

Is a Consumer-Directed Strategy Right for Your Technology?

Strategic investment and product development considerations need to incorporate both reimbursement and patient payment options.

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Evaluating the market potential for a new medical technology requires an in-depth understanding of a product's intellectual property, regulatory pathway, clinical application, and reimbursement potential. Performing due diligence and understanding strategic options along these four dimensions are critical to making go/no-go investment and development decisions. Consideration of how your product would be used if reimbursed or sold directly to consumers can determine its success or failure in the marketplace.



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Rise of Consumer-Directed Healthcare

The rise of consumer directed healthcare (CDHC) has altered the reimbursement landscape in many ways. The concept refers to patients or consumers who want more control of how they spend their healthcare dollars.

Through the last half of the 20th century, the percentage of healthcare expenses paid for by consumers decreased. In the 1960s, consumers paid out-of-pocket for 49% of their healthcare. By 2002, that number had dropped to 14%.¹ In this type of market, the only way for a medical product to survive is to get coverage from Medicare and private insurers. If coverage is denied, individuals are unlikely to spring for the cost on their own.

Some health industry economists and policy experts believed that consumers' lack of direct exposure to healthcare costs resulted in inappropriate levels of consumption. If consumers were spending their own money on healthcare, the thinking went, they would be more conscious of healthcare costs and use of healthcare resources.

In recent years, consumer-directed healthcare has grown rapidly. Data from 2006 showed 4% of insured Americans in CDHC plans, while a 2008 survey showed 11% of people in similar plans.^{2,3} As individuals exert more control over their healthcare expenditures, they have become more aware of where their dollars go and more savvy about how they spend them.



The growing role of direct consumer participation in the healthcare market captured the imagination of entrepreneurs and innovators. The poster child for the direct-to-consumer movement is likely Botox—an ongoing annuity stream that consumers readily pay for in cash. However, the economic downturn has threatened companies that focused their business strategy solely on consumers. It is important to understand the history and environment associated with various technologies that have been positioned in the CDHC space, especially if a manufacturer believes it is going to rely on a consumer-targeted strategy.

CDHC Payment Models

Three main payment models have emerged for medical technologies that have been marketed to consumers. They are:

1. Marketing a product to consumers for some indications, seeking coverage from insurers for others.

Allergan has seemingly mastered the strategy of getting insurance companies to reimburse the cost for their products for certain medically approved indications while marketing their products directly to consumers for other indications.

Take the example of Botox. In 1989, FDA approved the use of Botox for strabismus, or crossed eyes, in patients over the age of twelve.⁴ In addition to strabismus, Botox is currently FDA-approved to treat blepharospasm (uncontrollable blinking), cervical dystonia (involuntary neck spasms), and hyperhidrosis (excessive sweating). Most insurance plans cover the use of Botox for these indications. Allergan is also expecting Botox to be approved within a few years for the treatment of migraines and bladder control for people with spinal injuries.⁵

The most well-known use of Botox, though, is for cosmetic purposes. The botulinum toxin paralyzes muscles, making wrinkles disappear. In 2007 Botox sales increased by nearly 30% to \$1.2 billion, accounting for almost one-third of Allergan's overall sales.⁶ Despite the fact that most insurance plans do not cover the Botox injections for aesthetic indications, those procedures contributed to most of the increase in sales.⁷

Another drug manufactured by Allergan that has both therapeutic and cosmetic uses is Lumigan. It was approved by FDA to treat glaucoma, but during clinical trials a unique additional effect was noticed: eyelash growth. Allergan decided to market the drug under a different name, Latisse, and promote it as a prescription drug that helps grow eyelashes. The drug received FDA approval in late December of 2008 and David E.I. Pyott, Allergan's CEO, predicted worldwide sales of over \$500 million.⁸

Allergan has maximized the revenue potential of its drugs by getting them approved for multiple indications and correctly identifying whether to market directly to consumers or seek coverage for each indication.

2. Declining to seek insurance coverage for a product and targeting consumers directly for payment.

While some companies can position their products so that both consumers and insurance companies will pay for them, others have targeted consumers because use of their products is elective, or they failed to tailor their products for third-party payment. Many genetic testing companies have followed this payment model.

Mapping out the human genome became a reality within this decade and numerous companies have emerged to provide you with your genetic code. One of those companies is 23andMe. Founders Ann Wojcicki and Linda Avey claim that their product uses genetic determinants to provide you with information on your genetic traits as well as your susceptibility to diseases. In a widely publicized story, Sergey Brin, cofounder of Google and Wojcicki's husband, discovered after taking the test that he has a gene variant that exposes him to a higher risk of developing Parkinson's disease. Insurance companies do not cover 23andMe's genetic test, nor has the company run clinical trials to try to prove its worth to insurers. Instead, the 23andMe sells its product directly to consumers.

This direct-to-consumer approach may not be viable in the current economic environment. Purportedly to make the test more affordable for the public—but possibly because of low demand—23andMe slashed the price of its consumer genetic test in September of 2008 from \$999 to \$399.⁹ Another genetic testing company, deCODE Genetics, has tailored its tests toward chronic conditions like diabetes, cardiovascular problems, and cancers. The company is marketing its tests to corporations that want to protect their employees and insurance companies that want to limit risks.¹⁰ It is possible to have a successful product that is marketed to consumers, but neglecting to consider third-party reimbursement carries significant risks if market demand is insufficient.

3. Targeting consumer payment out of necessity after failing to obtain insurance coverage for a product.

Other companies have tried to get third-party reimbursement after having received FDA approval but have decided to target consumers directly for payment after Medicare and private insurers denied coverage. A recent example of this is computed tomography colonography, or virtual colonoscopy. In a proposed decision memo from February 2009, the Centers for Medicare & Medicaid Services (CMS) announced that they would not cover virtual colonoscopy for colorectal cancer screening since it did not provide significant clinical benefit over regular colonoscopy and may actually be worse at finding smaller polyps than regular colonoscopy.¹¹

The proposed benefits of this technology are that it is minimally invasive and more patients would be willing to undergo screening since they would find it more tolerable compared with regular colonoscopy. Its proponents insist that it's better, safer, faster, and cheaper than conventional colonoscopy.¹² However, neither regulatory approval nor

patient preference and comfort are enough to guarantee insurance coverage, especially during an economic recession.

On February 13, 2009, the American Recovery and Reinvestment Act passed. It includes \$1.1 billion to be spent on comparative effectiveness research, which has a stated goal of comparing the clinical outcomes of similar treatments. Criteria for coverage may be more difficult to meet if new products have to prove their superiority over all similar treatments. Therefore, it is important to develop an effective strategy for marketing a new product to consumers in the event that it fails to obtain coverage.

Hoping for a Market Is Insufficient

Each example cited above illustrates how important it is for product development to consider insurer payment policies and the potential market demand. A set of payment options should be identified, assessed, and acted upon. The goal is not simply to develop a technology and hope that it finds a market.

The economic recession certainly has raised questions about the viability of product strategies centered on CDHC. The market for refractive surgery such as LASIK, which is typically a self-paid, elective surgery, has suffered, while cataract surgery, which is covered by Medicare, has been relatively unaffected.¹³ Even sales of Botox, which many doctors and pharmaceutical executives anticipated would weather the financial storm, have fallen.¹⁴ Numerous companies are considering the implications of the recession on their forecasts and projections.

So how should companies think about CDHC within their investment strategies?

Third-party reimbursement planning should not be avoided simply because it is complex and difficult. Companies should assess the market for similar products, determine how much reimbursement they should expect, decide what sort of trials need to be conducted, and determine whether they should seek coding changes. Reimbursement is not guaranteed, but conducting the necessary research at the front end of the process means that decisions are likely to be more informed and companies will better understand how to navigate the process.

This does not mean that consumer out-of-pocket spending should be ignored, either. Though the recession has made it difficult for companies whose sole source of revenue is consumer spending, CDHC itself is not dead. Individual responsibility for healthcare expenditures may still be a viable and effective way to cut medical costs, and once the economy recovers, one could expect out-of-pocket payment to rise again. For now, as CDHC plans grow and consumers are increasingly in control of their healthcare spending, companies that market to thrifty consumers may have a competitive edge. Every company in the medical technology arena needs to determine the suitability of their products for different indications and patient populations. Then they need to decide whether targeting insurance companies for reimbursement or consumer spending would be more viable.

Your success depends on the strategic consideration of all your options.

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