As diagnostic tests continue to advance in their complexity and abundance, manufacturers face great challenges in finding support for these tests in an increasingly crowded marketplace. As innovation continues to evolve, healthcare payers and physicians are equally challenged to determine which test is the most effective and beneficial for their patient. The reimbursement of diagnostic tests has become the greatest barrier to integration and commercialization, and is currently a top priority across the industry. Now more than ever before, companies must provide exacting data proving their product has a greater value and utility than existing test methods.

As commercial payers throughout the country continue to demand higher levels of clinical evidence in order to support reimbursement, diagnostic manufacturers are left to determine how and when to best present their clinical evidence to support value and positive reimbursement decisions. One key topic to be addressed is the collaboration of commercial payers and diagnostic manufacturers to best communicate and identify the value of a test and ultimately secure reimbursement.

Another key topic to be address is the long-awaited release of new CPT codes for molecular diagnostic tests. With the first series of new CPT codes slated to take effect in January 2012, it is imperative that reimbursement executives are prepared for the implementation and utilization of the new codes.

Overall, this program will address the challenge of diagnostic reimbursement in a pragmatic and straightforward manner, allowing for conversation and frank dialogue between leading industry executives and payers. Real-time case studies, round-table panel discussions and thorough, in-depth, lessons learned sessions will provide attendees, speakers and sponsors with an ideal educational and networking opportunity. Building upon the many successful Q1 reimbursement focused conferences of the past several years, this conference promises to be an enlightening and valuable program for the participants.

**DISTINGUISHED PRESENTERS INCLUDE:**

- William Sarraille, Partner
  - SIDLEY AUSTIN

- Jamie Reynoso, VP, Emerging Business Group
  - UNITEDHEALTH GROUP

- Marie Mindeman, Director Coding and Regulatory Services
  - AMERICAN MEDICAL ASSOCIATION

- Shawn Becker, MD, VP, Marketing and Reimbursement
  - PATHWORK DIAGNOSTICS

- Rina Wolf, Vice President of Commercialization Strategies, Consulting & Industry Affairs
  - XIFIN

- Elise Berliner, Director of Technology Assessment Programme, Center for Outcomes
  - AHRQ

- Kyle Fetter, Director of Molecular Diagnostic Services
  - XIFIN

- Becky Foster, Director, Managed Care Marketing
  - CRESCENDO BIOSCIENCE, INC

- David Parker, Ph.D., Vice President
  - BOSTON HEALTHCARE ASSOCIATES, INC
9:20 CASE STUDY: COLLABORATION WITH PRIVATE PAYERS TO COMMUNICATE VALUE AND SECURE REIMBURSEMENT

As commercial payers throughout the country continue to demand higher levels of clinical evidence in order to support reimbursement, diagnostic manufacturers are left to determine how and when to best present their clinical evidence to support value and positive reimbursement decisions. While diagnostic companies may have a large amount of clinical data to support the value of their product, understanding the key trigger points for payers is paramount when presenting the information for review. Through a real-time example, this case study will explore how a diagnostic company and a commercial payer worked together to best communicate and identify the value of a test, ultimately achieving reimbursement.

- Methods for developing evidence to support product reimbursement
- Presenting and delivering evidence to payers
- Recognizing key areas of utility for payers: Cost-effectiveness, accuracy, ease of use
- Successful payer reimbursement pathways

Susan Garfield, Vice President
BRIDGEHEAD USA

10:10 COFFEE & NETWORKING BREAKS

10:30 CLINICAL UTILITY OF MOLECULAR DIAGNOSTICS - HUMAN GENOMIC GUIDANCE PROGRAM

From 2006-2010, Humana conducted a study consisting of 952 enrolled women with early stage breast cancer. The women were tested using Genomic Health’s Oncotype Dx for the probability of recurrence, the chemotherapy benefit, and the decision impact of reoccurrence score. In the end, the model estimated an average test saving of $1160 per patient resulting in immediate direct savings for chemotherapy drugs, supportive care, and management of adverse events. The adoption of the Oncotype Dx test led to targeted management of women with early stage breast cancer and an estimated on million dollars in savings to the payer. This case study presentation will examine the details of this study and Oncotype Dx’s role in the future of coverage and reimbursement for diagnostic tests.

11:20 PANEL DISCUSSION: Q&A WITH PRIVATE PAYER PANEL

Both public and private payers have specific evidence based requirements for new diagnostic technologies that must be achieved prior to obtaining a favorable coverage and reimbursement status. Diagnostic companies continually face challenges in understanding, assessing and implementing strategies for successful private payer reimbursement. Hurdles arise from difficulty in comprehending the private payer perspective on reimbursement criteria. Attendees will gain insight into perspectives of a variety of private payer representatives on the relationship between private payers and diagnostic companies.

- How do payers perceive value?
- What do payers perceive to be key drivers, indicators and influence of value?
- Why type of health economic modeling do payers like to see related to approving & denying coverage?

Jamie Reynoso, VP, Emerging Business Group
UNITEDHEALTH GROUP

Willard Harms, M.D., Medical Director, Medical Policy and Adjudication
BLUE CROSS BLUE SHIELD OF ILLINOIS

12:10 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:30 OPPORTUNITIES FOR OVERCOMING CMS REIMBURSEMENT LIMITATIONS SURROUNDING DIAGNOSTIC INNOVATION

It is well recognized throughout the diagnostic industry that decisions set forth by CMS are not always in-line with the latest and most sophisticated innovations. The lack of recognition and support for progressive diagnostic testing has made securing coverage for new tests extremely difficult, with standards for clinical evidence thresholds often unclear. This session will focus on tactics that diagnostic companies can take to create a strong working relationship with CMS to assure that products being considered are not only clinically beneficial but also cost-effective.

- Effectively presenting data and results to agency decision-makers
- Maintaining relationships and setting standards leading up to coverage decisions
- Impact of healthcare reform will have on CMS technology evaluation
- Sustainability of diagnostics in light of CMS reimbursement process

Bruce Quinn, MD., PhD, Senior Health Policy Specialist
FOLEY HOAG LLP

2:20 EXAMINING PROGRESSIVE OPPORTUNITIES IN WORKING WITH MEDICAL CONTRACTORS: PALMETTO GBA CASE STUDY

In 2010, Palmetto GBA launched a new program that is intended to increase the Medicare administrative contractor’s (MAC) accuracy rate for determining reasonable and necessary laboratory and molecular diagnostic services. Based on this program, many molecular diagnostic companies have viewed Palmetto GBA as a progressive leader for more accurate reimbursement surrounding testing services that are not listed in the current CMS laboratory fee schedule. Palmetto Medical Director, Dr. Elaine Jeter will discuss the status of the program one year after the initial launch and the future outlook for the progressive reimbursement program.

Elaine K. Jeter, MD, Contractor Medical Director
PALMETTO GBA

3:10 COFFEE & NETWORKING BREAK

3:30 ENGAGING ACCOUNTABLE CARE ORGANIZATIONS IN THE UTILIZATION OF COST EFFECTIVE DIAGNOSTICS

As a result of The Healthcare Reform Act, officially called the Patient Protection and Affordable Care Act (PPACA) of 2010, Medicare providers will soon have the option to form accountable care organizations (ACOs) to improve quality and efficiency of care. In turn, ACO participants may share financial gains from improved clinical and economic performance, considering that quality goals and patient precautions are met. As the Centers for Medicare & Medicaid Services (CMS) strives to implement the ACO option by year end, diagnostic reimbursement executives are eager to understand how this healthcare model will impact the role of diagnostics in healthcare and future coverage decisions.

Debbie Stephens Ledet
Director, Health Policy, Reimbursement & Accountable Care
GAMBRO AMERICAS

4:20 LEGAL IMPLICATIONS AND COMPLIANCE CONCERNS FOR COVERAGE AND REIMBURSEMENT

As sales and marketing teams reach out to customers, one of the first things that are asked regarding a new product relates to the reimbursement and payment status. Assuring that this information is communicated in a legal manner is absolutely critical in a market where there have been several prominent cases of misrepresentation of coding and reimbursement information for medical products. Understanding what can and cannot be communicated is the responsibility of executives handling reimbursement efforts and must be passed along to sales and marketing teams to ensure compliance.

- Complaint marketing materials
- Educating the sales team on coding information
- Maintaining effective channels of communication with marketing and sales throughout the product lifecycle

William Sarraille, Partner
SIDLEY AUSTIN

5:10 DAY ONE CONFERENCE CONCLUDES
DAY TWO / TUESDAY, NOVEMBER 8

7:30 REGISTRATION & CONTINENTAL BREAKFAST
7:55 CHAIRPERSON’S OPENING REMARKS

8:00 A LOOK AT PROPOSED REIMBURSEMENT MODELS IN LIGHT OF HEALTHCARE REFORM

The 2010 epic Healthcare Reform Act has promised to provide the US with comprehensive healthcare coverage that will ultimately benefit the economy and provide better health outcomes. As time has gone on, many diagnostic companies are asking the same key questions: what does healthcare reform truly mean for the diagnostic industry and what are the proposed reimbursement models? By understanding the anticipated reimbursement models, diagnostic companies can focus their efforts on implementing key strategies and prepare for future coverage of new products.

- Overview of proposed reimbursement models
- Understanding how payment systems evolving as a result of reform
- Private payers and their role in evolving payment models

Paul W. Radensky, M.D.
MCDERMOTT WILL & EMERY LLP
Robin Harper Cowlie
BIODESIX, INC.
Danielle Scelfo, MHSA
GENOMIC HEALTH
Becky Foster
CRESCENDO BIOSCIENCE, INC

9:00 BUILT FOR COMMERCIALIZATION: DEVELOPING A REIMBURSEMENT STRATEGY TO SPEED MARKET ENTRY

In the commercialization process for molecular diagnostic technologies, successful market penetration is inextricably linked to reimbursement strategy and execution. In this case study analysis, we review at two similar labs and analyze how marketing and execution of different billing and reimbursement policies affected performance. Key indicators, including growth in sales, average reimbursement rate per accession, and average days outstanding, tell dramatically different stories for the two labs. Discover:

- How to incorporate reimbursement into your commercialization strategy
- Which policies have the most impact on performance
- How to leverage reimbursement in the sales cycle
- What to do if you are getting to reimbursement late in your process

Rina Wolf, VP of Commercialization Strategies, Consulting & Industry Affairs
Kyle Fetter, Director of Molecular Diagnostic Services

XIFIN

9:50 COFFEE & NETWORKING BREAK

10:10 PANEL DISCUSSION: MAINTAINING AN ONGOING EFFECTIVE AND DYNAMIC REIMBURSEMENT PROGRAM

Whether you are seeking reimbursement for a newly developed test or overseeing coverage for existing products, reimbursement activities are complex and never-ending. Aside from working with payers, executives in this area oversee numerous activities such as setting billing guidelines, development of reimbursement web sites and hotlines and communicating product reimbursement with hospitals and labs. Maintaining an ongoing strategic, dynamic and effective program can be convoluted and overwhelming but not impossible. This roundtable discussion will provide attendees with shared lessons learned and best practices for managing and balancing a successful reimbursement program.

Shawn Becker, MD, VP, Marketing and Reimbursement
PATHWORK DIAGNOSTICS

Rina Wolf, VP of Commercialization Strategies, Consulting & Industry Affairs

XIFIN

11:00 PATHWAYS FOR DEMONSTRATING VALUE AND COST EFFECTIVENESS TO PAYERS ON A GLOBAL SCALE

For many diagnostic companies, obtaining coverage and reimbursement in the U.S. is just the first step in fully commercializing their new technology. Looking to global markets such as Europe, Asia and Latin America is a logical next step as companies integrate their product into the world-wide healthcare system. Although similarities in payment structures do exist, the process of securing reimbursement and funding for a diagnostic test on a global scale is extremely challenging. Understanding which markets are perhaps more opportunistic for products and recognizing what key areas of evidence payers are looking for will ensure a more successful integration of new technologies into the global market.

- Reimbursement structures OUS
- Global cost-effectiveness & comparative effectiveness requirements
- Impact of regional health technology assessments (HTA)

Stephen Hull, Principal
HULL ASSOCIATES

11:50 BREAKOUT SESSIONS: AN EXCHANGE OF IDEAS

Whether your company is large or small, IVD of LDT focused the breakout sessions will provide conference attendees with an opportunity to identify topics they wish to discuss further in smaller, more focused groups. Conference facilitators will take volunteer moderators to assist with each discussion. During the breakout sessions, all attendees, speakers and sponsors are encouraged to become active participants, allowing for better open discussion.

12:40 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:40 CHALLENGES POSED TO DX BUSINESS MODELS BY COMPANION DIAGNOSTICS AND PERSONALIZED MEDICINE

Personalized medicine offers the potential to improve well-established practices for physicians and patients, but the concept presents a direct challenge to other health care stakeholders essential to its realization — especially diagnostics companies. At the core of the challenge is the question “How will the emergence of a personalized medicine paradigm change these companies’ innovation and commercialization approaches?” This presentation will examine sources of value for companion diagnostics and discuss how diagnostics companies can retool to capture it in the future.

David Parker, Ph.D., Vice President
BOSTON HEALTHCARE ASSOCIATES, INC

2:30 UTILIZING HEALTH TECHNOLOGY ASSESSMENTS TO RECOGNIZE VALUE AND SECURE REIMBURSEMENT

Health technology assessments are playing an increasingly vital role in the decision making process of healthcare payers and providers, as they look to additional evidence based research to make decisions for both payments as well as courses of treatment. For diagnostic companies unfamiliar in working with HTAs, the process often seems daunting and potentially harmful, should the assessment return a non-favorable opinion. Recognizing how HTAs are conducted and how their findings are then disseminated to healthcare providers will ensure diagnostic companies can make the most of these studies.

- Recognizing exactly how HTAs are conducted
- Building relationships with HTAs
- Understanding how findings are distributed to healthcare

Ellise Berliner, Dir. of Technology Assessment Programme, Center for Outcomes

AHRQ

3:20 COFFEE & NETWORKING BREAK

3:40 ESTABLISHING A COHESIVE VALUE-BASED PRICING STRATEGY FOR NEW DIAGNOSTIC TESTS

As diagnostic innovation continues to evolve, the pricing environment has become increasingly challenging. Today, payers are progressively driving towards value-based assessment and as a result, evidence requirements are in demand more than ever before. Reimbursement and pricing executives struggle to define and defend the value of a test, communicate long term costs savings and justify pricing. Through understating the payers pricing perspective along with value-based pricing best practices, diagnostic companies can align their strategy for market success.

- Key evidence needed to prove value
- Understanding how payers suggest diagnostic companies price tests
- Encouraging doctors to use a test for long-term cost savings
- Value-based pricing best practices

Ravikant Avva, Pricing Executive

SIEMENS HEALTHCARE DIAGNOSTICS

4:30 FUTURE OPPORTUNITIES AND REIMBURSEMENT POTENTIAL FOR COMPARATIVE EFFECTIVENESS RESEARCH

In light of the Healthcare Reform Act, comparative effectiveness research is said to become increasingly prevalent in the coming years. Still, reimbursement and commercialization are currently significant challenges in the personalized medicine and comparative effectiveness arena. Many clinical laboratories and start-up companies looking to enter the molecular diagnostic space are struggling to evaluate the market and its true reimbursement potential. This session will examine the future outlook of comparative effectiveness and realistic reimbursement opportunities for diagnostic organizations.

- Review of comparative effectiveness role in healthcare reform
- Future landscape of cost-effectiveness & comparative effectiveness requirements
- Methods used to calculate and measure value

5:20 CLOSING REMARKS & CONFERENCE CONCLUSION
ATTENDEE PROFILE:
Executives that will be most interested in participating in this conference program will be those involved in securing reimbursement for new or existing diagnostic tests. Job titles of executives that will be most applicable for this program include VPs, Directors and Managers of:

- Reimbursement & Market Access
- Health Policy
- Payer Relations
- Government Affairs
- Health Technology Assessment
- Clinical Research
- Health Economics & Outcomes Research
- Regulatory Affairs
- Sales & Marketing

SPONSORSHIP OPPORTUNITIES:
At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Reimbursement Consultants
- Regional Reimbursement Experts
- Health Economics Researchers
- Health Technology Assessors
- Clinical Research Organizations

PREVIOUS ATTENDEES INCLUDE:
Global Reimbursement Manager, 3M
Director of Reimbursement, Abbott
Dir Reimbursement & Health Policy, Abbott
Director of Managed Care, Agendia
Director of Quality & Reg Affairs, Artemis Health
Director of Commercial Operations, Asuragen
Dir Health Policy & Reimbursement, Beckman Coulter
Director of Reimbursement, Berkeley HeartLab
Global Marketing Head, BioPlex
Senior Medical Director, Blue Cross Blue Shield
Director of Billing, Calloway Labs
Director of Toxicology, Calloway Labs
Dir Research and Planning & Administration, Canon
Director of Government Affairs, Cepheid
CEO, Crescent Diagnostics
EVP & Chief Commercial Officer, Cypress Bioscience
VP Strategic Marketing, Dako Denmark A/S
CFO, Diadexus
Chairman & CEO, Diatherix Laboratories
Director of Insurance & Medical Billing, Diopsys
CMO, Dominion Diagnostics
Vice President for Operations, Dominion Diagnostics
Vice President of Finance, Dominion Diagnostics
Director of Reimbursement, Exiqon
CEO, First Light Biosciences
Senior Health Policy Specialist, Foley Hoag LLP
Policy Manager, Coverage & Reimbursement, Genentech
Dir of Technology Assessment, Genomic Health
Chairman & CEO, Genova Diagnostics
VP of Finance & CFO, Genova Diagnostics
Senior Product Manager, GTI Diagnostics
Director, Genetics Test Evaluation Program, Hayes, Inc.
CEO, IntegraGen
CEO & President, ntrinsic LifeSciences
Director of Health Plan & Payor Markets, Ipsogen
CEO & President, JS Genetics
Vice President of Companion Diagnostics, LabCorp
VP of Sales & Marketing, Leica Microsystems
Vice President of Global Marketing, Leica Microsystems
VP Worldwide Evidence Based Medicine, LifeScan
CEO & President, LineaGen, Inc.
Payer Relations Manager, Liposciences
Associate Director of Strategic Marketing, Luminex
Executive Vice President of Research, MedImmune
Director of Managed Care Contracting, NeoGenomics
Director of Finance, NeoGenomics Laboratories
VP of Health Economics & Reimbursement, J&J
VP, Research Ventures & Licensing, Partners Healthcare
Director of Portfolio & Economic Strategy, Pfizer
Dir of Patient Services & Reimbursement, PGX Health
Senior Director of Managed Care, PGXHealth
Director of Managed Care, PGXHealth
Director of Payor Relations, Precision Therapeutics
Director of Revenue Services, Quest Diagnostics
Director of Revenue Management, Quest Diagnostics
Vice President of Marketing, Saladax Biomedical
Vice President of Managed Care, Sequenom
Director of Global Strategic Pricing, Siemens
CEO, Tissue Genetics, Inc.
Manager of Healthcare Economics, Toshiba
Director of Reimbursement Services, Ventana Medical
Director of Molecular Diagnostic Services, XIFIN