

The Changing Health Care Reimbursement Landscape

The Role of Health Economics

Regulatory approval has been, and remains, the primary focus for manufacturers that develop drugs and devices. Securing the necessary pre-clinical and clinical data is paramount to ensuring that products receive regulatory approval and thus reach the market. In bygone days, companies would primarily use that safety and efficacy data to engage physicians to prescribe new, innovative therapies once they became available in the marketplace.

Increasingly, patient access to new products is determined not solely by physicians, but also by a broad array of key economic stakeholders such as health care organizations and insurers. Third party payers and large health care delivery organizations now serve as gatekeepers between the physician and patient, potentially limiting access to new therapies. Their considerations are not limited to clinical trial safety and efficacy but also include unmet clinical needs, real-world clinical efficacy,

patient-reported outcomes, budgetary impact, pragmatic considerations, and emerging industry trends. They are interested in the holistic impact of new therapies, rather than just the narrow focus of clinical trial-based safety and efficacy.

A good example of an instance where health care reform could have a profound impact on the commercial viability of a drug can be found in the case of an expensive biologic therapeutic agent indicated for the treatment of an exceedingly rare disease. Effects of this disease are manifold; perhaps the most highly visible of these is renal failure. Once patients reach dialysis, the proverbial horse seems out of the barn with respect to renal failure, and the therapeutic agent has been scarcely (if ever) used among dialysis patients. However, burden of illness studies we conducted demonstrated that dialysis patients with this disease were hospitalized much more frequently than other dialysis patients, and that the

excess hospitalization burden is related to other manifestations of this disease. As a result, there is immediate impetus for insurers to consider permitting administration of the therapeutic agent to dialysis patients.

This new model for health care decision making is in alignment with the new paradigm of medical decision making. Still using dialysis as an example, the incentive for dialysis providers to use this type of data will increase as global capitation emerges and dialysis providers become economically responsible for related hospitalization costs.

As a result of the transforming health care marketplace, there will be a need for an integrated model for the discovery, development, and delivery of therapies that address the needs of all potential stakeholders.

A “value proposition” is required for this integrated model: a statement of fact that places the clinical and economic value of the new product

into the context of existing therapies and the health care landscape. The success of this model offers tremendous benefit both to patients who will be reached by the product, as well as to manufacturers because it ensures access to their product by patients. Conversely, failure to establish a solid value proposition may result in products being under-utilized by the very patients who will most benefit from it. Successful development of a value proposition ultimately requires that all important clinical and economic levers be identified and considered rigorously within the broader context of other health care options.

The constantly evolving health care environment means that the landscape into which a product launches may bear little resemblance to the landscape that had been present at the time of product inception. It is critical that such trends be taken into account. To take one specific example, an emerging oral drug for use in hemodialysis patients was found to be safe and as effective as existing therapies for the primary indication, and also to reduce utilization of other concomitant intravenous medications, and to decrease hospitalization rates. Under the current reimbursement paradigm, wherein oral medications are excluded from capitated reimbursement, adoption of the

new drug may seem like a good choice for a dialysis provider: lower utilization of concomitant intravenous drugs for which dialysis providers must pay, fewer missed dialysis treatments due to hospitalizations (i.e., fewer opportunity costs), and no offsetting expense. However, with planned changes to Medicare reimbursement whereby oral drugs will be included in the capitated payment rate, it was uncertain whether the drug would still be a viable option. We developed models to quantify budgetary impact of the drug under both the current and future reimbursement scenarios. These models demonstrated a clear aggregate benefit of the drug in both reimbursement environments. In this instance, a detailed understanding of the proposed policy changes and their potential impact on provider economics allowed the development of robust models, which in turn could be used to support the clinical and economic value proposition of the drug.

With increasing pressures to reduce health care costs while at the same time improve patient outcomes, the appropriate allocation of resources by health care providers is critical. One way in which this can be achieved is to ensure that therapies are correctly targeted to the patient populations that most stand to benefit from

them in terms of both clinical outcomes and subsequent health care spending. However, caution is needed to ensure that this type of risk stratification approach is appropriate and meaningful in real-world clinical practice. Consider an example where a disease management program hired a third party to develop a clinical risk prediction tool to identify patients who might be at risk for a catastrophic clinical outcome and therefore be good candidates for therapeutic intervention. There was considerable excitement when the predictive tool was found to be 92% accurate in predicting the outcome in question. However, among the predictors used by the tool were insurance claims for procedures performed when the outcome is imminent. Such claims are a clear signal that treating clinicians were already well aware of patients' high risk status and the tool therefore 'predicted' what was already clinically obvious, imparting little-to-no economic or clinical value. A thorough understanding of the clinical context in which care is provided is clearly essential for such predictive tools to be effective in achieving the intended goals of reduced costs and improved patient outcomes.

Under the old paradigm for commercialization strategy, physicians and patients were targeted with clinical messages after the launch of a new product.

However, the current health care marketplace demands that consideration of how new therapies will be integrated into the health care system occurs in parallel with drug development, such that messaging addressing clinical aspects of the therapy as well as savings in health care utilization or other associated costs can be

developed prior to launch. Fundamental to success under this new paradigm is the need for a nuanced understanding of clinical conditions, their treatments, and the surrounding circumstances and health care delivery models. Health economics and outcomes research studies undertaken to support value proposition development

require a comprehensive approach that is attuned to the full spectrum of clinical, economic, and pragmatic issues, and ambient industry trends. Such studies can best be handled by CROs that are part of health care organizations and thus have unique insights into the problems and solutions of the new integrated health care models.