Market Access Strategy and Planning: Succeeding in the Age of Value-based Reimbursement

Presented by: Michael J. Lacey, Senior Director, Strategic Consulting (Life Sciences)
Date: March 01, 2017
Agenda

- Truven Health Analytics Background
- Factors Driving Value-based Reimbursement Trends
- Evolving Payer Requirements and Patient Engagement
- Alternative Payment Models and Value Frameworks
- Adapting Market Access Strategies for Success
- Discussion
A Quick Refresher on Truven Health Analytics…
ABOUT TRUVEN HEALTH ANALYTICS

Providers
- Strategic, analytic, and Lean enterprise transformation services
- Clinical Decision Support linked to real-time data
- Hospital operations efficiency and effectiveness

Payers
- Cost management, workforce productivity
- Consumer engagement resources
- Operational efficiencies and effectiveness
- Regulatory compliance

Consumers

Life Sciences
- Health economics, outcomes research, market analytics, epidemiology
- Value demonstration and effective communication globally

Government
- Control costs and ensure access to high-quality healthcare
- Advanced analytics to fight fraud
- Integration services
- Policy research, support
Our Expertise to Link Data Supports Studies of Increased Complexity

- Retrospective and Hospital Claims, Gov’t
- Registries, Surveys, Productivity data
- EMR And PRO Data
- Claims-linked to EMR

Serving Payers, Governments, Providers, and Life Sciences

9,000 Customers
2,300 Employees
Working in 50 U.S. states and more than 90 countries
Strategic Consulting and HEOR Research

**STRATEGY**

- Strategic Services
  - Portfolio Strategy & Planning
  - Market Access & Value Strategy
  - Value Communications Strategy & Planning
  - HEOR Strategy & Planning

Programmatic approach linking tactical capabilities with strategy execution

**TACTICS**

- Tactical Products & Services
  - Retrospective Database Research
  - Observational Studies
  - Modeling
  - Clinical Outcomes Assessments
  - Survey Research
  - Literature Based Services
  - Dossiers
Factors Driving Value-based Reimbursement Trends
Situation Summary

New realities in global payer environment are driving change

- Globally regulatory bodies are no longer the only critical driver of market access
  - Budget limits due to the ongoing Global financial crisis are *driving rapid change* in procurement practices.

- The US market is rapidly consolidating into larger provider-based accountable care organizations (ACOs) and payer groups.
  - Insurers, hospitals, ambulatory surgery centers (ASCs), and large physician groups are aligning economic incentives to take advantage of bundled payment and shared savings programs.
  - Macro-economic forces will drive continued evolution into value-based care reimbursement models and increased patient-engagement going forward.

- Outside the US, this process is rapidly moving from pharma focus to pharma and device focus.
Situation Summary (continued)

*Payers are driven by business imperatives and political pressure to constrain budget growth*

- Health Technology Assessments to limit access are in place globally and gaining momentum in the US
  - Level of review of medical devices and procedures increasing to pharma levels outside of the US and evolving in US

- ISPOR is sponsoring “The Initiative on US Value Frameworks”
  - Initiative was created to inform the shift towards a value-driven health care system by promoting the development and application of high-quality, unbiased value-assessment frameworks.
  - Multiple US value frameworks have been proposed –
    - ”2016 is the year of the value framework”
  - ISPOR group has assessed that these emerging frameworks vary widely and can lead to variable evaluations of treatments.
  - Defining *value in the context of the decision problem* continues to be a vexing and unresolved issue.
Situation Summary (continued)

*Payers are driven by business imperatives and political pressure to constrain budget growth*

- Demand for *scientifically valid and peer-reviewed studies* demonstrating clinical and economic value increasing to set coverage and price:
  - Focused on products seeking new reimbursement (i.e., premium price compared to *local standard of care*)
  - Larger well-controlled *comparative studies*
  - Data on *local populations*, with *locally relevant* comparators, adapted to *local context*
  - Proxy measures of efficacy being displaced by demand for *real-world effectiveness and proof of economic cost-offset*

- Influencing economically driven decision makers requires:
  - Clearly incorporating “*voice of the payer*” into R&D and commercialization plans
  - Collecting the relevant clinical and economic data on the right populations to create best conditions for market access
New Technology Product Mix is Evolving

Capturing value for new strategic products (i.e., innovative pharma, drug/device combinations, interactive monitoring) will require comparative data and substantial investment in market development.

High Price Premium vs. Standard of Care

Low Need for Market Development
- Limited HEOR investment required
- Established brands and line extensions
- Demonstrate marginal benefit head to head
- Define new market for doctors and payers, establish market and reset value point versus no or low value

High Need for Market Development
- Demonstrate unmet need, burden of illness, cost-offsets, cost effectiveness

Low Price Premium vs. Standard of Care
New Technologies Increasingly Span Markets

**Drugs & Devices Are Different!**

### PHARMA
- Systemic effects
- High risk/ high reward
- High development cost
- Large market opportunities
- Long-term protection
- Few iterations

### DEVICES
- Local effect, physician skill
- High hit rates
- Moderate development costs
- Small to mid-sized markets
- Incremental products
- No long-term IP protection
Why Do Life Sciences Firms Need Enhanced Market Access & Value Demonstration Capabilities?

*In God We Trust – all others bring data – Edward Deming.*

- Increase Access
- Defend/Grow Share
- Drive Growth
Fragmenting Paths to Sustained Market Access

- **FDA/ Market Authorization**
  - US - 510k, PMA
  - Post-market, Labeling

- **Payer/Tech Assessment**
  - Local, National, Conditional Coverage
  - Payment

- **Market**
  - Patient, Physician

- **Innovator**
  - Risk
  - Hit rate
  - Capital access

- **Investor**
  - Cost of capital
  - Investment
Diverging Regulator and Payer Perspectives: 
*Requirements for success are a moving target*

**Market Authorization**
- Homogenous groups
- Controlled setting
- Isolate treatment effect
- Binary approval

**Payer**
- Heterogeneous groups
- Real-world impact
- Population health
- Conditional coverage
- Cost control
Increasing Hurdles to Global Markets:
Impact on Timely Patient Access to Cost-effective Care

Medical Innovator
- Research & Development
- Pivotal Clinical Studies

FDA/Regulator
- Regulatory Approval
- Post-approval Studies

Govt. Payers/Private Payers
- Coverage & Payment

Procedure Physician & Department
- Physician Adoption
- Hospital Purchasing

Patient Consumer Driven Care

Time
Alternative Payment Models and Value Frameworks
Global Health Technology Payment Frameworks
Paying for Value in Health Care

Model 1: Technology-based
- Payment based on regulatory requirements of safety and performance, clinical benefit

Model 2: HTA-informed
- Payment based on demonstration of clinical effectiveness and economics

Model 3: Value-based
- Payment linked to value to patient, institution, health system, and broader societal benefits

Model 4: Outcome-based
- Payment linked to real-world patient outcomes

Drivers of change
- Technology
- Advancement
- Financial crisis
- Ageing population
- Quality of care
- Equity

Change Already Happening In the US: Government (CMS) has set a target to move from current 80% technology-based and fee-for-service payment in 2016 to 50% Alternative Pay for Value Models in 2018

# Model 1: Technology-based Payment

<table>
<thead>
<tr>
<th>Payment Based on:</th>
<th>Evidence Requirements</th>
<th>Payer Considerations</th>
<th>Key Levers to Activate Business Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory requirements of safety and performance, clinical benefit</td>
<td>● CE marking</td>
<td>● Fee-for-service</td>
<td>● Gain market share using value communication tools to support physician preference and economic story</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● Procedure-based prospective payment schemes (e.g., DRG – tariffs)</td>
<td>● Post-launch evidence generation to gain inclusion in care pathways</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● Positive list</td>
<td>● Seek premium reimbursement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● Innovation payments</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>● Premium reimbursement</td>
<td></td>
</tr>
</tbody>
</table>

**Define Unmet Need and Economic Value**

**Establish Product Value**

**Demonstrate Value**

**Communicate Value**

**Assess Real World Impact**
## Model 2: HTA-informed
### France, Germany, United Kingdom

<table>
<thead>
<tr>
<th>Payment Based on:</th>
<th>Evidence Requirements</th>
<th>Payer Considerations</th>
<th>Key Levers to Activate Business Growth</th>
</tr>
</thead>
</table>
| Demonstration of clinical effectiveness and economics | ▪ EU legislation | ▪ HTA to inform decision on reimbursement, pricing  
▪ Does technology address priority unmet need?  
▪ What is the budget impact? | ▪ Develop robust evidence-generation plan to optimize market access to improve revenue, market share, and price positioning  
▪ Establish credible burden of illness, unmet need, sources of local cost data for cost-effectiveness and budget-impact  
▪ Ensure value communication tools are designed to secure local reimbursement |

### Define Unmet Need and Economic Value

### Establish Product Value

### Demonstrate Value

### Communicate Value

### Assess Real World Impact
Model 3: Value-based

<table>
<thead>
<tr>
<th>Payment Linked to:</th>
<th>Evidence Requirements</th>
<th>Payer Considerations</th>
<th>Key Levers to Activate Business Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value to patient, institution, health system, and broader societal benefits</td>
<td>▪ EU legislation</td>
<td>▪ What is the willingness to pay for product value?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Demonstrate benefits of product value</td>
<td>▪ What is the overall economic value delivered relative to price?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Confirm value demonstration in real life</td>
<td>▪ Is it worth investing in new technology?</td>
<td>▪ Assess readiness to enter into contractual value-based agreements</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Integration of reimbursement, health economics, HTA, Pricing and Tendering teams</td>
</tr>
</tbody>
</table>

- Define Unmet Need and Economic Value
- Establish Product Value
- Demonstrate Value
- Communicate Value
- Assess Real World Impact
## Model 4: Outcome-based

<table>
<thead>
<tr>
<th>Payment Linked to:</th>
<th>Evidence Requirements</th>
<th>Payer Considerations</th>
<th>Key Levers to Activate Business Growth</th>
</tr>
</thead>
</table>
| Real-world patient outcomes | Post-market negotiation | ▪ Does a negotiated contract with post hoc adjustment make business sense?  
▪ Can utilization and outcomes measurement be implemented? | ▪ Develop appropriate real-world evidence (RWE) studies to support value claims  
▪ Willingness to invest in structural set up to facilitate collection of data  
▪ Develop business case for establishing a patient outcome based model |

**Define Unmet Need and Economic Value**  
**Establish Product Value**  
**Demonstrate Value**  
**Communicate Value**  
**Assess Real World Impact**
ISPOR Value Frameworks Overview

- ISPOR has identified:
  - a “need for a set of standards that are robust, transparent, methodologically sound, and that involve the input of all key stakeholders to guide the development of value assessment frameworks for health care decision making.”

- Meeting was designed to convene stakeholders across all segments of health care to generate input and help guide the scope of work for the Initiative’s Special Task Force.

- More that 250 health care stakeholders attended the conference

Value Framework Comparison

Table 1: Overview of Value Assessment Frameworks

<table>
<thead>
<tr>
<th></th>
<th>ACC-AHA</th>
<th>ASCO 2.0</th>
<th>DrugAbacus</th>
<th>ICER</th>
<th>NCCN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Services Addressed</strong></td>
<td>Treatments, primarily drugs</td>
<td>Drug regimens</td>
<td>Drugs</td>
<td>Primarily drugs, has been extended to devices and delivery system programs</td>
<td>Treatment regimens, primarily drugs</td>
</tr>
<tr>
<td><strong>Conditions Addressed</strong></td>
<td>Cardiovascular</td>
<td>Oncologic</td>
<td>Oncologic</td>
<td>All conditions, particular focus on new drugs anticipated to be high impact</td>
<td>Oncologic</td>
</tr>
<tr>
<td><strong>What is the “Value” Output?</strong></td>
<td>Level of value assessment (high, medium, low, uncertain, not assessed)</td>
<td>Numerical net health benefit score; drug regimen cost</td>
<td>Value-based price</td>
<td>Value-based price benchmark; assessment of care value (high/intermediate/low)</td>
<td>Score (1-5) for each of 5 evidence blocks: efficacy, safety, quality of evidence, consistency of evidence, affordability</td>
</tr>
<tr>
<td><strong>Evaluations to Date</strong></td>
<td>1 guideline includes concept, but makes no assessment</td>
<td>10 examples using initial draft framework; 4 examples using updated framework</td>
<td>Tool includes 54 drugs approved from 2001-15</td>
<td>8 topics have been completed; 5 are in process</td>
<td>12 guidelines include evidence blocks</td>
</tr>
<tr>
<td><strong>Selection Process for Future Evaluations</strong></td>
<td>As guidelines are updated, value assessments will be added</td>
<td>Undetermined at this time</td>
<td>Will eventually include other cancer drugs and other indications</td>
<td>Selected by ICER and three advisory boards informed by horizon scan and payer input</td>
<td>As clinical practice guidelines are updated, evidence blocks will be added</td>
</tr>
</tbody>
</table>

- Though not a presenter – the National Pharmaceutical Council (NPC) has developed a summary comparison and critique of the various frameworks.
Value Framework Workshop – Key conclusions

- All frameworks hinge on a common issue of lack of high-quality, rigorous data needed at the point of decision.

- Strategic planning, evidence generation and communication of high-quality, rigorous evidence of clinical and economic value at the point of decision can help manage downside market access risk.

- Value frameworks will need to incorporate the “voice of the patient” both within the physician/patient shared-decision making context and the broader payer context.
Adapting Market Access Strategies for Success
“Gold Standard” Market Access Process

Development Stage

Proof of Concept R&D

Clinical/Registration

Launch

Post Market

Market Access Process

Define Unmet Need and Economic Value

- Evidence generation blueprint
- Payer value development plan
- Payer and provider stakeholder discussions

Establish Product Value

- Early stage economic model to establish value benchmarks
- Develop data sources and evidence

Demonstrate Value

- Global economic model
- Global value dossier and negotiation toolkits

Communicate Value

- Market access plan
- Adapt global models to local market

Assess Real World Impact

- Ongoing market access support
- Post-launch effectiveness studies
HEOR and Market Access Teams
Collaboration to drive strategy, generate evidence and communicate product value to stakeholders

HEOR groups are responsible for generating the evidence to obtain access

- Outcomes Research - Scientific discipline seeking to demonstrate effectiveness of interventions to the patient and health care system.
- Health Economics – quantifying value for money (value-based pricing) of alternative intervention strategies to a given stakeholder.
- Develop value dossier and global economic models

Market Access groups package material to gain access, negotiation with payers

- Define value-based positioning by stakeholder
- Establish relationships and market requirements with payers.
- Adapt global value dossiers and HEOR models and insights to specific environment
- Negotiate to gain reimbursement authorization and payment
Global Value Strategy Planning Teams

Empowered cross-functional product-value planning teams need to address new realities in global life sciences markets.

- Broaden R&D and Regulatory objectives to address all three sets of market requirements across lifecycle.

- Senior Leadership Team Council to drive overall strategy and resourcing
- Franchise or product teams to drive product strategy and implementation
Pro-forma Product Planning Triage Process:
Strategic HEOR Product Evaluation to Assess Value-based Positioning

Does it work?
How strong is the clinical evidence base?
Is there a clear differentiation versus key comparators?

Can we prove it?
Clinical publications and messaging
Global awareness and positioning

Will they buy it?
Is pricing strategy aligned with clinical and economic value?
What are the payer and provider opportunities and hurdles?
Evolution to Address Needs of Stakeholders in the New Global Market

Broaden value demonstration to remain partner of choice.

- Economic Impact
  - Budget impact & ROI
  - Cost-effectiveness
  - Reduced health resources
  - Value-added consulting & practice management

- Quality of Life
  - Safety
  - Well-being, improved lifestyle
  - Direct Cost

- Clinical
  - Technical Features and Benefits
  - Quality of care
  - Clinical outcome rates – BCVA
  - Safety or complication rates – PCO
  - Payment, efficiency, patient annuity
Critical to Triage Evidence Development Resources

- Leading companies have developed triage process to guide R&D and post market evidence development spend.
  - Fully integrated into investment decision and life-cycle business model to ensure funding at a program level
- Sample criteria include
  - Is the product a breakthrough?
  - Is the product of strategic importance?
  - Is the target price and volume estimate likely to raise payer hurdles?
  - Is reimbursement adequate to fund the new technology?
  - Does our plan address the needs of the our four major stakeholder groups – physicians, regulatory, payers, and patients?
  - Does technology support suite of leading technologies and can evidence be used to maintain market dominance by erecting barriers to entry?

- Iterative products without clear value differentiation don’t receive marginal investment – pricing and volume expectations are adjusted accordingly.
The HEOR strategy must address each stakeholder’s perception of value, which underpins treatment and coverage decisions.

The perceived value to a *stakeholder* is based on*....

\[ V = R +/ - D \]

**Reference Value**
(Price of the Best Alternative)

**Differential Value**
(Value of the differentiation)

- **Value** must address unmet needs in the Condition markets
- **Value** is comparative statement (treatment with Product X\(^\text{\textregistered}\) vs. routine care)
- **Value** is stakeholder specific
  - payers
  - physicians
  - patients

---


©Truven Health Analytics Inc. All Rights Reserved.
Discussion
Thank you.

Michael J. Lacey, Senior Director, Strategic Consulting (Life Sciences)
mlacey@us.ibm.com