

# Evidence and Coverage as the True Pathway to Product Uptake

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Quorum Consulting



## INNOVATION

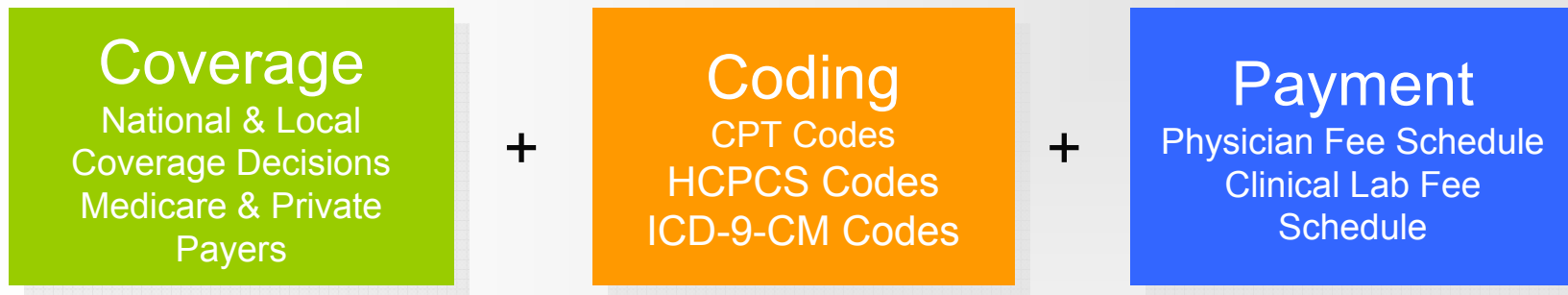
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# Innovation: Disruptive & Constructive?

**PROLOGUE:** “Disruptive innovation,” a concept popularized by Harvard Business School’s Clayton Christensen (right), has intuitive appeal to people who believe in markets and capitalism. We celebrate the fact that Japanese auto-makers’ emphasis on quality and lean production methods forced

***“Disruptive technologies must be matched with innovative business models.”***

# Sound Clinical Foundation + Reimbursement Fundamentals = Reimbursement Success



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**U.S. Food and Drug Administration**



# Commonly Asked Questions

1. Can you help me get a code?
2. Can you help me get a higher payment rate?

*Sure, but...*



What does your clinical data show?



Is your test covered by payers?



What is the pricing of your test?

# U.S. LABORATORY REFERENCE TESTING

## *Market Profile & Pricing Trends 2008*



WASHINGTON  
G-2 REPORTS

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*Reference testing costs rose by an average of 12.1% in 2005.*

### Causes:

1. An **explosion of molecular-based testing** in a large number of laboratories;
2. The recognition by many laboratories that because many molecular-based tests are labeled “complex,” **they cost more, but also have higher reimbursement value.**

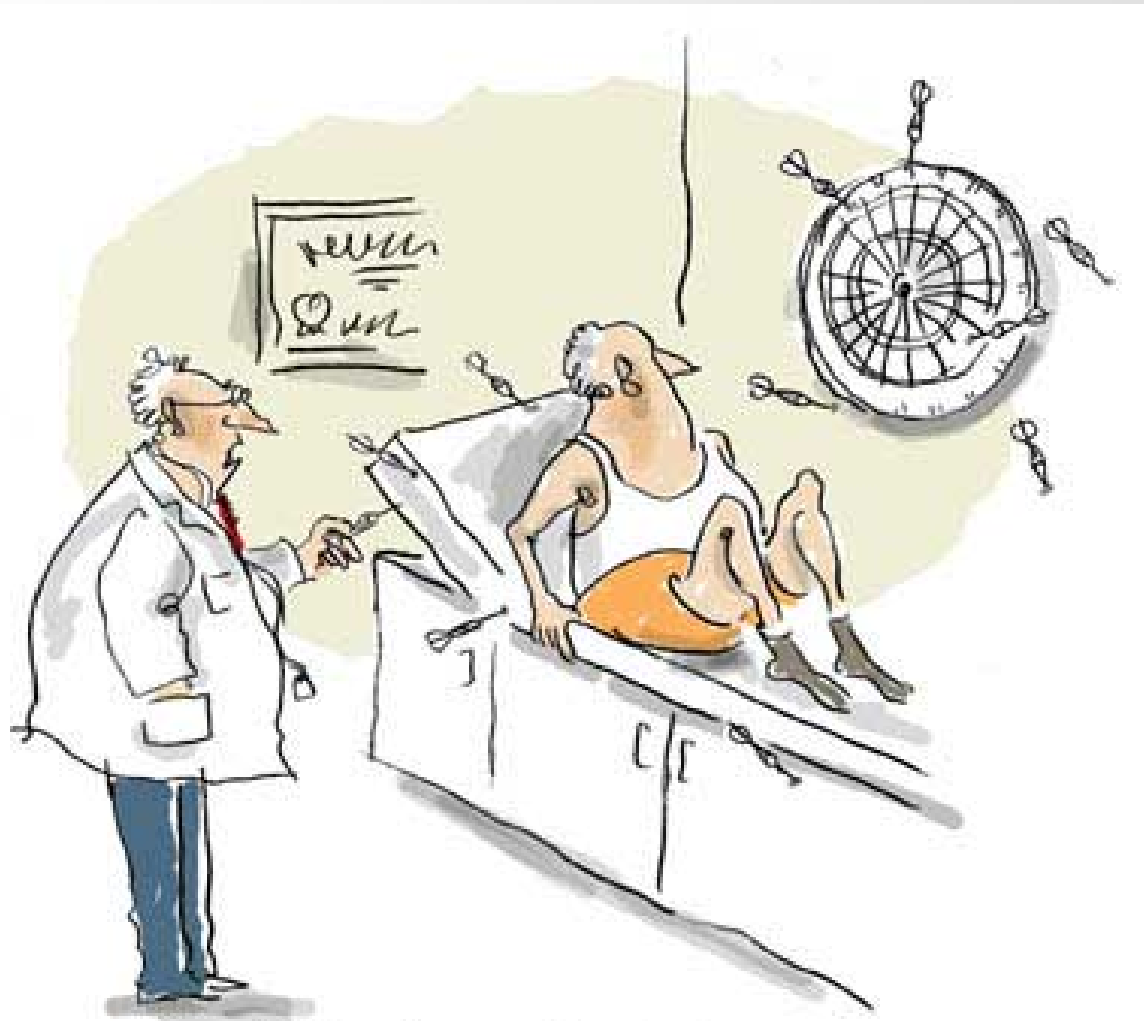
# Barriers to access

Table 3.5

**What is the biggest barrier your laboratory faces in expanding its esoteric testing menu?**

	2005	2004	2002
Low test volume does not justify bringing in-house.....	36%	39%	46%
Budget constraints/lack of capital to purchase necessary equipment.....	15%	16%	16%
Inadequate reimbursement from Medicare and/or managed care payers .....	14%	11%	16%
Esoteric testing reagents are too expensive.....	11%	11%	10%
Not enough floor space in laboratory.....	11%	9%	3%
Difficulty in hiring laboratory staff with necessary skills.....	7%	9%	9%
Other.....	6%	5%	0%

Source: Washington G-2 Reports, U.S. Laboratory Reference Testing Market Profile & Pricing Trends 2008



**"I like to practice before  
I start acupuncture treatment!"**

# Evidence levels for diagnostics in the spotlight

## The New York Times

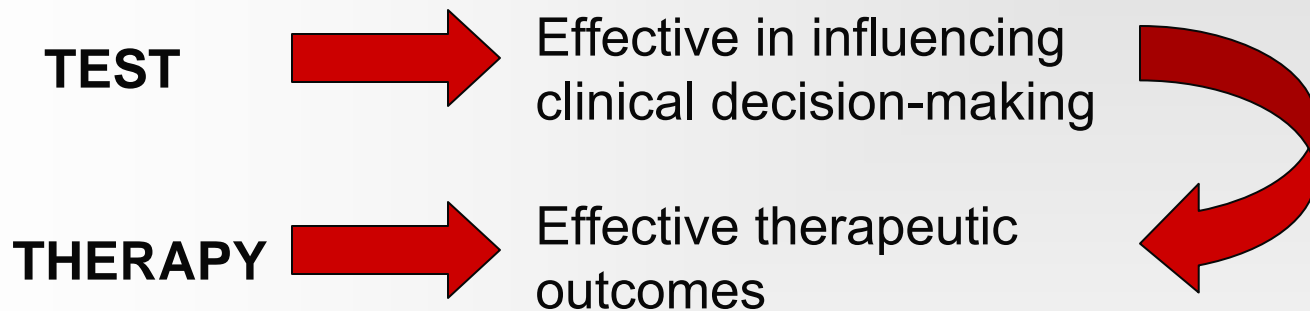
### Cancer Test for Women Raises Hope, and Concern

By ANDREW POLLACK

Published: August 25, 2008

A new blood test aimed at detecting ovarian cancer at an early, still treatable stage is stirring hopes among women and their physicians. But the Food and Drug Administration and some experts say the test has not been proved to work.

# Trofile: partnered with Maraviroc for evidence development



Maraviroc FDA approval + Trofile launch: *August 2007*

Trofile CMS coverage + coding guidance: *September 2007*

# Coding does not guarantee incremental reimbursement



## **ADA Guideline Recommendations (2007):**

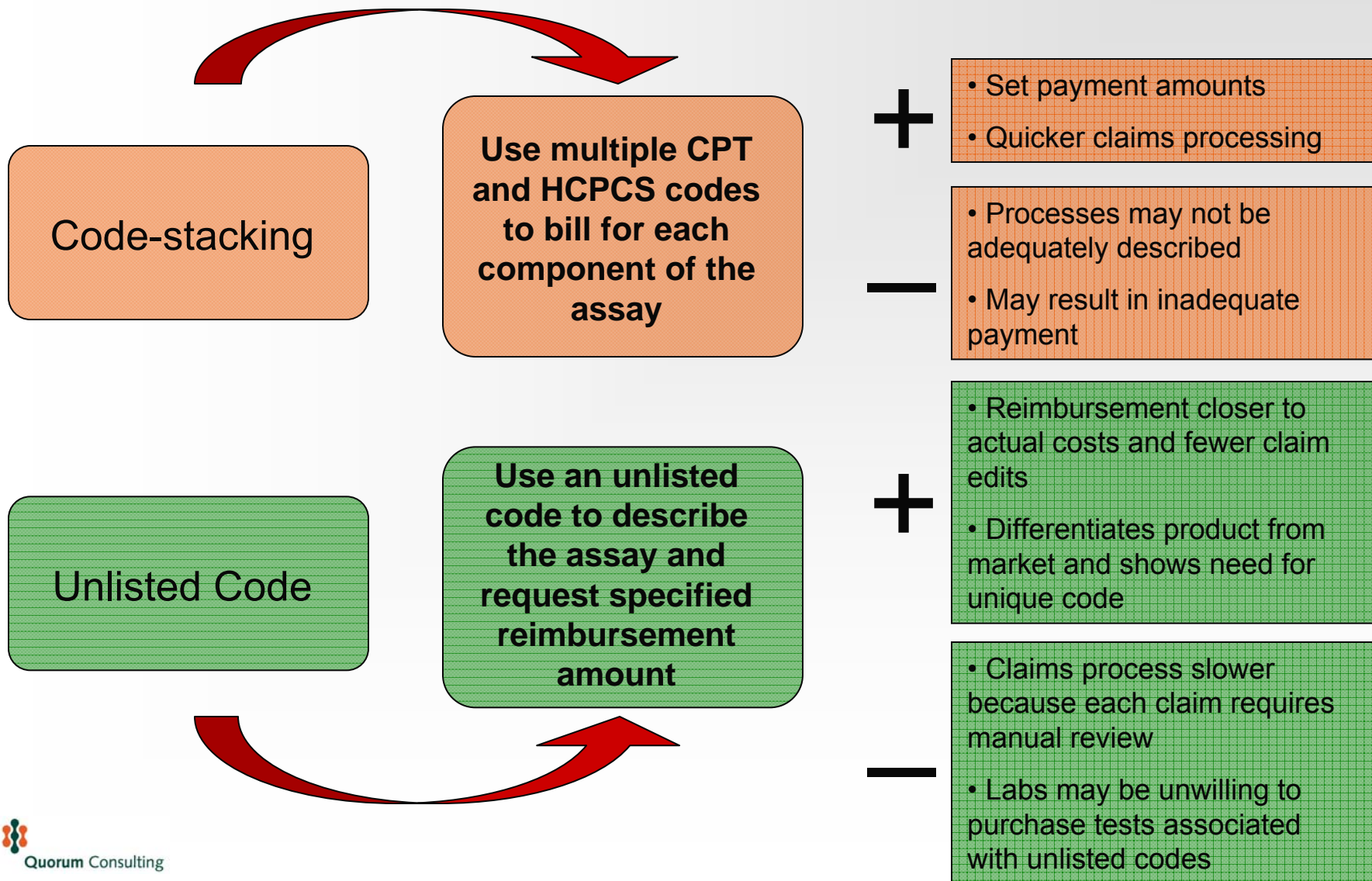
Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed.

## **Milestone 1: Unique CPT 83037 for POC test**

## **Milestone 2: Incremental reimbursement ... *for a time***

*Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is **labeled by the Food and Drug Administration for home use** and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).' (Source: Medicare, Medicaid, and SCHIP Extension Act of 2007 )*

# Do you need your own code?



# Code Stack Example: Myriad's BRCA Panel

CPT	Units	Description	Payment
83891	1	Molecular diagnostics; isolation or extraction of highly purified nucleic acid	\$4.45
83898	82	Molecular diagnostics; amplification of patient nucleic acid (e.g., PCR, LCR), single primer pair, each primer pair	\$20.79
83904	82	Molecular diagnostics; mutation identification by sequencing, single segment, each segment	\$20.79
83894	5	Molecular diagnostics; separation by gel electrophoresis (e.g., agarose, polyacrylamide)	\$4.45
83912	1	Molecular diagnostics; interpretation and report	\$4.45

**Reimbursement = \$3,440.71**

Sources : Myriad Reimbursement Specialist and  
UT Clinical Laboratory Fee Schedule Carrier Rate

# Coding options for kits sold to hospital facilities

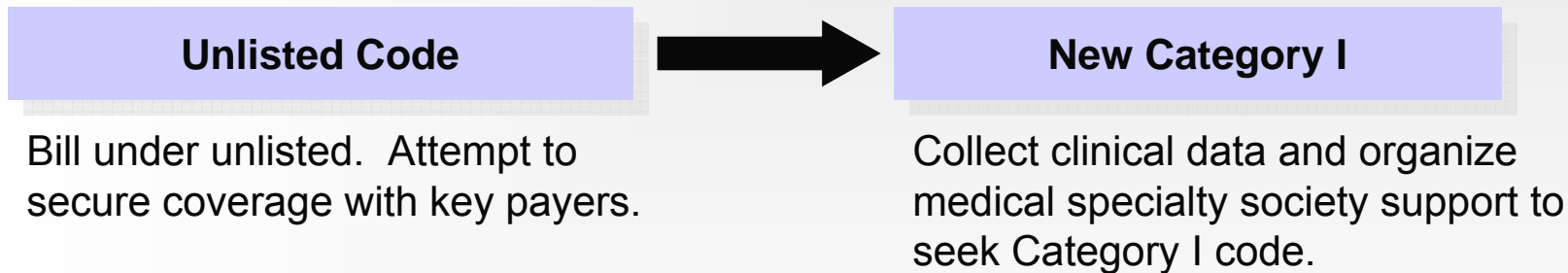
## Option A



Define, test and refine code stack. Educate customers to bill using revised code stack.

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## Option B

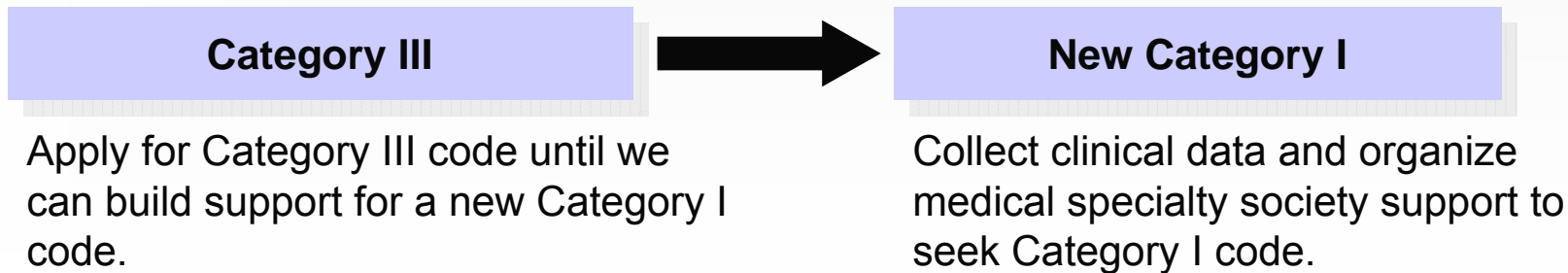


Bill under unlisted. Attempt to secure coverage with key payers.

Collect clinical data and organize medical specialty society support to seek Category I code.

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## Option C



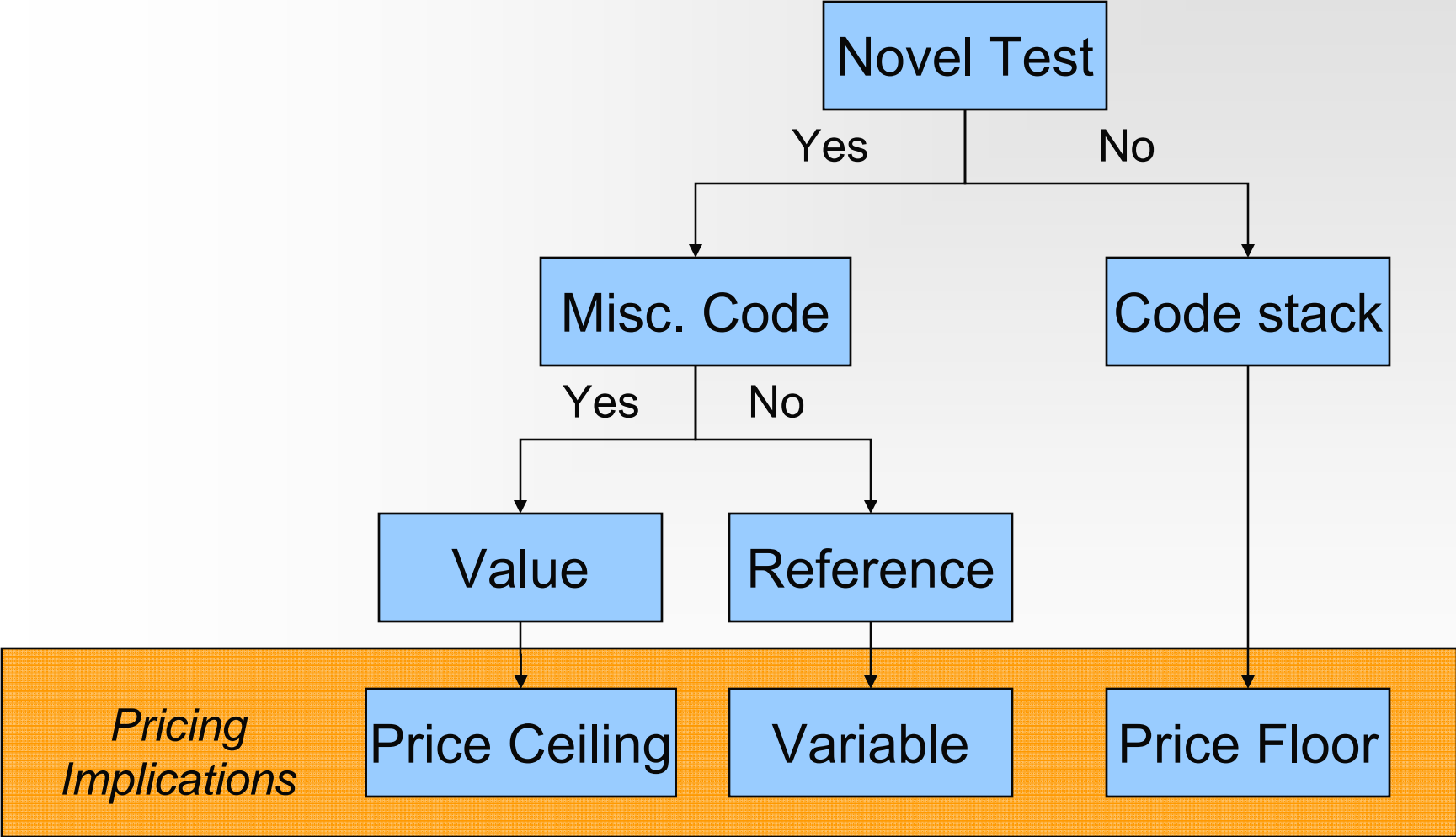
Apply for Category III code until we can build support for a new Category I code.

Collect clinical data and organize medical specialty society support to seek Category I code.

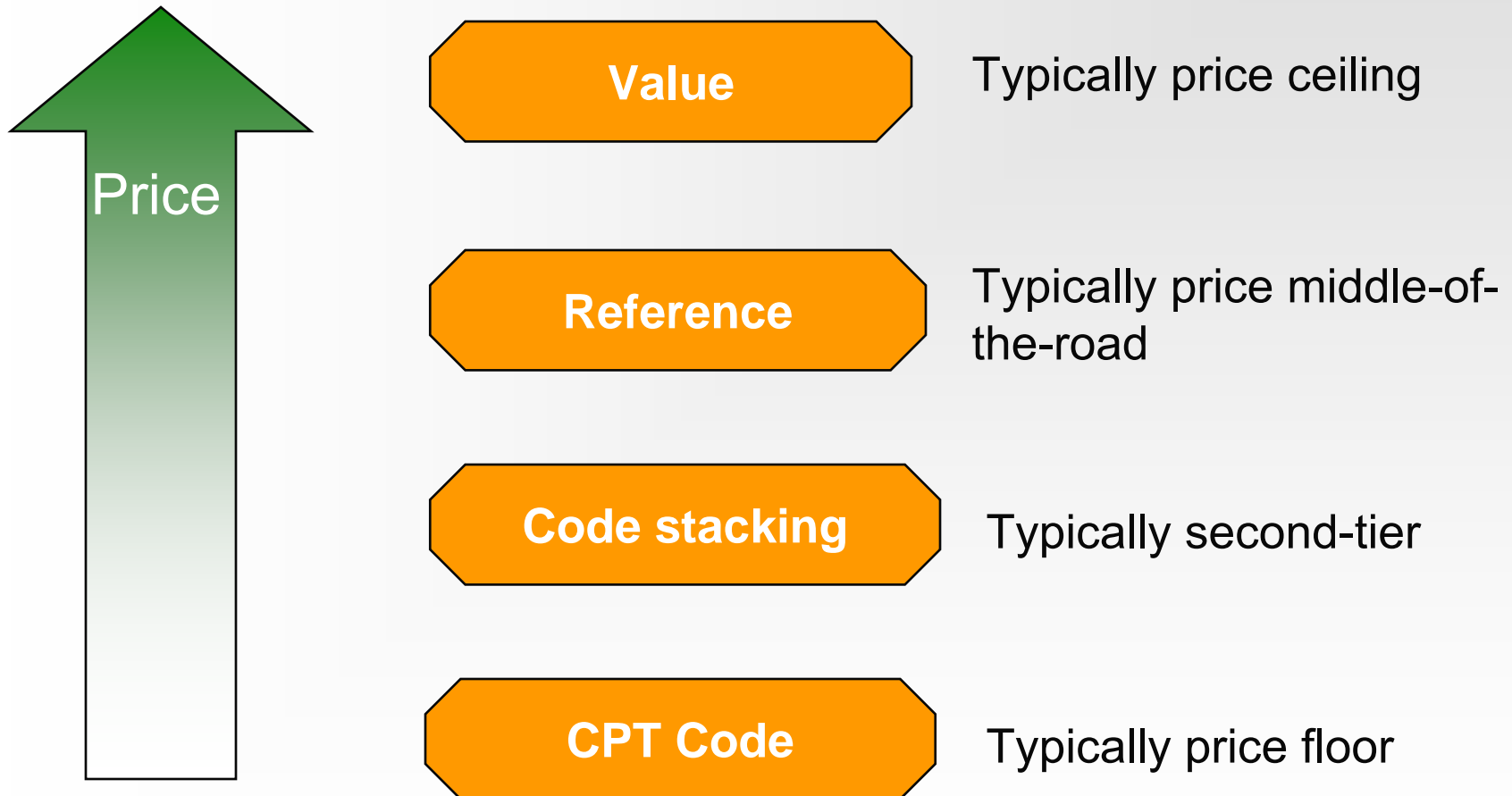


"Testifying against another doctor would violate my ethics, so I'll have to charge double."

# Link between test pricing and coding options



# Pricing spectrum for diagnostics



# Cost effectiveness analysis (CEA) can help with coverage and justifying price

- Layman's definition =

*CEA compares what the test costs with what you gain by using it.*

- ICER = incremental cost-effectiveness ratio

*Payer accepted ICER range for innovation = \$50,000 to \$100,000 per gain*

# CEA findings for Oncotype Dx

**TABLE 2**  
**Cost-Effectiveness of 21-Gene RT-PCR Assay**

Treatment strategy	Cost (\$) per life year saved (LYS)				
	Cost	LYS	$\Delta$ Cost	$\Delta$ LYS	$\Delta$ C/E LYS
Tamoxifen	\$11,890	26.07	—	—	—
RS-guided	\$16,162	28.27	\$4,272	2.197	\$1944
Chemotherapy and Tamoxifen	\$18,418	28.10	\$6,527	1.928	\$3385

C/E indicates cost effectiveness; RT-PCR, reverse-transcription polymerase chain reaction.  
 Under baseline conditions; no quality of life adjustment.



*Oncotype DX's findings show that it both improves outcomes and lowers overall costs*

RS-guided – Recurrence score guided

Impact of 21-gene RT-PCR Assay on Treatment Decisions of Early-stage cancer - Cancer

# How do the CEA results compare?

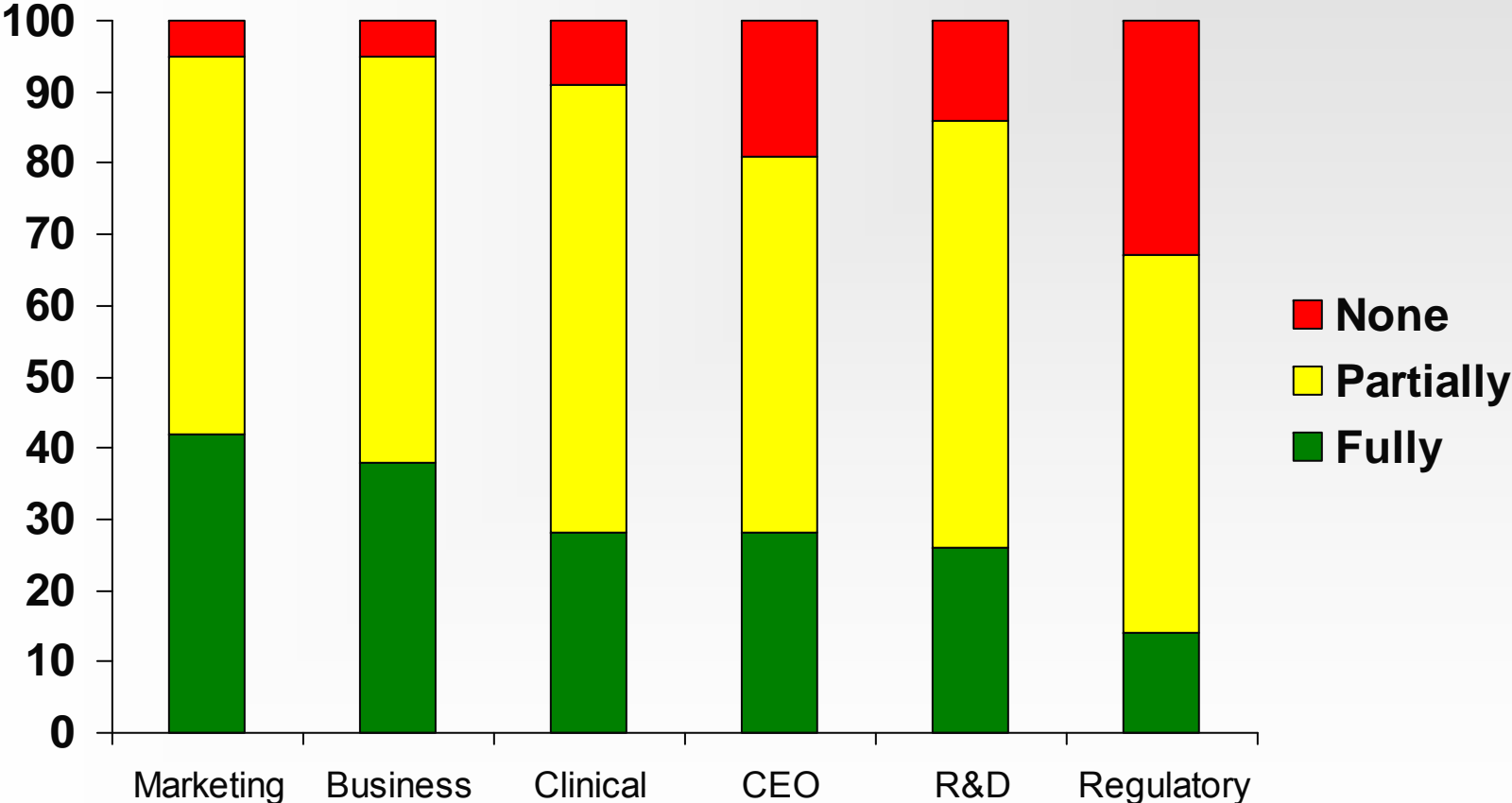
Cancer Therapy	Indication	Comparator	Time Frame	ICER	Source
Trastuzumab	Breast cancer	Standard therapy	Life time	\$26,417/QALY	Garrison
			20 yr	\$34,201/QALY	
Sorafenib	Renal cell carcinoma	Best supportive care	Lifetime	\$ 75,354/LYG	Gao
Sorafenib	Hepatocellular carcinoma	Best supportive care	Lifetime	\$ 64,301/LYG	Muszbek
Sunitinib	Renal cell carcinoma	IFN- $\alpha$	Lifetime	\$ 52,593/QALY	Remak
Erlotinib	Pancreatic cancer	Gemcitabine alone	Lifetime	\$ 364,680/YLG- \$498,379/LYG	Grubbs
Bevacizumab	Colorectal cancer	FU/FA IFL	Lifetime	£ 88,436/QALY £ 62,857/QALY	McCormack
Cetuximab	Head and neck cancer	Radiotherapy	Lifetime	€ 8,568/QALY- € 10,836/QALY	Brown
Lapatinib	Breast cancer	Weighted treatment group	5 years	€ 12,230/QALY	NCP

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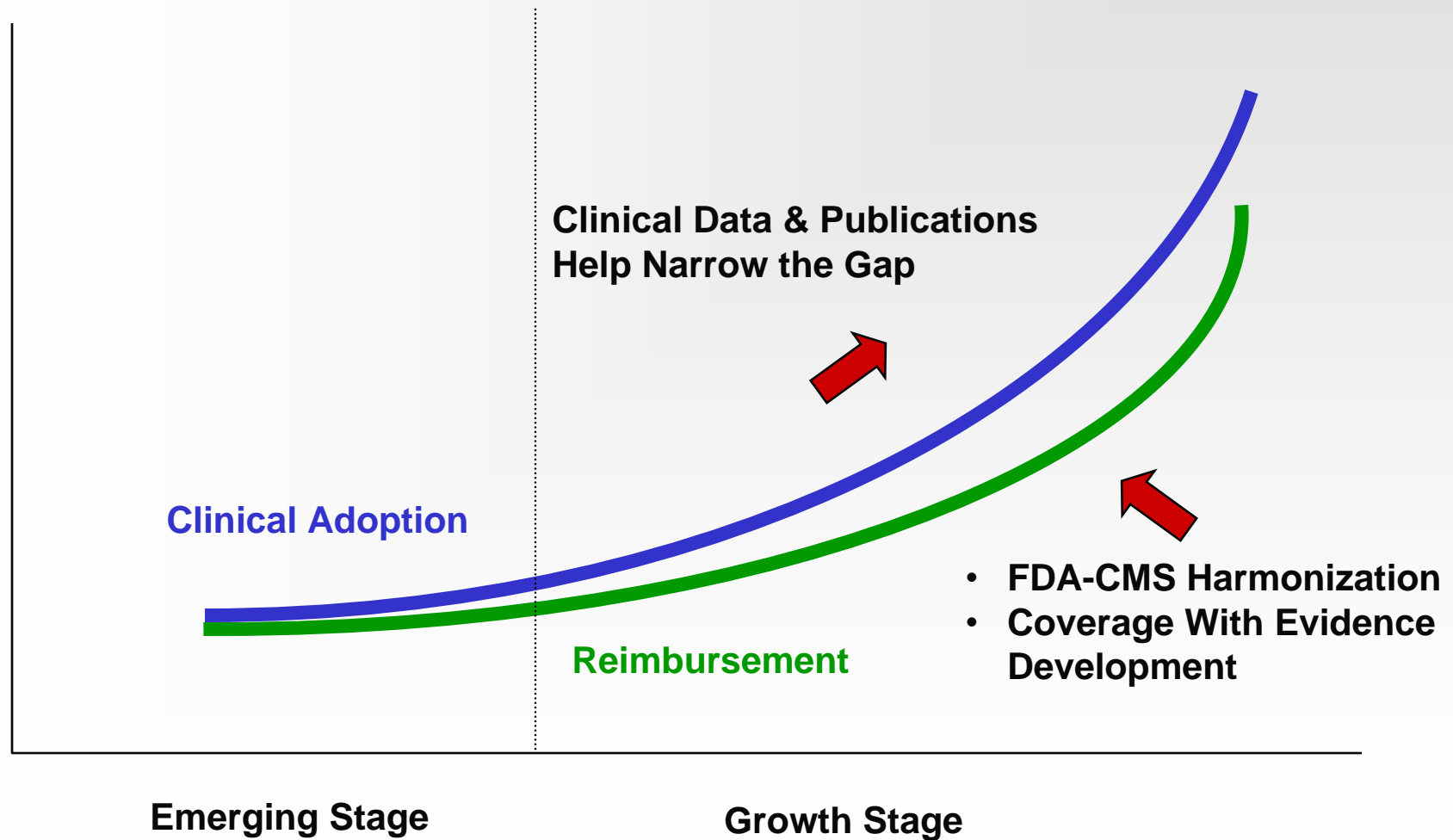
Sometimes I just feel like processing some data, but I have no data to process - other times I have the data, but I have nothing to process it with.

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

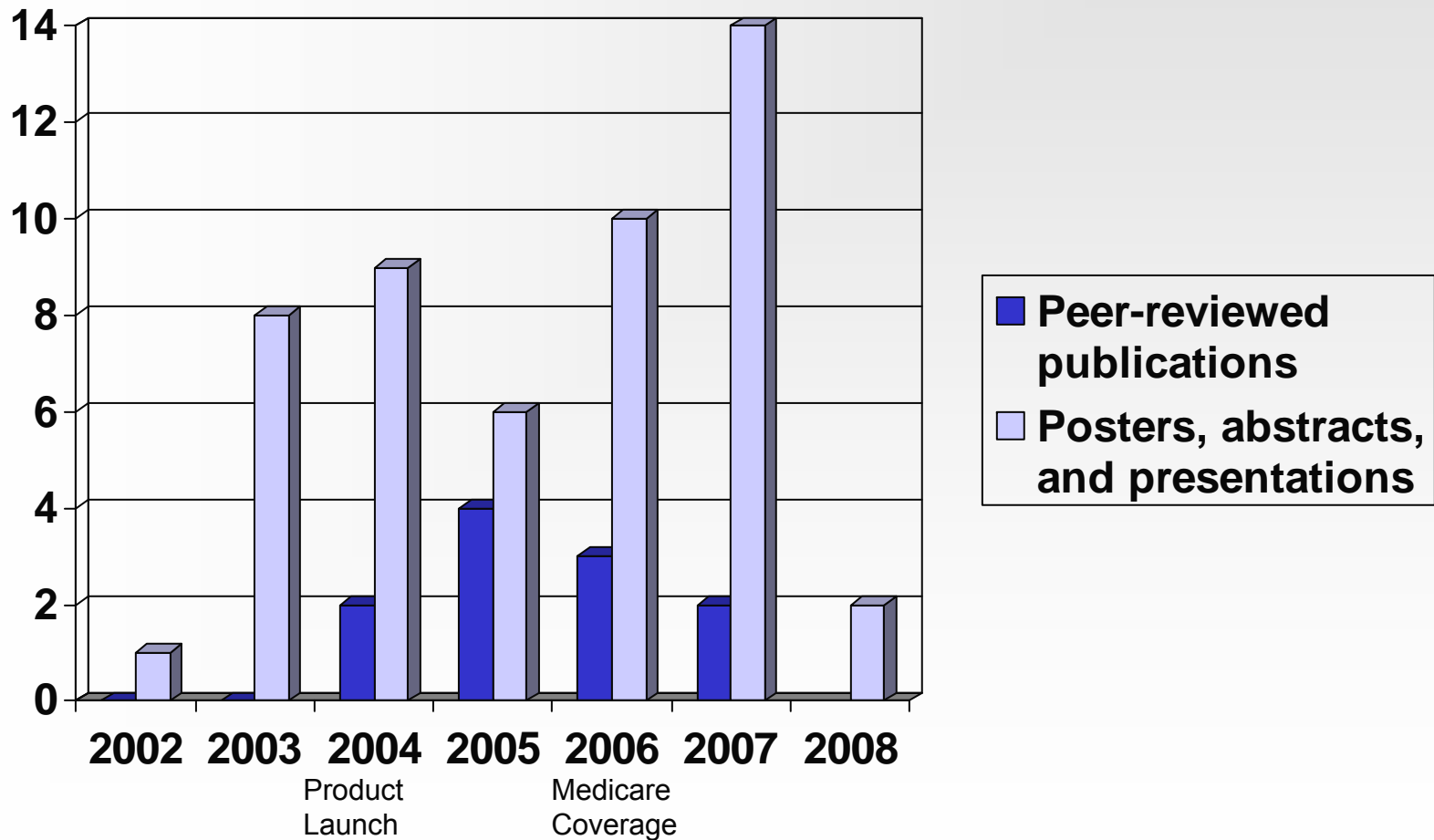


DiMasi et al. 2001

# The new business model: recognize the relationship between clinical adoption and reimbursement

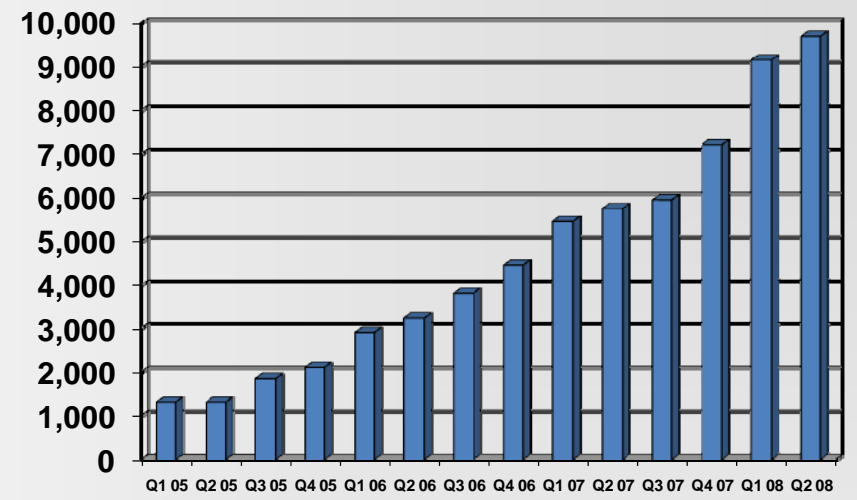


# Oncotype Dx: Number of publications and presentations

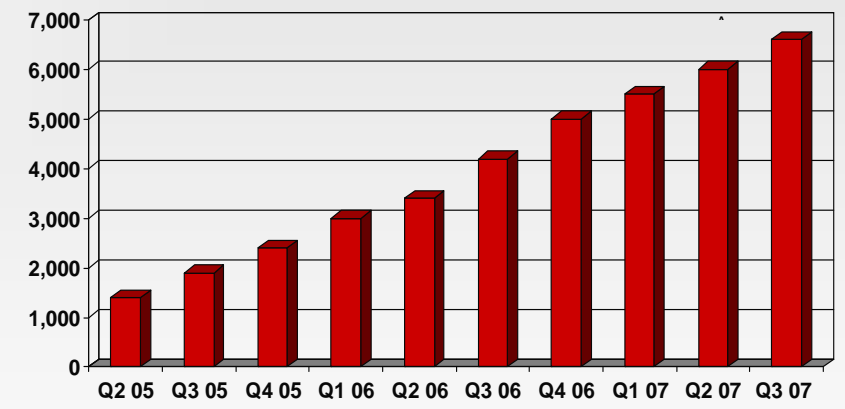


# Progression in ...

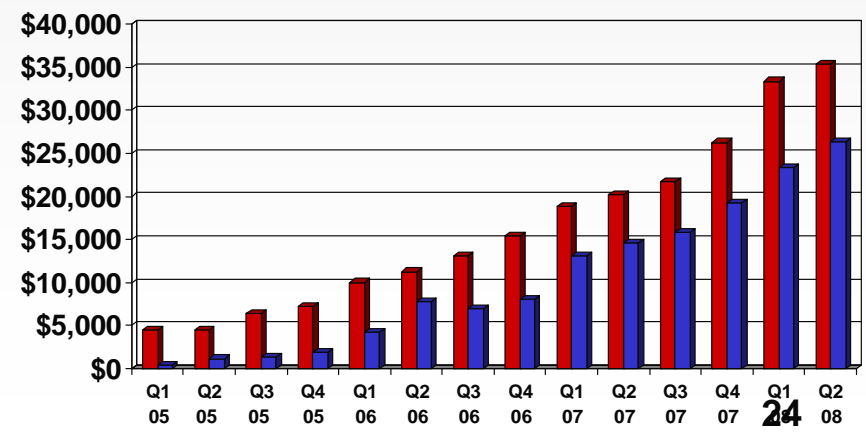
*Tests ordered*



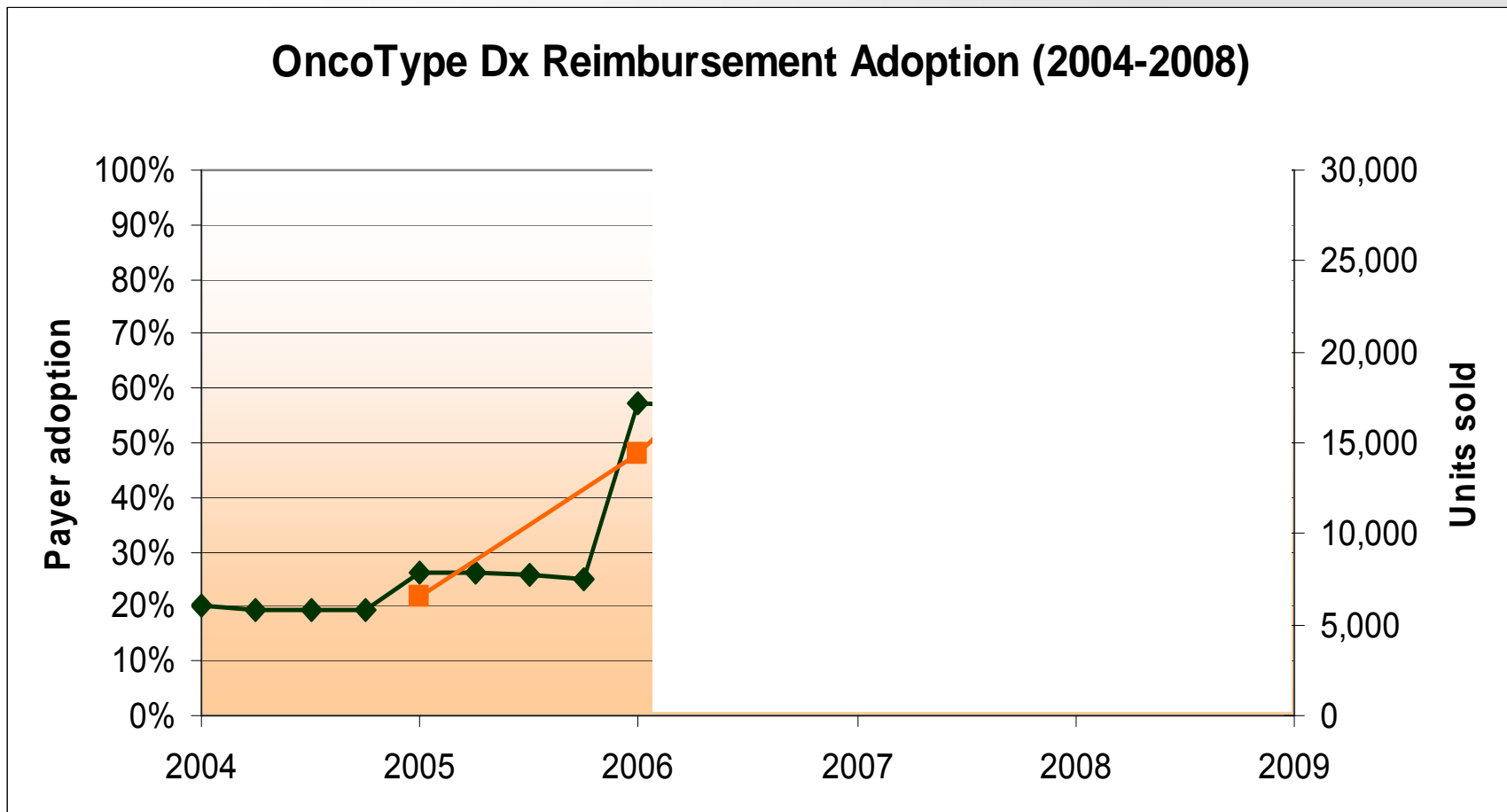
*Ordering physicians*



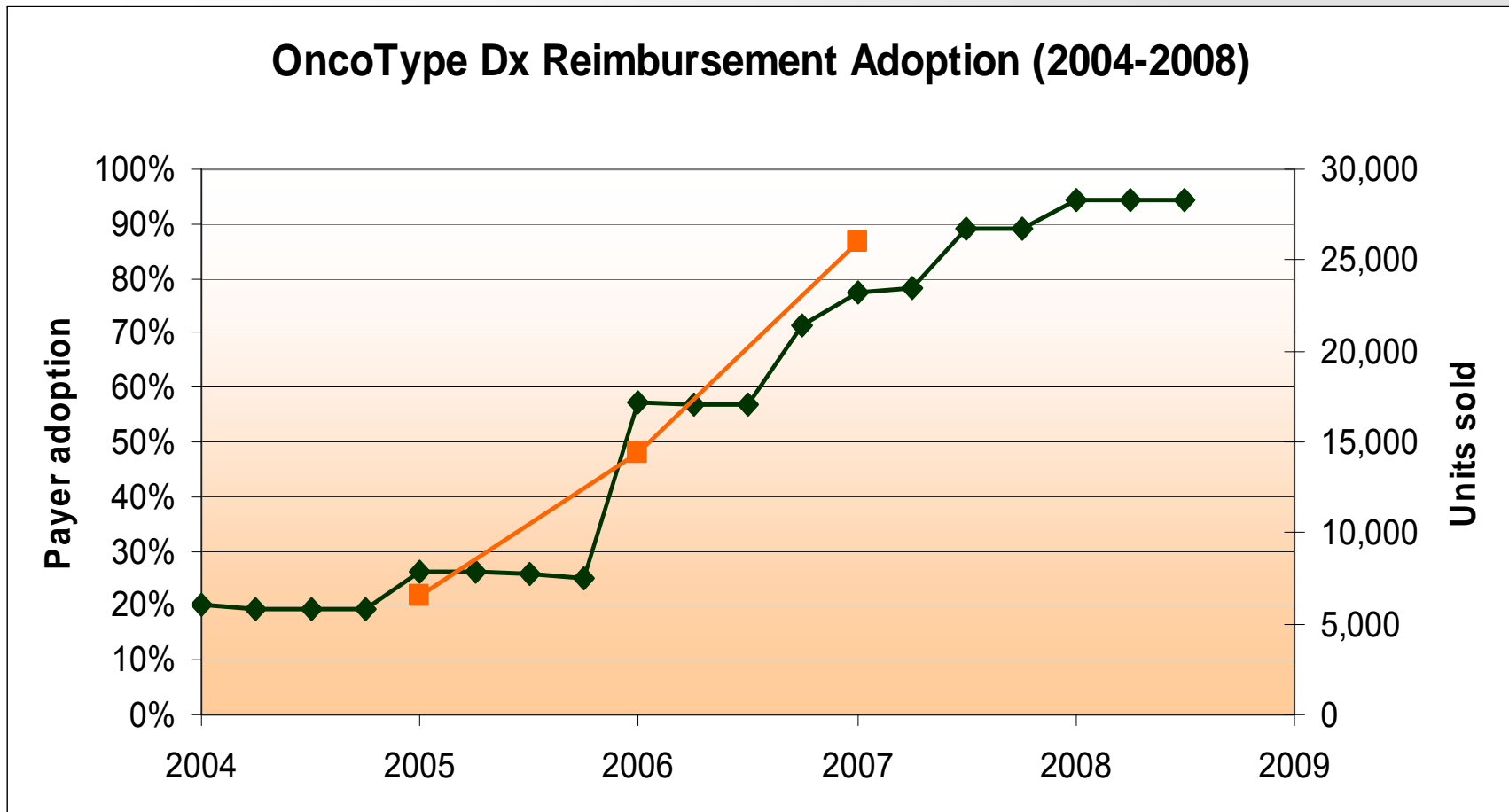
*Tests paid*



# Evidence-based clinical adoption is the initial groundwork



# Positive coverage is the “boost”



# Thank you!

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