Major transitions in technology, markets, and government policy are drastically altering the playing field and rewriting the rules of commercial success and competition in the Pharmaceutical/Biotechnical Industry. The convergence of the legislative, regulatory, commercial, clinical, and technology components of healthcare necessitates that healthcare and pharmaceutical executives be well informed across the entire horizon of reimbursement.

In the field of healthcare, reimbursement is defined as the process by which medical technologies and services are assessed for coverage and payment. Devising an effective reimbursement strategy is now a much more important measure pharmaceutical companies must take to ensure a high return on the investment (ROI) for their products. In this report, I want to share with you a number of key points companies should consider when developing their reimbursement strategy. These key considerations will help companies avoid common pitfalls and begin to build a complete, effective strategy to maximize ROI.

The reimbursement status of a product is a significant factor in determining its potential patient population and is a core aspect of securing maximum ROI. Ensuring that the product achieves a highly desired reimbursement status over its life cycle should be a primary component of the business strategy for all biopharmaceutical companies.

Ironically, according to Datamonitor, a key industry research source, many executives stated that their companies were failing to commit adequate time and resources to the reimbursement challenges that they will eventually face. More than ever before, as companies go through the various development phases of bringing a new drug to market, the alignment of drug development and demonstrated value of the new product is essential.
Navigating the United States Private Insurance Landscape

Although there are currently 46 million uninsured, the majority of Americans have health insurance coverage. Most coverage is through a third party payer, either an employer sponsored health plan or a government funded program such as Medicare or Medicaid. It takes careful planning on the part of companies to successfully navigate through the maze of a patient’s access to products. This is a critically important skill for companies to master.

Starting from launch and working backwards is a primary best practice for reimbursement. As a company moves a product through the R&D process (i.e. from drug discovery to preclinical to Phase I and Phase II), the typical steps include safety and efficacy trials. However, these various steps must now account for a reimbursement and value strategy. Even the design of Pharmaceutical economics trials will be a critical step in meeting the requirements of the multiple regulatory and payer bodies. Doing this well requires a broader set of organizational capabilities than many pharmaceutical and healthcare companies have traditionally possessed. To put the right people in place to ensure success, many companies have chosen to create a team to deal specifically with reimbursement-related issues. Some have hired former government employees who worked in beneficiary reimbursement or those who worked as employees of commercial payers and managed care organizations.

Key Considerations for Reimbursement Strategies

Not every company has a reimbursement expert or team of experts on hand, so we offer some basic questions that you should consider as you build your company’s reimbursement strategy. (These are in no particular order of importance.)

1. Does your product have a value proposition that explains the economic impact as well as its clinical benefits?

2. How will patients have access to your product? Have you done a diagnosis of prescription information, financial status, and level of insurance coverage that your patient population has?

3. When do you need to begin the process of assessing the reimbursement strategy for a product in clinical development?

4. Have you considered all of your payer segments: Medicare, Medicaid, Managed Care, the Department of Veterans Affairs and employer sponsored health plans?

5. What is your payer and pricing strategy?

6. How and where will physicians use the product (outpatient, inpatient, in office)?

7. Where will patients access your product? What is the payer setting (outpatient, inpatient, in office)?

8. Who are your stakeholders for success?

9. What is the cost effectiveness profile for your product? Does it have fewer side effects? Does it reduce hospitalization time, office visits, lab tests, the need for concomitant medications?

10. Do economic trials show clear evidence of the safety and efficacy of the product and also the cost benefits to your population (i.e. for Medicare patients, what were the outcomes and costs)?

11. Have you discussed and consulted with Key Opinion Leaders on the cost and reimbursement strategy for the product?

12. Have well designed Phase II trials shown cost benefits and differentiation where possible?

These questions give your organization a head start to developing a comprehensive strategy for reimbursement. The next critical piece is to have a thorough understanding and a well thought out strategy for each of the groups that will eventually provide payment for your product. The payers can be broken down into two basic categories (private insurance and government sponsored programs), with subgroups under each.

Private Insurance

Private or commercial payers can be characterized by either the traditional indemnity or managed care. Managed Care today is an assortment of payers including HMOs (health maintenance organizations) and PPOs (preferred provider organizations).

Managed Care organizations provide prepaid health care services, including prescriptions to defined populations such as employee groups. There are three types of Managed Care Plans: Health Maintenance Organizations (HMO), Preferred Provider Organizations (PPO), and Point of Service Plans (POS). The distinguishing characteristic of managed care plans is that they place providers at risk. The risk arrangement can take different forms including capitation (physicians are paid prospectively for services) and risk pools in which the portion of payment for services are put in a pool. All of the managed care organizations have their own demands for coverage and payment of pharmaceutical, biotech, and healthcare products.
**Key Points to Consider When Developing Private Insurance Reimbursement Strategy**

1. Payers’ main goal is attempting to control costs, so you need to show how your product helps them do that. Tools payers use to do this include: prior authorization, preferred drug list, 3- and 4-tiered formularies, maximum allowable cost programs, and generic substitution.

2. Data is king. Any relevant data on the cost effectiveness or cost offset of your product will be critical to gaining optimal easy access reimbursement.

3. Each payer is different. Discover the requirements for being added to the formulary. Find out what information you will need for gaining a priority or preferred drug status of your competitors.

4. Early on (Phase II) in the development process, begin the market research to understand the possibilities of reimbursement of your product.

5. Specifically in the managed care markets, you need to think about ways to achieve your product’s potential. You will need to present your value proposition, product positioning, and pricing and contracting guidelines.

6. Develop specific messages for the managed care market audience. This includes the Chief Medical Officer, Director of Pharmaceutical Services, etc.

7. Determine who will execute your strategy. Companies need to plan who will be responsible for the relationship and interaction with the various payers. Traditionally, well-trained national account managers have been utilized.

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**Private Pay Commercial and Indemnity**

Most private pay health insurance in the U.S. is either employer sponsored programs or the self insured commercial plans. The health insurance ensures payment of the health care provider for their services to the patient. Most of these commercial insurance plans are very comprehensive in nature and combine hospital, physician services, and prescription drug benefits. Things to consider as you seek reimbursement of your products or services in this environment:

1. How does the private pay health insurance reimburse providers?

2. How much will a patient actually have to pay out of pocket?

3. Is there a formulary submission and approval process?

4. How does the private pay health insurance control its costs?

5. Are health insurance plan members required to pay a copay, deductible, or utilize a Pharmacy Benefit Manager (PBM)?

6. What relationship does the insurance have with a Pharmacy Benefit Manager?

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As you build your reimbursement strategy, careful consideration should be given to the payers’ policies. A comprehensive reimbursement strategy needs to not only consider the private insurers but also take into account the requirements of public or government-sponsored payers. A good reimbursement strategy is a vital contributor to maximum product ROI and a tool that should not be shortchanged by company management.

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**Next Steps**

We hope that this paper has given you some points to consider as you build your company’s reimbursement strategy. The next part of this series will discuss key considerations for Medic-aid and Medicare reimbursement.

We would love to chat with you as you develop your reimbursement strategy. Roadmap to Reimbursement’s author, Bill Ashton, is available for telephone consultation. Please call us at 610-725-0290 x 446 or e-mail bplevelich@ashtontweed.com with any questions or to schedule time to speak with Bill. And stay tuned for Part 2 of Roadmap to Reimbursement to be delivered to your inbox shortly.
About the Author
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Bill is a Fortune 100 senior executive with over seventeen years experience in Biotechnology management. Bill recently retired from a lengthy career at Amgen Inc., the world’s largest biotech firm, where he served as VP of Commercial Affairs and Reimbursement (2003 – 2005) and was directly responsible for strategy development and corporate activities designed for key government agencies including: Centers for Medicare and Medicaid Services, Office of Inspector General, Government Accountability Office, Office of Management and Budget, and MedPAC. Prior to that, Bill was VP/General Manager for one of the Amgen key business units where he had responsibility for sales and marketing of Amgen’s largest customer base including Health Systems, Managed Care Organizations, Commercial and Government Payors, Distribution Channel, GPO’s and Physicians’ Practice Management Groups. Bill holds both Bachelor and Master degrees in Education and is currently an Associate Professor at the University of the Sciences in Philadelphia.