprecedented step of assigning it to new DRGs prior to FDA approval.”

Case Study B – Medical Device

- 510(k) Approval by FDA in 2002

- No clinicals

- Medicare policy (2004)
 - *de facto* national coverage through local Medicare carrier
 - 93799 unlisted cardiovascular service or procedure

Case Study C – Medical Device

- October 2004 PMA Approval by FDA
- Randomized clinical trials involving 375 patients enrolled in 15 U.S. centers
- Private payer review

“The evidence is insufficient to determine whether the use of product X improves the net health outcome or whether they are as beneficial as any established alternatives.”

- Medicare policy

“Effective May 16, 2006, Product X is not covered by Medicare for beneficiaries over 60 years of age, i.e., on or after the beneficiary’s 61st birthday.”

Case Study D – Molecular Diagnostic

- Company founded in 2001; commercial product launch in 2004; per procedure charge > \$3,000 per test
- Publication of clinical validation in NEJM in 2004
- IPO in 2005 with market cap of \$600 million as of Sept 2008
- Medicare Coding
 - *“The test should be submitted as CPT Code 84999 (unlisted chemistry procedure)”*

Case Study E – Medical Device

- November 2005 PMA Approval by FDA
- Randomized clinical trials involving 200 patients enrolled in 9 U.S. centers
- Medicare policy (Aug 2006)

“Centers for Medicare and Medicaid Services (CMS) approved a special add-on payment for hospitals that offer Product X, with a maximum add-on payment of \$4,400 per case”
- \$80 million IPO (Nov 2006)

“Currently, most procedures are coded under CPT code 22899, unlisted procedure. Effective January 1, 2007, the following two new Category III CPT codes have been developed: Category III codes are temporary codes for emerging technology and services, and we cannot assure you at this time how the level of reimbursement would be impacted by the new codes.”
- \$500 million+ acquisition Jan 2007

Case Study Answers

- **Added reimbursement pre-FDA approval** → **J&J CYPHER Drug Eluting Stent**
- **510k device, no clinicals, national coverage** → **CardioNet Mobile Cardiac Outpatient Telemetry (MCOT)**
- **PMA device with negative coverage** → **J&J CHARITÉ Total Artificial Disc Replacement**
- **Molecular diagnostic billed @ \$3,000 under unlisted code** → **Genomic Health Oncotype DX Breast Cancer Test**
- **PMA device with add-on hospital payments; IPO** → **Saint Francis X STOP Interspinous Process Decompression System**

THE EARLY STAGES OF
DEVELOPMENT ON THE
"CAMERA-IN-A-CAPSULE"

MAKE A NOTE OF
THIS... "TAKE CAMERA
OFF TRIPOD FIRST"

WE'RE
REALLY
GETTING
SOMEWHERE!



Comparison of FDA and CMS Perspectives on Evidence from Clinical Trials

TRIAL DESIGN FEATURES	FDA PERSPECTIVE	CMS PERSPECTIVE
Overall Study Design Objectives	To maximize internal validity and patient safety (efficacy).	To balance internal validity with generalizability to real-world patient populations and standards of practice for Medicare beneficiaries (effectiveness)
Treatment Indication	Protocol usually includes a precise definition of intended use.	Must be an indication falling within statutory coverage as well as “medically necessary for treatment of illness of injury.”
Study Patient Characteristics	Enrollment constrained by specific inclusion and exclusion criteria; patients with serious comorbid conditions are often excluded.	Include patients who are representative of the Medicare population; these patients often have comorbid conditions.
Physician Characteristics	Trial “...restricts the use of the device to skilled surgeons trained in the proper technique to implant the device.” (Text of an actual trial protocol.)	Would probably prefer a range of settings and physician types to more closely mimic real-world situations.

Note: Perspectives represent the author’s opinion and are not official policy

Comparison of FDA and CMS Perspectives on Evidence from Clinical Trials

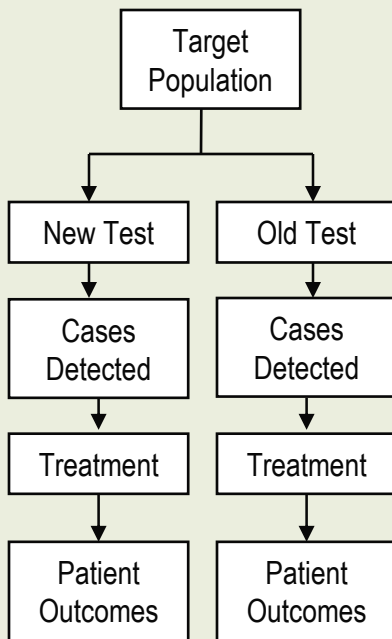
TRIAL DESIGN FEATURES	FDA PERSPECTIVE	CMS PERSPECTIVE
Study Comparator	As justified by intent of the trial: historical control, placebo, standard of care, sham treatment.	Compare with community standard of treatment.
Course of Treatment During the Trial	Treatment administered per protocol with scheduled visits and procedures.	Appropriate treatment, in accordance with guidelines and the standard of care.
Study End Point	FDA accepts intermediate end points clearly linked to the intervention (e.g., “obesity surgery results in significant weight loss”).	CMS differentiates between intermediate end points and outcomes that describe patient welfare (e.g., “obesity surgery can achieve reduction in cardiovascular disease”).
Duration of Follow-up	Sufficient to evaluate specified end points and safety.	Sufficient to establish a lasting effect on patient health and functional status as appropriate to the nature of the intervention.
Incremental Cost of Treatment Relative to Standard of Care	Not relevant.	Clinical end points accepted by FDA, such as hospital readmission, have economic significance.
Incremental Cost-effectiveness Relative to Standard of Care	Not relevant.	Evidence to justify new codes and payment, higher payment for existing code, or add-on payment.

Technology assessment criteria

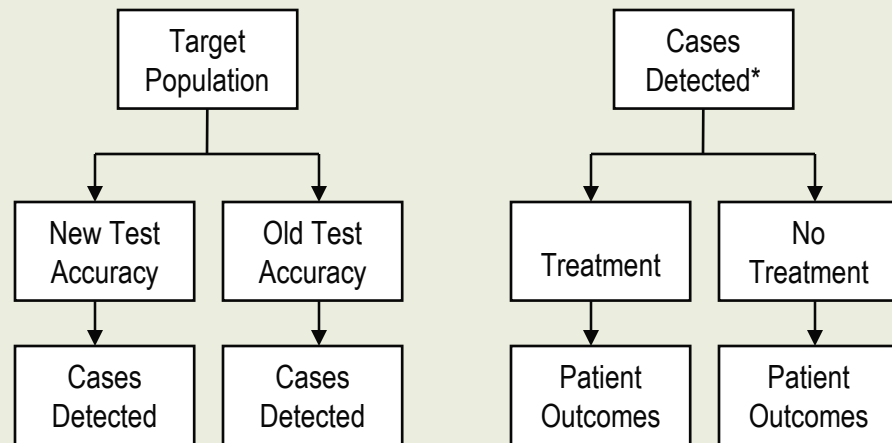
- **The technology must have final approval from the appropriate governmental regulatory bodies**
- **The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes**
- **The technology must improve the net health outcome**
- **The technology must be as beneficial as any established alternatives**
- **The improvement must be attainable outside the investigational settings**

Trial Evidence versus Linked Evidence of Test Accuracy and Treatment Efficacy

Randomized Trial



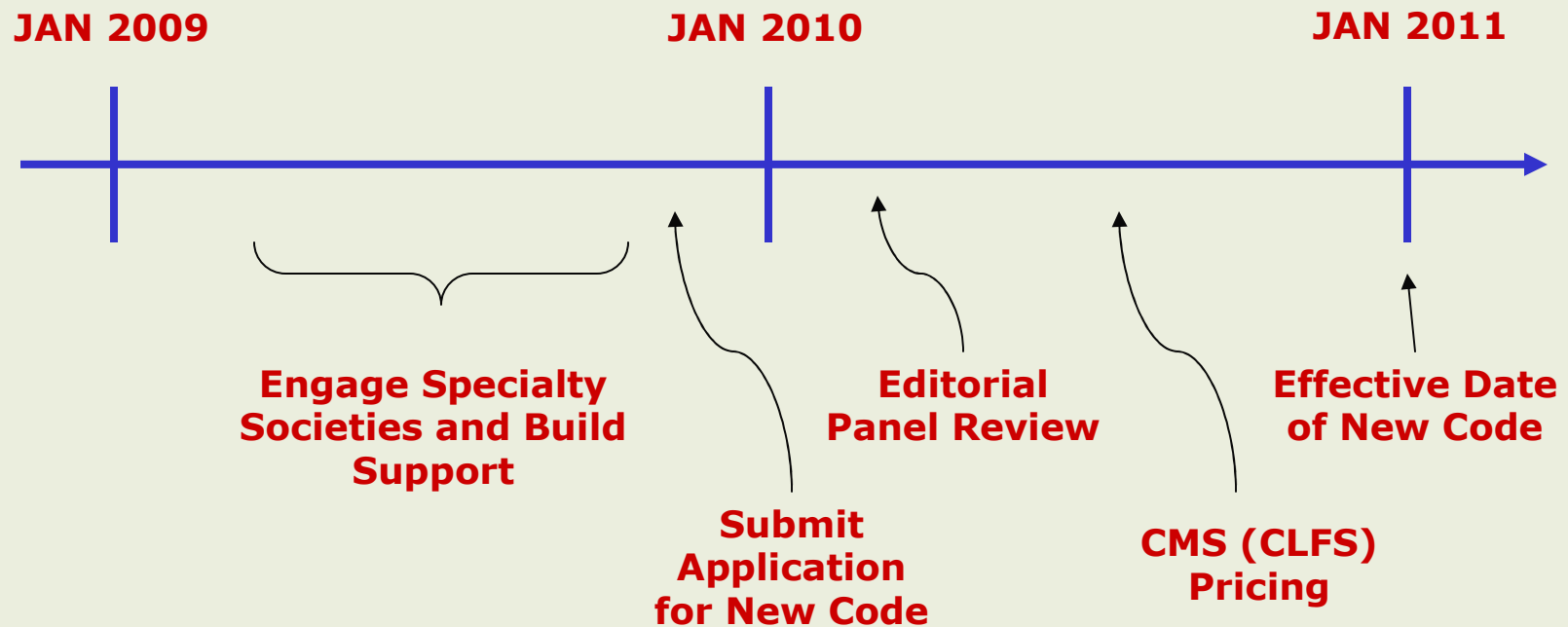
Test Accuracy Study plus Randomized Trial of Treatment Efficacy



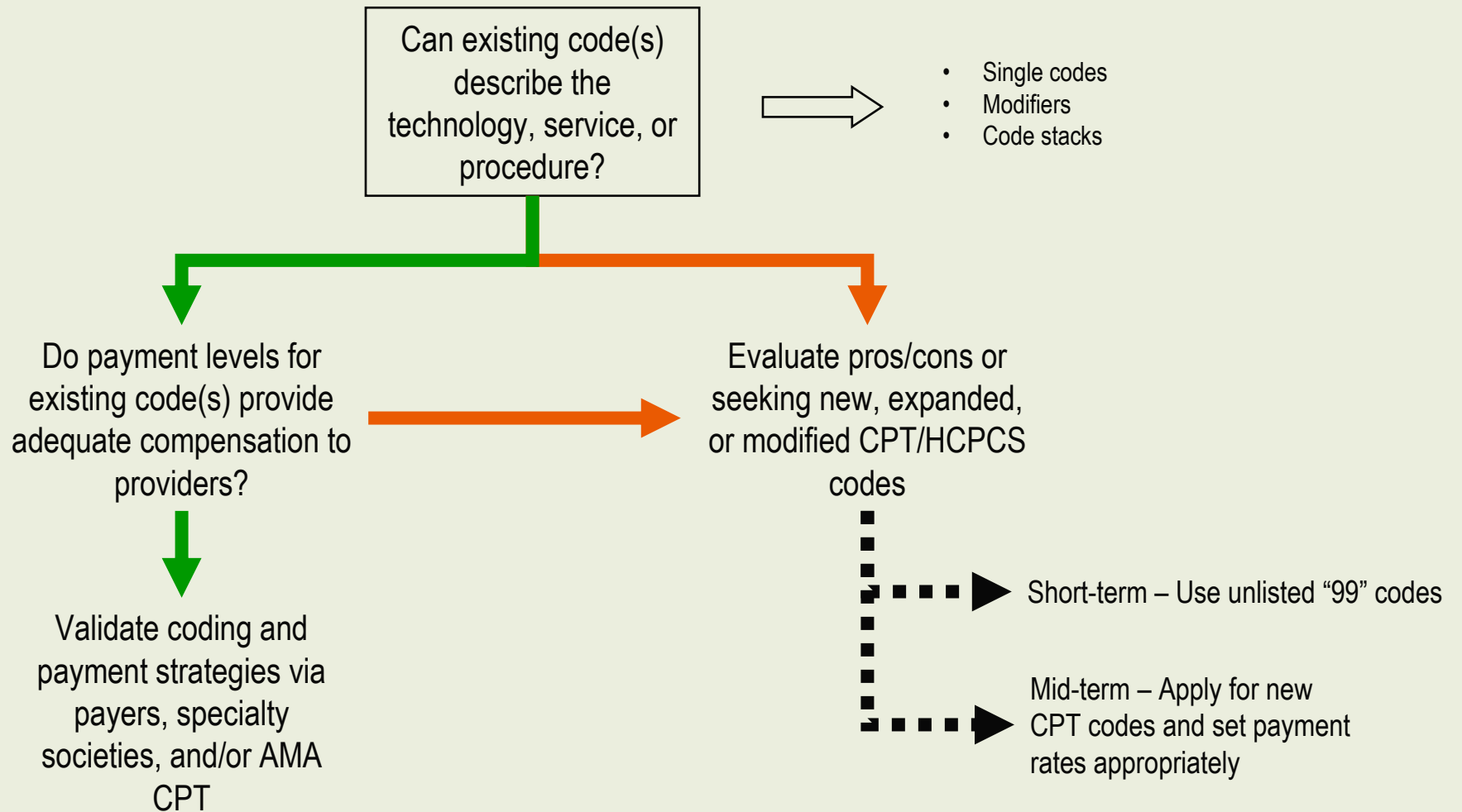
*Cases detected by the new and old test may not show similar response to treatment.

6 June 2006/Annals of Internal Medicine/ Volume 144 – Number 11/ 851

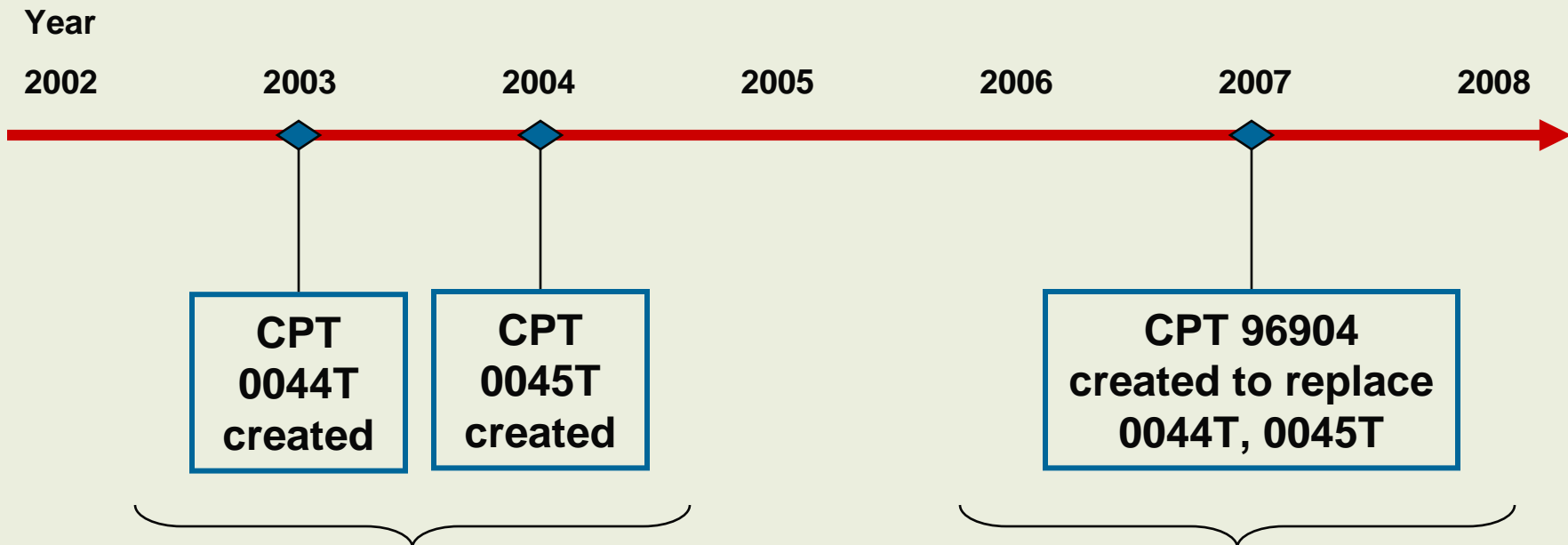
AMA CPT Coding Timelines for Category I Code



Sample Coding Pathways for New Technologies



Dermatoscopy Coding History



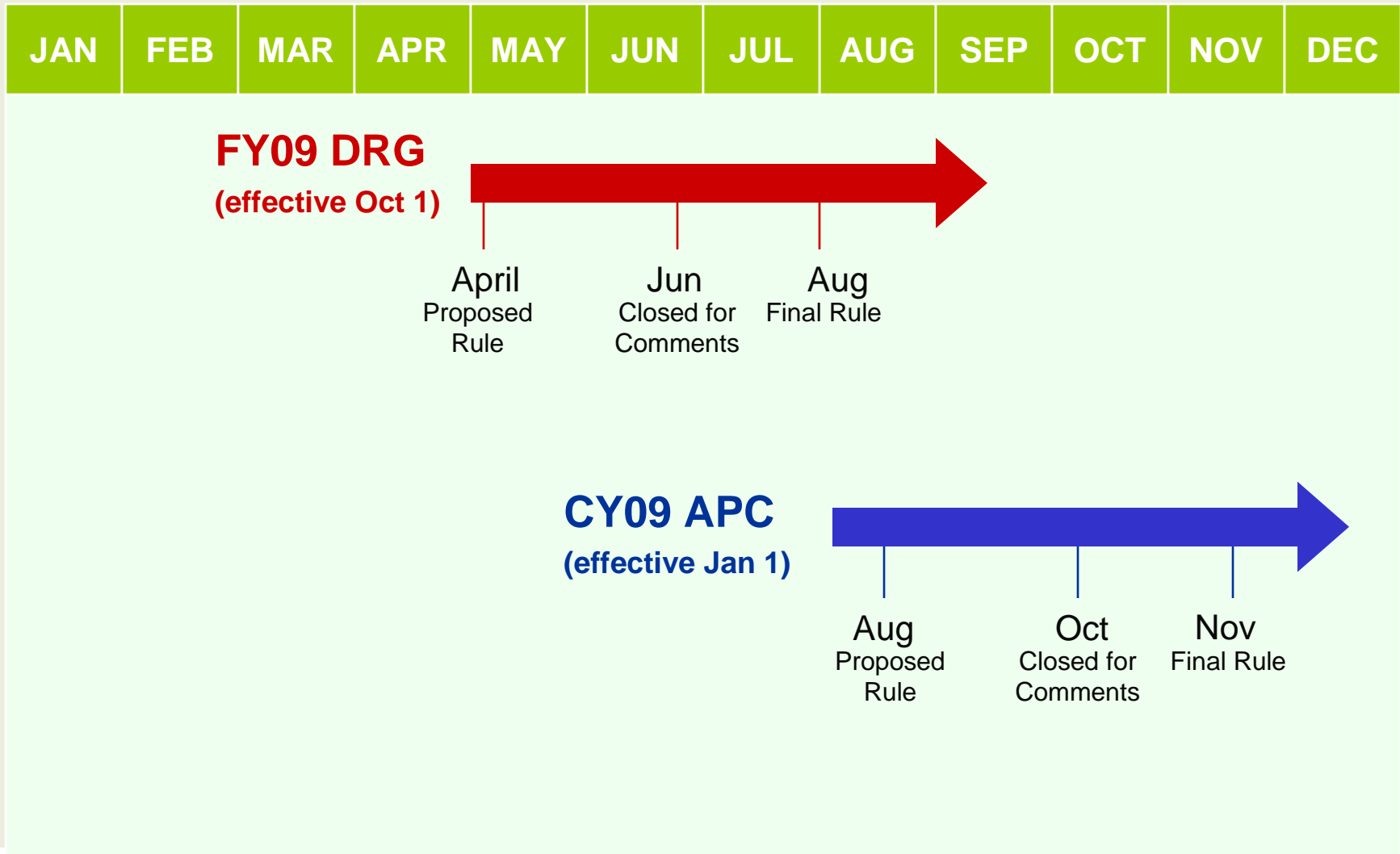
Category III CPT Codes

- Temporary codes for emerging technology, services, and procedures.
- Allow data collection for these services or procedures.

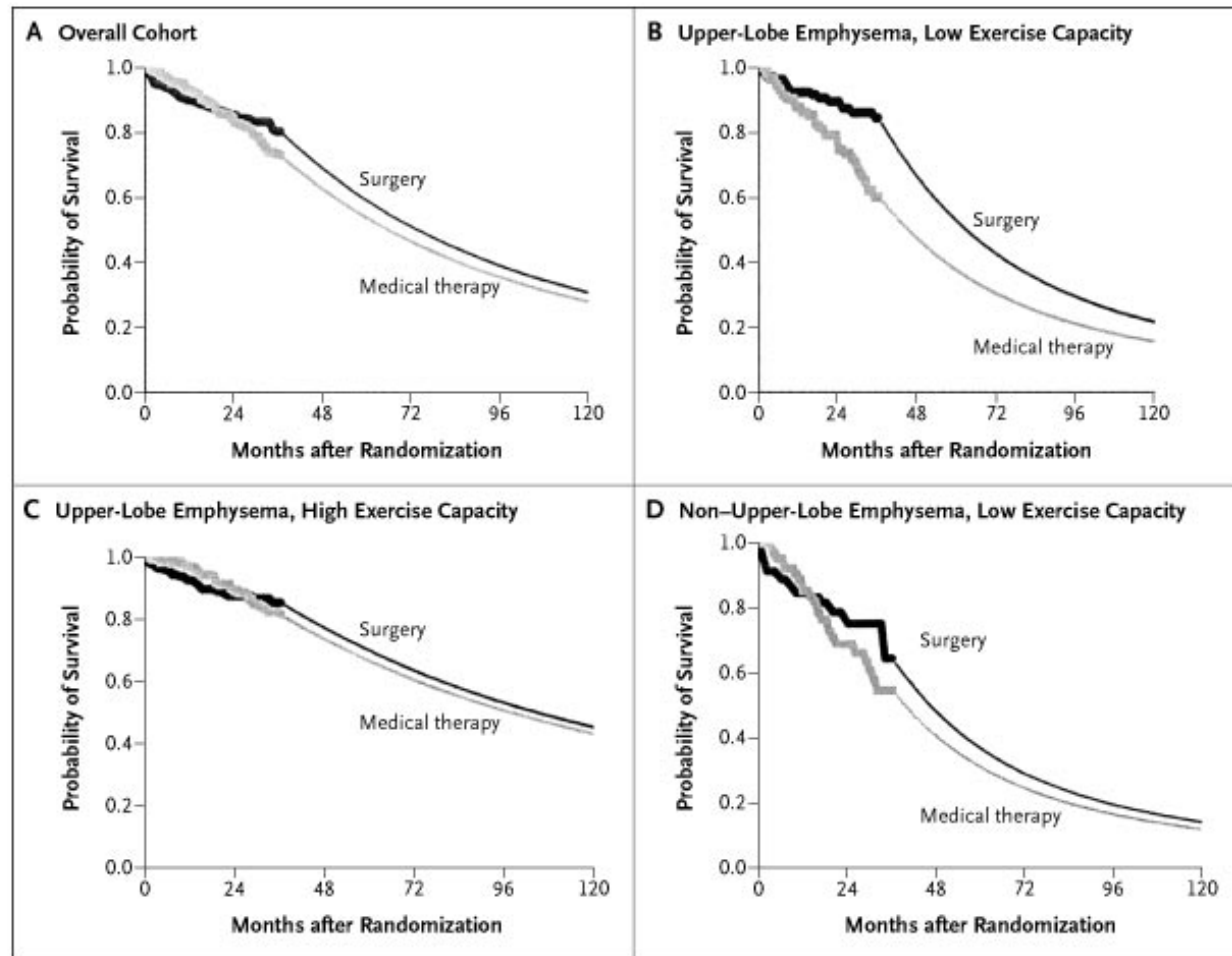
Category I CPT Code

- Permanent code to describe procedure or service consistent with contemporary medical practice

Timelines for Establishing Payment Rates for Hospital Inpatient and Outpatient Services



Observed Survival Curves (Thick) and Extrapolated Survival Estimates (Thin) under the Assumption of a Relative Hazard of Death of 1.0 at Three Years



National Emphysema Treatment Trial Research Group. N Engl J Med 2003;348:2092-2102



The NEW ENGLAND
JOURNAL of MEDICINE

Mean Direct Medical Costs and Total Health Care-Related Costs According to Time after Randomization

Table 2. Mean Direct Medical Costs and Total Health Care-Related Costs According to Time after Randomization.*

Variable	Surgery Group		Medical-Therapy Group		P Value
	No. of Patients	Mean Cost (95% CI) \$	No. of Patients	Mean Cost (95% CI) \$	
0–12 Mo after randomization	531		535		
Direct medical costs		61,145 (56,069–66,220)		15,738 (14,006–17,470)	<0.001
Total costs		71,515 (65,921–77,109)		23,371 (21,056–25,686)	<0.001
13–24 Mo after randomization	407		424		
Direct medical costs		9,474 (8,260–10,688)		15,648 (12,934–18,362)	<0.001
Total costs		13,222 (11,479–14,964)		21,319 (18,004–24,635)	<0.001
25–36 Mo after randomization	277		278		
Direct medical costs		10,199 (8,161–12,236)		12,303 (9,977–14,629)	0.18
Total costs		14,215 (11,529–16,901)		17,870 (14,785–20,954)	0.08

* Costs are reported in 2002 dollars. Direct medical costs include Medicare reimbursements and pharmacy costs. Total costs include direct medical costs plus the value of the time spent by caregivers, the value of the time spent by the patient, and travel costs. After year 1, costs were discounted by 3 percent per year. P values were derived by two-sided t-tests for equality of means. CI denotes confidence interval.

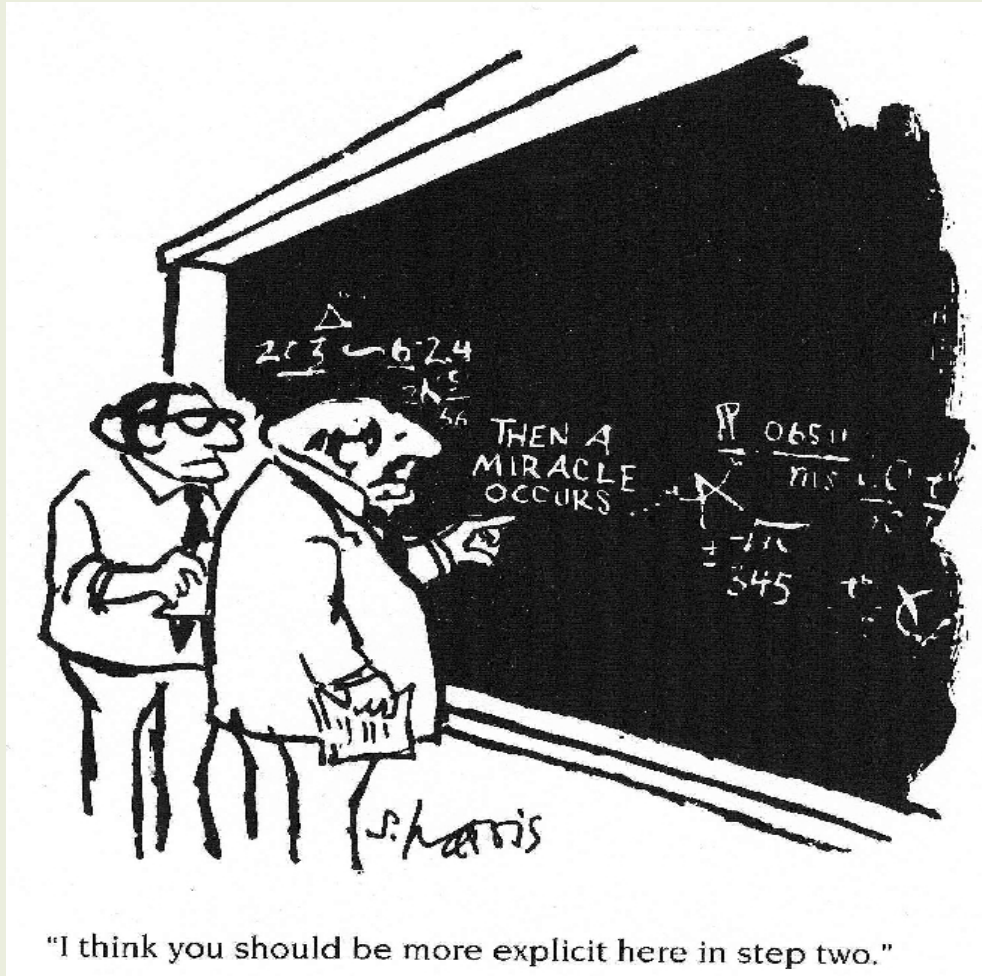
Total Health Care-Related Costs, Quality-Adjusted Life-Years Gained, and Estimated Cost-Effectiveness Ratios at Three Years

Table 3. Total Health Care-Related Costs, Quality-Adjusted Life-Years Gained, and Estimated Cost-Effectiveness Ratios at Three Years.*

Variable	Surgery Group		Medical-Therapy Group		P Value	Incremental Cost-Effectiveness Ratio for Surgery (\$)
	No. of Patients	Mean (95% CI)	No. of Patients	Mean (95% CI)		
All patients	531		535			190,000
Total costs (\$)		98,952 (91,694–106,210)		62,560 (56,572–68,547)	<0.001	
Quality-adjusted life-years gained		1.46 (1.46–1.47)		1.27 (1.27–1.28)	<0.001	
Patients with predominantly upper-lobe emphysema and low exercise capacity	137		148			98,000
Total costs (\$)		110,815 (93,404–128,226)		61,804 (50,248–73,359)	<0.001	
Quality-adjusted life-years gained		1.54 (1.53–1.55)		1.04 (1.03–1.05)	<0.001	
Patients with predominantly upper-lobe emphysema and high exercise capacity	204		212			240,000
Total costs (\$)		84,331 (73,699–94,962)		55,858 (47,161–64,555)	<0.001	
Quality-adjusted life-years gained		1.54 (1.54–1.55)		1.42 (1.42–1.43)	<0.001	
Patients with non-upper-lobe emphysema and low exercise capacity	82		65			330,000
Total costs (\$)		111,986 (93,944–130,027)		65,655 (52,075–79,236)	<0.001	
Quality-adjusted life-years gained		1.25 (1.23–1.26)		1.10 (1.09–1.12)	<0.001	

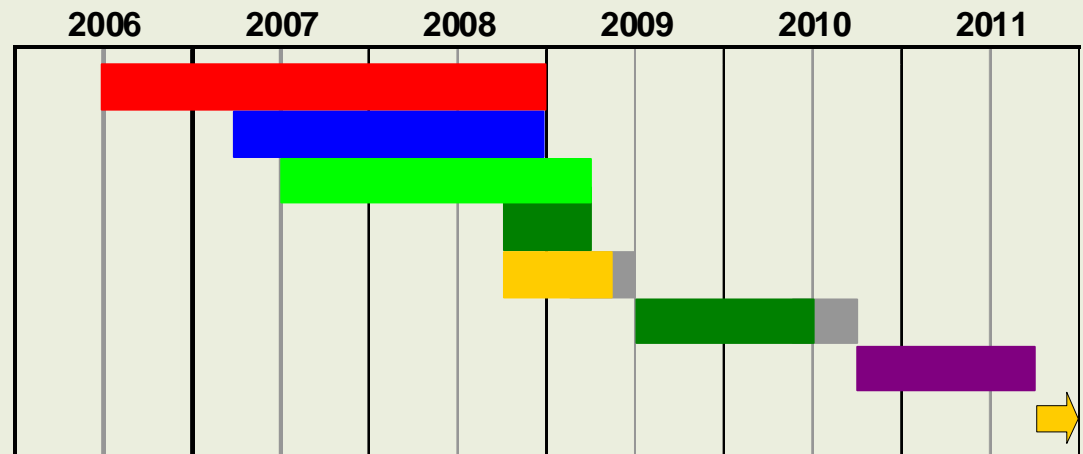
* Upper-lobe predominance of emphysema was defined according to the results on computed tomography. Exercise capacity was defined as the maximal workload on bicycle ergometry. Low exercise capacity was defined as a workload of 25 W or less for women and 40 W or less for men; a workload above these thresholds was considered to represent high exercise capacity. P values were derived by two-sided t-tests for equality of means. The results for the overall cohort exclude 140 patients previously found to be at high risk for death, 3 patients who were not enrolled in Medicare, 8 patients who were enrolled in Medicare+Choice plans, and 1 patient whose claims records were missing. Total costs include direct medical costs (Medicare reimbursements and pharmacy costs) plus the value of the time spent by caregivers, the value of the time spent by the patient, and travel costs. After year 1, costs were discounted by 3 percent per year. The incremental cost-effectiveness ratio is the cost per additional quality-adjusted life-year gained with lung-volume-reduction surgery. The subgroup of patients with non-upper-lobe emphysema and high exercise capacity is not included, because in this subgroup, surgery was associated with higher total costs and fewer quality-adjusted life-years gained than was medical therapy. CI denotes confidence interval.

What does it take to get secure reimbursement from CMS and other payers?



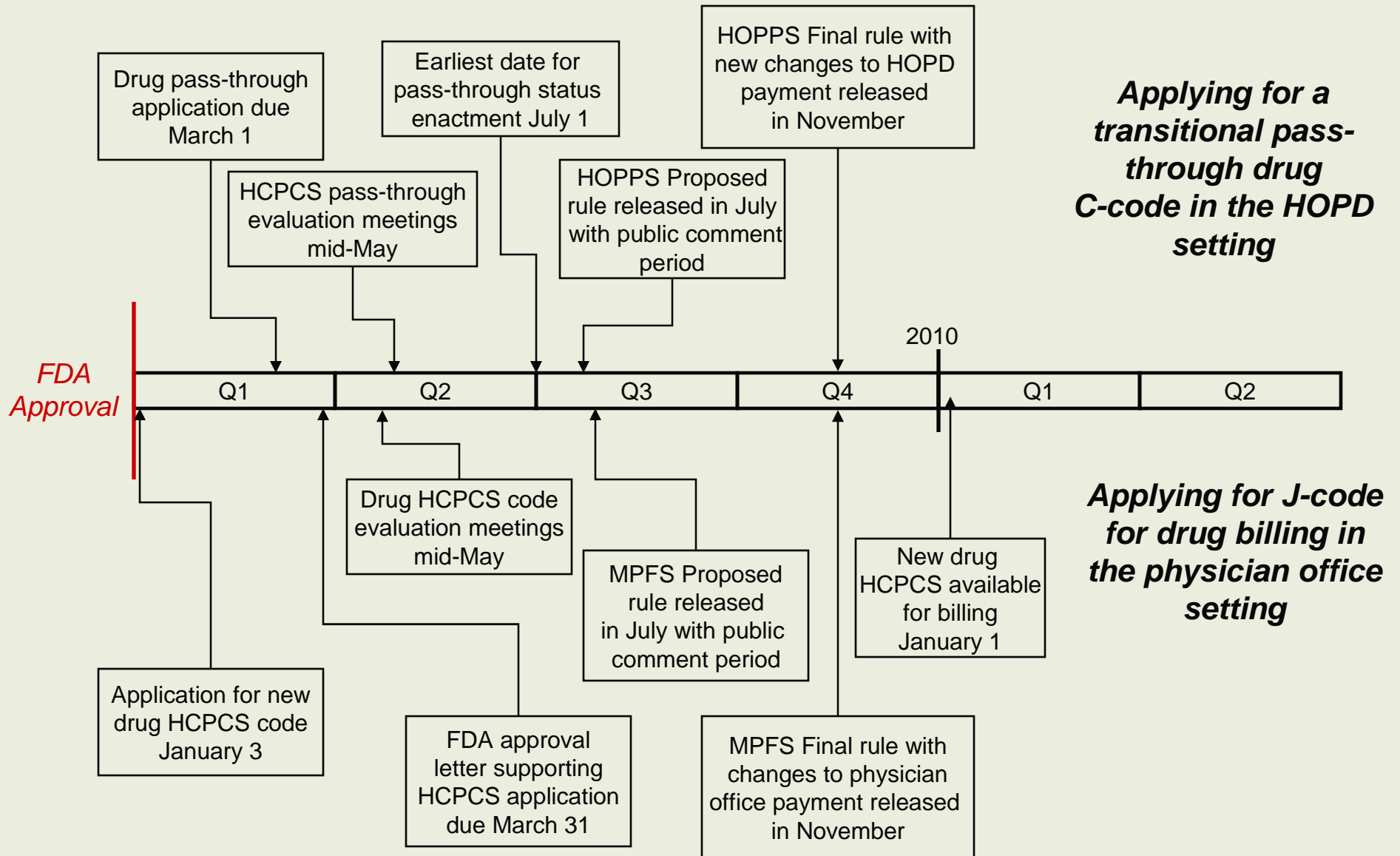
Establishing proper timelines to incorporate reimbursement milestones

Phase I Pilot Studies
 Algorithm Development
 3rd Generation Scanner Development
 3rd Generation Scanner Phase I Studies
 Pre-IDE Meeting / IDE Filing
 Phase II/III Clinical Trials
 PMA Submission to Approval
 Launch

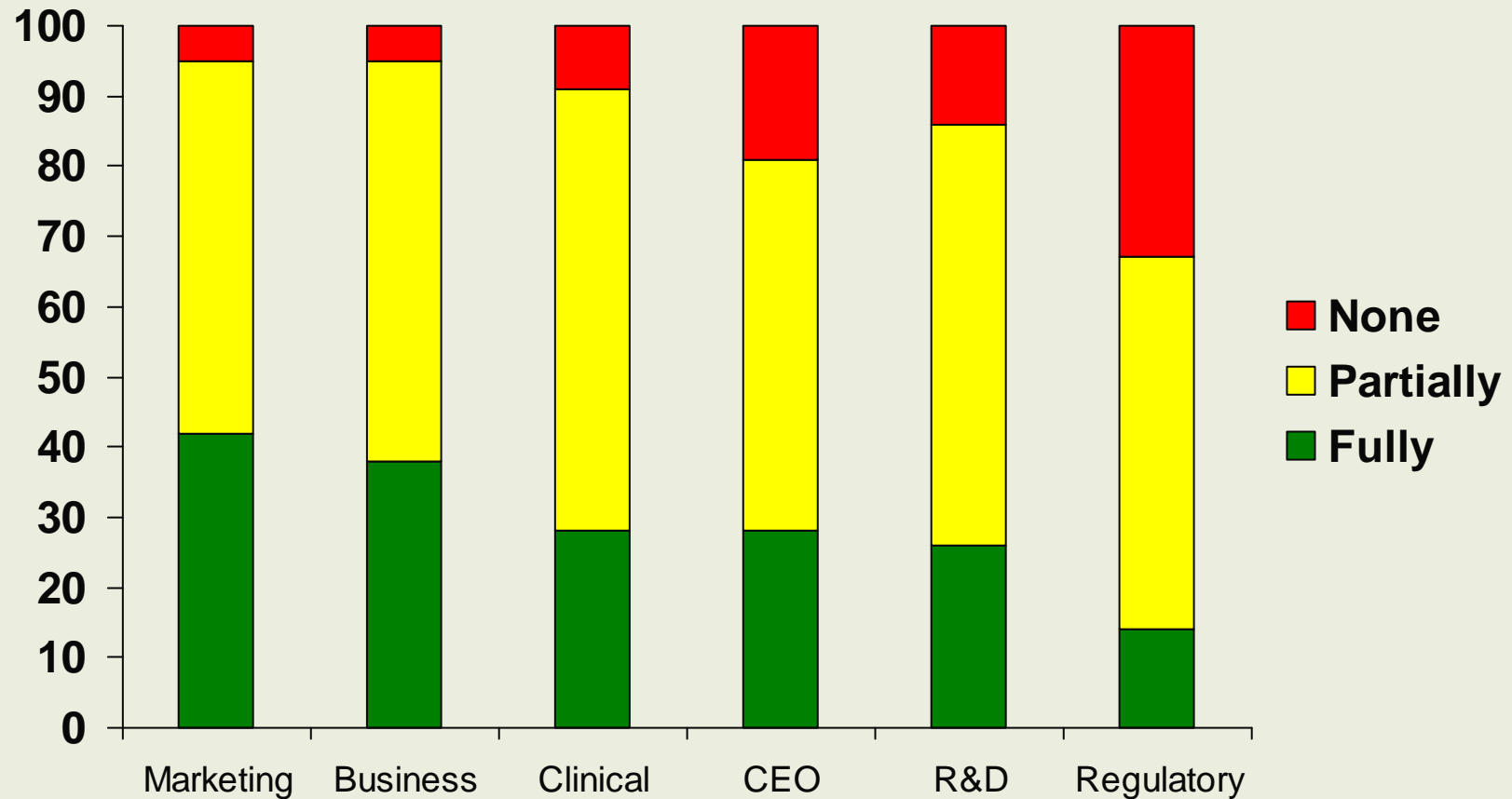


	2011	2012	2013	2014	2015
Post Launch Timelines	PMA Approval	Billed as unlisted code		Secure new category I CPT code	

Drug/Device Coding Timelines

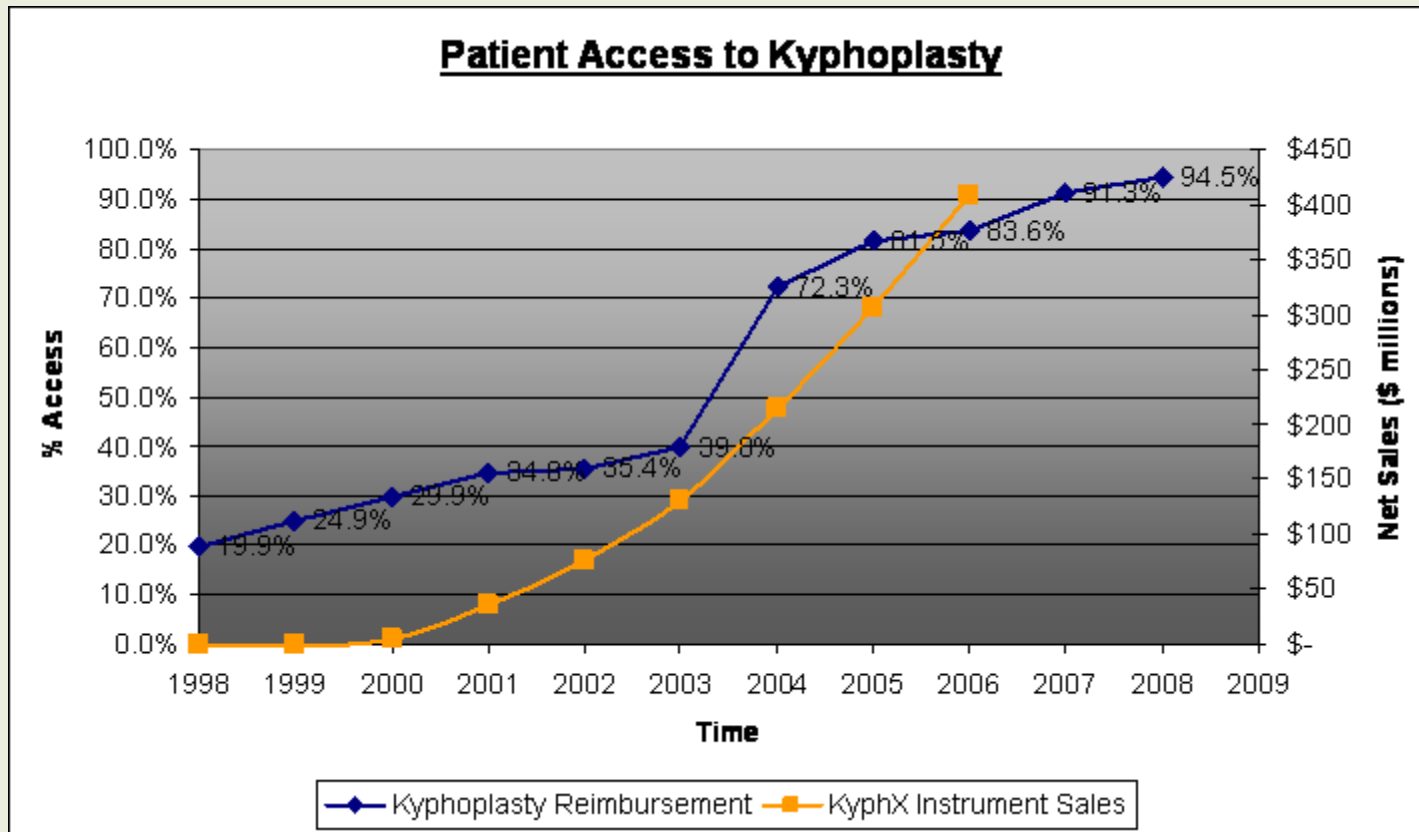


Management buy-in regarding the importance of health economics and reimbursement

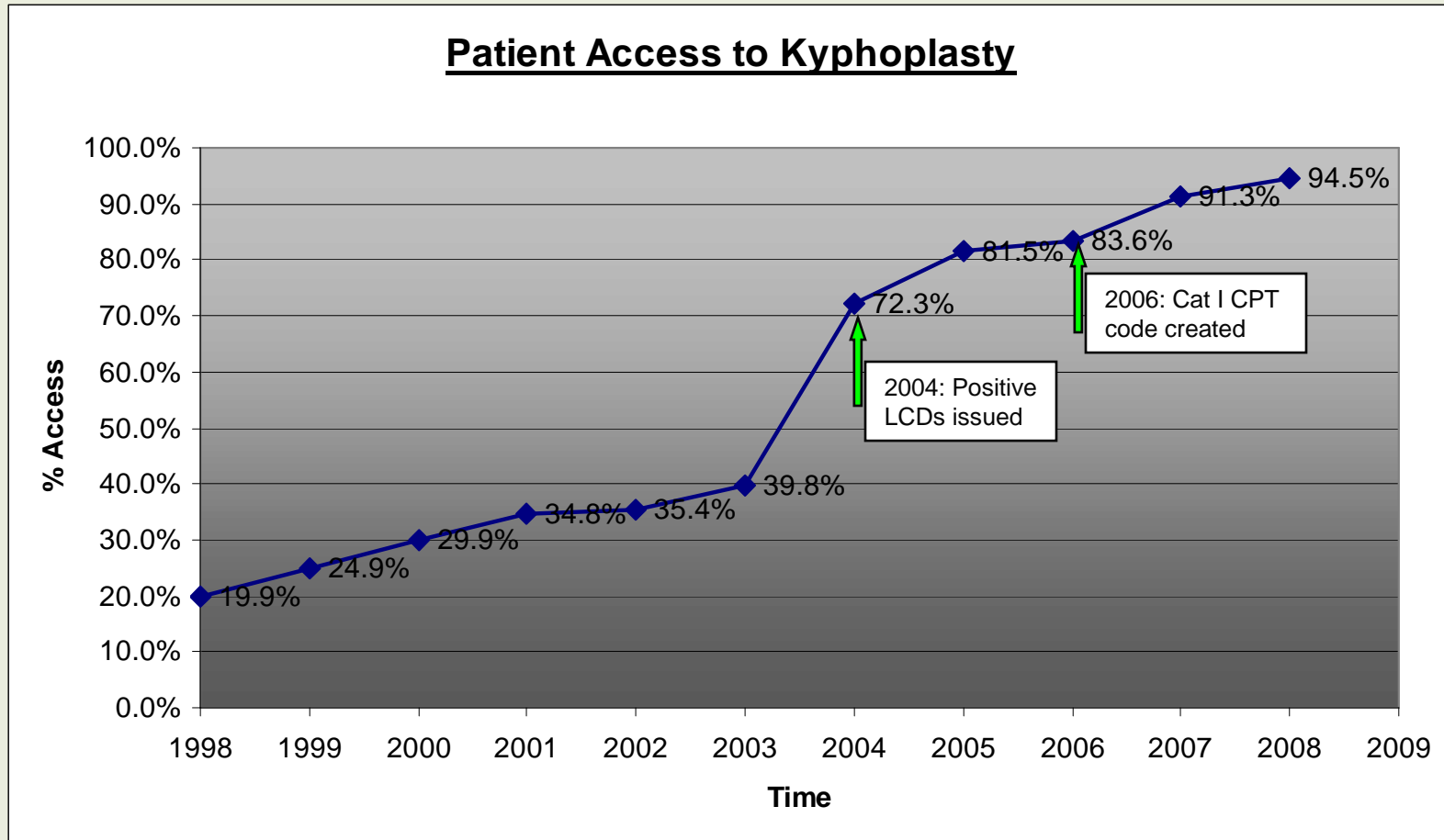


DiMasi et al. 2001

Relationships between payer coverage policies and market adoption



Reimbursement penetration case study - Kyphoplasty



Thank you!

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