

Medical Device Coverage and Reimbursement Conference

July 13-14, 2009
Chicago, IL



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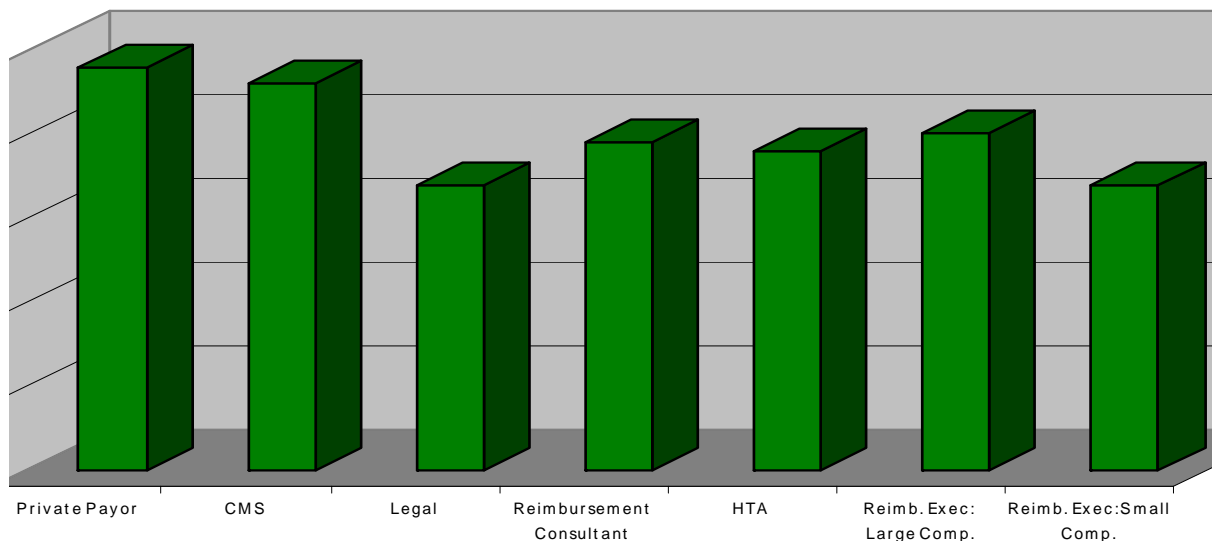
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Ensuring Successful Reimbursement and Coverage Decisions through the Enhanced Utilization of Cost-Effectiveness Data, Health Technology Assessments and Development of a Payor Mix.

Building upon Q1 Production's highly successful series of Reimbursement conferences for the medical device industry, this year's meeting focuses on uncovering strategies for the reimbursement executive which are most critical in our current economic and political environment. Over the past decade the industry has watched as payment rates have declined, the coding system has become more and more complex and payors, both federal and private, have moved towards a less transparent system with increasing evidentiary requirements for coverage. The reimbursement landscape has changed drastically as it went from a later-stage commercialization issue to a primary challenge for most medical device companies. One that must be planned for early on and will undergo scrutiny throughout the product's lifecycle.

Executives Rank Perspectives in order of Interest (5:highest, 1:lowest)



Distinguished Presenters Include:

Jacob Drapkin
Vice President of Reimbursement and Health Economics

Ethicon Endo-Surgery

Naomi Aronson, PhD
Executive Director and Director of Evidence-Based Practice Center

Blue Cross Blue Shield Association Technology Evaluation Center

Sandra Gottschalk-Reed, MBA
President

Healthcare Strategies, LLC

James Reinstein
Vice President of Sales and Marketing & International General Manager

Cyberonics

Rob Wenthold
Director

Boston Healthcare

George Emont
Partner

Triathlon Medical Ventures

Richard K. Baer, PhD
Medical Director, Medicare Part A
National Government Services

Allison Shuren
Partner
Arnold & Porter LLP

Steven Annunziato
Senior Vice President, Marketing and Sales
Synapse Biomedical

Christine Maroulis
Director, Health Economics & Reimbursement
Ethicon, a J&J Company

Wendy Wifler
Senior Director of Health Policy and Payment
Accuray

Linda Pauer
Director of Reimbursement
Arthrocare

Daniel Johnson
Chief Reimbursement Officer
VQ Orthocare

Edward Stone
Vice President, Compliance & Regulatory Affairs
CardioNet

Maggie McMahon
Director, Global Health Economics
KCI

Martin Rosendale
Chief Executive Officer
Cytomedix

Stephen Hull
President
Hull Associates Medtech Consulting

Brent O'Connell, MD, MHSA
Chief Medical Officer, **Argenta Advisors**
Managing Partner, **Argenta TEC**

Medical Device Coverage and Reimbursement Conference : Day One

8:00 Registration & Continental Breakfast

8:30 Chairperson's Opening Remarks & Conference Welcome

8:40 Pre-Conference Tutorial:

Building the Foundation for Successful Reimbursement for Device Start-ups

Reimbursement issues must be addressed for devices on their path to commercialization. The manufacturer's resources, experience, therapeutic area, etc. play a major role in how these issues will be handled. Ensuring the understanding between corporate leadership, clinical staff, marketing, and the reimbursement team on strategies and initiatives will result in positive outcomes. A concise knowledge of this process benefits everyone involved, especially manufacturers who may have only begun to consider reimbursement for their device. A user's guide on:

- Device classifications
- National and Local Coverage Decisions
- Medicare 101
- Third party payer considerations
- Formulating realistic goals for reimbursement

Garrett Schwab, *Vice President of Clinical and Reimbursement*, **Emphasys**

Medical *invited*

9:40 Potential Effects on the Industry in an Evolving Healthcare Landscape

As if bringing new medical products to the market is not complicated or challenging enough; major changes to our current health care system, ongoing and forecasted, will alter the way device companies are reimbursed and sell their products. These influences, which often have a global reach, fall on the shoulders of reimbursement and health economics executives as they make increasingly important decisions effecting product and company success. Our speaker discusses movements within the industry such as:

- Medical device gainsharing programs and the likelihood that they will be implemented
- Value-based insurance programs and their effect on payor coverage
- Changes to the coverage with evidence development policy

Jacob Drapkin, *Vice President of Reimbursement and Health Economics*, **Ethicon Endo-Surgery**

10:30 Coffee & Networking Break

10:50 Increasing Emphasis on Health Tech Assessments

Technology assessments influence coverage decisions, health policy and regulatory standards, and physicians; making them a critical part of a new product's introduction to the marketplace. Unlike many aspects of reimbursement, device executives must take a hands-off approach to these reports to maintain an objective assessment. Therefore, understanding the process and what each assessment means translates in a more proactive view of the assessment after it is made. BCBSTEC assessments apply methodologies for calculating the clinical utility of medical interventions. In this session, hear from the Blue Cross Blue Shield Technology Evaluation Center on the methodology they use for assessing new technologies.

- What technologies are assessed and why?
- Aside from peer-reviewed literature and clinical data, what other sources of information are used in a technology assessment?
- How cost-effectiveness data plays into the overall assessment of a device
- What are insurance payors looking for in tech assessments?

Naomi Aronson, PhD, *Executive Director of the Technology Evaluation Center and Director of the Evidence-based Practice Center*,

Blue Cross Blue Shield Association Technology Evaluation Center

11:40 Combining Physician Advocacy and Education in the Reimbursement Strategy

One of several building blocks that make up the reimbursement scheme is physician advocacy. Often there is no better marketing resource than key opinion leaders and distinguished surgeons who come with positive outcomes and peer-reviewed literature to convince potential customers, insurance payers and policy makers of the advantages to a new technology. Over the years, the medical device industry has developed methods and channels to partner with physician societies, therapeutic associations, and other healthcare related organizations. This session presents a case study of one company's technology, the coalition and society which have formed to support it and result in positive reimbursement outcomes.

Wendy Wifler, *Senior Director of Health Policy and Payment*, **Accuray**

11:40 Luncheon for All Attendees, Speakers and Sponsors

1:00 The Evolving Role of the Health Economics & Reimbursement Function in an Evidence-Based Value Environment

The global demand for demonstrating evidence-based value is accelerating, leading to the need for investment in lengthier and more costly studies to satisfy stakeholder data requirements. As a result, device manufacturers will need to become more efficient, appraising a product's evidence-based value earlier in product development to inform ROI calculations. This will allow manufacturers to have a realistic sense of the incremental cost and impact of data pursuits necessary to drive adoption and will also inform decisions to stop or decrease funding of products that do not objectively have an adequate evidence-based value proposition. Thus, the health economics and reimbursement functions must evolve to meet these demands and become integrated in more upstream and cross-functional processes. This presentation discusses how the role of the health economics and reimbursement functions can change to meet the growing evidentiary demands.

Rob Wenthold, *Director*, **Boston Healthcare**

1:50 International Reimbursement and Coverage: Understanding E.U. Healthcare Market

Considering the global nature of healthcare and the life science industry today, most device companies cannot focus completely on the US market, but consider Europe and several other emerging markets into their commercialization strategy. Due to stark variances in healthcare systems, payment methods, coding, etc. reimbursement strategies must take into account these aspects and best practices which apply to each region. Hear an overview focusing on reimbursement structures and methods prevalent for the European Union:

- Advantages and disadvantages to a centralized decision-making process
- Concentration on healthcare economics and cost-effectiveness in reviews
- The influence of technology assessment
- Similarities and differences in reimbursement decisions between European countries

Maggie McMahon, *Director*, **Global Health Economics, KCI**

2:40 Coffee & Networking Break

3:00 Coverage with Evidence Development: Has it Been Successful?

In this session the 2006 guidance and the revisions to follow are discussed with special focus on the device industry's role in the decision-making thus far. Providing an Overview of coverage with evidence development and importance of trial protocol in CED. An expert on CMS' continually developing program and several pressing questions:

- Development of studies that answer meaningful questions
- Case studies illustrating CED
- How does CED factor into the use of NCDs vs. LCDs
- Is CED changing collection methods for new data.
- Instances where CED data, and therefore coverage was denied.
- Is the process from CMS' side really transparent?
- Does this decision effect additional indications for use?
- How have Coverage with Appropriateness Determination (CAD) and Coverage with Study Participation (CSP) been used since the guidance was released?

3:50 Incorporating the Need for Cost-Effectiveness within the Sales Strategy

Medical Device companies understand the importance of educating their sales team on the aspects of reimbursement. As the healthcare market becomes increasingly aware and cautionary of their budgets; the cost of medical products, especially new technology is scrutinized. Desire to see cost-effectiveness information is not unique to payors and tech assessments; hospitals are changing the way in which device companies approach potential sales. This case study discusses one company's experience in:

- Recognizing an opportunity for their device in a dismal capital market
- Re-training and education for the sales team
- Analyzing aggregate gain and ROI through forecasting models
- Positioning cost vs. incremental revenues to the hospital CFO

Sandra Gottschalk-Reed, MBA, *President*, **Healthcare Strategies, LLC**

4:40 Panel Discussion:

Strategies and Case Studies for Reimbursement Professionals

Executives from several device manufacturers come together in this roundtable discussion to share with the audience their unique and challenging reimbursement situations. Audience members will be able to take away valuable insight and do's and don'ts. Panelists include:

Steven Annunziato, *Senior Vice President, Marketing & Sales*, **Synapse Biomedical**

Daniel Johnson, *Chief Reimbursement Officer*, **VQ Orthocare**

Edward Stone, *Vice President, Compliance & Regulatory Affairs*, **CardioNet**

Stephen Hull, *President*, **Hull Associates Medtech Consulting**

Linda Pauer, *Director of Reimbursement*, **Athrocare**

Brent O'Connell, MD, MHA, *Chief Medical Officer*, **Argenta Advisors, Managing Partner, Argenta TEC**

Medical Device Coverage and Reimbursement Conference : Day Two

8:00 Registration & Continental Breakfast

8:30 Coding Overview: CPT codes and the RUC process

A major topic concerning reimbursement is coding. It is absolutely necessary for the device industry to have a plan for coding on new products. A myriad of scenarios can arise when products utilize pre-existing, miscellaneous, or underpaid codes for billing of services.

- Billing and coding overview including: CPT, HCPCS, ICD-9
- Impact of providing devices gratis
- Conducting a thorough coding assessment
- Changes to bundling and DRG codes

Allison Shuren, *Partner, Arnold Porter*

9:20 Understanding the LCD Process and Communicating with Medicare Contractors

The medical directors making coverage decisions are some of the most sought after perspectives in the device reimbursement field. Insight into the methodology behind coverage for procedures, resources they utilize and what information is most influential for them.

- Understanding the role of Medicare contractors and their decision-making process
- Comprehending and meeting evidentiary requirement set forth by the contractor
- Negative LCDs and the appeals process and open public meetings
- Outlook on cost-effectiveness data and its use in future determinations.

Richard K. Baer, PhD, Medical Director, Medicare Part A, **National Government Services**

10:10 Coffee & Networking Break

10:30 Creating a Strategic Payor Mix for New Products

Reimbursement for medical devices is an extremely complex challenge to take on and see successful results. Partially, because financial resources are decreasing while new technology is continually flowing into the marketplace. Overwhelming intricacies arise due to magnitude of private payors, each with their own decision-making process and region to cover. When the several types of healthcare coverage plans are added on to this coverage network; it is no surprise this layered web of insurance payments have device companies scrambling to understand how their product will be covered and by whom. A reimbursement expert shares the strategy behind:

- When to begin identifying potential payor's for the product
- Where Medicare/Medicaid fits into the Payor Mix
- Influence of historical decisions effecting the device's coverage
- How to systematically and proactively approach coverage decisions

Christine Maroulis, *Director Health Economics and Reimbursement, Ethicon, a Johnson & Johnson Company*

11:20 International Reimbursement & Coverage for Medical Devices: Guidelines for Working Within the Asian Healthcare Market

Like almost every other manufacturing industry, medical devices have been looking to foreign markets to conduct trials and eventually market their products. Foreign markets mean varying healthcare systems and dissimilar purchasing and payment processes for medical devices. While time to reimbursement can be less than in the US, criteria such as clinical and economic are assessed quite differently. Our speaker discusses his experience and lessons learned while working in countries such as Japan, China and Korea and navigating the reimbursement challenges.

James Reinstein, *Vice President, Sales and Marketing and International General Manager, Cyberonics*

12:10 Luncheon for All Attendees, Speakers and Sponsors

1:10 Non-Coverage Decisions:

Implications and Strategic Planning for the Future

Often touted as worst-case scenario for new medical products, a non-coverage decision can be devastating especially to smaller start-ups. Decisions coming from Medicare set a standard which is difficult to overturn in addition to overcoming the "ripple-effect" it can have with third party payors who look to CMS for historical decisions. When companies form their strategic reimbursement plan for a new product, measures should be taken to avoid this result. However, when a negative decision is made, many companies are caught in a reactive position which they are not prepared for. An expert shares experience in these situations as well as advice for:

- Appealing for reconsideration from CMS
- Understanding what information is needed for resubmission
- Utilizing patient advocacy for appeals

Martin Rosendale, *CEO, Cytomedix*

2:00 Creating a Cooperative Environment for Clinical & Reimbursement Teams to Achieve Product Success

Medical Device companies consist of many departments specializing in highly focused and skilled aspects of product development and commercialization. Recognizing the critical impact reimbursement has on each and every product is not only a concern of the reimbursement specialist. Clinical research, reimbursement, and marketing departments require tremendous foresight and a cohesive internal strategy. As regulatory and government administrations along with payors continue to tighten regulations and reimbursement rates, medical device companies are faced with a tremendous challenge of creating studies that will support the data requirements needed for both regulatory and reimbursement approval. Senior management must ensure that reimbursement specialists and clinical and regulatory affairs have adequate resources, a plan of action and external expertise.

Daniel Johnson, *Chief Reimbursement Officer, VQ Orthocare*

2:50 Coffee & Networking Break

3:00

Industry Compliance and Reimbursement: Keeping to Code

Some of the largest orthopedic device manufacturers as well as several other organizations from the device industry are in hot water facing continual investigation, penalties and major declines to their stock value. Compliance, as it relates to the device industry encompasses many aspects; off-label use, doctor's incentives and last but not least, reimbursement information. Many companies affected have entire reimbursement teams dedicated to working out the intricacies of coding, payment rates, physician advocacy and support for hospitals and consumers. These same companies have large national and international sales teams and marketing resources behind their products. Due to lack of oversight and miscommunication more companies are falling into noncompliance issues. Reimbursement teams are concerned about their sales teams using non-sanctioned information to promote off-label use, suggest codes and payment rates and other information not meant to be directly suggested to consumers.

- The Reimbursement executive's responsibility in compliance
- Effective reimbursement education for sales and marketing teams
- Constructing a chain of communication and information transfer constructed to avoid these pitfalls

3:50 Venture Capital Perspective: Working in a Tighter Investment Environment

New medical technology has seen a tremendous amount of growth in the last decade. Innovation originating in small start-up entities is made possible by angel investors and venture capital. The past year has resulted in a significant decrease for investments in the life science industry. Investors are being increasingly selective, requiring companies to meet more stringent criteria. The economic environment is also impacting company financings. Topics covered include:

What makes a company an exciting venture capital investment – revised for 2009

- Explaining what venture firms look for in a reimbursement plan
- Suggestions for building an internal reimbursement team
- Overview of movements within the industry

George Emont, *Partner, Triathlon Medical Ventures*

4:40 Conference Conclusion