



## Medical Technology Reimbursement Professionals Workshop

Arnold & Porter  
Washington, DC  
September 22 -24, 2009

### Tuesday, September 22<sup>th</sup>

**8:30 – 9:00**                      **REGISTRATION AND CONTINENTAL BREAKFAST**

**9:00 – 9:05**                      **Welcome**  
*Thomas Maeder, Executive Director, MTLI, AdvaMed*

**9:05 – 10:30**                      **Introduction to Reimbursement for Medical Technology**  
*Mary Walchak, Director of Strategic Reimbursement, Global Marketing, GE Healthcare*

- Overview of CMS coverage, coding, & payment, and of other public and private sector plan and reimbursement schemes. What are the key characteristics of reimbursement for medical technology (devices, diagnostics, and combination products), and how do reimbursement considerations affect the development and introduction of new technologies?

**10:30 – 10:45**                      **BREAK**

**10:45 – 12:15**                      **Coding Systems**  
*Barbara Calvert, Director, Medical Products Reimbursement, Abbott Laboratories*

- What are device, diagnosis, procedure, and other codes? How are they determined, what do they mean, what impact do they have on medical technology companies? What resources are available?

**12:15 – 1:15**                      **NETWORKING LUNCH**

**1:15 – 2:00**

**Technology Assessments**

*Robert McDonald, President, Aledo Consulting (former Corporate Director of Medical Policy at Anthem)*

- The evidence-based assessment of therapeutic interventions and diagnostic tests is an important component of reimbursement decisions. What are technology assessments, why are they important, who makes them and how, and what constructive input do manufacturers have on them?

**2:00 – 2:45**

**The CMS Coverage Process**

*Gail Daubert, Partner, Reed Smith*

- How is coverage determined at a national and local level? How is evidence translated into coverage decisions by both public and private payers? What are the roles of MCACs and CACs?

**2:45 – 3:00**

**BREAK**

**3:00 – 3:45**

**Inpatient Payment**

*Barbara Calvert, Director, Medical Products Reimbursement, Abbott Laboratories*

- The Inpatient Prospective Payment System (IPPS), DRGs, payment variations under DRGs, additional reimbursement for new technologies, and DRG reassignment.

**3:45 – 4:30**

**Outpatient Payment**

*Gail Daubert, Partner, Reed Smith*

- The Inpatient Prospective Payment System, APCs versus DRGs, how APCs work, APCs and new technologies, special issues for medical devices, ASCs.

**4:30 – 5:15**

**Physician Payment Under the Physician Fee Schedule**

*Ed Dougherty, Senior Vice President, B&D Consulting*

- Physician fee schedules, practice expenses, professional and technical components, and the resource-based relative value scale system

**5:15 – 5:45**

**Reimbursement Tools – General Discussion**

- Reimbursement is a moving target. Where do you find current information on coverage decisions, coding, payment, tech assessments, and other key topics? What free or subscription on-line or other sources of information exist? Faculty and attendees discuss their favorite sites and research methods.

**5:45 – 7:00**

**RECEPTION**

**Wednesday, September 23<sup>rd</sup> :**

**8:00 – 8:30**

**CONTINENTAL BREAKFAST**

**8:30 – 9:15**

### **Health Care Reform and Medical Technology**

*Thomas Gustafson, Senior Policy Advisor, Arnold & Porter*

- Whatever the result of health care reform, a new world is upon us. Tom Gustafson – economist, former senior CMS administrator, and leading health policy expert – discusses what changes are likely and how they are likely to affect the medical technology industry and the role of the reimbursement professional.

**9:15 – 10:15**

### **Evidence Development**

*Ed Dougherty, Senior Vice President B&D Consulting*

- What types of evidence are necessary and credible to support technology assessment and coverage decisions? What are the sources of such information, and how can companies establish and integrated, coordinated program to collect or generate it and use it to their best advantage?

**10:15 – 10:30**

### **BREAK**

**10:30 – 11:15**

### **Cost-Effectiveness**

*Speaker TBA*

- In the US and abroad, payers increasingly expect evidence that the benefits of technology justify the cost. Independently, companies may need to make analogous calculations for internal assessment of product viability on the market. What is the global landscape of cost-effectiveness and comparative effectiveness requirements? What methods are used to calculate these measures, and what advantages and pitfalls do they hold?

**11:15 – 12:00**

### **Strategic Positioning: Evaluating Where You Are**

*Tina Ommaya Iovic, Director of Reimbursement, Thoratec*

- Evaluating the potential payer landscape for your technology and planning the best route to market. How can reimbursement considerations affect product design, the choice of targeted patient populations and indications, and regulatory, clinical, and sales & marketing strategies?

**12:00 – 1:00**

### **LUNCH**

**1:00 – 1:45**

### **Implementing Payer Strategies and Avoiding Postmarket Surprises**

*Bonnie Handke, Director, Health Policy & Planning, Medtronic Neuromodulation*

- Planning, implementation and mid-course correction of your implementation strategy. Who's in charge, and who needs to know what when and why? How do you set up early warning systems when something has changed or should change, and insure that new information results in appropriate action?

**1:45 – 2:30**

### **Building Government Relations into Your Reimbursement Strategy**

*Paul Seltman, Director, Public Policy & Government Relations, BD*

- How companies – large and small – can use government relations to their advantage as part of a comprehensive reimbursement strategy. What to do, what not to do, and how to do it.

**2:30 – 3:15**

### **Reimbursement Advocacy**

*John McInnes, Associate, Arnold & Porter LLP*

- Physicians, patients, patient advocacy groups, and professional societies can also be helpful in building the case for coverage. How and when should their support be enlisted, and how can you work with experts to build a useful case? What other allies are available to help in your advocacy efforts?

**3:15 – 3:30**

### **BREAK**

**3:30 – 5:30**

### **Getting Your New Widget Approved and Paid**

*Thomas Gustafson, Senior Policy Advisor, Arnold & Porter*

*John McInnes, Associate, Arnold & Porter*

- The trials and tribulations, solutions, and ultimate success of a medical technology company ushering a new technology through the system. Participants break up into groups and, with the help of faculty facilitators, design a reimbursement strategy for a new medical technology.

**5:30 – 7:00**

### **RECEPTION**

## **Thursday, September 24<sup>th</sup>**

**8:00 – 8:30**

### **CONTINENTAL BREAKFAST**

**8:30 – 9:00**

### **Case Study Presentation – Carotid Artery Stenting**

*Barbara Calvert, Director, Medical Products Reimbursement, Abbott Laboratories*

**9:00 – 10:00**

### **The World Outside CMS**

*Robert C. McDonald, Aledo Consulting (former Corporate Director of Medical Policy at Anthem)*

- While CMS is the single largest payor for medical technology, there are a number of other payors that pay for the great majority of health care costs. What are these other payors? How do their objectives and philosophies differ from those of CMS? When does thinking about these different payors become important in the early (strategic) and later (tactical) phases of a company?

**10:00 – 10:30**

### **Case Study Presentation – Left Ventricular Assist Device**

*Tina Ommaya Iovic, Director of Reimbursement, Thoratec*

**10:30 – 10:45**

### **BREAK**

**10:45 – 11:45**

**Maintaining an Ongoing Reimbursement Campaign**

*Bonnie Handke, Director, Health Policy & Planning, Medtronic Neuromodulation*

- Reimbursement activities never end. Guidelines for creating billing guides, web sites, hotlines, communicating with hospitals about getting reimbursed for your products. What do you need to do to keep up on new reimbursement developments relevant to your products, and how can you maintain a nimble, dynamic, effective, ongoing reimbursement program?

**11:45 – 12:30**

**Appeals and Working with Providers**

*Donna Thiel, Shareholder, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC*

- What do you do when reimbursement is denied? What help can companies offer to providers with reimbursement problems?

**12:30 – 1:30**

**LUNCH**

**1:30 – 2:30**

**Legal Guidelines for Reimbursement and Marketing**

*Donna Thiel, Shareholder, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC*

- Legal considerations and guidelines for empowering your sales force while staying within appropriate limits. How reimbursement professionals can productively interact with sales and marketing. The permissible and the forbidden – where promotion ends and practice of medicine begins. Issues and limitations related to off-label uses. What new developments in the law and codes of ethics apply to the area of reimbursement?

**2:30 – 3:15**

**Reimbursement in the Rest of the World**

*Speaker TBA*

- What major categories of different reimbursement structures exist outside of the US? How should a reimbursement professional contemplate the OUS market? What strategies exist, and are there logical sequences of countries or regions that help leverage prior evidence and experience?

**3:15 – 3:30**

**BREAK**

**3:30 – 4:00**

**Reimbursement in the Overall Corporate Context**

*Tina Ommaya Ivovic, Director of Reimbursement, Thoratec*

- Where does reimbursement generally live within large and small companies? What might be a typical organization chart, and is the typical appropriate?

**4:00 – 5:00**

**The Role of Reimbursement**

*Panel Discussion*

- What can be done to further empower reimbursement

professionals and insure their participation at all stages where their input holds value?

**5:00**

**ADJOURNMENT**

***Important Notice***

*The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.*