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Getting reimbursement for your product in the United States

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Receiving reimbursement for your product is just as important as receiving regulatory approval.

Bringing a new biotechnology product to market can be a daunting task. The complexities of day-to-day business management are often overshadowed by the endless struggle to raise capital and the challenges of lengthy research and development cycles. The goal of achieving marketing approval is often like a light at the end of a very long tunnel and becomes an all-consuming ambition. With myriad issues facing a biotechnology company, it is no wonder that the questions of "who will pay for this new product?" and "at what price?" are rarely considered during the early stages of development.

In the United States and most westernized countries, healthcare is unique in that the consumer is rarely the payer or purchaser of the product—the payer is generally a third-party private or governmental insurer (payer and insurer will be used interchangeably within this article). Before approving a new medical technology for reimbursement, private and governmental payers analyze clinical and economic data to determine the clinical value and cost-effectiveness of the new product as compared with currently available treatments.

Reimbursement is the term commonly used to describe the complex set of rules, regulations and processes by which physicians and hospitals deliver products and services and receive payment from third-party payers (see Box 1). Although reimbursement was once considered the sole responsibility of the provider, it is now understood that to achieve sales success, companies must participate in and even lead the reimbursement process. Failure to understand the economics of the healthcare marketplace and reimbursement can relegate a potentially successful, innovative technology to commercial failure (see Box 2).

Approaching reimbursement proactively can have a positive impact both during the early stages of product development and well after product launch. Many companies analyze reimbursement as part of the early business-planning process to identify economically attractive indications and market opportunities. When working with finite resources, the ability to select the markets with the fewest reimbursement barriers can be a critical business strategy.

Getting prepared

Some common reimbursement problems companies face when introducing technologies to US markets include:

- The absence of codes that properly identify the product in insurers' data systems.
- Denials because the product has been categorized as investigational (often a function of coverage policies).
- Unwillingness of payers to approve the product and write coverage policies because of insufficient clinical and cost-effectiveness data.
- Inadequate payment to providers.

Although these challenges are not insurmountable, overcoming them can take months to years, and often involves providing appropriate clinical and cost-effectiveness evidence—evidence that should have been collected during clinical trials.

Developing a strategy.

Preparations should begin early in the product development process, starting with the development of a comprehensive strategic reimbursement

plan. Much like a business plan, a reimbursement plan will help companies identify opportunities and obstacles and craft appropriate strategies and tactics (see Box 3).

Step 1: Identify the decision makers.

The first step in reimbursement strategy development is to identify the key payer types (also called payer mix) that directly influence the use of the product. In the United States, payers include Medicare, Medicaid and private insurance. A thorough analysis of the market potential will determine the demographics and subsequent payer mix that will influence product use. Payer type is often a function of the demographics of the marketplace.

If the target market for a product is a senior population, there is a strong likelihood that Medicare will represent a considerable percentage of the overall payer mix (see Table 1). Products that address heart disease, diabetes, arthritis and osteoporosis usually generate substantial use in the Medicare population.

Table 1: How to determine the payer mix for your product

Age (years)	Income level	Employment	Health status	Payer
0–64	Average to high	Employed	Average	Private
0–64	Low	Employed/unemployed	Average	Medicaid
N/A	N/A	N/A	Disabled	Medicare
65+	N/A	Unemployed	Average	Medicare
65+	N/A	Employed	Average	Medicare/private

Step 2: Define the market model.

Once the payer mix is identified, you should then determine how similar technologies or classes of technologies are covered and paid for: the market model. This analysis provides an opportunity to measure the value that payers place on current treatment options. This process would include an analysis of the payment methodologies for the product in various care settings, such as in an acute care hospital or physician's office, or as self-administered by the patient.

Occasionally, a new technology emerges for which there is no comparable product on the market, thus making the strategy development more difficult. In such a case, reimbursement estimates of predecessor or replacement technologies can be made. Although not entirely accurate, such estimates can serve as a starting point for determining your market model.

Step 3: Identify coding gaps.

The various coding systems, which are used by payers to track products, were initially developed by universities and other private entities for epidemiological purposes to track the types and quantities of health services delivered to patients. As these systems were refined, insurers adopted them for use in payment systems. The lack of a definitive code for a product has little negative impact on its use as an epidemiological tool, but when a code is used as a payment mechanism, its absence could be disastrous.

A new code is often required to identify newly developed technology to insurers. The process requires interaction with either the American Medical Association (AMA; Chicago, IL) or the Centers for Medicare and Medicaid Services (CMS; Baltimore, MD). Depending upon the type and use of the technology, a new code could take between one and three years to obtain.

Step 4: Determine regulatory or legislative issues in reimbursement.

Fluctuations in reimbursement result from changes in healthcare legislation and regulations at the federal and state levels. It is important to identify regulatory or legislative issues that might impact the reimbursement of the product.

A recent example of regulatory change that had substantial reimbursement consequences for medical technology was Medicare's implementation of the Outpatient Prospective Payment System (OPPS) in August 2000. OPPS represented a major change in the way in which Medicare reimbursed hospitals for biologics and medical devices used in the outpatient environment.

Outlining tactics

Cultivate and train key opinion leaders.

Key opinion leaders, oftentimes your clinical investigators, must be trained to interface with insurers and coding bodies. Medical advisory boards are frequently relied upon to provide companies with clinical feedback and

support throughout the R&D and commercialization process. A similar model should be developed to support the reimbursement process. Much like a medical advisory board, key opinion leaders (KOLs) are physicians and clinicians that have experience with, understand and support your product. These individuals are often either the principal investigators during clinical trials or early product adopters. The KOLs, when properly cultivated, can become the champions of your product and facilitate the reimbursement process.

Develop strong relationships with specialty medical societies.

Coding and payment processes are influenced by various specialty medical societies in both formal and informal ways. In addition to their other functions, specialty societies represent the financial interests of their constituents to entities such as the AMA and CMS, both of whom have responsibility for various components of the coding and payment systems.

Working closely with an appropriate specialty medical society can help build support between the clinicians that will use your product and an organization that will have substantial influence in the reimbursement process for your product.

For a list of specialty medical societies and links to their websites, see AMA's web page.

Organize data to demonstrate cost-effectiveness and clinical value to insurers.

In the United States and abroad, private and governmental insurers are incorporating evidence-based medicine standards in their decision-making processes. Evidence-based medicine combines the clinical expertise of the reviewer, typically a medical director or policy analyst, with relevant clinical data published in well-recognized peer-reviewed journals. In addition, insurers are increasingly making use of cost-effectiveness analyses (CEA) to assess the financial "value" of new technologies, especially pharmaceutical or biopharmaceutical products.

Although Medicare is restricted from making coverage and payment decisions based on cost issues alone, it does incorporate CEA into its decision process. Private payers, having more latitude in their decision-making processes, tend to place greater emphasis on the results of CEAs.

Although many companies have data to support clinical effectiveness, the majority of clinical trials are structured to prove the safety and efficacy of a product and to address the data requirements of the US Food and Drug Administration (FDA; Rockville, MD) and other regulatory agencies. Trials rarely evaluate the economic end points necessary to prove the cost-effectiveness of the product. Therefore, companies need to collect information on the cost of delivering the treatment, including all ancillary services (radiological exams, laboratory tests and pathology testing, for example), and compare these costs to those associated with the current standard of care.

Develop a publication strategy and communicate clinical information to insurers.

As entities with finite resources, insurers are required to function in a cost-efficient manner while supporting an acceptable standard of medical care. To keep pace with changes in medical care, insurers constantly seek information on new treatments and technology. When seeking information, they tend to place greater value on data published in reputable, peer-reviewed journals than on data presented in other formats.

Preparing a publication strategy can ensure regular dissemination of new clinical and economic data related to your product. A successful publication strategy should include:

- A calendar that identifies the articles to be published at specific stages of product development.
- A list of targeted journals for article submissions.
- Agreements with principal investigators to publish at regular intervals.

To maximize the effectiveness of a publication strategy for reimbursement purposes, you should distribute published articles to medical directors and key decision makers at large third-party payers on a regular basis.

Conclusion

It is not uncommon for biotechnology companies with products in early stages of development to defer the reimbursement issue until product launch or delegate the responsibility to a marketing partner. But there is a value to be placed on a sound reimbursement strategy, which can translate directly into a company's royalty fee or acquisition price. Failure to account for reimbursement barriers can drive companies back to the bargaining table or even worse, out of business entirely.

Box 1: Glossary

American Medical Association (AMA). A private organization organized to represent the professional and educational interests of its member physicians.

Ancillary services. Services other than room, board, medical and nursing services, such as laboratory, radiology, pharmacy and therapy services, which are provided to patients during a course of treatment.

Centers for Medicare and Medicaid Services (CMS). A federal agency within the US Department of Health and Human Services that runs the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) programs.

Cost-effectiveness analysis (CEA). A form of economic analysis in which the outcome of intervention is measured in improved health conditions.

Coverage. Services that are reimbursable as a health plan benefit.

Coverage policies. Formal written policies identifying services that are reimbursable as a health plan benefit.

CPT-4. The Current Procedural Terminology version 4, a system of five-digit codes developed by the American Medical Association to identify medical and surgical procedures.

Health maintenance organizations (HMOs). Licensed health insurance entities that proactively manage the care of their enrollees, who are either individual policy holders or employees of corporations that receive health benefits through their employer.

Insurers. See Third party payers.

Medicaid. A US federal program that provides medical assistance for certain individuals who meet predetermined state requirements (often low-income or "medically needy" individuals). Medicaid is funded by both federal and state governments, but is administered entirely by state governments.

Medicare. A US national, federally funded and administered program that covers the cost of healthcare services for people aged 65 and over, for persons eligible for social-security disability payments for two years or more, and for certain workers and their dependents who need kidney transplantation or dialysis.

Providers. Clinicians and medical institutions that provide medical care, such as physicians and hospitals.

Third-party payers. Private and governmental insurance companies, such as Medicare, Medicaid and Blue Cross plans.

Box 2: Case study: Apligraf

Apligraf, the first medical device containing living allogenic cells to be approved by the FDA, met with coverage and payment challenges immediately after its launch in June 1998. The product, manufactured by Organogenesis (Canton, MA) and marketed by Novartis Pharmaceuticals (Basel, Switzerland), was a novel technology within a new class of technologies; it had neither appropriate coding nor coverage approval from either Medicare or private payers. At the time of its launch, the clinical benefit and cost-effectiveness of Apligraf was unproven. At $975 per unit, payers considered Apligraf a costly alternative to traditional wound-care treatments such as collagens, hydrogels and human cadaver-tissue products.

Because of Apligraf's uniqueness, Organogensis endured a protracted reimbursement process that involved educating payers about the properties and clinical advantages of its product. The ensuing reimbursement difficulties caused Organogensis and Novartis to fall substantially short of their sales goals (*Nat. Biotechnol.* **20**, 1178–1179, 2002).

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Box 3: Checklist for achieving product reimbursement

Develop a strategic reimbursement plan that will identify:

- Decision makers: key payer types for the product (Medicare, Medicaid, commercial or HMO), which are often a function of market demographics.
- The market model: the current reimbursement environment for the product, predecessor technology and competing technology.
- Coding gaps: the presence or absence of appropriate codes to identify and reimburse your product.
- Regulatory or legislative issues that might affect reimbursement.

Develop strategies and tactics to overcome identified obstacles:

- Train key opinion leaders (oftentimes your clinical investigators) to interface with insurers and coding bodies.
- Develop strong relationships with appropriate specialty medical societies.
- Prepare economic models to prove cost-effectiveness to insurers.
- Prepare a publication strategy that allows for the regular communication of important clinical findings.
- Communicate important clinical information to insurers on a regular basis.