Health Economics & Reimbursement: Device Company Considerations for the US Market

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Health Economics & Reimbursement
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Provide device company perspective on new device considerations to help assure commercial success of a new technology.

(emphasis added!)
• Role of Health “Policy” Within a Device Company

• The Selling Environment and Impact on Commercialization

• The DNA of Health Economics & Reimbursement: Coding, Coverage, and Payment

• Company Considerations: Through the Lifecycle
HE&R Capabilities: Support multiple objectives

<table>
<thead>
<tr>
<th>Business Planning/Proposal Definition</th>
<th>Development</th>
<th>Validation/Scale-up</th>
<th>Launch</th>
<th>Full Potential</th>
<th>Next Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Market sizing/site of service data</td>
<td>• Global reimbursement strategy</td>
<td>• Cost-effectiveness studies</td>
<td>• Customer reimbursement education</td>
<td>• Hospital specific marketing</td>
<td>• Technology assessments</td>
</tr>
<tr>
<td>• Epidemiological studies</td>
<td>• Clinical trial reimbursement</td>
<td>• Budget impact models</td>
<td>• Sales strategy input</td>
<td>• Post-marketing registries</td>
<td>• Market sizing/site of service data</td>
</tr>
<tr>
<td>• Treatment &amp; referral patterns</td>
<td>• Piggyback economic studies</td>
<td>• Return on investment models</td>
<td>• Sales training</td>
<td>• Treatment &amp; referral patterns</td>
<td>• Customer reimbursement education</td>
</tr>
<tr>
<td>• Reimbursement &amp; health economics assessment</td>
<td>• Trial site identification</td>
<td>• Reimbursement dossiers</td>
<td></td>
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</tr>
</tbody>
</table>

- Medicare policy analysis and advocacy
- Private payer strategies
- Publication strategies
Road Map

• Role of Health “Policy” Within a Device Company

• The Selling Environment and Impact on Commercialization

• The DNA of Health Economics & Reimbursement: Coding, Coverage, and Payment

• Company Considerations: Through the Lifecycle
Why $2.5 trillion in US spending?

- Two biggest factors related and affect medical devices directly, but...value side of equation missing.
- Device challenge: demonstrate value

Other Factors:

- Local decision making, even in “national” plans
- Physicians’ freedom and patient choice key values
- Decline in out-of-pocket cost sharing (40% in 1970 to 15% in 2005)
- Lack of evidence...more on this later!
More choices... for more conditions

Drugs
- Acute stroke
- Alzheimer’s
- Depression

Devices
- Atrial fibrillation
- LVADs

Robotic surgery
Non invasive diagnostics
Angiogenesis
Cancer vaccines
Neurotransplantation
Regulators & payers becoming more risk averse

- Vioxx
- LST
- ICD recalls
- Avandia
- InFuse
- Stryker Biotech

- More stringent regulatory reviews
- Post-market data collection/surveillance
- More conservative coverage expansions
Global Healthcare Climate
- Rising health care budgets in all major OUS markets
- Greater level of medical device regulation in OUS markets...not necessarily harmonized, increasing regulatory burden
- Tighter evidentiary requirements for clinical and cost effectiveness

US Political/Financial Climate
- Budget Deficit ($1.3 trillion in FY2010; 9% of GDP).
- $900 billion (give or take a billion) financial bailout
- Medicare trust fund cash flow turning negative soon
- US tax provisions expire in 2010 ($4 trillion)
- Iraq/Afghanistan still major cost items.
US health policy agenda

• Greater oversight of FDA
• Tighter approval & post-market requirements
• Preemption
• More sunshine

• Medicare reform/cuts
• Comparative effectiveness
• Health information technology
• Coverage expansion (nor not?)
• Medicaid relief
Reimbursement & Policy Trends: Increasing pressure on payers, providers

- **Cost pressures will continue…**
  - US spending expected to grow by 6.2% through 2018
  - Pressure to cut spending:
    - Employers to stay competitive
    - Medicare & Medicaid burden on taxpayers

- **Evidence pressure grows…**
  - Comparative effectiveness (HTA) goes global (UK to US to Japan to China)
  - Customers face pay for performance reimbursement systems (US, Australia, UK)
  - Price transparency and foreign reference pricing requirements (Asia, EU, Latin America)

- **Forcing delivery systems changes…**
  - Procedure migration to ASCs and MD office
  - More restrictions on physician ownership of facilities
  - Selected restrictions on off-label use of drugs and devices

- **And leading to different cost containment levers…**
  - Foreign reference pricing (setting reimbursement level in one country by using pricing/reimbursement levels in other countries)
  - Diagnosis related groups and other prospective/bundling systems (systems where payment is based on clinical and cost similarities of procedures)
  - Health technology assessments (systematic analysis/comparison of technologies and procedures; includes safety, clinical effectiveness, and sometimes, economic perspective)
Case Study

- What additional information do we need to better assess the reimbursement and health economics situation for YZ’s upcoming product?
Case Study

• What are the implications of the current and near-future “selling environment” on YZ’s neurostimulator?
• Should YZ launch first in the US and then OUS?
Road Map

- Role of Health “Policy” Within a Device Company

- The Selling Environment and Impact on Commercialization

- The DNA of Health Economics & Reimbursement: Coding, Coverage, and Payment

- Company Considerations: Through the Lifecycle
The Components of Reimbursement

<table>
<thead>
<tr>
<th>Coding</th>
<th>The language of providers and payers (What was done and/or what was diagnosed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage</td>
<td>Eligibility for payment (Does the payer cover what was done?)</td>
</tr>
<tr>
<td>Payment</td>
<td>Dollars for care (How and how much will they pay?)</td>
</tr>
</tbody>
</table>

Reimbursement Process

<table>
<thead>
<tr>
<th>MD Performs Service</th>
<th>MD Dictates Notes</th>
<th>Coder Translates Notes</th>
<th>MD and Facility Submit Separate Claims</th>
<th>Payer Pays Claims Based on Codes</th>
</tr>
</thead>
</table>
## Codes are the Keys to the Reimbursement System

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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</thead>
<tbody>
<tr>
<td>What are codes?</td>
<td>Alpha-numeric systems that provide information to insurers (e.g., CPT, ICD-9)</td>
</tr>
<tr>
<td>What do codes describe?</td>
<td>Medical services, supplies, and diagnoses</td>
</tr>
<tr>
<td>Where are codes used?</td>
<td>On insurance claims forms</td>
</tr>
<tr>
<td>What do codes do?</td>
<td>Enable insurers to process claims and pay providers</td>
</tr>
<tr>
<td>Why are codes important to medical products?</td>
<td>Allow processing of claims and appropriate reimbursement for medical services</td>
</tr>
</tbody>
</table>
5 Major Coding Systems Affect Medical Devices

• CPT (Current Procedural Terminology) Procedure Codes
  – Physician services in any setting + facility charges for Hospital Outpatient and Amb. Surgi-Center care – The “WHAT” of coding

• ICD-9-CM Diagnosis Codes
  – patients’ illnesses/reasons for treatment – The “WHY” of coding

• ICD-9-CM Procedure Codes
  – hospital inpatient services and procedures

• HCPCS (pronounced “HIK-PIKS”)
  – Level One = CPT (controlled by the AMA)
  – Level Two = CMS-defined national codes for medical supplies/drugs
  – Level Three = Local Codes (Being phased out)

• Revenue Codes
  – assign inpatient and outpatient products and services to hospital accounting cost centers

At least 2 coding systems (diagnosis + procedure) required on each insurance claim form.
Case Example

• What is the coding situation like for YZ’s new product?
Implications of Coding for Reimbursement Planning

• **FIRST:** Does the product/procedure require novel coding?

• **SECOND:** TIMING!!!

  New code timelines are measured in years … with no guarantees!
  - Clock **starts** at Regulatory (FDA) approval
  - Peer-reviewed literature development takes YEARS
  - Factor application requirements in product development planning
  - Specialty society support/advocacy
  - Incorporate into commercialization and financial plans

• **THIRD:** Tracking mechanism(s) to insure that widespread adoption of procedure is demonstrable

• **LAST:** Educate providers/customers on appropriate coding
  - Accurate coding must be represented in claims data used by payers to set future payment rates.
Coverage

The range and extent of services and products for which an insurer will pay

• May be formalized in policy or granted on a case-by-case basis
  – Three basic options:
    • Coverage
    • No coverage
    • Coverage with conditions

• Coverage Drives both coding and payment
  – *If positive coverage*, then coding and payment will (likely) follow
  – BUT: If just coding, coverage and payment do not necessarily follow
  – AND: You cannot have payment without coverage, but you can have payment without a code
Coverage – A Legal Analogy

Payer’s View

Benefit Language
= Constitution

Medical Policy
= Set of Laws

Medical Necessity
= Individual-specific Decision
Coverage: It’s More Than FDA Approval

- FDA = **Regulator** of US market
- FDA=safety and efficacy
- Studies in research settings
- More post-market data

- CMS = Largest **Purchaser** of health care in world
- Legal limits on what it can purchase
- FDA approval not always ≠ CMS payment
- Effectiveness in clinical practice
Coverage: Multiple criteria and decision makers

Medicare coverage determined by assessing whether service is:

- “Reasonable & Necessary”
- Appropriate for Medicare patients
  - Coverage of routine costs for Medicare patients in clinical trials
  - Coverage of Category B investigative devices
- Safe and effective
- Not experimental
- Not a screening or preventive technology

Private payers have similar criteria:

- Must have relevant regulatory approval
- Scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
- Improves net health outcome
- Must be as beneficial as any established alternative
- Improvement must be attainable outside of the investigational setting

Organizations Involved:

- Center for Medicare and Medicaid Services (CMS)
- Major national third party payers and benefit managers
- Medicare Intermediaries and Carriers, DMERCs
- Regional health plans
- State Medicaid administrators
- IHDSs
- Physician medical groups
Case Example

• What is the coverage situation like for YZ’s new product?

• Should YZ be worried about coverage?
### When It Comes to Payment … Site of Service Matters!

<table>
<thead>
<tr>
<th>Customer purchasing device</th>
<th>Customer influencing purchase and using device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicare:</strong></td>
<td><strong>Private Payers:</strong></td>
</tr>
<tr>
<td>National payments adjusted for local wage and other differences</td>
<td>Frequently provider-specific contracts</td>
</tr>
</tbody>
</table>

#### Inpatient hospital

- **Hospital payment**
  - Diagnosis Related Groups (DRGs)
  - New technology add-on
  - DRGs
  - Per-diem
  - Percent of billed charges
  - New technology carveouts
  - Retrospective caps

- **Physician payment**
  - Resource-based relative value (RBRV) for “work” plus practice expense
  - RBRVs
  - Capitation

#### Outpatient hospital

- **Hospital payment**
  - Ambulatory Payment Classifications (APCs)
  - Pass-through for new technology
  - New technology APCs
  - APCs
  - Percent of billed charges
  - New technology carveouts
  - Retrospective caps

- **Physician payment**
  - Resource-based relative value (RBRV) for “work” plus practice expense
  - RBRVs
  - Capitation

#### Ambulatory surgery center

- **Ambulatory surgery center**
  - Percent of APC
  - Percent of billed charges
  - New technology carveouts
  - Retrospective caps

- **Physician payment**
  - Resource-based relative value (RBRV) for “work” plus practice expense
  - RBRVs
  - Capitation

#### Physician office

- **Physician Office**
  - Resource-based relative value (RBRV) for “work” plus in-office practice expense such as supplies, cost of medical devices, etc.
  - RBRVs
  - Pre-determined contractual pricing
## Resource use drives payment: Averages matter!

### Major Acute Care Payment Systems

<table>
<thead>
<tr>
<th>Elements</th>
<th>Hospital Inpatient</th>
<th>Hospital Outpatient¹</th>
<th>Physician Fee Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coding System(s)</td>
<td>• ICD-9 Px</td>
<td>• CPT</td>
<td>• CPT</td>
</tr>
<tr>
<td></td>
<td>• ICD-9 Dx</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification System</td>
<td>• Diagnosis Related Groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement Scale</td>
<td>• Cost-based relative weights</td>
<td>• Ambulatory Payment Classifications</td>
<td>• None…paid on CPT code basis</td>
</tr>
<tr>
<td>Base Payments</td>
<td>• Standardized Amount</td>
<td>• Standardized Amount</td>
<td>• Conversion Factor</td>
</tr>
<tr>
<td>Special Adjustments</td>
<td>• Cost of living differences</td>
<td>• Cost of living differences</td>
<td>• Cost of living differences</td>
</tr>
<tr>
<td></td>
<td>• Special payments for certain hospitals</td>
<td>• Special payments for certain hospitals</td>
<td>• Underserved areas</td>
</tr>
<tr>
<td></td>
<td>• Outlier payments</td>
<td>• Outlier payments</td>
<td>• Multiple services, other special circumstances</td>
</tr>
<tr>
<td></td>
<td>• New technology payments</td>
<td>• New technology payments</td>
<td>• Non-MD practitioners</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Site of service</td>
</tr>
<tr>
<td>Annual updates</td>
<td>• Inflation factor</td>
<td>• Inflation factor</td>
<td>• Sustainable growth rate</td>
</tr>
<tr>
<td></td>
<td>• Rebase</td>
<td>• Rebase</td>
<td>• Rebase</td>
</tr>
<tr>
<td></td>
<td>• Updated data</td>
<td>• Updated data</td>
<td>• Updated data</td>
</tr>
<tr>
<td>Quality Reporting</td>
<td>• Yes, lower rates if no data sent</td>
<td>• Yes, lower rates if no data sent</td>
<td>• Yes, lower rates if no data sent</td>
</tr>
<tr>
<td>Major implications</td>
<td>• System of average payments</td>
<td>• System of average payments</td>
<td>• Greater “specificity” of payment</td>
</tr>
<tr>
<td></td>
<td>• One large bundle per stay</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹Ambulatory surgery center service payment tied to OPPS beginning 2008.
Medicare Physician Payment Formula

Adjusted for:

- Modifiers (50-bilateral, 80-assistant surgeon, etc.)
- Non-physician personnel (NP, PA, etc.)

Case Example

• What is the payment situation like for YZ’s new product?
• What are key challenges? Opportunities? Watchouts?
Payment Wrap-Up

• What payment classification is likely…
  • Technology will be included within a global payment
  • Technology will be paid for separately
  • Payment will be limited to certain patients or treatment settings

• Versus what is possible…
  • Can the payment classification be impacted by Legislation, Data or Economics?
  • Establish the value proposition for your technology

• Target your messaging to the stakeholder accruing the benefit

• Seek opportunity for external advocacy
  • Physicians
  • Patients
  • Politicians
• Role of Health “Policy” Within a Device Company

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• The DNA of Health Economics & Reimbursement: Coding, Coverage, and Payment

• Company Considerations: Through the Lifecycle
Measuring & Demonstrating Value for Medical Procedures

High-Level Medical Procedure Value Chain

<table>
<thead>
<tr>
<th>&quot;INPUTS&quot;</th>
<th>&quot;PROCESS&quot;</th>
<th>&quot;OUTPUTS&quot;</th>
<th>&quot;PAYMENT&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resources Invested by Stakeholders</td>
<td>Health Service Provided/Procedure Performed</td>
<td>Value Created By Procedure</td>
<td></td>
</tr>
</tbody>
</table>

Transferring Value

Capturing Value

Patient

Society

Payers

Facility

Physician

Major Stakeholders

Payers

For A Particular Device, Important To Focus On The Most Relevant Metrics/Analyses

Clinical outcomes
- Safety (various endpoints)
- Efficacy (various endpoints)
- QoL

Economic outcomes
- Cost of illness
- Cost effectiveness
- Cost utility

Financial outcomes
- Out-of-pocket costs
- Relative facility payment/hr
- Contribution margin
- Budget impact of adoption
- Revenue projections
- Payment trends
- Head-to-head comparative analyses
- Relative MD payment/hr
- Net income after device costs
- Payment by site of service
- Revenue projections
- Payment trends

Metrics

Patient

Society

Payers

Facility

Physician

• CMS
• Commercial
• Self Pay

• Hospital (In)
• Hospital (Out)
• ASC
• Office

High-Level Medical Procedure Value Chain

CLINICAL

HEALTH ECONOMICS

REIMBURSEMENT

For A Particular Device, Important To Focus On The Most Relevant Metrics/Analyses

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### Table: Audience, Objective, Type of Data Necessary

<table>
<thead>
<tr>
<th>Audience</th>
<th>Objective</th>
<th>Type of Data Necessary (Global)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulator</td>
<td>Get to market</td>
<td>Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical</td>
</tr>
<tr>
<td>Clinicians</td>
<td>Convince the physician</td>
<td>Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical</td>
</tr>
<tr>
<td>Payers</td>
<td>Convince the payer</td>
<td>Clinical</td>
</tr>
<tr>
<td>Hospital/Physician/GPO</td>
<td>Convince the economic purchaser</td>
<td>Economic</td>
</tr>
<tr>
<td>Patient/Families/Media</td>
<td>Convince the patient</td>
<td>Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical</td>
</tr>
<tr>
<td>All Stakeholders</td>
<td>Stay in market</td>
<td>Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Economic</td>
</tr>
</tbody>
</table>

- Differential evidence/data requirements for stakeholders
- Requirements guided by role within each health care system
  - US FDA not responsible for economic analysis
  - Not all hospitals/physicians are economic buyers in all markets

**Anticipate the Audience**
### Key Criteria

<table>
<thead>
<tr>
<th>Key Criteria</th>
<th>Safety</th>
<th>Clinical</th>
<th>Economic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanted</td>
<td>Yes</td>
<td>Yes</td>
<td>Only if very expensive</td>
</tr>
<tr>
<td>High ASPs (&gt;$1000)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2nd generation or later</td>
<td>Yes</td>
<td>Yes?</td>
<td>Depends?</td>
</tr>
<tr>
<td>Shift from surgical to less-invasive or medical to procedure</td>
<td>Yes</td>
<td>Yes</td>
<td>Depends</td>
</tr>
<tr>
<td>What is the health system impact?</td>
<td>Depends</td>
<td>Yes</td>
<td>Yes, if positive impact.</td>
</tr>
<tr>
<td>Do we want to take a price increase?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Implications for lack of data

- Market Withdrawal
- Lower Share
- Lower ASPs
### Contribution to Winning: Scalable HE&R Deliverables

<table>
<thead>
<tr>
<th>Funding Levels</th>
<th>Next Generation (Similar)</th>
<th>Nature of Product Fast Follower</th>
<th>Game Changer (1st to Market)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sufficient</td>
<td>• Protect funding</td>
<td>• Differentiation:</td>
<td>• Positioning:</td>
</tr>
<tr>
<td></td>
<td>-- customer economics</td>
<td>-- customer economics</td>
<td>-- customer economics</td>
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<td>-- QoL</td>
<td>-- QoL</td>
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<tr>
<td></td>
<td></td>
<td>• Protect funding</td>
<td>• Protect funding</td>
</tr>
<tr>
<td>Insufficient</td>
<td>No Action Should Occur:</td>
<td>• Increase funding</td>
<td>• Increase funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Evidence for payers:</td>
<td>• Evidence for payers:</td>
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<td></td>
<td></td>
<td>-- real world efficacy</td>
<td>-- real world efficacy</td>
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<td>-- economics</td>
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<td>-- quality of life</td>
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<td></td>
<td></td>
<td>-- QoL</td>
<td>-- QoL</td>
</tr>
<tr>
<td>None</td>
<td>No Action Required:</td>
<td>• Obtain funding</td>
<td>• Obtain funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Evidence for payers:</td>
<td>• Evidence for payers:</td>
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<td>-- real world efficacy</td>
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<td>-- QoL</td>
<td>-- QoL</td>
</tr>
<tr>
<td>Global funding</td>
<td>Viable despite funding</td>
<td></td>
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<tr>
<td>Broader indications</td>
<td>level.</td>
<td></td>
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</tr>
<tr>
<td>OUS: May require funding resubmissions.</td>
<td></td>
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<tr>
<td>Viable despite no funding.</td>
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</table>
Wrap-up: Key Takeaways

- Most technology fits into existing codes, coverage, and payment…if it fits and the payment/financials are good enough, go with it!
- Funding = coding, coverage, and payment
- In US, reimbursement based on resource use…not value!
- Influence of medical societies
  - US: control MD coding (all payers) & recommend physician payment (Medicare)
  - OUS: submit/sponsor reimbursement dossiers; consult to government on funding levels
  - Practice guidelines & OUS utilization guidelines
  - Input into technology assessments
- Initial pricing can affect funding
- Fragmentation of funding & financing systems
  - Requires variety of economic/QOL evidence in flexible formats
**Product Life Cycle: HE&R Deliverables**

<table>
<thead>
<tr>
<th>Business Planning/Proposal Definition</th>
<th>Development</th>
<th>Validation/Scale-up</th>
<th>Launch</th>
<th>Full Potential</th>
<th>Next Generation</th>
</tr>
</thead>
</table>

**Funding Sufficient/All Product Types**

<table>
<thead>
<tr>
<th>Reimbursement &amp; Health Economics Assessment</th>
<th>Strategic Plan -- demonstrate potential economic/QOL value</th>
<th>Evidence Package -- sales tools -- publications -- econ models</th>
<th>Communicate Package -- customers -- KOLs</th>
</tr>
</thead>
</table>

**Funding Insufficient or No Funding**

<table>
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<th>Reimbursement &amp; Health Economics Assessment</th>
<th>Strategic Plan -- increase funding -- demonstrate potential economic/QOL value</th>
<th>Evidence Package -- tech assess -- dossiers -- publications -- econ models -- sales tools Gov’t/Payer Engagements</th>
<th>Communicate Package -- payers -- KOLs -- customers Gov’t/Payer Engagements</th>
</tr>
</thead>
</table>

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**Critical inputs for success**

- ✔ Marketing strategy
- ✔ Clinical data
- ✔ Sales strategy

- ✔ Early input calibrates expectations
- ✔ Continuous HE&R involvement critical