

Reimbursement: Plan Early, Says US Compliance Consultant

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Thinking about the reimbursement implications of a product should be done at the product development stage, argues John Avellanet, managing director of Cerulean Associates. Here, he tells *Clinica* readers how to start the process of building reimbursement expectations into the design stage and what pitfalls to avoid

Traditionally, reimbursement tends to be something that is reviewed and determined as the product gets close to market approval.

However, given the high cost of developing new medical products - something that is likely to continue as we develop new knowledge, new technology and new combinations - figuring out if and how profitable a medical product will be is not something we want to leave to the end of the expensive development process.

Ideally, it is something that we want to know as early as possible. This allows us to take true advantage of the "fail fast, fail early, fail cheaply" mantra.

If I know I'm only ever going to be able to get my new product reimbursed at a rate equivalent to \$20, then I better make sure I can make it for some amount less than \$20 that covers not only my manufacturing and compliance costs but also all my development costs (and potentially, my development costs from other failed products or projects).

So, when we think about any medical development process, there are some key decision-points and key planning points where having at least a preliminary idea of what our potential reimbursement rates are, can be extremely helpful.



John Avellanet: "The challenge is how to get regulatory affairs, reimbursement, clinical, preclinical, engineering, manufacturing, supply chain and quality management people, among others, all talking together rather than at each other."

The pre-trial period

The period before clinical trials are initiated is one point at which we might want to assess competitor products already on the market, or, if our new product is truly unique, then we assess the adjacent products or treatments.

This requires a review that includes the reimbursement levels of those other products and treatments. This may also lead to assessments of our prospective patients as well as healthcare providers.

For instance, what drives physicians to use/prescribe a product for which the patient will not receive full reimbursement? This then drives questions around what type of data - which means what studies, what clinical trial components - do we need to design in order to provide the information the doctor wants to see to prescribe our not-fully reimbursed medical product to his/her patients?

Advantages of thinking ahead

There are three advantages that a company gains when it thinks ahead. First, a firm can very quickly determine its potential revenue points such as whether the new product will be profitable, and how profitable will it be.

For a firm with a portfolio of profitable products, having the isolated unprofitable product may be acceptable. However, the reverse also holds true: if a firm has a series of products that are not profitable or are barely breaking even, knowing at least a preliminary level of reimbursement early in the development of a new product will help the company answer a key shareholder question: can we afford to develop and commercialise this new product?

Secondly, with these prospective profit points in mind, executives can then ask: “What can we do in the rest of development to clearly show that this new product deserves a higher reimbursement rate (from insurers and other payers)?”

One of my clients developed a wound care product that was originally slated, based on comparisons with other products on the market, to be a particular level of reimbursement associated with competitor products already on the market. They brought in an outside reimbursement consultant who then provided insights into what they would need in order to justify a higher reimbursement rate.

With this information in hand, my client then identified tests within the development period – disintegration rates, biologics absorption rates, materials schematics – that they could then use to justify a request for a higher reimbursement rate (in other words, not to be lumped in with their prospective competitors and provide themselves with a competitive edge).

As a result of this, they then developed a simple product-to-product visual test to show the reimbursement specialists (from insurers) that demonstrated why this was the superior product and had a superior level of efficacy and safety.

Thus my client's new product warranted the higher reimbursement rate. Not only did they get that higher rate, but two of the private insurers decided they would reimburse the product at a rate level two stages higher, so impressed were the insurers with the data and the visual demonstration.

The third type of competitive advantage this provides is a longer-term one: it allows the firm to better position itself to compete with the inevitable copycats and knock-offs and lower-cost competitors that might come from overseas or come about in the future.

It's a bit subtler and not so obvious, but by knowing the total cost of development and production versus the likely rate of reimbursement, the firm can streamline and simplify its internal processes, such as around quality systems and regulatory affairs, to give it the best buffer or margin to be able to adjust to eventual competitors.

Pitfalls

Among the pitfalls of not thinking ahead, there is an obvious one. A company spends millions on design, development, validating the process, clinical trials and submission and then comes to find out that they can't make money selling it.

It seems obvious, but one of my clients produced a product that cost them \$250 to make and yet they could only get it reimbursed if they marketed it with a \$180 price tag.

They brought me in to help them optimise their regulatory affairs and quality systems structures and processes, but even that was not enough to make up all of this type of differential. There's only so much streamlining and productivity improvement you can do after the fact.

Another pitfall to watch out for is this: it's crucial that a firm uses preliminary reimbursement numbers to figure out when the product will make back the cost of its entire development effort.

Let's say you have a patent on a product that lasts 20 years. Now, that's nice in the textbook, but the reality is, you're going to get the patent long before you hit the market - you may have eight, 12, 14 years of patent protection on the market.

What if you cannot turn a profit in that time? Say, for instance, in eight years of clear patent protection, you cannot make up all the costs you spent in development and design. Preliminary reimbursement can give you the ability to figure this out.

Also, at a global level, we all know that some countries put up barriers that say "well, if you want to sell your product here, it has to be at this price point". If you know, early on in your development efforts, that in order to get this product into a particular market, it had better be at a

specific price point, then you have questions to answer early on, such as is it worth it? Where can you make up the difference?

Without figuring out preliminary reimbursement levels and strategies, you leave your company open to far too much chance. And isn't medical product market approval and profitability enough of a gamble already? Why stack the odds against yourself?

Bring in the specialists

If you do not have reimbursement specialists in your company, you need to talk to an outside reimbursement consultant.

As a lean compliance proponent and advisor with insight across the product development spectrum, I have seen the most return on investment in bringing in a reimbursement expert at the preclinical stage of design and development. Have the outside expert provide insight into the reimbursement levels of comparative products as well as what differentiates adjacent levels (products in higher and lower rates). This information can then help drive your development and design decision-making.

That said, all of my clients reiterated a follow-up to this: many reimbursement consultants are not comfortable discussing reimbursement rates early in the development process; they are used to focusing on products closer to the finished look and feel, not early prototypes.

Thus, use the reimbursement consultant's expertise to get competitive intelligence on potential reimbursement rates. Knowing your options for potential reimbursement levels can also help you further define your prospective patient and customer.

Your customer is not just the patient – customers also include the hospital administrator and the physician, among others.

Getting a handle on reimbursement rates early helps you start strategising about targeting your message to each of those customer types. What studies might a doctor like to see versus a nurse? Does the target patient population worry about reimbursement or is this something that is not really a good selling point?

Who are the competitors in this reimbursement range and what is their level of efficacy? What improvement in efficacy speaks to customers? If customers have to pay extra out of their pocket for a new product because it's not going to be reimbursed, what improvement in efficacy or safety will justify the extra cost? What tests and trials need to be conducted to demonstrate those improvements in efficacy or safety?

Pay to play

There are several "pay-to-play" agreements on the books already (market approval is conditional upon certain levels of efficacy and safety being maintained - for patients who do not see these levels, the company has to pay for the cost of treatment).

Knowing the potential reimbursement rates early on can give firms a better negotiating hand. It can even give the company the initiative to offer this type of deal.

One of the hardest tasks is putting together a cross-functional team to identify, incorporate, plan out, track, and follow-through on building in reimbursement early in medical product development.

The challenge is how to get regulatory affairs, reimbursement, clinical, preclinical, engineering, manufacturing, supply chain and quality management people, among others, all talking together rather than at each other.

How can executive teams get these very diverse professions and areas of specialty speaking the same language? How can executives drive these groups to a set of common plans, procedures and protocols, triggers, achievements that can then be incorporated, tracked, and reviewed all along development?

There are some key tactics such as stage gates, regulatory affairs road-mapping, and clinical regulatory integrated strategic plans, that I discuss in detail in my book, *Get to Market Now*, that can help firms put these cross-functional structures in place and ensure they operate as smoothly as possible. And it's these tactics and strategies, such as bringing in reimbursement considerations as early in development as possible, that help traditional support services such as regulatory affairs and quality management provide direct, tangible bottom line benefits.

John Avellanet is the author of *Get to Market Now*, offering strategies and tips on how firms can turn compliance into competitive advantage. The book will be published in May 2010 through Logos Press in the US. Mr Avellanet can be contacted via Cerulean Associates at www.ceruleanllc.com.