The Science and Art of Value in Pricing for Medical Technology

Health Industry Forum
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Overview

- Factors in Technology Pricing
  - Distinct Differences Between Pharma and Medical Technology
- Payment System Impact on Pricing Process
  - Coding, Coverage and Payment
- A Case Study
- Conclusions: Stimulating Innovation for Fair Value
New, Innovative and Complex Technologies

- Devices are getting smarter and are providing more information
  - Intelligent Devices
  - Biotechnology Revolution
  - Personalized Medicine
  - Preemptive, Predictive, acute to home
Unique Technology-Specific Confounders When Designing Studies to Assess Value

- **Risk:** Range of technologies require different threshold of necessary evidence. (New non-invasive MRI tests need the same type of study as a new brain aneurysm stent?)

- **Operator Skill:** How do we capture the value of skilled physician/user techniques on patient outcomes and study design?

- **Life Cycles:** Do we expect to conduct studies on all iterative technologies with required publications when medtech’s life cycles are less than 2 years?

- **Combinatorial Science:** How do we account for all the manufacturing confounders (polymers, voltages, wires and metals, drugs) on patient outcomes?
Understanding the Structure of Financial Risk Can Help to Focus a Pricing Strategy

- Financial risk flows through health plans (governments) and provider structures in different ways.
- The ‘holder’ of financial risk typically controls decisions about purchase and use of new technology.
- *The strategies and tactics associated with obtaining reimbursement and setting price depend on the integration of all reimbursement elements.*
Challenge: Convince Providers to Purchase Technology Without a Guarantee that a Payer Will Reimburse

Medical device company sells technology to Provider

Provider renders service (with use of technology)

Provider looks to the payer to reimburse for the service and technology
Technology Pricing Basics

- **External Assessment (ROI):** Value to Your Customer In Competitive Environment
  - Who Buys It (or leases it)? Hospital (GPOs), Distributor, Home Health Agency, Physician (IDNs), Direct Consumers, or Governments (VA, Global)

- **Internal Assessment (ROI):** Value and Costs of Producing
  - How to determine costs/price? Plastics, software, metals, data management, R&D, sterilization, drug licensing for combo products, electronics, plants, suppliers, regulatory rules, etc.
Pricing Conundrums

- Launch early at a low price, or launch later at a higher price with all the supporting evidence by financial stakeholder value.

- Determine financial gatekeeper and perceived value before launch.
  - Drugs, it’s the prescriber, the patient and the payer (an insurer)—free market.
  - Devices, it is multiple large buyers, financial gatekeepers with conflicting value systems. Budget systems are “fixed” (e.g., hospital budgets) adding to budget woes, with “benefits” realized by the INSURERS—payment gap—free riders. Payers accrue benefit while providers bare the cost.

- Produce evidence of product value to financial gatekeeper.
Know Your Target:
The U.S. Healthcare System
Major CMS Payment Systems

- **PROSPECTIVE PAYMENT SYSTEMS:**
  - Inpatient PPS
  - Outpatient PPS
  - Inpatient Rehab
  - Long-term Care Hospital
  - Inpatient Psych
  - Skilled Nursing Facility
  - Home Health

- **FEE SCHEDULES:**
  - Physicians
  - Ambulatory Surgical Centers
  - Clinical Labs
  - Durable Medical Equipment, Prosthetics & Orthotics
  - Ambulance
  - ESRD
Payment Divergences

- Each payment system has its own rules, based in statute, and uses data from the providers it pays
  - Different payments in different sites for the same items or services
  - Can create inappropriate incentives
Components of Reimbursement for a Device

- **Coding**
  - The language of providers and payers (What was done and/or what was diagnosed)

- **Coverage**
  - Eligibility for payment (Does the payer cover what was done?)

- **Payment**
  - Dollars for care (How and how much will they pay?)

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**Payment Process**

- MD Performs Service
- MD Dictates Notes
- Coder Translates Notes
- Finance Submits Bill
- Payer Pays Bill Based on Codes
Where and How Does a Provider Get Paid?

Follow the Code

Coding

What was done

CPT/HCPCS/ICD-9 procedures

Does not guarantee payment

Reason for service

ICD-9 Diagnosis codes

Trigger for payment

Payment
A request for a CPT code to reflect changes in clinical practices and technologies results in short and long term strategic planning and the need to negotiate.

Key driving concept:
- Payments for this service or existing services may be negatively impacted.

Goal:
- To optimize RVU assignment.
- To avoid RVU devaluation.
Example of Payment Divergences

Diagnostic Colonoscopy – CPT 45378

1.15 million procedures performed in 2003

<table>
<thead>
<tr>
<th></th>
<th>Payment</th>
<th>Site Utilization</th>
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<tr>
<td>OPPS</td>
<td>$513</td>
<td>56%</td>
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<tr>
<td>ASC</td>
<td>$446</td>
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<tr>
<td>PFS-PE</td>
<td>$177</td>
<td>6%</td>
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</table>

physician fee schedule (PFS)
practice expense (PE)
Components of Reimbursement

Coding
The language of providers and payers
(What was done and/or what was diagnosed)

Coverage
Eligibility for payment
(Does the payer cover what was done?)

Payment
Dollars for care
(How and how much will they pay?)

Payment Process

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<tr>
<th>MD Performs Service</th>
<th>MD Dictates Notes</th>
<th>Coder Translates Notes</th>
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<td><img src="image3.png" alt="Coder Translating Notes" /></td>
<td><img src="image4.png" alt="Finance Submitting Bill" /></td>
<td><img src="image5.png" alt="Payer Paying Bill" /></td>
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</table>
Evidence Demands

Decision-Making Occurs at Multiple Levels

- National
- Regional
- Local

Organizations

- CMS, (Global–International)
- Major national third party payers and benefit managers
- Medicare Intermediaries and Carriers, DMERCs
- Regional health plans
- Medicaid administrators
- IDNs
- Physician groups
- Hospitals
- Jiffy Lubes

- 8,000 private payers in the US
- Contracts negotiated with “Providers”
- Providers negotiate with doctors, hospitals, suppliers, pharmacies, hospitals that own doctors, etc.

➤ So, where do you target to show the value of your technology? Value to whom? Primary audience?
Higher Evidence Thresholds: Fundamental Disconnect Between Regulator and Payer

EVIDENCE (data)
Components of Reimbursement

**Coding**
- The language of providers and payers
  (What was done and/or what was diagnosed)

**Coverage**
- Eligibility for payment
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**Payment Process**
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Private/Commercial Payments

- Negotiated rates with hospitals & physicians
- Payments: usually a percentage over Medicare’s for physician services
- Utilization restrictions, pre-authorization & “case-management” arrangements for many services, particularly “post-acute” and rehab services
- Minimal, often capped, DME coverage
Example: A Promising Technology to Moving Care From Acute to Home…

Inpatient Hospital: Acute Stroke Care
PT/OT Evaluation
Initiate Treatment

Discharge to:

Inpatient Rehabilitation Facility
Skilled Nursing Facility
Home

Hospital-based Outpatient Therapy
Office-based Therapy
In-home Therapy
Example: Daily home dialysis restrained by payment

- Major clinical benefits
  - LVH, heart failure improvement
  - Anemia
  - Rehabilitation/QOL

- 15-25% annual savings potential ($10-17K of 70K costs)

  • Kaiser promoting home dialysis
Daily home dialysis challenges

Total Annual Costs of Care:
- $65-70,000 per patient

- Hospital ($24,000)
- Drugs ($9,000)
- Dialysis ($19,000)
- Physician ($9,000)
- Other ($8,000)

Portion of Medicare savings occur in drugs, which are profit generators for providers
Daily home dialysis challenges

Largest savings in hospital costs, which are part of a different budget (Part A vs. Part B) and are not realized by the dialysis provider.
Daily home dialysis

- In-center dialysis continues to dominate, despite data
- Product pricing/market potential not sufficient to attract broad investment given payment system
- Patient access is skewed to those with commercial insurance, and Medicare beneficiaries are denied
### A True Story: Finding the Right Path

#### Physician-Delivered Model Works Best

<table>
<thead>
<tr>
<th></th>
<th>Existing Category</th>
<th>Physician Delivered</th>
<th>Home Health Delivered</th>
<th>Weight</th>
<th>Control</th>
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<tbody>
<tr>
<td>Pharmacy Risk</td>
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<td>⚫</td>
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<tr>
<td>Speed to Discrete Coding and Payment</td>
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<td>✔️+++</td>
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<tr>
<td>Market Potential</td>
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<td>✔️+++</td>
<td>⚫</td>
<td>⚫</td>
</tr>
<tr>
<td>Prescriber Motivation/Feedback</td>
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<td>✔️+++</td>
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<tr>
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<tr>
<td>Speed to Commercialization</td>
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<td>✔️+++</td>
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<td>⚫</td>
</tr>
<tr>
<td>Number of Economic Stakeholders</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️+++</td>
<td>⚫</td>
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</tbody>
</table>

**Good** ☑  **Better** ☑☑   **Best** ☑☑☑

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**NEOCURE**

Bioeconomic Strategies  
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Pricing Technology means navigating U.S. Reimbursement System

- Pre-launch Environmental Analysis
  - Investigate the coverage, coding and payment issues
  - Develop precise strategies for addressing these issues, e.g. applying for new codes, developing alliances
  - Develop materials and data that are both credible and compelling for distribution and presentation to providers and payers

- Post-launch: Customer and Reimbursement Support

- Build the Value Story
  - Develop data to demonstrate the financial impact of the technology under realistic assumptions of coverage, coding and payment by Financial Gatekeeper
Doonesbury - 7/29/04

[Comic Panel]

What kind of leg are you getting, Daddy?

Well, eventually, I'll probably get a C-leg.

It's this very cool-looking prosthesis packed with processing chips. It's made with titanium and costs as much as a Lexus!
Doonesbury - 7/29/04

WOW... REALLY?

YUP!

CAN YOU GET THE LEXUS INSTEAD?

YEAH, WOULDN'T THE REGALE BE BETTER?
Conclusions

- Medtech pricing is subject to site of service, payer considerations
- System reform is needed to appropriately align incentives
- Works in Kaiser-like systems where physician payment is not linked to utilization; providers and payers are aligned
- Imposing new evidence requirements prematurely without alignment in payment systems may have irreversible consequences in the growth and adoption of new technology