A parallel revolution: payment for new in vitro diagnostic technologies

LINDA P. IVOR

To secure a successful product in today's era of cost containment, manufacturers and developers of new in vitro diagnostic technologies must consider payment issues—coverage and reimbursement by healthcare insurers—as critical market forces that must be addressed in the business plan. Similar to the regulatory hurdles involving 510(k)s and premarket applications, the requirements for payment are related to the unique features of the technology, its costs, and its effect on clinical outcomes. Because cost containment continues to be a driving force for change in healthcare, the business plan must not only include strategies for optimal payment at the product's introduction, but also contain provisions for continuous monitoring of the payment environment throughout the product's life cycle.

INDEXING TERMS: outcomes • reimbursement • business plan • coverage

Innovation is the hallmark of the in vitro diagnostic industry—an industry that includes developers and manufacturers of clinical laboratory tests. In most cases, innovative products have met with few obstacles, with the clearance or approval process of the US Food and Drug Administration (FDA) serving as the primary hurdle and the implementation of a successful marketing campaign as another.¹ Today's revolution in technologies has challenged the FDA to review its processes to adapt to new levels of analytical sophistication; in response, changes are being made. In the area of sales and marketing, however, a new gatekeeper has emerged in response to the efforts by federal and private sector healthcare insurers (payers) to contain costs. As a result, innovators face new demands to demonstrate the value of their product to healthcare in addition to its safety and effectiveness. To ensure success, manufacturers now must assess the product's value to healthcare at the feasibility phase of development and continue this assessment throughout the product life cycle.

THE VALUE STORY
Defining healthcare value is hardly an exact science. In general, the value of an in vitro diagnostic test is based on its accuracy, reproducibility, and conditions for use. These qualities may be considered intermediate to the overall value of the test, which includes the associated costs of obtaining a test result balanced with the health consequences to the patient as a result of having the test performed. More simply stated, the value is the sum of costs plus health consequences (outcomes). Costs must include all aspects of testing, including kit costs, personnel and overhead, repeat testing, standards or calibrators, and controls. In this equation, high costs will tend to bring value down, whereas low costs may help to improve value. Outcomes must consider what happens to the patient's health as a result of being tested. For example, if according to an established treatment protocol the test results are an indication for further medical intervention, the patient may have improved health outcomes for having prevented further disease. Conversely, the patient may have poor health outcomes if misdiagnosis leads to unnecessary procedures and potential morbidity. As with costs, good or poor outcomes will tend to influence the value equation with an additive or subtractive effect.

The balancing of costs and outcomes is the primary determinant of value. Some tests may have low costs and high outcomes, making the value quite high. Other tests may have high cost and poor outcomes, resulting in an undesirable low value. Most tests will fall into a middle area, where costs and outcomes are counterbalanced. For example, a test's high outcomes may be seen as so desirable that concern about its high costs (a subtractive factor) is minimized. Or a test's costs and outcomes may be low except for a narrow patient population for whom it improves outcomes.

Using the value assessment, the manufacturer has the opportunity to determine whether product enhancements are needed. For example, the product design may require modification of its projected clinical sensitivity and specificity to ensure a higher product value, or the marketing plans may need to be refocused on selected diseases or patient populations. Later, the value story should be reassessed by using the data generated during the

278 Dolphin Cove Court, Del Mar, CA 92014. Fax 619-350-0824; e-mail livor@sol.com.

¹ Nonstandard abbreviations: FDA, Food and Drug Administration; CPT, Current Procedural Terminology; and PMA, premarket application.

Received May 29, 1996; accepted July 8, 1996.
clinical trial. Using this larger database will help provide a more
accurate estimate of the product's value.

Although payers are increasingly requiring justification for
coverage of new technologies, a value story is not always
required. In general, a test's value would not be critical when it
is obvious that the cost of testing and the patient's health are not
negatively affected. For example, if a product is shown to be
substantially equivalent to an existing product and the cost of
testing is less than that of the predicate device, the value is
simply that of minimizing cost. For other situations, several
questions may help determine the need for a value story:

1) Does it have uncertain health outcomes? A new technol-
ogy may affect changes in medical practice without first estab-
lishing a long-term health benefit. This would also apply to
established technology that has been tested for a new intended
use.

2) Is its use controversial? The medical community and those
in allied healthcare fields are using more sophisticated means of
designing investigations and analyzing clinical data, often with
conflicting conclusions. This may place the payer's coverage
decisions on hold, which will further delay use of the technol-
ogy.

3) Does it increase costs over current practice? That is, is use
of the new technology more expensive than the diagnostic
method that is being replaced? Any test or procedure that will
increase costs will require justification for payers to provide
coverage and offer reasonable reimbursement.

4) Is it subject to high utilization? All payers review the
frequency of use for any covered product or procedure. If it is
anticipated that a product or procedure will be used or is being
used more frequently than expected, the cost and health benefits
must be established.2

Any new product or medical procedure that meets any of
these criteria has a high probability of needing a value story to
obtain coverage.

INCLUDE PAYMENT STRATEGIES IN THE BUSINESS PLAN
Because today's in vitro diagnostic market is increasingly de-
dent on the coverage offered by payers and, as an ancillary,
coverage at an optimal reimbursement amount, payment plan-
ning must become part of the business plan. Without a payment
strategy, even the most innovative and relevant of technologies
will have a diminished market introduction because of the lack
of coverage and adequate reimbursement for potential custom-
ers. Although this is not the primary determinant of a successful
product introduction, addressing these payment activities in the
business plan will help to ensure a stronger market entry with a
shorter time before coverage is offered and sales begin.

EARLY ASSESSMENT OF PAYMENT ENVIRONMENT
At the feasibility phase of development, the payment environ-
ment as well as the targeted market should be evaluated. Cost
assessments should include both those costs associated with
current medical practice and the reimbursement amount for any
competitive products or methods. Is there an existing CPT code
(a Current Procedural Terminology code, used for billing
purposes) that fits the new technology? Does it code for a
reasonable reimbursement amount? If there is no CPT code,
should the application process begin now, assuming that it takes
1–2 years to complete? Have medical guidelines been estab-
lished for treating the disease state? Would the technology
easily fit into the protocols defined in the guidelines? If the
technology needs a value story, one must determine what
economic and health benefit data are necessary. Because the
payment environment may change at any time from the feasi-
ibility phase to market entry, it is important to schedule future
assessments at meaningful time points to ensure that the same
conditions are in effect.

INCLUDE ECONOMIC QUESTIONS IN THE CLINICAL TRIAL
DESIGN
For those technologies needing an economic justification as part
of the value story, the clinical trial design should address
associated costs as well as clinical sensitivity and specificity.
Following treatment pathways established by the clinical inves-
tagors, developers should determine the cost per test result and
the cost of any medical intervention that is undertaken because
of the test result. This determination should also include such
direct costs as the cost of adverse reactions after a false-positive
or false-negative test result. It may be necessary to obtain similar
costs for a competitive product or procedure. Depending on the
economic and health benefit analysis to be performed, the
treatment pathways may require modification and possible
consideration of comparative testing. Consultation with health-
care economists who perform cost-effectiveness analysis is rec-
ommended. For some products, e.g., those that may lead to
invasive procedures or that diagnose predisposition to life-
threatening or life-debilitating diseases, it may be appropriate to
assess the patient's quality of life relevant to having the test
performed. For these investigations, preexisting questionnaires
may be qualified and incorporated into the clinical trial protocol.

REGULATORY CONSIDERATIONS
The type of FDA submission, 510(k) for substantial equivalence
or PMA for premarket application approval, may have implica-
tions for the amount that payers will reimburse for the new
product. The 510(k) submission is the faster regulatory route to
market introduction, but its use implies equivalence to a predi-
cate device. Because payers do consider FDA decisions in their
coverage reviews, the new product will be covered. However,
the reimbursement will be at the same amount as for the
predicate device—even if the new product is more accurate,
 faster, adaptable to multiple settings, and probably improves
patient health outcomes. Therefore, selection of a predicate
device should receive careful consideration.

PMAs, which represent new technologies and old technolo-
gies with new intended uses, do not have reimbursement
amounts set equivalent to a predicate device. For PMA products,
the manufacturer has an opportunity to meet with the payer and

2 From: Littell, CL. Successful strategies for IVD development, clearance/
approval and marketing. Jan, 30, 1995 (conference presentation). See also:
Outcomes measurement: a guide for the medical device and diagnostics industry.
propose reimbursement amounts based on the product pricing and other information. Regardless of the regulatory route selected, payers do rely on peer-reviewed publications of clinical studies in their coverage decisions, so it is advisable for developers to publish early and often.

PARTNERSHIPS
Just as partnering with the clinical investigators is key to a successful trial, forming partnerships with conceptual leaders within the medical community can be key to obtaining coverage. As managed care organizations increase in number and enrollment, they are increasingly seen as role models for coverage decisions by other payers. As such, these organizations should be considered as clinical trial sites or potential marketing study sites. In this approach, it is wise to meet with the managed care medical and policy staff to determine their criteria for coverage of new products or procedures. This meeting should occur well in advance of the clinical trial, to ensure that the study design will include all of the required protocols.

Medical directors of the nation's biggest payer, Medicare, and of other payer groups may be valuable partners, as might be renowned members of medical specialty groups. Moreover, although educating potential partners on the technology is critical, the manufacturer/marketer must also have a clear vision of the potential healthcare benefits to be realized. Having enlisted the interest of potential partners early in the project's development will help to promote their support of the clinical trial's conclusions and any health benefits determined.

MONITOR COVERAGE POLICY DEVELOPMENT
One of the attempts to control medical costs is the development of medical guidelines. As standards of care, the guidelines provide optimal treatment pathways for different disease states. Developers of such guidelines include the Agency for Health Care Policy and Research (AHCPR), medical specialty groups, and institutions such as medical centers and managed care organizations. More recently, state-based healthcare reform has prompted the creation of technology assessment groups to make recommendations on a technology's effectiveness. Payers will use these recommendations as they develop their policies for coverage. The implication of the guidelines and state-based assessments for developers of new technologies is to ensure that use of the technologies is not excluded or at least not blocked. Accomplishing this requires familiarity with the organizations and monitoring of newsletters that announce projects for new guideline development. Most groups will invite manufacturers with relevant expertise to submit educational material and, in some cases, will provide an opportunity for public comment on draft documents. Because it is not always possible to comment before a guideline is published, information on new technologies should be shared with the guideline developers for the next edition.

PREPARE THE VALUE STORY
Although the content may vary with the type of technology and the setting for use, five basic items should be included in every value story: (a) a summary of the current medical practice with references to any existing medical guidelines; (b) a summary of the product's safety and effectiveness; (c) a copy of the product's FDA clearance or approval letter; (d) copies of all publications describing the new technology and its applications; and (e) an assessment of the technology's health benefits and costs in the form of an economic or actuarial model. As a powerful marketing tool, the final value story must be clear, concise, and flexible so that it can be adapted to the needs of different payers.

In summary, today's emphasis on containing healthcare costs will favor those manufacturers who address payment issues in their business plan. Considering the following four steps will help ensure a successful product introduction: First, assess the payment environment early and throughout the product development continuum. Second, ensure that the clinical trial design includes the appropriate measures for economic data. Third, identify key partners who would support and promote the new technologies. And fourth, monitor the agencies, payers, and specialty groups for new trends in coverage decisions. With a clear value story, in vitro diagnostic manufacturers and developers can join the new gatekeepers in the payment revolution and succeed in bringing new technologies to the market.