

Payback Time

For medtech companies, conducting a reimbursement assessment can capture VC funds and make favorable payer decisions more likely.

Judith M. Hickey

Historically, pharmaceutical and medical device companies have been a safe haven for investment capital because growth in healthcare sectors continued whether or not the economy was strong. But with the trajectory of the future U.S. economy now in some doubt, the investment community is understandably skeptical about the growth potential of any industry.

Many analysts in recent years have given as the biggest reason to invest in medtech companies the increasingly aging population, particularly the ranks of baby boomers approaching senior citizen status. That argument makes obvious sense, but it's too simple. The same projected increase in the number of customers gives the healthcare community reason to be concerned about rising costs.

As the population of aging citizens grows and the costs of medical care increase, payers within the healthcare system are playing a much stronger role in determining what types of care will be covered. The patterns of their decisions will seriously affect the likelihood of new medical technology introductions being successful.

Therefore, the greatest potential for growth in the medtech field will be realized only if venture capitalists (VCs) choose their investments wisely. Savvy investors are coming to realize how important it is to understand the reimbursement environment of the companies they are considering funding.

Requests for reimbursement assessments coming from venture funding concerns and medtech companies have increased considerably in the past two years. VCs, small medtech companies looking for investment capital, and the new-venture divisions of large companies have all expressed their interest.

A reimbursement assessment gathers and analyzes data pertinent to the user groups for which a particular kind of

product is intended, the centrality of the technology to the delivery of necessary medical care, and the reimbursement history of similar products. It helps company executives and potential investors understand industry's economic conditions and potential barriers to adoption by the healthcare payer community that could limit a company's return on investment (see sidebar, page 71). Now more than ever, a strategic reimbursement assessment ought to be part of the business plan for new medical technology.

The current market conditions are making investors much more cautious. According to VentureOne (San Francisco), a leading VC research firm, VC investment has declined steadily since the first quarter of 2000, with the first quarter of 2001 showing the greatest quarter-to-quarter decrease in history.¹ The amount of money invested in medical technology rose in 2000 before this year's decline, but the number of rounds financed by VCs has been shrinking. The median amount invested in one round of financing is higher than ever. Because they invest more money per deal in medtech than they would in most other industries, VCs are increasingly cautious about making deals with medtech firms. There are many more device companies looking for funding than blocks of capital to invest. The available money will go to the best candidates.

Why Reimbursement Matters to VCs

VCs have been burned in the past by companies that gathered little or flawed reimbursement data and then represented their new product in an inaccurate light with respect to payment prospects. Private investors who thought there would be no problem with reimbursement learned only after market release that the product would not be paid for by insurers, thereby greatly reducing sales and delaying profitability. VCs need a reimbursement

Key Interests for Device Manufacturers

Device companies need information pertinent to reimbursement that will give their new technologies the best chance to be chosen for use and thus establish a secure market niche. Growth is also a goal. Answers to the following questions can help them determine how a new product will need to be priced in the marketplace, what the barriers to product acceptance might be, and what kind of support services customers will expect to ensure payment by third-party payers.

What is the reimbursement and competitive environment for products used to treat the condition or disease? If competition is considerable, there may be extensive pricing pressure.

What are the payment rates for various therapeutic options to treat the same disease? If other options are less expensive than the technology being considered, then prospects for a reduction in overall costs must be evaluated. Another response might be to position the product on the basis of improved patient outcomes.

Are competitors providing services to help customers gain appropriate reimbursement? If yes, the manufacturer must determine whether it can provide the same services or better, and at what cost to the company.

assessment that is objective and based on factual data. They often want an outside resource to evaluate a technology's reimbursement potential. Private consultants, payer representatives, other companies in the same field, medtech associations such as the Medical Device Manufacturers Association (Washington, DC) and AdvaMed (also Washington), and the Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Financing Administration; Baltimore) have all been reliable sources of such information.

Knowing that reimbursement is becoming a major hurdle in the path to product and business success, VCs want to be apprised of any possible issues in this area and whether they can be overcome (see sidebar, page 73). The days of developing a medical technology for quick adoption in the marketplace are virtually over, unless the technology significantly reduces healthcare costs or addresses an important unmet need. Examples of young technologies that have been welcomed by both healthcare providers and payers because they satisfy these conditions are laparoscopic intervention and home glucose monitoring. Laparoscopic surgery had to dispel the initial perception that it was a costly technique because the cost of the equipment used in this intervention was higher than that of conventional surgical instruments. It did, by reducing hospital stays and ancillary costs, and thus overall healthcare costs. Home glucose-monitoring systems make it easier for patients to monitor their glucose levels regularly, helping patients and physicians manage cases of diabetes more aggressively and ultimately reducing costs

associated with debilitating complications from the disease.

In the past, regulatory approval was the driving force for product acceptance. Once a product's safety and efficacy had been confirmed, physicians would start using it and payers would handle the necessary costs. But now, with managed-care organizations (MCOs) and Medicare determining ahead of time what procedures and therapies they will cover, the healthcare system is becoming increasingly sensitive to the cost of medical technology.

Pressure exerted on healthcare providers by MCOs has resulted in inadequate reimbursement rates for some procedures and a demand for supplier services to be bundled with product purchases in a single price. The heavy hand of the MCO has further

dampened medtech development by bringing about reduced contract pricing for volume purchases and slower rates of purchasing for expensive capital equipment. Any concepts for new medical technology or modifications to existing technology must now be evaluated as to how easy it will be to gain reimbursement. Physicians may be hesitant to adopt a new technology without a clear understanding of whether payers will adequately cover it.

Hearing aids, for example, are not covered owing to a statutory exclusion in the Medicare provisions, and private insurance generally will not pay for them. Unless their cost is modest, this could be a barrier to product acceptance. Hearing aids within a price range that patients will accept do have a market. But a company developing a sophisticated hearing-restitution technology that also requires surgical intervention and involves a total cost of \$25,000 will confront a barrier to acceptance under current coverage provisions. Certain products that treat severe hearing loss, such as cochlear implants, are, however, covered by the payer community.

Even reasonably priced technology can run into reimbursement limitations. With procedure costs being bundled together under all-inclusive payment codes used by Medicare and followed by other insurers, hospital charges, product costs, and ancillary charges are all part of a single, restricted reimbursement rate. This results in the healthcare system scrutinizing every charge and pressuring device companies to keep costs down.

For example, physicians may use a coronary thrombectomy device to remove thrombus prior to a percutaneous transluminal coronary angioplasty (PTCA) procedure and stent placement. Only the PTCA procedure is reimbursed. Payment for the other procedures is bundled into the PTCA reimbursement at a set rate that does not increase to accommodate costs of the additional procedures conducted at the same time.

As VC firms become more aware of reimbursement issues like these, they demand more information from medtech companies with new products to market.

CID Equity Partners (Chicago), for example, was analyzing a company developing a therapy to treat benign prostatic hyperplasia. The investors told the manufacturer to include reimbursement assessment activities in the funding requirements section of its business plan. They felt there had to be a budget for conducting an appropriate reimbursement assessment and then addressing the issues prior to and following market release. Without a line in the product development budget for reimbursement assessment, VCs may choose not to invest.

Reimbursement assessments can vary dramatically in price depending on the complexity of the reimbursement environment and the answers to the following questions.

- Does reimbursement exist for similar technology?
- What are the payment rates?
- Is the product primarily for use by the Medicare population or by a variety of age groups?
- Does the medical community consider the technology reasonable and necessary?

A positive reimbursement decision will not be easy to attain unless the answers point strongly toward the technology having appeal to MCOs.

Many VCs insist on the necessity of understanding the reimbursement environment for a new technology and on funding analysis of it. Gregg Tobin, principal of CID Equity Partners, sees hospital and physician purchasing groups being more sensitive to issues of reimbursement for new technology. Before buying, they want to know how quickly they will be able to recoup their investment in capital equipment based on the reimbursement rate per procedure. If reimbursement does not exist, there must be a very compelling reason to use the product.

This attention paid by VCs to reimbursement and their willingness to fund analysis and a tactical plan are new. It stands in contrast to the past practice of companies who often tried to deemphasize reimbursement because

of the possible negative effect on chances for obtaining venture capital.

What to Include in a Reimbursement Assessment

To adequately understand how reimbursement issues can affect their company's prospect for success with a new product, medtech executives should gather the information outlined in the following sections as a first step toward producing an analytical reimbursement assessment. Of course, the company will also collect data from clinical trials.

Who Will Pay for the Product? Possibilities are private insurers, MCOs, workers' compensation, Medicare, Medicaid, and patients themselves. Data on the payer mix are available through the National Center for Health Statistics (Hyattsville, MD) and several private information vendors.

Therapeutic Delivery Sites. All possible healthcare contexts in which the product might be used should be determined. These could be the physician's office, ambulatory surgery center, hospital outpatient or inpatient clinic, skilled nursing facility, long-term care facility, or patient's home. Each site has its own coding structure. Current coding books are *Current Procedural Terminology*, available from the American Medical Association (AMA; Chicago), and the CMS *Common Procedure Coding System Level I* and ICD-9-CM manuals.

Current State of Coverage. The manufacturer should conduct research to determine whether the product or procedure is currently reimbursable. FDA clearance does not ensure coverage. The research should also discover whether codes for products in the same category exist. Medicare's coverage manuals are on-line at the CMS Web site. Many commercial insurers make coverage policies available on their Web sites as well.

Published Clinical Results for Use Indications. It must be established that clinical studies have been completed and reported, and that they included the appropriate patient population. Peer-reviewed journals are the most credible venues for clinical reports from the payer perspective. Manufacturers should encourage clinical investigators to submit papers to journals such as *The New England Journal of Medicine*, *The Journal of the American Medical Association (JAMA)*, or specialty journals related to the technology. Of course, any article must be accepted for publication to be given credence.

Associated Costs. Costs associated with use of the product besides the cost of the device itself should be calculated. This determination would include diagnostic testing, laboratory costs, drugs used during or after a procedure.

procedure involving the device, cost of the procedure, and any follow-up.

Actual-Cost Data. To be able to demonstrate whether the technology will add or reduce costs to the healthcare system, the manufacturer must, during the clinical trial period, work directly with hospitals or clinics to gather cost and charge data. Anecdotal information will not be accepted.

Current Standard of Care. The manufacturer must research current practice guidelines for treating the disease or condition its product is intended to ameliorate. New technology should fit within normal practice guidelines and be able to demonstrate a favorable contribution to longer-term outcomes. When reviewing the current standard of care, a company must be able to demonstrate that its technology equals or is better than the standard—that is, that patients using the product would be released from the hospital more quickly, become ambulatory sooner, require less drug therapy, and so on. Sources of this information are medical professional organizations such as the AMA and the American College of Cardiology (Bethesda, MD) and governmental agencies such as the Agency for Healthcare Research and Quality (Rockville, MD).

How Small Companies Are Responding

Small medical technology companies are beginning to draft business plans that include a reimbursement assessment for the benefit of the board of directors. VCs sit on the boards of many small companies, and they are asking questions.

Kris Johnson, general partner with Affinity Capital Management (Minneapolis), participates in several companies' board meetings and feels that more and more medtech executives have a clear understanding of the challenges their companies face in gaining reimbursement. "Management often knows they must conduct a reimbursement assessment early," she says. "Several companies we work with have initiated reimbursement discussions prior to the clinical study phase." Commonly, companies have waited until after clinical trials to pay attention to reimbursement. "Gaining reimbursement is just as important as obtaining regulatory clearance for many companies," adds Johnson.

Key Interests for VCs

Venture capitalists (VCs) contemplating funding a medtech company with a new product to introduce want to know whether the technology will be likely to win the favor of payers and thus possibly become a market leader in a short time. Reimbursement issues of interest to them include the following.

What are the economic sensitivities for products in the same therapeutic category? This can be learned by reviewing clinical practice guidelines for the disease or condition treated and finding out the payment rates for different options at various sites of service.

Who will ultimately pay for the product? Will it be the patient, physician, hospital, Medicare, private insurance, workers' compensation, or some other agent? Determining how the product will be used, and in which setting—whether in the home, the physician's office, or the hospital—can help define who will pay for it. So can ascertaining the age of the patient population.

Does reimbursement exist for the technology and will it be adequate to justify widespread utilization of the product? Reviewing current reimbursement codes and existing payment rates can help a manufacturer learn whether the technology will be adopted quickly or will have a difficult time being accepted in the marketplace.

Spiration Inc. (Redmond, WA), founded to develop novel treatments for chronic obstructive pulmonary disease (COPD), has three VCs on its board—Richard Lin, MD, partner at Three Arch Partners (Menlo Park, CA), Sigrid VanBladel, PhD, partner with New Enterprise Associates (also Menlo Park), and Rebecca B. Robertson, founder and managing director of Versant Ventures (also Menlo Park). Often, VC firms focusing on medical device companies include people whose extensive knowledge of industry can deliver valuable insights to a manufacturing company positioning itself for growth.

Early in the product development process, Spiration conducted a complete reimbursement assessment to learn the intricacies of payment issues surrounding treatment for COPD. The intention was to be able to answer all questions from the company's management and funders, and to develop business plans that include reimbursement strategies.

The product definition stage is not too early to produce a reimbursement assessment. In fact, the earlier the assessment is completed, the easier it is to modify a product during development to improve its chances for being deemed reimbursable. A solid product definition is necessary, or else the reimbursement assessment can be flawed. And an inaccurate assessment may be worse than worthless.

Also at an early stage, the company needs to be sure of the patient population for its products, the sites of service

where the product will be used, and any other treatment options currently in use to diagnose or remedy the disease or condition.

Product Definition. A new technology may potentially be used on different areas of the anatomy to treat different conditions. A good product definition will select one application for the device, usually where a need is currently unmet, and specify how it is to be used in one part of the body. It will also pinpoint which kinds of practitioners at which sites of service will use it to achieve cost reductions. This information is critical for setting the direction for reimbursement. Other applications can be pursued individually, and need to be. It is not feasible to get a blanket reimbursement for multiple uses, because of differences in coding and payment rates.

Patient Population. The device manufacturer must clearly understand which group of patients can expect to benefit from its product. Identifying the appropriate population is key to several strategic decisions. For example, if the patient population includes or is limited to those under the auspices of Medicare, it is important to analyze Medicare's policies within the therapeutic category. If Medicare doesn't cover the procedure, the company must look at other payer options, such as payment by the consumer, and consider the impact of reimbursement on its regulatory strategy. Of course, a determination of which patient population is suitable for a developmental device has an important bearing on recruitment for clinical trials and for marketing the approved product as well.

Therapeutic Sites. A product may be defined as much by where it is used (which may also mean how it is used) as by on whom it is used. As mentioned in the previous section, a valid reimbursement assessment will accurately reflect all possible settings in which the product may be therapeutically administered.

Clinical Trials and Product Approval. Tailoring a new product for a 510(k) regulatory filing may not be the best strategy if the product will be more expensive than substantially equivalent predecessors. Also, it is not uncommon for a company pushing for a 510(k) to cite a precedent product that may not be appropriate. The 510(k) may be a quicker route to regulatory clearance, but a demonstration of product equivalence will limit reimbursement potential.

A premarket approval (PMA) application could be a superior strategy, one with obvious implications for the direction of technology development for the new device. Data collected during the clinical trial program can help to establish new indications for use and improved patient outcomes, which could justify a relatively high product price. These data can also be used to support product differentiation claims. While a PMA takes longer to traverse

the clinical and regulatory phases than the 510(k), the greater likelihood of attaining adequate reimbursement in the marketplace can make the delay worthwhile.

During clinical trials, companies may want to charge for new technology in order to establish a procedural cost history, says Susan Rowinski, senior director of marketing at PharmaSonics Inc. (Sunnyvale, CA). Charging for use of the product enables the healthcare system to track costs and capture them in its databases.

"This can be especially useful when coding does not exist for a technology," she notes. "Charging for an investigational device provides an opportunity to create a code for reimbursement that is defined by specific features and applications."

Failing to consider reimbursement questions early in the product development process may come back to haunt a company. Delays of 3, 5, and even 10 years between the time FDA clears a product for marketing and the time the device gains reimbursement have occurred. Needless to say, investors are concerned about such delays.

Medtech companies that deal with reimbursement issues early will be better prepared to satisfy requirements of the payer community. They will know up-front what demands need to be addressed.

Rowinski continues, "When existing codes are not appropriate, it will take time to obtain new codes. Starting this process during clinical trials puts the product in a better position for a positive reimbursement decision at market release."

How Large Companies Handle Reimbursement Concerns

Large medical device firms generally have reimbursement specialists on staff who will conduct reimbursement assessments. This is in contrast to small companies, which are more likely to rely on outsourcing the information-gathering function.

Often, small companies will decide that they don't need to look into reimbursement issues if they have an exit strategy to license or sell a technology to a larger company that will market the product. This could not be further from the truth.

Large companies want to know what potential reimbursement problems exist in advance of licensing or acquiring the technology. Because they have staff experienced in the reimbursement area, such issues do not necessarily turn them away from the business arrangement. However, if the obstacles are too great, they may look elsewhere.

Larger firms might consider acquiring new technology from smaller companies in order to expand the range of

therapeutic options they offer. Or perhaps they wish to diversify into other areas where they have not previously participated. In either case, major medical device companies will conduct top-line reimbursement assessments on new technology to provide guidance for their internal specialists to use in devising a plan to address the issues.

Conclusion

Conducting a reimbursement assessment provides medtech executives with valuable information that can help to clarify the strategic direction of the business, improve the chances for product success, and, increasingly important, provide answers to questions that will come from potential investors. Following are some of the key things that managers will learn.

- Whether reimbursement already exists for products in the same therapeutic category, and whether established rates will be adequate to cover the price they hope to charge for the product.
- If reimbursement codes and payment rates do not exist, how difficult it will be to gain reimbursement and what must be done.
- Whether current practice guidelines will block the introduction of a new technology and make it nearly impossible to gain reimbursement without substantial effort and cost.

Companies that do not have a reimbursement specialist on staff are encouraged to consider using an outside resource to help them gather and interpret assessment information accurately. Reimbursement issues are complex. A qualified outside specialist with extensive experience in this important area will keep a medtech company's managers focused on the most pertinent issues and direct the company's efforts along the most cost-effective and advantageous route to a positive reimbursement decision.

And companies that stay on top of the reimbursement challenge will be in a better position to attract investment funding and see business growth.

Reference

1. "The PricewaterhouseCoopers MoneyTree Survey in Partnership with VentureOne" [on-line] (San Francisco: VentureOne, 2001 [cited 1 May 2001]); available from Internet: <http://www.ventureone.com/ii/FR1Q2001.xls>.

Judith M. Hickey is president of Princeton Reimbursement Group (Minneapolis), a firm that provides strategic assessment services to the medical device industry. ■