Articulating the Value Proposition of Innovative Medical Technologies in the Healthcare Reform Landscape

October 18, 2013
Outline

• The Changing Landscape

• Evolving Care Delivery and Incentive Models
  - Provider Consolidation
  - New Technology Assessment Methods
  - Aligning Care Delivery with Payment / Health Reform

• Value Demonstration in the New Health Care Environment
The Changing Landscape
Value in Health Care is Determined by Quality, Access, and Cost: Health and Payment Initiatives Are Occurring Due to Underperformance in These Areas

- A growing number of uninsured and underinsured Americans
- Inefficiencies and variability in care and associated costs

• Highest total health expenditure (as % of GDP) among all OECD nations
• Payment structure that incentivizes overuse

• Relatively poor outcomes in key indicators
Providers Have Responded to the Increasing Pressures to Reduce Costs and Improve Value in at Least Three Different Ways

1) Provider Consolidation
   - Physicians have become salaried employees of hospitals
   - Hospitals buy other hospitals
   - More economies of scale / more leverage to negotiate / preserve price

2) New technology assessment methods
   - Old method: doctor-driven decision-making
   - New method: value assessment committees

3) Align care delivery activities with the direction of new payment systems and health reform
   - ACOs, bundled payments
   - Quality initiatives
Evolving Care Delivery and Incentive Models

Provider Consolidation
The Changing Health Care Environment is Driving Consolidation of Physician Practices and Direct Employment of Physicians by Hospitals

- Changing payment models and risk sharing are driving practice consolidation and hospital employment of physicians
  - Smaller practices are unable to bear the financial challenges / risks associated with declining reimbursement / payment reform
- The level of individual physician decision-making will likely decrease as practices and hospital systems merge
  - Physicians that previously had the power to make decisions regarding use of medical devices may be tied to hospital / health system decisions

Whereas the primary customer has historically been the clinician, it will now be hospital administrators or technology adoption committees. Innovators will need to realign their value propositions to meet the needs of the new customer.

Like Physician Practices, Hospitals are Also Experiencing a Trend Towards Consolidation

The health care environment in the U.S. is experiencing consolidation of providers across the continuum of care. This is reducing the number of individual customers to whom innovators will need to demonstrate the value of their technology (bigger prizes, bigger risks).

Evolving Care Delivery and Incentive Models

New Technology Assessment Methods
Hospital Technology Purchasing Process in the New Environment

Value assessment committees are the gatekeepers to new technology adoption within health care institutions (sometimes for multiple hospitals if part of a large health care system).

- Sales representative approaches customers
- Provider or department requests purchase of new technology and presents to...

Hospital Value Assessment Committee (VAC)

- Clinicians Representing Various Specialties
- Nurses
- Hospital Administrators (Finance, Risk Management)

Evaluating:
- Clinical benefit
- Cost-effectiveness/revenue/budget impact
- Impact on quality improvement initiatives

If a positive assessment, a recommendation to purchase technology is made to appropriate hospital personnel (finance or potentially hospital C-suite/board if high-cost capital purchase)
Judgments about New Technologies are Based on a Number of Factors

- Presentations are often made by a physician champion who has been prepared by a sales representative (but rep is often not allowed at the meeting)

- New initiatives are often required to be submitted in advance of the presentation (often 4-6 weeks in advance, or more) to allow for a thorough financial assessment

- If the technology is deemed inappropriate by the VAC, there is typically an appeals process

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<thead>
<tr>
<th>Key Elements of Review</th>
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<tr>
<td>Revenue impact</td>
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<td>ROI</td>
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<tr>
<td>Complication rate</td>
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<td>Accuracy</td>
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<td>Safety</td>
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<tr>
<td>OR turnaround time</td>
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<tr>
<td>Ease of use</td>
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<tr>
<td>Price</td>
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<tr>
<td>Patient outcomes</td>
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<td>LOS</td>
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Evolving Care Delivery and Incentive Models

Aligning Care Delivery with Payment / Health Reform
Payers and Providers are Addressing the Three Aims of Health Reform Through Payment and Delivery System Reform

Medicare and private payers are piloting a variety of programs to drive quality improvement and better control costs.

- **Financial incentives:** for quality improvement and cost containment
  - Hospital value-based purchasing
  - Shared savings models (e.g., Accountable Care Organizations)
  - Meaningful Use EMR: Stage 1

- **Financial penalties:** for missing financial targets or not meeting clinical outcome / quality goals
  - Hospital Inpatient Quality Reporting Program
  - Hospital Readmissions Reduction Program
  - Shared risk models
  - Meaningful Use EMR: Stage 2

- **Payment reform as a mechanism to drive clinical outcomes without specified incentives / penalties**
  - Bundled payments

Over time
Accountable Care Organizations (ACOs) Have Been at the Center of the Payment Reform Debate Due to Their High Profile in the Medicare Program as Well as Among Commercial Payers

- ACOs are contractual relationships between providers and payers that incentivize cost reduction and quality improvement through shared savings and other financial risk models
  - ACOs result in a change in care delivery as providers seek to meet quality and financial outcomes

- No matter the ACO structure, there are three critical value demonstrations for innovations in ACOs:
  1) Assist in meeting quality and performance measures
  2) Promote a decrease in utilization
  3) Decrease overall cost of care

Innovators should be able to demonstrate value in the ACO environment as the number of hospitals and physician groups that have entered into ACO contracts has been growing exponentially in recent years.

The Medicare Bundled Payments Initiative Incentivizes Providers to Coordinate Across Care Settings and Reduce Costs for Defined Episodes of Care

Bundled payments differ from ACOs in that they focus on specific high-cost episodes of care (e.g., stroke, heart failure) as opposed to the total cost of caring for beneficiaries. Technologies and therapies that can reduce costs within these specific episodes will have high value for providers participating in bundled payment programs.
There Are Two Primary Programs within CMS Aimed to Drive Reporting of Quality Measures

Electronic Health Records Meaningful Use Program: Clinical Quality Measures

- EHR meaningful use program is being deployed in two stages: Stage 1 provides an incentive payment for demonstrating meaningful use, and Stage 2 mandates a reimbursement cut for not demonstrating meaningful use
- Beginning in 2015, Medicare professionals who do not demonstrate meaningful use will be subject to a payment adjustment (starts at 1% and increases each year to a 5% maximum)
- Measured results are not publicly reported at this time

Hospital Inpatient Quality Reporting Program

- Requires hospitals to report specific quality measures which are posted on the CMS Hospital Compare website
- There is a 2% reduction in the annual market basket update (measure of inflation in costs of goods and services) for not successfully reporting on all required measures

In general, CMS chooses NQF-endorsed measures to be included in quality initiatives. Measures that aren’t endorsed are only chosen when CMS feels that there is enough significant in their measurement to benefit the broad population.
There Are Many Different Types of Quality Measures; CMS is Interested in Moving Toward a Greater Number of Outcome Measures Rather than Process Measures

<table>
<thead>
<tr>
<th>Measure Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>Access</td>
<td>A measure that focuses on a patient or enrollee’s attainment of timely and appropriate health care.</td>
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<tr>
<td>Composite Performance</td>
<td>A combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure, with a single score.</td>
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<tr>
<td>Efficiency</td>
<td>A measure of cost of care associated with a specified level of quality of care. A measure of the relationship of the cost of care associated with a specific level of performance, measured with respect to the other five IOM aims of quality.</td>
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<tr>
<td>Outcome</td>
<td>A measure that assesses the results of health care that are experienced by patients—patients’ clinical events, patients’ recovery and health status, patients’ experiences in the health system, and efficiency / cost.</td>
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<tr>
<td>Patient Reported Outcome-Based Performance</td>
<td>A performance measure based on “any report of the status of a patient’s health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.”</td>
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<tr>
<td>Patient Experience</td>
<td>A measure that focuses on a patient’s or enrollee’s report concerning observations of and participation in health care.</td>
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<td>Process</td>
<td>A measure focusing on a clinical process which leads to a certain outcome, meaning that a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome.</td>
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<tr>
<td>Cost and Resource Use</td>
<td>Refers to broadly applicable and comparable measures of health services (in terms of units or dollars) applied to a population or event (broadly defined to include diagnoses, procedures, or encounters).</td>
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<tr>
<td>Structural</td>
<td>A measure that assesses features of a health care organization or clinician relevant to its capacity to provide health care.</td>
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Private Payers Are Also Testing Innovative Care Delivery Models

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<tr>
<th>Example Commercial Payer Quality / ACOs Initiatives</th>
<th>Example Commercial Payer Bundled Payment Initiatives</th>
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<tbody>
<tr>
<td>• BCBS MA Alternative Quality Contracts</td>
<td>• BCBS of Western NY Cardiovascular Bundle</td>
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<tr>
<td>- Shared savings contracts between BCBS MA and its providers</td>
<td>- Reimburses a portion of heart surgery services under a bundled payment, covering 30 days before and 90 days post operation</td>
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<tr>
<td>- Saw both an increase in quality scores and a drop in cost trends (readmissions, admissions, ER use, etc.)</td>
<td>- BCBS NC Knee Replacement Bundle</td>
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<td>• Florida Blue Oncology ACO</td>
<td>- Includes pre-operative tests and office visits for 30 days before the procedure, all inpatient care, and related outpatient care for 90 days post operation</td>
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<tr>
<td>- Focuses on the most prevalent cancers in South Florida</td>
<td>- BCBS of Western NY Cardiovascular Bundle</td>
</tr>
<tr>
<td>- Looks at readmission rates, adherence to chemotherapy regimens, adherence to accepted clinical guidelines, and efficiency of care delivered to the patient</td>
<td>- Reimburses a portion of heart surgery services under a bundled payment, covering 30 days before and 90 days post operation</td>
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Commercial payers are moving towards disease-specific ACOs to decrease the cost of care in high-cost disease areas.

Many commercial payers have piloted bundled payment programs in the area of orthopedics. These programs are continuing to expand into other high cost episodes of care.

The health care system in the United States is shifting away from fragmented fee-for-service delivery and payments to paying for integrated, quality care. This trend is expected to continue as the number of insured Americans increases due to coverage expansions of the ACA.
Value Demonstration in the New Health Care Environment
All Stakeholders within the U.S. are Under Pressure to Control Rising Health Care Costs; Innovators Must Present the Value of Their Products to Hospitals and Health Systems in This Context

Providers are rethinking their approach to value determinations to meet the demands of payers and align with health reform payment models. Innovators need to be aware of this and use it to craft their own value messaging when developing customer engagement strategies.

Rising cost of health care in the United States puts pressure on payers to control costs.

Payers put pressure on hospitals and health systems to control costs. Providers are forced to demonstrate their value in order to maintain payment levels.

All providers place increasing pressure on technology and therapy innovators to demonstrate cost and clinical benefit.

Drug, Device, and Diagnostic Service Innovators:
- Need to take a holistic approach to value demonstration
- Need to build or accelerate connections between these parties

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Refine Our Value Proposition: In the Evolving Health Care Value Environment, Innovators Must Combine Both Technologies and Processes to Deliver Clinical, Economic, and Practice Success for Customers

**Value Dimensions**

- Clinical Impact
- Economic Impact / Revenue and Cost
- Training / Education
- Performance Measurement and Documentation
- Distribution / Logistics
- Patient Satisfaction / Experience / Others

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

**Strategic Solutions that address Customer Value Perspectives**

Stakeholders will demand more than novel drugs and devices: Customers will need the tools to effectively integrate these technologies into clinical practice and demonstrate value.
Geographic and Program Variability Means that Tailored Approaches Will Have to be Developed to Address State and Local Level Decision Making

- Innovators will have to move away from “one-size fits all” approaches to meeting evidence demands and contracting needs
  - Wide variation in stakeholder quality and financial incentives

Example: The Number of Medicare Shared Savings Contracts Varies Widely by State

Profile and monitor these changing relationships and incentive programs. Be prepared to rapidly prototype and pilot solutions in several geographies.

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Thank You

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