

MEDICAL DEVICE AND DIAGNOSTICS REIMBURSEMENT STRATEGIES

Ensuring Favorable Coverage, Coding and Payment Decisions
Based on Clinical and Health Economic Evidence

February 23-24, 2010 • Hilton San Diego Mission Bay • San Diego, CA

★ *A representative from Palmetto GBA will be available on Wednesday, February 24th, for one-on-one meetings. Please indicate your interest in setting up a meeting time when registering for this event.* ★

CMS PAYOR PERSPECTIVE:

"Examination of Local and National Coverage Strategies for Device and Diagnostics Manufacturers"

Arthur Lurvey M.D., FACP, FACE, Director,
Jurisdiction 1 Medical Affairs, **Palmetto GBA**

CONFERENCE CHAIR:

Sheri Dodd, MSc, Vice President, World Wide
Economics and Reimbursement, **Ethicon, Inc**

INDUSTRY AND ACADEMIC PERSPECTIVES FROM:

Linda Pauer, Director, Reimbursement and
Payor Relations, **ArthroCare Corp.**

Scott Reid, Director, Health Policy and Payment,
Boston Scientific

John Hornberger, M.D., MS, CEO and President,
Cedar Associates LLC.; Adjunct Clinical Professor of
Medicine, **Stanford University**

Gretchen Benko Mruk, MBA, Commercial Marketing
Manager and Reimbursement Manager, **Concentric Medical**

Ann K. Thompson, MBA, BSN, Director,
Health Economics and Outcomes Research,
Edwards Lifesciences LLC

Jacob Drapkin, Vice President, Reimbursement and
Healthcare Economics, **Ethicon Endo Surgery, Inc.**

Hamid Sadri, Pharm.D., Director, Health Economics,
Medtronic Canada Ltd.

Mark Erwin, Senior Director, Reimbursement and
Government Affairs, **Prometheus Laboratories, Inc**

John Ridge, Director, Reimbursement Services,
Ventana Medical

Anne Abreu, MBA, Director, Reimbursement and
Business Development, **Ventus Medical**

- Discuss how CER will influence market adoption and reimbursement for new and existing medical devices and diagnostics
- Hear one company's approach to engaging commercial payors when a non-coverage policy is in place
- Understand why innovations that decrease overall costs to the healthcare system may also decrease reimbursement rates
- Hear case studies about the challenges of conducting randomized controlled trials after 510(k) clearance
- Examine the ex-U.S. reimbursement environment and criteria of governing bodies
- Position novel products for positive coverage from public and private payors
- Identify what data is necessary to support optimal payment for miscellaneous codes
- Understand the importance of developing a strategic partnership with private payors

Choose from Two Pre-Conference Workshops — Tuesday, February 23, 2010

A: REIMBURSEMENT PROGRAM DEVELOPMENT —
A PRIMER FOR SMALL- TO MID-SIZED MEDICAL DEVICE
AND DIAGNOSTICS COMPANIES

B: DEVELOP A HEALTH ECONOMICS PROGRAM EARLY IN
YOUR COMMERCIALIZATION STRATEGY

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FORUM HEALTHCARE

8:30

A

REIMBURSEMENT PROGRAM DEVELOPMENT — A PRIMER FOR SMALL- TO MID-SIZED MEDICAL DEVICE AND DIAGNOSTICS COMPANIES

Workshop Objective

Small- to mid-sized device and diagnostics companies face unique challenges in building a reimbursement program with limited resources, often demanding they do more with less. This workshop examines the process of planning, structuring and launching an effective reimbursement program from the small-company perspective. Explore how to maximize resources to develop internal reimbursement expertise including key considerations for selecting outside assistance/vendors.

Key Questions to Be Addressed

- Where should a reimbursement program fall within the organization — R&D, marketing or elsewhere?
 - * who are the key stakeholders and when should they become involved in the process?
 - * how should reimbursement collaborate with clinical, regulatory, R&D, sales and marketing over the continuum of the product lifecycle?
- What are the various roles that reimbursement plays across a product lifecycle?
- How does a company determine the most appropriate coding strategy for its product?
- What factors should be considered in determining a list price?
- How should changing guidance be monitored and integrated to ensure compliance?
- What aspects of a small reimbursement program make the most sense to outsource?
 - * how should vendors be evaluated?

Workshop Outline

I. Reimbursement Program Structure

- Identify and involve key personnel
- Define departmental goals and priorities when resources are scarce
- Align program goals with other departments and understand the impact on timelines
- Consider and determine a logical reporting structure
- Understand the importance of organizational awareness and senior level buy-in

II. Understanding Compliance Considerations

- Red flags to avoid
- Tips for communicating coding and payment information compliantly

III. Strategies to Maximize Limited Resources

- Understand which functions make the most sense to keep in-house and which lend themselves to outsourcing
- Set standards for evaluating vendors
- Leverage CRO experience to facilitate clinical trials and adherence to coverage criteria

12:00 *Close of Workshop A*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

Workshop Leaders

Rina Wolf is Vice President of Commercialization Strategies, Consulting and Industry Affairs at **XIFIN, Inc.** She is a nationally recognized expert in the field of laboratory commercialization and reimbursement, with over twenty years of experience in the diagnostic laboratory industry, specializing in molecular diagnostic laboratories. She was recently Vice President of Reimbursement and Regulatory Affairs at **Axial Biotech, Inc.** Previously, she was the Vice President of Reimbursement and Regulatory Affairs at **RedPath Integrated Pathology, Inc.**, responsible for creating and managing all billing activities and policies; patient advocacy programs; public and private payor coverage/contracting; including obtaining Medicare coverage with value-based pricing for RedPath's PathFinderTG platform and was the liaison to the appropriate regulatory and industry entities. Previously, Ms. Wolf was Director of Reimbursement and Payor Relations for **Genomic Health, Inc** where she helped develop reimbursement strategies and programs that led to positive coverage policies with major third party payors, as well as a favorable local coverage determination from Genomic Health's Part B Medicare Carrier, NHIC and contributed to establishing Oncotype DX as a model for value-based pricing for a clinical laboratory test. Formerly, Ms. Wolf worked at **Esoterix** (now **LabCorp**) as Vice President of Reimbursement and Contracts. In addition, she worked for both **Schering Plough** and **Searle Pharmaceuticals** as a hospital and managed care specialty sales representative. She is a former President and board member of the California Clinical Laboratory Association. Ms. Wolf has also testified to the Small Business Committee of the U.S. House of Representatives on the impact of CMS billing regulations on Personalized Medicine. She has a BA from UCLA and a Masters of HealthCare Administration.

Anne Abreu, MBA, is the Director of Reimbursement and Business Development at **Ventus Medical**, a venture-backed start-up that makes a therapeutic device for the treatment of Obstructive Sleep Apnea. In this position, Ms. Abreu is responsible for development and implementation of reimbursement strategy that includes coverage, coding and payment/pricing. She works with internal Ventus team members and external consultants to drive development and publication of clinical and economic data that will support the reimbursement needs of key stakeholders, including both governmental and commercial payors. Additionally, she is responsible for identification and implementation of the coding strategy, as well as direction of both payor relations and specialist society, physician and patient advocacy efforts. Ms. Abreu joined Ventus medical in 2008 after spending over eight years at **Abbott Vascular** (via acquisition of **Guidant Corporation**). While at Abbott/Guidant, she developed a deep knowledge of the medical device industry and held positions of increasing responsibility in Marketing, Business Development and ultimately was Associate Director of Reimbursement for Abbott Vascular, responsible for the U.S. policy and reimbursement activities of interventional cardiology, endovascular and carotid business units. She holds an MBA from the Walter A Haas School of Business and a BA from the University of Colorado at Boulder.

8:30

B

DEVELOP A HEALTH ECONOMICS PROGRAM EARLY IN YOUR COMMERCIALIZATION STRATEGY

Workshop Objective

Quantifying the overall economic benefits that your product brings to the healthcare system is an increasingly important part of positioning it for a positive coverage decision for any size company. Commercial and private payors want to understand the net benefit an innovation brings to the healthcare system and expect data that validates the ROI of using your product to be available upon request. In this workshop, explore the importance and integration of health economics early in a commercialization strategy, the development of effective health models and techniques for communicating value to payors.

Key Questions to Be Addressed

- When should health economics be considered in the commercialization process?
- What type of information is useful for purchasers and payors?
- How do I present the information to each stakeholder?
- What are the resources necessary for a health economics program?
- What type of training or expertise is necessary?

Workshop Outline

I. Considerations for an Internal Health Economics Program

- Understand factors to consider in assessing the overall value of an innovation
- Identify purchasers' and payors' economic decision criteria
- Explore what data is important to health plans and hospitals
- How should small- and mid-sized companies incorporate health economics into their reimbursement programs?
- Examine what expertise is required
- Determine overall value to purchaser and payor

II. Economic Model Development and Tools

- Examine modeling as a tool to demonstrate the ROI of using your products to health plans
- Explore the importance of early modeling to guide strategic development of value messages

12:00 *Close of Workshop B*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

Workshop Leaders

Ann K. Thompson, MBA, BSN, is Director, Health Economics and Outcomes Research at **Edwards Lifesciences LLC**, leading the strategic development of economic evidence for transcatheter heart valve technologies in support of global market access and reimbursement. She has worked in the field of health economics and reimbursement with the medical device and pharmaceutical industry for the past eighteen years. Prior to joining Edwards, Ms. Thompson worked at **Johnson and Johnson Inc.** for nine years where she served as the Director, Payor Relations with **Cordis Corporation**, responsible for affecting payment and coverage policies for cardiovascular, endovascular and neurovascular devices in the U.S. market. Also, while at Johnson and Johnson she worked in the pharmaceutical sector and served as the Director of Regional Outcomes Research, a field science team responsible for customer-based outcomes research and dissemination of outcomes information pertinent to health policy decisions. Prior to Johnson and Johnson, Ms. Thompson worked in the pharmaceutical industry for twelve years and held positions in managed care marketing, pricing and economic analysis, clinical development and health outcomes research. She has co-authored more than thirty publications in the health economics field. She previously served as adjunct faculty at the **University of Kansas Medical Center** and the Co-Director of **Pharmaceutical Education and Research Institute**, Pharmacoeconomics and Quality of Life Training Course. Ms. Thompson received a BSN from the University of Kansas and an MBA with an emphasis in economics, from Washington University, St. Louis, MO.

Marianne Laouri, Ph.D., is Practice Leader, Health Economics, Outcomes and Analytics at **Quorum Consulting, Inc.** Dr. Laouri has a deep understanding of the business of healthcare, having worked across the industry on the manufacturer, payor, policy and consulting sides. Currently, she is responsible for building the practice, business development and client management across pharmaceutical, biotechnology, medical device and diagnostics business sectors at Quorum Consulting. Her clients range from big pharma to venture-backed start-up firms. She previously led health economics and outcomes research for **Genentech Immunology** in support of all immunology products from early pipeline to marketed drugs. Dr. Laouri served as Senior Program Officer at the **California HealthCare Foundation** where she was responsible for over \$11M in grants related to pharmacy market trends, benefits and legislation, hospital and nursing home financial performance and the state of California emergency medical services. As senior director at **Medco**, she co-led client reporting efforts for fourteen disease management programs for Fortune 500 clients. As corporate director at **PacifiCare**, she spearheaded the creation of a data mart and developed the analytic competency in support of quality measurement and reporting for PacifiCare Health Systems and its subsidiaries. She also provided leadership to company-wide clinical guidelines, technology assessment and benefit interpretation. She started her career at the **RAND Corporation** focusing on quality of care research, where she led nationally-recognized research teams in the development of utilization and quality measures. She received her Ph.D. in Health Services from UCLA.

“EXCELLENT REAL-TIME INFORMATION WITH A STRONG FOCUS ON THE INDUSTRY.”

— Previous Attendee, Sylvia Lundell, Manager, Reimbursement, **Abbott**

MAIN CONFERENCE

Day One — Tuesday, February 23, 2010

12:00 *Main Conference Registration*

1:15 *Chairperson's Opening Remarks*

*Sheri Dodd, MSc, Vice President, World Wide Health Economics and Reimbursement, **Ethicon, Inc***

*Ms. Dodd leads a global team of health economists, outcomes researchers, reimbursement and health policy specialists in support of the development and implementation of evidence generation and reimbursement strategies and tactics for the entire Ethicon portfolio. Ms. Dodd has over seventeen years of experience in the development and conduct of health economics, outcomes research and reimbursement activities across the pharmaceutical and medical device industries, as well as experience in clinical practice and international health. Prior to Ethicon, she held various positions of increasing responsibility at **JanssenOrtho-McNeil Janssen Scientific Affairs** including co-leading a regional outcomes research function, which included conducting data generation and data dissemination activities with regional payors/decision-makers. She also spent several years implementing clinical office-based outcomes research studies in the area of orthopedics, obstetrics and gynecology and worked at the **World Health Organization** in Geneva with responsibility for the implementation of disease management and health policy interventions for twenty two countries.*

EVOLVING INDUSTRY DYNAMICS THAT INFLUENCE REIMBURSEMENT STRATEGIES

1:30 **Medicare Budget and Coverage Decisions — Navigate Changes and Understand the Impact on Your Business**

Current and proposed healthcare policy changes are unsettling device and diagnostics manufacturers.

These changes include concern around Medicare Physician Fee Schedule (MPFS), Outpatient Prospective Payment System (OPPS), ICD-10 Coding as well as Medicare Part B laboratory testing, to name a few. In this session, examine Medicare budget and coverage decisions for new therapies and products and explore the impact of current and proposed changes to your customers and business strategy.

- Hear an update on current and proposed changes
- Examine impact to hospitals and other stakeholders
- Explore implications for your business strategies
- Understand how CMS developments influence private payors

*Scott Reid, Director, Health Policy and Payment, **Boston Scientific***

2:10 **Challenges of Comparative Effectiveness Research (CER) in the Commercial Payor Market — Comparing a Novel Device and Drug**

Hear about unique challenges that arise when a novel device is compared with an existing drug as commercial payors develop coverage policies. Discussion includes communications with commercial payors to improve understanding of technology as it relates to existing drugs for covered beneficiaries. This session discusses the lessons learned that might be translated into considerations for trial design. Understand one company's approach to engaging commercial payors when a non-coverage policy is in place.



- Explore challenges when a device is compared to a drug in CER
- Hear about the technology assessment committee process
- Learn how to help commercial payors understand key differences and how to plan for commercial payor coverage needs

*Gretchen Benko Mruk, MBA, Commercial Marketing Manager and Reimbursement Manager, **Concentric Medical***

2:50 **Evaluate and Meet Standards for Generating Credible, Useful Evidence**

Healthcare policymakers have an interest in basing decisions on credible and useful evidence. Proposals to increase NIH funding — especially for CER — reflect that interest. Not as publicized and discussed, but perhaps as important a priority, is how to assure that research design, conduct and communication generate evidence that is truly valuable. There may be a renewed focus on and introspection about the quality of research and how it is communicated. Attendees explore some examples and techniques to assure that research design, conduct and communication is effective in generating this kind of evidence.

- Hear study examples and understand what they reveal about the relative strengths and weaknesses of different types of research designs
- Examine possible reasons for discordant findings across research designs
- Establish best practices for presenting transparent, unbiased and complete evidence

*John Hornberger, M.D., MS, CEO and President, **Cedar Associates LLC;** Adjunct Clinical Professor of Medicine, **Stanford University***

3:30 *Networking and Refreshment Break*

4:00 **Evidence Basis of Value for Innovative Devices and Diagnostics**

As healthcare stakeholders continue to seek value, they are reshaping policy and payment mechanisms around clinical and economic evidence. Increasingly, this manifests as outcomes- or performance-driven coverage and payment, value-based purchasing, pay-for-reporting and pay-for-performance reimbursement mechanisms, expansion of the “financial episode of care” and alignment of economics with outcomes. In this session, develop an understanding of how evidence will become the critical driver of value for innovative technologies — and what you can do to turn this trend to your advantage.

- Hear how global health systems are evolving to more cost-effectiveness driven value models
- Explore the correlation of an innovation's clinical and economic impact to reimbursement and market access risk
- Understand stakeholders' different perspectives on the value of various types of evidence
- Learn how the Health Economics and Reimbursement function must support multiple evidence-based value activities

*David Parker, Ph.D., Vice President, **Boston Healthcare Associates***

4:40 **Bracing for Change in the 510(k) Clearance Environment**

The 510(k) approval process offers manufacturers a pathway for expedited market clearance based on “substantially equivalent” product status but can complicate later attempts to establish reimbursement. This session explores the challenges and benefits of 510(k) approval as well as new evidence requirements for 510(k) from the FDA. Attendees learn about the impact of changing requirements on overall program costs, time to launch and post-launch safety surveillance.

- Evaluate pros and cons of a 510(k) strategy
- Hear case studies about the challenges of conducting randomized, controlled trials after 510(k) clearance
- Examine how 510(k) product reimbursement fits with market labeling and how best to work with payors
- Understand changing evidence requirements and enforcement climate at the FDA
- Plan for the impact of this changing climate on reimbursement and sales activities

Linda Pauer, Director of Reimbursement and Payor Relations, ArthroCare Corp.

5:20 **Evolution of Global Risk Sharing and Implications for U.S. Medical Device and Diagnostics Manufacturers**

Risk sharing, also known as conditional reimbursement and funding, has been widely practiced in the international pharmaceutical industry for years. Risk sharing allows companies to market products when there is uncertainty on the clinical and economic data with an agreement that further studies and information will be provided within a certain period. This practice is gaining momentum in the medical device and diagnostics sector in the EU, Canada and emerging markets. The device and diagnostics industry has been largely exempt from providing significant clinical information compared with other healthcare sectors (i.e., pharmaceutical industry) with 510(k) strategies and relatively smaller studies considered sufficient to gain market approval. In this session, attendees learn about the global evolution of risk sharing and how it is poised to impact the U.S. medical device and diagnostics industries.

- Discuss risk sharing agreement examples
- Explore how other countries are approaching risk sharing and the impact on the medical device industry
- Examine what clinical information and economic analysis are necessary to persuade payors

Hamid Sadri, Pharm.D., MSc., Director of Health Economics, Medtronic Canada Ltd.

6:00 *Close of Day One*



6:00-7:00 **Networking, Wine & Cheese Reception**

Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

Day Two — Wednesday, February 24, 2010

7:30 *Continental Breakfast*

8:00 *Chairperson's Review of Day One*

Sheri Dodd, MSc, Vice President, World Wide Health Economics and Reimbursement, Ethicon, Inc

PAYOR ADDRESSES

8:15 **Examine Local and National Coverage Strategies for Device and Diagnostics Manufacturers**

In this session, hear about different paths that CMS and other payors are taking towards reimbursement. Understand, from a payor perspective, the rationale behind coverage and non-coverage decisions and how different information is weighted during the decision-making process. This address explores differences between local and national policies and examples of how to best leverage local coverage to maximize product reimbursement. Benefit from case study examples of both successful and unsuccessful applications for coverage. The pros and cons of various coding options — AMA, HCPCS, temporary or no code — are also highlighted.

- Understand differences between local and national policies
- Hear case study examples of successful and unsuccessful applications for coverage including what you need to do to prepare
- Learn how to leverage local coverage to maximize reimbursement
- Examine path towards reimbursement for Medicare and insurance companies
- Understand advantages of different code types including AMA, HCPCS, temporary and of no code

Arthur Lurvey M.D., FACP, FACE, Director, Jurisdiction 1 Medical Affairs, Palmetto GBA

EXTENDED PANEL DISCUSSION

9:00 **Understand Implications of Comparative Effectiveness Research for Diagnostics and Medical Device Manufacturers**

CER is part of the platform for long-term healthcare reform, and the Obama administration has allotted over \$1B from ARRA toward CER. Opportunities to conduct CER for pharmaceutical interventions may be obvious, since regulatory approvals often involve controlled studies versus placebo and more head-to-head comparative studies are needed. However, CER for devices and diagnostics is more challenging. In this panel, attendees not only review the basics of CER, but also discuss how CER will influence market adoption and reimbursement for new and existing medical devices and diagnostics.

- Understand where comparative data is coming from
- Examine how U.S. and EU payors are encouraging CER activities
- Evaluate how CER will affect coverage and payment for competing diagnostic and therapeutic interventions
- Profile a case study of one of the first ARRA CER grants — PCI versus CABG
- Compare and contrast CER studies for therapeutic interventions versus diagnostics
- Evaluate strategic threats and opportunities both for technologies on the market and those in development

Moderator: Kuo Bianchini Tong, Founder and President, Quorum Consulting, Inc.

*Panelists: Scott Reid, Director, Health Policy and Payment, Boston Scientific
John Ridge, Director, Reimbursement Services, Ventana Medical*

9:50 *Networking and Refreshment Break*

10:20 **Position and Communicate the Overall Value of Your Product Effectively to Stakeholders**

Today, device and diagnostics manufacturers must not only understand the importance of evaluating overall health economics. Equally important, they also need to understand how to have effective conversations about these benefits to different external stakeholders whose decisions influence the use of their products. Learn how to position economic data and savings to a health plan to gain coverage for new technologies.

- Identify key stakeholders and understand the unique value(s) your product brings each
- Refine the discussion for each stakeholder (hospital, health plan, etc.)
- Understand effective tools to aid communication

Jacob Drapkin, Vice President, Reimbursement and Healthcare Economics, Ethicon Endo-Surgery, Inc.; Board Member, Reimbursement and Hospital Outpatient Committee, AdvaMed

11:00 **Consensus Standards — A Means for Industry to Contribute to Improvements in Healthcare Delivery**

An overlooked problem that may contribute to excessive healthcare costs and relatively poor quality clinical outcomes is failure to work collaboratively among the key medical care stakeholders with responsibilities for healthcare development, investment, delivery and payment. Usually, medical device companies have deep knowledge of clinical needs and their possible technological solutions, and they also have access to technological and financial resources that are needed to realize improvements in healthcare delivery. However, their advice is typically mistrusted as lacking objectivity and influenced by marketing considerations. This session focuses on untapped opportunities to overcome these problems through collaboration and consensus standards.

- Explore collaborative effort behind standard F2311
- Understand how industry, FDA, NIST, academics and physicians worked together
- Examine consensus standards process as a model of collaboration between industry, providers and payors for addressing various issues of concern

Frederick Cahn, Ph.D., CEO, BioMedical Strategies LLC.

11:40 **Strategic Relationships with Private Payors — Are Partnerships a Possibility?**

Private payors collectively represent more membership than Medicare and Medicaid combined. Dependent on your technology's payor mix, the relationships you develop with private payors may have a greater impact on your business than Medicare or any other payor. Despite this, medical device manufacturers often view private payors as a secondary issue and adopt a "fly under the radar" approach with private payors or simply assume as goes Medicare so goes the rest of the industry. In today's world, device manufacturers cannot afford *not* to make private payors a top priority in reimbursement and overall business strategy. In this session, understand the importance of developing relationships with private payors.

- Understand what motivates private payors
- Explore which business issues private payors and medical device manufacturers have in common
- Learn what non-economic items medical device manufacturers have to offer private payors
- Are there "precedents" of collaboration between private payors and manufacturers?
- Determine a good starting point for developing a strategic relationship or partnership with a private payor

Dave Daflou, MS, Director Consulting Services, Prescott Associates; Former Director of Contracting and Provider Networks, AmeriHealth Insurance Company

1:35 **Considerations for Ex-U.S. Reimbursement — Understanding the Global Environment**

Reimbursement processes and criteria vary from country to country. Companies interested in market expansion must understand regulations from established bodies, such as NICE, as well as evolving reimbursement environments in emerging countries of interest. Examine reimbursement challenges when launching a product globally including processes, environment and cost considerations.

- Examine the ex-U.S. reimbursement environment and criteria of governing bodies
- Understand necessary infrastructure for approaching global reimbursement
- Explore the implications of global planning for product launch timelines
- Learn why innovations that decrease overall costs to the healthcare system may also decrease reimbursement rates

Sheri Dodd, MSc, Vice President, World Wide Health Economics and Reimbursement, Ethicon, Inc

2:15 **Design and Development of Clinical Trials to Support Positive Coverage Decisions**

Reimbursement and coverage are critical to the successful commercialization of new medical technologies. Therefore, it is important to understand which criteria private payors and Medicare truly consider important including what information they perceive as must-have versus nice-to-have in making a coverage decision. In this session, attendees explore how best to position themselves for a positive coverage decision including when to involve payors in the process and best strategies for communication with payors.

- Clinical trial design considerations
- Timing of engagement with payors
- Improving communication and approach
- Exploring top considerations for coverage
- Examining the impact of health economics data

Jonathan Freudman, M.D., Founder, Freudman Healthcare Consulting; Former Medical Policy Director, Blue Shield of California

2:55 **Positioning Novel Products for Positive Coverage from Public and Private Payors**

Innovators understand that their products may not fall neatly under specific guidance or fit into established reimbursement pathways. In this case study, attendees hear how one company approached reimbursement before, during and after the launch of innovative diagnostic tests. Understand the role of headquarters and field personnel in optimizing reimbursement strategy and positioning novel products for positive coverage decisions.

- Understand challenges for product reimbursement before, during and after launch from an innovator's perspective
- Examine pros and cons of choosing a miscellaneous code versus attempting to find codes that match your product
 - * understand what data is necessary to support optimal payment for miscellaneous codes
- Explore how health economics was incorporated into the reimbursement process

Mark Erwin, Senior Director, Reimbursement and Government Affairs, Prometheus Laboratories, Inc



WHO SHOULD ATTEND

This conference benefits Vice Presidents, Directors and Managers at medical device or diagnostics companies with responsibilities in the following areas:

- Pricing and Reimbursement
- Health Policy
- Health Economics and Outcomes
- Pricing Policy
- Account Management
- Managed Care
- Commercial Operations
- Payor Affairs
- Product Management
- Marketing
- Government Affairs/Relations

This conference also benefits law firms and consultants working in managed care, Medicare, reimbursement, health economics and health policy.

HEAR WHAT PREVIOUS ATTENDEES HAD TO SAY:

“Great overview of reimbursement issues and emerging trends.”

— Vincent Polkus, Marketing Manager, GE Healthcare

“Current and pertinent information for the medical device industry.”

— Rich Szulenski, Director, Partnership Strategies, Smith and Nephew

“Wonderfully informative!”

— Kristin Norton, Vice President, Business Development, Practice IT

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CBI's 5th Forum on

MEDICAL DEVICE AND DIAGNOSTICS REIMBURSEMENT STRATEGIES

Ensuring Favorable Coverage, Coding and Payment Decisions Based on Clinical and Health Economic Evidence

February 23-24, 2010

Hilton San Diego Mission Bay • San Diego, CA

CONFERENCE HIGHLIGHTS:

- Understand health policy changes and how CMS developments influence private payors
- Learn how risk sharing is poised to impact the U.S. medical device and diagnostics industries
- Design and develop clinical trials to support positive coverage decisions
- Understand changing 510(k) evidence requirements and enforcement climate at the FDA

Choose from Two Pre-Conference Workshops — Tuesday, February 23, 2010

- A:** REIMBURSEMENT PROGRAM DEVELOPMENT — A PRIMER FOR SMALL- TO MID-SIZED MEDICAL DEVICE AND DIAGNOSTICS COMPANIES
- B:** DEVELOP A HEALTH ECONOMICS PROGRAM EARLY IN YOUR COMMERCIALIZATION STRATEGY

CD-Rom Compendiums

If you are unable to attend the conference or you would like extra copies for your colleagues, you can order your conference CD-Rom today. Don't miss out on the valuable information presented by industry leaders exclusively at this event. The CD-Rom is available for only \$198 and includes the conference agenda, presentations and speaker biographies. Simply fill out the order form and the CD-Rom will be shipped to you 2 weeks after the conference occurs.



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| Conference only | \$1,695 | \$1,295 |
| Workshop only | \$895 | \$895 |

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- **Phone reservations:** 1.800.445.8667 and mention the Medical Device Reimbursement Conference.

Cut-off date is **February 5, 2010**. Reservations made after the cut-off date or after group room block has been filled (whichever comes first) will be accepted on a space and rate availability basis. Rooms are limited so please book early.

All travel arrangements subject to availability.

Venue:

Hilton Mission Bay • 1775 E. Mission Bay Drive • San Diego, CA 92109
Hotel reservations: 1.800.445.8667
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