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11:45 A.M.–12:30 P.M.

Panel Discussion: Developing Reimbursement Strategies

Chair: Kuo Bianchini Tong
President and Founder
Quorum Consulting

By now, it's well accepted that reimbursement is a key driver of commercial success for medical technologies. Medtech company leaders who have come across any primer on reimbursement have probably heard about the need to evaluate coverage, coding, and payment as defined below.

- *Coverage* is what, where, when, and why the technology is eligible for reimbursement from an insurer or third-party payer.
- *Coding* allows the technology or service to be identified on claims forms.
- *Payment* is the dollar amount, typically associated with a code or series of codes, reimbursed by the payer to the provider of the service.

While biotech-device-drug combination products may pose particular challenges and nuances, reimbursement for these innovative products often still comes down to understanding and breaking down these three components.

In spite of the fact that reimbursement is recognized as being on the critical path, many entrepreneurs, investors, and key decision makers still think of reimbursement as an impenetrable black box. Reimbursement experts themselves may be part of the problem. They often overwhelm their audience with an alphabet soup of acronyms ranging from APC, CPT, DRG, HCPCS, to RBRVS and everything in between.



Another part of the problem is the anecdotal stories that either set unrealistic expectations or frighten

Medtech executives seeking to get reimbursement for new medical technologies shouldn't focus on just coverage, coding, and payment.

the industry with potentially dire outcomes. Following are two examples.

Drug-Eluting Stents. Recogniz-

ing the medical value of drug-eluting stents, the Centers for Medicare and Medicaid Services (CMS; Baltimore) moved forward with approval of incremental reimbursement for the new medical device, effective April 1, 2003. This new policy provided a significant increase over the previous reimbursement level for bare-metal stents.

To make this happen, Johnson & Johnson developed a strategy that, from the very beginning, established a close working relationship between its Cordis business unit (Miami Lakes, FL) and CMS. The result was that J&J was able to accomplish what no other

device company had been able to do—obtain a favorable Medicare coverage decision before FDA issued marketing authorization for the product.

Although the level of incremental reimbursement that CMS established for the new drug-eluting stent fell short of Cordis's recommendation, the decision enabled the company to assure hospitals that they would not have to withstand the two- to four-year delay that typically occurs before Medicare coverage decisions on new devices are handed down. By way of contrast, when J&J introduced the first bare-metal coronary stent, in 1994, it took three years and three months before Medicare set a reimbursement rate—a period of strain on both hospitals and product companies.

Artificial Spinal Disks. In May 2007, CMS said it did not intend to pay for artificial spinal disk replacement surgery in patients older than 60, despite the availability of FDA-approved products on the market. The Medicare program, which covers about 43 million people who are disabled or aged 65 and older, said in a draft proposal that it was rejecting coverage of the procedure no matter which disk was used. A final decision is expected in August. Regarding the available data, Medicare officials said, "Many questions remain regarding selection criteria, adverse events, and long-term outcomes for spine surgery in general."

A 10-Step Solution

But data don't drive every CMS decision. While turning away coverage for spinal disks, Medicare may still provide reimbursement for some investigational devices and related services.

And just to add to the confusion, private payers may take an entirely

Panelists

Kuo Bianchini Tong is president and founder of Quorum Consulting (San Francisco), where he works with his clients to understand how economic, financial, and reimbursement forces can be managed and how to influence product acceptance and utilization.



Tong is an active member of numerous professional organizations and societies including the Academy of Managed Care Pharmacy, American Public Health Association, American Society for

Blood and Marrow Transplantation, American Society of Clinical Oncology, Infectious Disease Society of America, International Society for Heart and Lung Transplantation, International Society for Pharmacoeconomics and Outcomes Research, and Society for Investigative Dermatology.

Prior to founding Quorum Consulting, Tong was a senior associate with Corning HTA (now known as Covance; Washington, DC), a healthcare consulting firm. Prior to entering the consulting field, he was active in clinical and health services research at the University of California at Los Angeles neuropsychiatric institute and the University of Pennsylvania department of medicine.

Tong holds a BA from the University of Pennsylvania and an MS in business and management from Johns Hopkins University.

Michael Beebe has worked for the American Medical Association (AMA; Chicago) since 1995. He is currently director of current procedural terminology (CPT). In this capacity he is responsible for all CPT content development and maintenance activities, as well as CPT education and licensing efforts.



Prior to assuming leadership over CPT, Beebe was director for the CPT-5 Project, which was an effort by AMA to make needed and practical improvements in the structure and processes of CPT to reflect the procedure-coding demands of the modern dynamic healthcare system.

Before joining CPT, Beebe worked as a senior social scientist in physician payment systems, where he was staff to the AMA-specialty society relative value scale update committee.

Beebe holds a BA from Pennsylvania State University and an MS from Boston University.

Robin R. Bostic is vice president for reimbursement at Thoratec Corp. (Pleasanton, CA), a world leader in products to treat cardiovascular disease. Bostic worked in the insurance industry for eight years before moving into medical manufacturing reimbursement. She has successfully worked with the Centers for Medicare and Medicaid Services and private payers to create national and regional coverage, coding, and payment for new innovative technologies as well as managed reimbursement and government affairs departments for medical device companies.



Bostic has been recognized by *MX* magazine as one of the top executives in the field of reimbursement. She is on the speaker faculty for AdvaMed, the Center of Business Intelligence, and the Institute for International Research.

Bostic holds a BS degree in political science from Baylor University.

different line of thought. J. Armstrong, a regional medical director for Aetna, indicates that FDA approval does not ensure coverage. “We don’t cover everything, even those that have FDA approval.”

What product financiers, entrepreneurs, and marketers really need to understand is that developing reimbursement strategies requires the same due diligence, preparation, critical thinking, evaluation of strategic alternatives, planning, and implementation that are typically applied to regulatory, clinical, marketing, and manufacturing functions.

When manufacturers are evaluating reimbursement barriers and opportunities for new medical technologies, a number of key areas are important to consider. Following are 10 areas that companies should review in order to develop the foundations of a reimbursement strategy.

Settings of Care. The manufacturer should define where the product will be delivered to the patient. Reimbursement policies can vary considerably among hospital, office, and home settings. The manufacturer should also decide which are the best short- and long-term options for rolling out a product throughout its life cycle.

Front-Office versus Back-Office. These terms help differentiate between technologies that are “visible” to third-party payers versus those that are in the back office, and thus not highly visible to payers. For example, some technologies afford operational efficiencies but are not separately identifiable services that can be billed to payers. For such back-office technologies, it may be more important to develop an economic or pricing strategy—one that focuses on the financial and operational benefits of the product—than to work on a reimbursement strategy.

Competition. In some cases, truly

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Before joining Monogram, Bui was the virology business unit director for DuPont Pharmaceuticals. In addition to her most recent sales management position at DuPont, she served DuPont and DuPont-Merck Pharmaceuticals for more than 10 years, from 1990 to 2000, in various commercial and product development roles, including physician and hospital sales, clinical development and education, healthcare policy and government affairs, and strategic market development.

Bui received her bachelor’s degree in international business with marketing emphasis from San Francisco State University and also studied abroad at the University of Liège, Belgium.

Reimbursement consultant **Gerald N. Rogan, MD**, is principal of Gerald N. Rogan, MD, Consulting (Sacramento, CA). Trained in emergency and family medicine, he practiced as an emergency physician in an underserved county hospital for two years and then moved to John Muir Medical Center (Walnut Creek, CA), where he helped start the East Bay’s first paramedic program. Focusing on less-expensive non-hospital-based primary and urgent care, he opened a family and urgent medical and surgery clinic.



In 1997, Rogan became the Part B Medicare carrier medical director for National Heritage Insurance Company (NHIC) in California, a position he held for more than six years. There, he helped practitioners understand, comply with, and appreciate Medicare billing rules. His responsibilities included claim data review, business planning, policy development, rule making, education, conflict resolution, legal analysis, and law-enforcement support.

Rogan maintains affiliations with the American Medical Association, the California Medical Association, and the Butte-Glenn Medical Society. He holds BA and MD degrees from the University of Michigan.

Guy P. Nohra is cofounder and managing director of Alta Partners (San Francisco), a leading life sciences venture capital firm that has funded more than 120 companies in the industry since 1996. Prior to cofounding Alta Partners, Nohra was a partner at Burr, Egan, Deleage & Co., which he joined in 1989. Previously, Nohra was product manager for medical products with Security Pacific Trading Corp.



Nohra currently serves on the boards of directors of several private companies, including AcclRx, ATS Medical, Carbylan BioSurgery, Coapt Systems, Paracor Medical, PneumRx, and Vertiflex, and he is the chairman of the board of USGI Medical. Nohra has been involved in the funding and development of notable medical technology and life science companies, including Cutera, Innerdyne, R2 Technology, deCODE genetics, and Vesica. He currently serves on the board of the Medical Device Manufacturers Association.

Nohra holds an MBA from the University of Chicago and a BA in history from Stanford University.

innovative technologies don't have existing competitors or counterparts. In order to identify what reimbursement principles have been established in the marketplace, however, it is still important that manufacturers identify how patients are currently being managed.

Standards of Care. This is where technology assessments, treatment guidelines, and other evidence-based reviews come into play. Manufacturers should determine whether standards of care have already been defined. In some cases, the standard of care may not be well documented and may instead be based on community practices. It's important for manufacturers to review what's been established so that the positioning of newer technologies clarifies how the technology will affect the standard of care.

Recommended Reading

Centers for Medicare and Medicaid Services, press releases [online]; available from Internet: www.cms.hhs.gov/apps/media/press_releases.asp.

"FDA Approves Landmark Treatment for Coronary Artery Disease," in Angioplasty.Org home page [online], (Sag Harbor, NY: Angioplasty.Org, 2003 [cited 12 July 2007]); available from Internet: www.ptca.org/pr_jnj/20030424.html.

"J&J: Getting Paid Up-Front for New Technology," *In Vivo: The Business & Medicine Report*, vol. 17, no. 11 (2003): 28; available from Internet: www.windhover.com/contents/monthly/exex/e_2003800209.htm.

Amanda K. Sarata, *Genetic Testing: Scientific Background for Policymakers* (Washington, DC: Domestic Social Policy Division, Congressional Research Service, 2007); available from Internet: http://opencrs.cdt.org/rpts/RL33832_20070126.pdf.

FDA Approval. Approval does not ensure reimbursement from third-party payers. Manufacturers should repeat this to themselves over and



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Evidence. Evidence-based medicine has been promoted in healthcare for some time. Along those same lines, CMS and other payers are engaged in developing evidence-based reimbursement policies. As in the case of artificial disks, Medicare officials frequently take the attitude that “many questions remain regarding selection criteria, adverse events, and long-term outcomes.”

Evidence to answer such questions would help resolve reimbursement barriers. A sound reimbursement strategy is harmonized with the evidence that already exists about the pertinent disease, as well as expectations regarding the types of evidence that will need to be generated about the use of a new technology.

Eligibility. Manufacturers should work to understand not only the target patient populations, but also the medical plans and health insurance entities that insure these patients. It is important for the company to determine whether the technology or service provided is eligible for insurance reimbursement.

For example, Medicare does not routinely cover preventive services, unless Congress has specifically authorized the agency to do so. Consequently, coverage for genetic tests and services that might be considered preventive may not be granted under Medicare. Eligibility for services may also differ between settings of care.

Reimbursement Policies. Manufacturers should determine whether reimbursement policies already exist for the pertinent disease or for predicate technologies, and whether those policies can be applied to the new technology. Companies should identify relevant case studies involving coverage, coding, and payment levels that may provide valuable lessons and insights into how payers will evaluate a new technology.

Clinical Utility. Third-party payers typically ask the following questions, which manufacturers should be prepared to answer with appropriate evidence.

- What are the benefits of the new technology, and to whom do they accrue?
- Does the new technology improve patient survival?
- Does the new technology improve patient quality of life?

As an example, many new diagnostic technologies identify biomarkers or other surrogate predictors of disease. Payers want to know how identification can be translated into improvements in net health outcomes.

Economic Value. Some technologies enhance the delivery of healthcare by improving provider operations and efficiency. Other technologies may greatly reduce the burden on caregivers, and thus provide indirect value to caregivers, families, and their productivity. Most entrepreneurs, investors, and marketers would like their new technology to be supported by a message that demonstrates its economic value. Deciding how to prove that value is a different story.

Conclusion

All too often, reimbursement is thought of as a stand-alone, independent process that holds the secret of commercial success. For example, medtech companies often want to know the extent to which they need to provide clinical trial data in support of reimbursement. However, answering that question requires an understanding of whether the product will be positioned as a me-too product or represents something revolutionary that requires significant

changes in reimbursement policy.

Another commonly asked question is when companies should evaluate reimbursement barriers and opportunities. All well-trained consultants will answer, “early and often.” If clear reimbursement pathways have already been established, however, then reimbursement planning may be a rather straightforward exercise. It would be safe to say, for example, that a device with the following characteristics has a really clear reimbursement strategy.

- A second-generation device.
- Well-established predicates that are widely and adequately reimbursed by payers.
- Existing billing codes can be used.
- Pricing similar to or lower than those for existing technologies.

But the more disruptive the technology, the more complex the reimbursement scenarios. And technologies that represent the convergence of biotechnology, medical devices, and pharma certainly have the potential to represent positive paradigm shifts.

Reimbursement strategies should not be thought of solely in terms of coverage, coding, and payment. Instead, reimbursement is a strategic exercise that requires iterative thinking and integrated planning with other key product development, R&D, regulatory, and marketing functions.

If companies address each of the 10 areas outlined above, digging into coverage, coding, and payment will start to make a lot more sense and provide a lot more value.

Kuo Bianchini Tong is founder and president of Quorum Consulting Inc., a medical technology reimbursement consultancy with offices in San Francisco and Washington, DC. ■