Overview of Reimbursement Strategies for Novel Medical Technologies

Nov 9, 2016
Goals and Objectives

Develop understanding of U.S. medical technology reimbursement landscape and provide information about reimbursement strategy development and implementation

Involves answering some important questions:

- What is reimbursement?
- Who are the stakeholders and what are their needs?
- How are technologies valued?
- What can medical technology developers do to maximize reimbursement opportunities and address potential challenges?
UNDERSTANDING REIMBURSEMENT
Why Does Reimbursement Matter?

- Take any product which represents an apparent improvement to clinical practice
- Is it safe to assume this device will be used by providers and paid for by payers?
- In many cases, yes but in some:
  - The payment paradigm does not align to allow for adequate value capture
  - Technologies can sometimes provide value that is counter to the alignment of current financial incentives
  - Certain technologies will face reimbursement challenges as they work their way through complex and often opaque reimbursement systems

Innovators need to understand how to align incentives for stakeholders (payers, physicians, hospitals, etc.) and navigate through reimbursement system by avoiding hurdles and maximizing opportunities.
Case Study #1: The Non-invasive Screening Test

- Innovator develops novel non-invasive screening test that detects people at-risk for a late-onset disease

- Problem #1: Non-invasive = quick and easy = in a cost based system this means low-cost

- Problem #2: No sample to send to the lab. This means the person who orders the test gets paid for it. Payers are concerned that this will lead to “over-utilization”

- Problem #3: At-risk means the person does not have the disease the right now. The patient may have their insurance through a different payer in 2-3 years so the current payer asks “why me?”

- Problem #4: Medicare (the largest insurance provider for individuals over age 65) does not typically cover screening (coverage requires an act of Congress)
Who are the stakeholders?

Different stakeholders will have different motivations and interests; understanding these differences is key.
Role of FDA Approval

- Different stakeholders have different evidence needs
- Regulatory approval is often only the first step

### Regulatory Barrier
- Safety
- Efficacy (PMA, 510K)
- Controlled setting aligned to best outcomes
- Single reviewer (FDA)
- “Aide to diagnosis” means less risk
- Cost is not considered

### Reimbursement Barrier
- Effectiveness
- Avoided costs of alternatives
- “Real world” where evidence evolves and improves over time
- Multiple stakeholders (1,200+ private payers, Medicare, Medicaid)
- “Aide to diagnosis” means one of many potentially useful tests (each adding cost)
- Cost is a key consideration

The types of evidence needed by payers is different than that which is required by regulators. FDA approval is helpful but not required to secure reimbursement.
Sources of Payment for Healthcare

1. Other public includes programs such as workers’ compensation, public health activity, Department of Defense, Department of Veterans Affairs, Indian Health Service, State and local hospital subsidies and school health.
2. Other private includes industrial in-plant, privately funded construction, and non-patient revenues including philanthropy.
3. Health insurance type is not mutually exclusive. Numbers scaled to 100% scale

Sources:
http://kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
Reimbursement

• Reimbursement is payment to providers by third-party insurers (payers) in exchange for medical items and services

• The main components of reimbursement are:
  ➢ Coverage
    • What is medically necessary and what is investigational/experimental?
  ➢ Coding
    • How does the laboratory describe the product/procedure?
  ➢ Payment
    • How much is paid for the technology?

All components need to work together to achieve routine optimal payment
Case Study #2: Low Payment with Current Code versus Higher Payment With New Code

- An innovative laparoscopic surgical device which allows doctors to perform a new procedure
- Physicians and payers believe it will improve patient care by:
  - avoiding the current painful and complicated open-surgical approach
  - reduce the number of expensive surgery related complications
- Problem #1: There is a Current Procedural Terminology (CPT) code which theoretically describes the procedure but the payment rate associated with it is below what the physician/manufacturer would like to see
- Problem #2: If the physician does not have an available code they must use a miscellaneous code to describe their use of the product:
  - Payers do not have a means of identifying it in claims systems
  - Some patients and physicians get frustrated by inconsistent payment associated with its use but in the long run it means larger financial reward

Solution: Go without a code but identify key information needed to secure a new code
Follow the Money

• Identify the party at risk for the cost of your technology
  • Who pays the manufacturer for the product?
    • I.e., Physicians, distributors, patients
  • Who will not have this cost reimbursed if a payer does not agree to pay for that service?

• The willingness to bear financial risk will vary with perceptions of whether or not there is money to be made
  • In some cases you can leverage perceived value into additional payment opportunities therefore higher price

• Also keep in mind how a new product impacts the current dollar flow
  • Does the procedure threaten to replace a trusted and well-paid procedure?
    • E.g., a bladder cancer diagnostic that replaces cystoscopy
Will your Product Paid for Separately?

- There are many medical goods and services which do not qualify for separate payment
- They are either captured in payment for a larger service or used in a setting with an all-encompassing global payment

**Separately Reimbursed**
- Physician services requiring CPT code
- Outpatient or physician office based diagnostic/laboratory tests
- Pharmacy products distributed through pharmacy or in doctor’s offices

**Not Separately Reimbursed**
- Inpatient hospital devices, drugs, and diagnostics
- Devices which are merely components of larger procedures or supplies
  - E.g., New types of rubber gloves, scalpels, syringes, or devices which help improve an existing service
Inpatient Payment for Hospitals

- Payment based on average cost of treating a patient with particular diagnosis
- Assumed some cases will fall below and some will be above average payment

- Hospital Bed Fee
- Inpatient Devices
- Diagnostics
- Goods and Services Used during stay
- Operating room time
- Inpatient Drugs
- Ancillary care and Rehabilitation during Inpatient stay
- Nursing Care

Payment based on average cost of treating a patient with particular diagnosis. Assumed some cases will fall below and some will be above average payment.
FUTURE OF REIMBURSEMENT
Payment mechanisms vary across payer and setting of care

**Historically:**
- Innovation
  - Value associated with “newness” of technologies

**Currently:**
- Impact on Clinical Care
  - Looking for technologies that truly improve patient care

**Future:**
- Value for Money
  - Evidence based medicine

Despite attention given to health economics much of current coverage is still made primarily as a result of demonstrations of improved clinical care.
Evidence Based Medicine

• Health economics and outcomes research evaluates and compares medical technologies and interventions on the basis of cost and outcomes
  • Medical technologies and interventions are competing for limited budgets
  • New technologies often add cost to care and health economics and outcomes research allows decision makers to balance cost and benefits

• Health economic analyses provide information for decision makers (payers, purchasers, and manufacturers) about:
  • Relative cost-effectiveness
  • Perspective on pricing
  • Cost-impact
  • Therapy selection (especially in crowded markets)
  • Patient selection (which patients will provide the “biggest bang for the buck”)

© 2016 Boston Healthcare Associates, Inc. | 16
Real-world data comes from a variety of sources, each with their own strengths and limitations.

**Real World Evidence**

**Strengths**
- Can provide answers to important clinical and economic questions without the cost and complexity of RCT prospective clinical trials
- Reflects actual behavior of physicians and patients in real-life care settings
- Once a real world data set is organized it can potentially be used for multiple purposes

**Limitations**
- No one data source can address all needs
- Data aggregation/organization and quality can be a challenge
- Data mining can lead to identification of relationships which are correlations rather than causative

Real-world evidence can be drawn from a variety of sources. Data integration and quality can be a real challenge. Clear research questions and a comprehensive plan for collection are needed.
Healthcare systems are increasingly focused on improving quality, expanding access, and mitigating cost.

- Historically, technologies were value purely for innovations sake.
- We are now moving into a world in which innovation is merely a tool to facilitate greater access and quality in a cost-effective manner.
- In the US this has come to a head in the form of the Patient Protection and Affordable Care Act (ACA), but payment reform and value seeking is an important trend both before and after the legislation.

**“Triple Aim”**

- Expanded Access
- Cost Control & Financial Stability
- Quality Improvement

**Key Drivers of Healthcare Reforms**

- Increasing health expenditures
- Relatively poor outcomes in key indicators
- Significant numbers of uninsured and underinsured
- Inefficiencies and variability in care and associated costs
- Impact of shifting demographics
- Payment structures that incentivizes overuse
Changing Risk Environment: Results in Changes to Who Products are Sold to and How they are Evaluated

In the evolving health care value environment, innovators must combine both technologies and processes to deliver clinical, economic, and practice success for Customers.

Stakeholders are seeking value through managing increased access, improved quality, and financial stability.

Stakeholders will demand more than novel tools: Customers will need the tools to effectively integrate these technologies into clinical practice and demonstrate value which can include healthcare IT.
Case Study #3: Potential Digital Health Business Models

- Innovator develops a “wearable” tool to monitor diabetes patients
- Early data shows promise in improving compliance and possibly health outcomes

<table>
<thead>
<tr>
<th>Customer</th>
<th>Benefits</th>
<th>Drawbacks</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payer</td>
<td>• Ties to payer value story</td>
<td>• Need payment mechanism</td>
<td>• None</td>
</tr>
<tr>
<td>Physician Office (w/ reimbursement)</td>
<td>• Financial incentive</td>
<td>• Puts docs at financial risk</td>
<td>Continuous Glucose Monitors</td>
</tr>
<tr>
<td>Physician Office (w/o reimbursement)</td>
<td>• Simply sale of commercial product</td>
<td>• Must identify value story or cost offset that are not reimbursement dependent (practice efficiencies)</td>
<td>VisualDx</td>
</tr>
<tr>
<td>Disease management integration model</td>
<td>• Links to changing care delivery and payment mechanisms</td>
<td>• Specific value of digital health product trumped by value of overall offering</td>
<td>Pathways programs</td>
</tr>
<tr>
<td>Independent Diagnostic Testing Facility (IDTF)</td>
<td>• Can secure direct payment for services</td>
<td>• Can require heavy service component</td>
<td>Remote cardiac monitoring</td>
</tr>
</tbody>
</table>

Key question: Who will pay for digital health and how will they determine what to pay?
REIMBURSEMENT STRATEGY AND TACTICS
Integrating Reimbursement Concepts into Marketing Strategy

Know Your Market

- What is value proposition to physician adopter, how does it align with message to payers?
- Who will bear financial risk? Identify stakeholder audience and know their incentives
- What are the distribution options?

Assess Current Landscape

- What is the current reimbursement environment for products in the space?
- Where will the product be used and the service delivered (office, outpatient, inpatient)?
- Will technology be used in a primarily a private, Medicare, or Medicaid market?

Data Development

- What clinical, cost-effectiveness, cost-outcome data will be needed to drive third party coverage/payment for the product?
- What reimbursement data endpoints can be collected in necessary trials?
Reimbursement Planning and Implementation

Coverage
- What coverage policies and restrictions are in place for existing technologies?
- Will the product be subject to a coverage policy? With limitations or restrictions?
- What are desired clinical and economic endpoints to facilitate coverage?

Coding
- Can existing codes be used or should new codes be pursued?
- If a new code(s) is/are needed, what type and for what purpose?

Payment
- What are the current benchmarks for payment? Are they acceptable and appropriate?
- Are there opportunities for separate payment? If not, can they be created?
- How does this fit into future payment models?
Thank You

Charles Mathews
cmathews@bostonhealthcare.com

Rob Wenthold
rwenthold@bostonhealthcare.com