PHARMACEUTICAL REIMBURSEMENT & MARKET ACCESS

From difficulties caused by a crowded marketplace to budgetary challenges with government, private payers & consumers, companies experience greater scrutiny & setbacks in securing reimbursement. By bringing together experts on pricing, market access & government affairs & private payers, this program will provide an opportunity for executives to learn & share knowledge.

Reeling from legislation focused on healthcare reform, companies look for clarity on what it means for the bottom line. Understanding implications of the new law & how it will affect pharma industry is essential. Hearing from these executives will provide industry with knowledge on relevant data that should be presented for review. Conducting a formal assessment of government affairs is an important part of creating a comprehensive reimbursement strategy. Ongoing changes with healthcare reform need to be well understood to optimize reimbursement. While it may be some time before changes are actualized, it is never too early to forecast scenarios that will impact product reimbursement.

Creating a comprehensive reimbursement plan that begins at early phases of product development is essential in successfully obtaining coverage. Incorporating health economics data has become increasingly relevant as private payers examine more outcomes data & HTAs. Exhibiting a consistent, value-driven message is incredibly relevant, & presenters will provide insight in driving home that message to private & government payers.

This program will create an opportunity for networking & knowledge share amongst participants with engaging presentations. Presenters will bring years of experience representing major pharma & biotech companies as well as innovative & emerging leaders. Participants will walk away with tangible strategies to improve reimbursement that can be implemented with immediate impact.

PROGRAM OVERVIEW

DISTINGUISHED PRESENTERS INCLUDE:

Rami Ben-Joseph, PhD
Vice President, Health Outcomes & PharmacoEconomics
ENDO PHARMACEUTICALS
Victoria Lopez, PharmD, Med, RPh
Health Outcomes & Pharmaco-Economics (HOPE)
Field Scientist
ENDO PHARMACEUTICALS
Anna Forsythe
Vice President, Health Economics & Managed Markets
SAVIENT PHARMACEUTICALS
Michael Huffer
Senior Vice President, Medical Pharmacy Management
CVS CAREMARK
Ed Pezalla
National Medical Director, Pharmaceutical Policy & Strategy
AETNA
Eleanor M. Perfetto, PhD, MS
Senior Director, Reimbursement & Regulatory Affairs
Pfizer INC
Ana Stojanovska
Senior Director, Reimbursement Strategy and Health Policy
XCENDA
Eric J. Kruep, PharmD, MS
Director, Managed Markets
XCENDA
Diana Dobrovolsky
Principal Consultant
BRIDGEHEAD INTERNATIONAL
Jane Horvath
Executive Director, Federal Policy
MERCK
Lynn Shapiro Snyder
Senior Member of the Firm
EPSTEINBECKERRGREEN
Stephanie Dyson
Senior Director, Government Affairs
GENENTECH
Stuart Altman
Sol C. Chaikin Professor of National Health Policy
BRANDEIS UNIVERSITY
Jordan Paradise
Associate Professor of Law
SETON HALL
John D. McDermott, Jr.
Vice President
COVANCE MARKET ACCESS SERVICES
John Carlsen
Vice President
COVANCE MARKET ACCESS SERVICES
Susan Capps
Executive Director, Global Pricing & Payer Planning
AMGEN
Andrea Bare, MBA
Director, Payer and Outcome Solutions
XCENDA
David A. Pizzi
Director, Political & External Relations
BLUE CROSS BLUE SHIELD OF FLORIDA
Estay Greene, PharmD, MBA
Director, Pharmacy Programs
BLUE CROSS BLUE SHIELD OF NORTH CAROLINA
Samuel Ang
Director, Global Pricing & Market Access, Emerging Markets & Established Products
PFIZER INC
Mary Roberts
Director Market Access & Reimbursement
EISAI INC.
Burton VanderLaan, MD
Managed Care Medical Director
8:00 KEYNOTE SESSION: 2012 AND BEYOND: FORECASTING THE PARADIGM SHIFT CAUSED BY HEALTHCARE REFORM

Healthcare reform directly impacts and challenges the current landscape of the pharma industry. As most components of healthcare reform take effect in 2012 and beyond, successfully predicting what the reimbursement landscape will look like is a critical task for executives. The reimbursement world will experience a paradigm shift in 2014, and it is imperative that pharmaceutical companies prepare, as much as possible, for the unknown effects of healthcare reform.

- Examining healthcare reform changes collectively rather than individually
- Preparing reimbursement teams for future paradigm shift
- Assessing political environment and where healthcare system is headed

Stephanie Dyson, Senior Director, Government Affairs

GENENTECH

8:50 UNCOVERING THE HEALTHCARE REFORM LAW’S IMPACT ON PRIVATE PAYERS

Changes brought on by healthcare reform affect all stakeholders related to the healthcare industry including life science companies, government and private payers. Pharmaceutical companies are especially interested in understanding the impact healthcare reform will have on private payers and what actions they are currently taking in response to the potential changes and implications. This session will provide insight into Blue Cross & Blue Shield of Florida’s perspective on healthcare reform and what plan of action is being put in place to combat potential challenges that are faced related to healthcare reform.

David A. Pizzi, Director, Technical & External Relations

BLUE CROSS AND BLUE SHIELD OF FLORIDA

9:40 COFFEE & NETWORKING BREAK

10:00 UNDERSTANDING IPAB’S ROLE AND PROGRESS AS A RESULT OF THE NEW HEALTHCARE LAW

In early 2011, the spotlight was shining heavily on the IPAB as much scrutiny was directed towards it. Created in 2010 by the Patient Protection and Affordable Care Act, IPAB has the responsibility of decreasing Medicare’s rate of growth while maintaining a high level of coverage and quality. Decisions made by IPAB will essentially become law unless Congress provides a rebuttal solution with similar or higher cost-saving measures. IPAB is one of many solutions provided by healthcare reform to tackle the exorbitant rise in healthcare spending, and as a result, physicians may experience a reduction in Medicare reimbursement.

- Defining the role of IPAB
- Examining the structure and up-to-date progress
- Understanding IPAB’s influence on reimbursement policy

Stuart Altman, Sol C. Chaikin Professor of National Health Policy

BRANDEIS UNIVERSITY

11:50 SHEDDING LIGHT ON THE HEALTHCARE LAW’S IMPACT ON MEDICAID

Over 53 million Americans from low-income brackets receive health insurance through State Medicaid programs. As a result of the new healthcare law, an estimated 20 million more citizens will be added to Medicaid coverage. The new law’s provisions present State government with a host of challenges in and around the Medicaid program. Reimbursement executives should understand these policy dynamics and the interplay of State and Federal involvement.

- Understanding important Medicaid changes outlined by healthcare law
- Understanding State government concerns around Medicaid law changes
- Understanding the Federal role in addressing State concerns

Jane Horvath, Executive Director, Federal Policy

MERCK

12:30 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

12:00 - 1:00 EXAMINING MEDICAL BENEFIT DRUG MANAGEMENT PROGRAMS - THE FIRST GENERATION SOLUTIONS

CVS Caremark introduced the first medical benefit drug management program offered to their PBM and specialty pharmacy clients beginning in 2012. This service comes as a response to the difficulty health plans and employers experience in managing specialty drugs under the medical benefit. This will assist payers and providers to improve management of specialty drugs while also improving the quality of care for patients, which will in turn create a smoother process for reimbursement approval.

Michael Huffer, Senior Vice President, Medical Pharmacy Management

CVS CAREMARK

2:50 BUILDING AND APPLYING PRODUCT VALUE AND REIMBURSEMENT STRATEGY TO MAXIMIZE MARKET ACCESS

The standards for establishing pharmaceutical value and the pharmaceutical reimbursement environment are becoming increasingly complex. The complexities include the increasing demands for evidence-based value propositions, differences in management approaches, and the role of health policy. As a result, it is becoming ever more essential for pharmaceuticals to deliver real value to payer decision makers in both private and public settings. This session is designed to achieve the following objectives:

- Identify key trends both in building product value propositions and assessing the reimbursement environment
- Understand the impact of health care reform on both developing value propositions and maximizing access / reimbursement
- Discuss sample approaches to payer segmentation/stratification efforts
- Examine key components of product value & reimbursement landscape assessments

Eric J. Kruep, PharmD, MS, Director, Managed Markets

XCENDA

Ana Stojanovska, Senior Director, Reimbursement Strategy & Health Policy

XCENDA

3:40 COFFEE & NETWORKING BREAK

4:00 SUPPORTING PATIENTS AND INCREASING ACCESS IN THE NEW HEALTHCARE REFORM ERA

With healthcare reform changes looming, pharmaceutical executives work to assess the potential implications on patient access to their products. Although the number of insured patients is set to increase dramatically in 2014, patients will most likely have to pay higher out-of-pocket costs for some drugs. This poses a great challenge for patient access, and pharmaceutical companies are searching for possible solutions that will ultimately support patient needs and increase the accessibility of therapies to patients.

- Reviewing the implications of an increase in underinsured patients
- Potential effects of higher out-of-pocket costs on reimbursement
- Implementing strategies to combat a decrease in patient access

Mary Roberts, Director, Market Access & Reimbursement Services

EISAI INC.

4:50 CREATING A PRICING & REIMBURSEMENT STRATEGY TO ENSURE PROFITABLE MARKET ACCESS IN CHINA

China is growing rapidly to become the 3rd largest pharmaceutical market in the world as it improves its healthcare infrastructure and aims for near-universal health coverage of its 1.3 billion population. With such staggering statistics of a high-growth emerging market, top multinational pharma companies strive to understand the complex P&R structures in China, a critical business driver that is vastly unfamiliar to US-based companies. The Chinese government P&R system is extremely intricate and evolving rapidly. It is essential for P&R teams to thoroughly comprehend the inner workings of the Chinese pharmaceutical market in order to achieve success.

Samuel Ang, Director, Global Pricing & Market Access, Emerging Markets & Established Products

PFIZER INC

5:40 DAY ONE OF CONFERENCE CONCLUDES
8:00 • LEVERAGING LESSONS LEARNED FROM GLOBAL MARKET ACCESS AND REIMBURSEMENT TRENDS

Payers from many countries have increased their approach to regulate the pharmaceutical market on both the supply and demand sides, and assess evidence regarding the impact of those different approaches on pharmaceutical prices, cost containment, and industry innovation. Manufacturers are faced with higher demands for health economics, comparators, defined place in care, and pricing transparency. Understanding the resulting reimbursement changes provides insights to navigate and direct product development and positioning for optimal access and reimbursement. Developing the product’s value story must directly address these demands.

- Personalized medicine and transparency in the US
- Recent and pending health system trends in major and emerging markets
- Implications for development of a reimbursement target profile

Diana Dobrovyolny, Principal Consultant
BRIDGEHEAD INTERNATIONAL

8:50 • PANEL DISCUSSION: HOW DO COMPANIES PLAN THEIR MARKET ACCESS STRATEGIES?

Market access is an evolving concept that has its roots in several disciplines like reimbursement, health economics, and pricing. The biopharma industry has a diversity of models for managing market access, ranging from formal integrated groups to informal collaboration across departments. This panel discussion will explore the approaches that pharma and biotech companies of varying sizes take when they develop market access strategies for their products:

- What topics and tasks are categorized under the market access function?
- How early in the development process do companies look at market access?
- Planning for market access with internal stakeholders in other departments
- What are success stories and best practices for effective market access planning?

John D. McDermott, Jr.
Vice President
COVANCE MARKET ACCESS SERVICES INC.

Susan Capps
Executive Director, Global Pricing & Payer Planning
AMGEN

Eleanor M. Perfetto, PhD, MS
Senior Director, Reimbursement & Regulatory Affairs
PFIZER INC

Anna Forsythe
Vice President, Health Economics & Managed Markets
SAVIENT PHARMACEUTICALS

9:40 • CASE STUDY: COLLABORATING WITH HEOR EXECUTIVES TO CREATE THE VALUE MESSAGE FOR A PRODUCT

Finding the value message for a product in a competitive environment proves to be a challenge for HEOR executives, which in turn can create headwinds in achieving adequate reimbursement. Companies work to incorporate CER and other tools to show differentiation while demonstrating unique value of a product to payers. Real-world examples will showcase the creation and implementation of strategies to show product superiority in comparison to competitors and generics.

- Weaving the reimbursement mindset in the creation of a value message
- Using innovative means to demonstrate product superiority
- Strategies of product differentiation to attain high level of reimbursement

Eleanor M. Perfetto, PhD, MS
Sr. Director, Reimbursement & Regulatory Affairs
PFIZER INC

10:30 • COFFEE & NETWORKING BREAK

Stephanie is the Senior Director of Public Policy and Reimbursement (PPR) with Genentech Government Affairs. Stephanie’s specialty is to provide health care advisory and leadership in the administration of CMS’s policy, regulatory priorities and government-wide reform initiatives. At Genentech, Stephanie leads the PPR department and serves as a strategic agent on behalf of the company. Her team provides policy analysis and development on a wide range of domestic policy issues with the potential to impact all facets of the organization.

Stephanie has extensive policy and regulatory experience. She held multiple senior-leadership positions at the Centers for Medicare & Medicaid Services (CMS). In these positions she provided executive leadership in the operation and administration of key national programmatic issues such as the Medicare Discount Drug Card and Prescription Drug Benefit.
Preceding discussion: Q&A session with private payers
Pharmaceutical companies continuously face challenges in understanding, assessing and implementing strategies for private payer reimbursement. Hurdles arise from difficulty in comprehending the private payer perspective on reimbursement criteria. Attendants will gain insight into perspectives of a variety of private payer representatives on the relationship between private payers and pharmaceutical companies and the private payer rationale for decision making regarding reimbursement.

Moderator: Andrea Bare, MBA, Director, Payer and Outcome Solutions

Panelists:
- Ed Pezzala, National Medical Director, Pharmaceutical Policy & Strategy, Aetna
- Estay Greene, PharmD, MBA, Director, Pharmacy Programs, BCBS of North Carolina
- Burton VanderLaan, MD, Managed Care Medical Director, Bridgehead International

Value of collaboration between reimbursement and clinical teams
Developing drugs with a payer's perspective in mind largely contributes to the reimbursement success of a product. Reimbursement and clinical teams can work together in the early stages of drug development and clinical study design to incorporate payer requirements and expectations of a pharmaceutical product. Through understanding the perspectives and goals of both teams, an environment of positive and profitable collaboration can be formed.

- Evaluating the benefits of working with clinical teams
- The clinical team’s perspective on working with reimbursement executives
- Implementing strategies for creating products with the payer in mind

Susan Capps, Executive Director, Global Pricing & Payer Planning, AMGEN

The devil is in the details: Health Care Reform, Biosimilars and Implementation Challenges for FDA
For those engaged in drug development and regulatory issues, the PPACA placed a major regulatory challenge in front of the FDA. The Biologics Price Competition and Innovation Act (BPCIA) grants broad authority to the FDA to develop and implement an approval pathway to market for “biosimilar” and “interchangeable” biological products.

- Surveying content and scope of BPCIA and requirements for submissions
- Presenting basics of intricate patent disclosure and resolution process
- Reviewing FDA’s recent actions related to BPCIA

Clayton Paradise, Associate Professor of Law, Seton Hall University

Closing remarks & Conference concludes

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