Achieving Payer Coverage
The who, what, when, where & how

Market Access Optimization
Webinar Series
October 12, 2017
We partner with life science companies, healthcare providers, and health plans and help them:

- Understand the impact of changing market pressures
- Develop and execute unique solutions across functional areas that transform their operational and technical capabilities
- Achieve results that make their strategies a reality
Experimental & Investigational Labels

- Insufficient Clinical Outcomes
- Undefined Clinical Utility
- No Coverage
- Lacking Sufficient Data
- No Treatment Guidelines
- Incomplete Body of Evidence
- Pre-Authorization Required
- Unintended Complications
- Not Medically Necessary
The Label’s Impact

> The E&I label has a real and significant cost to the business

> Expectations and patience of investors – increasing frustrations as time lags for coverage

> Your KOL’s can lose interest if access for their patients is not available
Break the Cycle

> There are **approaches you can employ** to overcome the E&I label

> The **cost efficiency and timing** of the approach you chose is critical

> The key is knowing how to **set up and message your argument** with available data
Payers are Inherent Skeptics

> Presume that all technology is cost additive
> Assume that the current standard of care is adequate
> Have demanding data requirements, including the infamous RCT
> They never want to be the first to cover a new device
Common Challenges

> Lack access to amount and type of data needed to build the clinical and economic studies that supports your product’s business case

> Struggle to understand the mindset of the payer executives so that studies address their key concerns
  - Structuring the argument to convert the skeptics is the key

> Do not have relationships with the payers
For Example…

Common Challenges

- Pivotal trial terminated for “futility”
- Minimal provider adoption beyond early adopters
- Limited to no payer coverage
- Expensive technology
Market Access “Recipe”
Clinical Evidence

Hierarchy

> There is a Continuum of Evidence

> The RCT, Level 1 Evidence, comes with the big price tag

> Change your perspective - Level 2 Evidence can build momentum
Clinical Evidence
Level 2 Options

Retrospective Claims Study
• Can show on a longitudinal basis how your device has performed
• Is reliant on coding or other methods (i.e. names of physicians using the device) to make a solid case

Retrospective Medical Record Study
• Can track individual device and other measures not available in the claims data
• Can be more expensive and take more time than claims analyses

Metadata / Systematic Analysis
• Allows you to compile all kinds of previous studies to increase your total sample and make a stronger study
• Requires enough previous studies with similar characteristics and measures

Registry
• Allows you to track patients prospectively and is less costly than an RCT
• Takes participation of sites and ongoing management
Economic Evidence

**Budget Impact Model**
- Should use real world data and speaks to payers with a per member per month impact
- Requires real world data (not lit sources), transparency, and should be interactive

**Longitudinal Analysis**
- Shows what is happening beyond the index procedure and can show savings downstream savings (also can be well understood by payers and providers)
- Payers prefer a PMPM and the technology must have enough volume for the tracking period

**Incremental Cost Effectiveness Ratios**
- Summarizes the cost effectiveness of a health care intervention as it compares to another intervention
- Is not yet widely embraced by US payers

**Micro-costing Analysis**
- Allows one to evaluate the direct cost associated with a procedure or the time associated with a procedure
- Requires site involvement and time
- Useful when clinical benefits are not highly differentiated
Speaking the Language of the Payer

Need to convert clinical utility and/or outcomes into an economic message typically expressed as a per member per month impact
For Example…
Economic Evidence

- Metadata / systematic review
- Retrospective medical record studies
- Retrospective claims analysis
- Registry development
Publications

Economic and Operational Implications of a Standardized Approach to Hemodynamic Support Therapy Using Percutaneous Cardiac Assist Devices

David Wohls, MD,⇑∥ Purushothaman Mathusamy, MD,⇑ Alan T. Davis, PhD,⇑∥ Mohsin Khan, MD,⇑∥ Joseph K. Posina, MD,⇑∥ Elbert E. Williams, BS,⇑ Cynthia M. Gilc, BS,⇑∥ Dennis J. Scotti, PhD,⇑∥ and David Gregory, MPa,⇑∥

Operational Implications of Utilizing 2 Advanced Technologies for Rendering Short-term Hemodynamic Support to Patients Presenting With Cardiogenic Shock: A View Through the Lens of Hospital Readmissions

Dennis J. Scotti, PhD, MS, MBA; David J. Gregory, MPA; Theodore L. Swettler, MD; Adolph Shroff, MD, MBA; Daniel R. Beck, MBA, MPa,

Outcomes of catheter ablation of ventricular tachycardia with mechanical hemodynamic support: An analysis of the Medicare database

Aarav Arya, MD, MS, MS; Andre d'Aylla MD, PhD; Christina C. Coad MPa, P

Marc A. Miller MD; Fernando C. Garcia MD; Gregory L. Sappal MD; Srinivas R. Rukhabhat MD; Dharmayya Lekhadev MD; T Jared Bunch MD; Mark R. Bowers MD, MS; Padmakar Gerald O'Neil MD; Vivek Y. Reddy, MD

A Budget Impact Model to Estimate the Cost Dynamics of Treating High-Risk Heart Failure Patients with Advanced Percutaneous Cardiac Assist Devices: The Payer Perspective

David Gregory, MPA, FACHE and Dennis J. Scotti, PhD, MBA, FACHE, PHFMA

Market Voice

> The provider community should lend its voice to help build your case

> Build out target profiles by doctor by hospital

> Develop and launch a campaign to your targeted profiles
Medical Society Guidelines

The 2011 ACCF/AHA/SCAI guidelines incorporate Impella for the first time including several class recommendations for:

- **Class I: 5.2.3 Cardiogenic Shock: Recommendation:** "A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384,424–427). (Level of Evidence: B).” This classification includes the statement: “Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients.”

- **Class II b: 5.6 Percutaneous Hemodynamic Support Devices: Recommendation:** “Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients (Level of Evidence: C).”

- **Other Update:** 4.8 PCI in Hospitals Without On-Site Surgical Backup: Recommendations: “Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer (Class III: HARM, Level of Evidence: C).”

<table>
<thead>
<tr>
<th>2013 Recommendation</th>
<th>2015 Focused Update Recommendation</th>
<th>Comment</th>
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<tbody>
<tr>
<td><strong>Class III: HARM</strong></td>
<td>PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI who are hemodynamically stable (11-13). (Level of Evidence: B)</td>
<td>Modified recommendation (changed class from “III: HARM” to “IIb” and expanded time frame in which multivessel PCI could be performed).</td>
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<tr>
<td><strong>Class IIb</strong></td>
<td>PCI of a noninfarct artery may be considered in selected patients with STEMI and multivessel disease who are hemodynamically stable, either at the time of primary PCI or as a planned staged procedure (11-24). (Level of Evidence: B-R)</td>
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*PCI indicates percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.*

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<th>2011/2013 Recommendation</th>
<th>2015 Focused Update Recommendations</th>
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<td><strong>Class IIa</strong></td>
<td>Manual aspiration thrombectomy is reasonable for patients undergoing primary PCI (20-32). (Level of Evidence: B)</td>
<td>Modified recommendation (Class changed from “IIa” to “IIb” for selective and bailout aspiration thrombectomy before PCI).</td>
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<tr>
<td><strong>Class III: No Benefit</strong></td>
<td>Routine aspiration thrombectomy before primary PCI is not useful (33-37). (Level of Evidence: A)</td>
<td>New recommendation (“Class III: No Benefit” added for routine aspiration thrombectomy before PCI).</td>
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*PCI indicates percutaneous coronary intervention; and LD, limited data.*
Market Access Checklist

Ensures the highest quality evidence is produced to support the use of your technology

> Ideal characteristics of clinical and economic evidence

> Strategies to gain support of medical societies

> Features of effective provider communication efforts

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<tr>
<th>Clinical Evidence</th>
<th>Economic Evidence</th>
<th>Medical Society Guidelines</th>
<th>Provider Communications</th>
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<tr>
<td>Sample size 200-300 patients</td>
<td>Utilizes real world data as opposed to literature sources</td>
<td>Actively request a reassessment of guidelines (guidelines are not necessarily updated annually)</td>
<td>Providers, particularly key opinion leaders and/or those with published literature within the specific medical field, should contact payers to discuss access to the medical technology</td>
</tr>
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<td>Clinical evidence is demonstrated in one of the following ways: RCTs, meta-analyses, prospective cohort studies, claims data analyses, or medical record reviews</td>
<td>Compares to the current standard of care</td>
<td>Request to reassess guidelines should come from providers (KOLs)</td>
<td>Providers should represent a reasonable cross-section of regions, payer mix and facility types</td>
</tr>
<tr>
<td>Outcomes measured are selected from those mentioned in positive payer policies, guidelines of the current standard of care or similar technologies or recommended by subject matter experts</td>
<td>Economic evidence is demonstrated in one of the following ways: interactive BIMs, longitudinal analyses, ICERs, and micro-costing studies</td>
<td>Targeting medical societies with guidelines relevant to the medical technology and cited most often by payers</td>
<td>Medical societies, ACOs, and patients can also influence payers</td>
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<tr>
<td>Analysis measures long-term outcomes</td>
<td>Analysis includes relevant pre and post (index) medical expenses in analysis</td>
<td>Clinical evidence supporting the technology’s benefit should be given to medical societies</td>
<td>Provider outreach to payers should be continuous and purposeful, but also focused on success stories and clinically meaningful observations</td>
</tr>
<tr>
<td>Induced reversion criteria and/or propensity matching is utilized to match cohorts</td>
<td>Appropriate timeframe is used to measure costs based on condition (e.g. acute or chronic disease)</td>
<td>Process should be in place to support physicians who communicate with payers on behalf of individual patients to attest to medical necessity of a technology</td>
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<td>Study conducted by provider or other third party</td>
<td>Studies must include data from the relevant patient populations (Medicare vs. commercial mix)</td>
<td>Analysis uses U.S. clinical and economic data</td>
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<tr>
<td>Findings published in a peer-reviewed medical journal and authored by a third party</td>
<td>Manuscript on study findings authored by a third party and published in a peer-reviewed journal with managed care leadership</td>
<td>Assumptions in analysis (e.g. market penetration used in a BIM) are transparent and conservative</td>
<td></td>
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<tr>
<td>Study results show significant clinical improvement compared to standard of care</td>
<td>Analysis uses U.S. clinical and economic data</td>
<td></td>
<td></td>
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<tr>
<td>Study is based on U.S. data</td>
<td>Assumptions in analysis (e.g. market penetration used in a BIM) are transparent and conservative</td>
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Paving a Path Forward
Reversing the Label

- Gaining Access to the Payers
- Tuning Your Message
- Disarming the Skepticism
- Building your Roadmap
Tuning your Message

> Build your message with the audience in mind

> Ensure you have structured the argument to address the common conceptions

> Make sure you have packaged the argument efficiently and effectively
Disarm the Skeptic

- A focused design to drive a successful study
- Conservative assumptions to drive to credible results
- Transparency into the data
- Based on “real world” data
- Applying subject matter expertise across multiple disciplines to test completeness of the case
Build Your Roadmap

> Who? Start small vs. big
> When? Outreach timing matters
> How? Proven outreach methods
> What? A concise yet complete message
Abiomed Stock Performance
Key Takeaways
Disclosure

The information provided here is of a general nature and is not intended to address the specific circumstances of any individual or entity. In specific circumstances, the services of a professional should be sought.

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