Ensuring a Compelling Value Proposition in Oncology

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As cancer disproportionally affects the elderly, the aging baby boomer population will further accelerate the demand for treatment. These changing demographics are putting added pressure on government and private payers to contain costs. Despite the severity of the condition, the bar for clinical value in cancer care is being raised in the face of these economic concerns.

As a result, high cost cancer therapeutics lacking a clear and compelling value proposition may be subject to greater payer scrutiny and control than in the past. Current payer sentiment reflects a desire to encourage patients to decline treatment with high cost drugs that are perceived to not offer clinical and economic value. For one high cost cancer drug in particular, a payer was recently heard to remark, “Rather than paying a significant amount of money for a few months of overall survival, I’d give the patient $50,000 cash and have him enjoy the rest of his life.”

In the face of escalating costs and rising competition in oncology, a clear and compelling value proposition will be critical to ensure that payer restrictions and other access barriers do not threaten the commercial potential of important, life-extending oncology treatments. Establishing a compelling value proposition by drug developers will help mitigate this risk since the perceived strength of a payer value proposition will ultimately determine successful access for a given branded drug.

A payer value proposition has three primary objectives:
1. Establishing that a need exists,
2. Demonstrating that the product meets this need, and
3. Demonstrating that it does so at a relatively predictable cost.

While the need is obvious, providing the justifiable benefits of a product is more challenging, and this is demonstrated through the use of clinical endpoints, outcomes measures, and demand from and endorsement by medical professionals. In addition, drug makers need to fulfill payers’ need for budget predictability by addressing those concerns regarding the indicated patient population and usage in likely responders.
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EFFICACY

ECONOMIC VALUE

SAFETY

Provenge within two months of its FDA approval in 2010, CMS was concerned that the product’s utilization may expand to the larger pool of patients in earlier-stage disease due to the lack of a restrictive indication in the label. Provenge’s high price, combined with its potential use in a larger patient population, likely precipitated CMS action because this product posed a challenge to the payer’s need for budget predictability.

In addition to addressing payer concerns about usage in a wider pool of patients, the value proposition of a product can be enhanced by prospectively identifying likely responders to the therapy. In order to shape a medical policy that minimizes payer coverage restrictions, the product would ideally be safe and effective for a predictable, well-defined patient population.

A number of elements contribute to the development of an effective value proposition including three of the most significant contributors in oncology today:

- A product indicated for a predictable, well-defined patient population
- A product that delivers clear and meaningful clinical value
- A product that delivers economic value to providers and payers

Creating a Well-Defined Patient Population

Lack of clarity regarding the size of an indicated patient population can be problematic from a payer perspective. For Dendreon’s Provenge®, Medicare coverage represents a significant component of the insurance mix for castrate-resistant prostate cancer patients. In initiating a National Coverage Analysis (NCA) of Provenge, CMS was concerned that the product’s utilization may expand to the larger pool of patients in earlier-stage disease due to the lack of a restrictive indication in the label.
Drug developers are prospectively identifying likely responders for a particular drug by developing novel and useful biomarkers and diagnostics. Roche took a major step in this direction in 2008 with the acquisition of Ventana Medical Systems, a leader in the fast-growing histopathology (tissue-based diagnostics) segment. The acquisition is helping Roche broaden its diagnostic offerings and is complementary to the progress that the company had already been making with in vitro diagnostic systems and oncology therapies.

Not only does the use of biomarkers and diagnostics have positive access and reimbursement implications, but they can also speed up development and approval timelines. Moreover, the oncology marketplace is increasingly fragmented into specific patient subtypes, and the use of biomarkers is one important way manufacturers can demonstrate to providers and payers the increased likelihood that treated patients will be responsive to therapy, and thus uphold drug prices.

Establishing Clinical Value

Establishing strong clinical value continues to be foundational and is particularly important for high-cost combination regimens (e.g., two or more branded biologics). Payers are increasingly looking to manufacturers to justify significant increases in total drug cost and are harboring expectations about the magnitude of effect and overall safety commensurate with cost. Payers are also seeking to understand why it is better to use drugs in combination versus sequentially, so synergies must be clearly delineated. Whether or not—and the extent to which—payer expectations of superior risk-benefit profiles for dual-branded biologic regimens affect their willingness and ability to manage utilization in cancer is an area for further study.

Recently approved, Perjeta® [pertuzumab; Roche/Genentech], is a novel monoclonal antibody designed to prevent dimerization of HER2 with other HER family receptors. This is the first FDA-approved combination biologic regimen. When used in combination with Herceptin®, Perjeta enables more comprehensive HER2 blockade to potentially inhibit cell growth. In the first-line treatment of women with HER2-positive metastatic breast cancer, the addition of Perjeta to Herceptin plus chemotherapy was associated with a 6.1-month improvement in progression-free survival compared with Herceptin plus chemotherapy alone. Patients treated with Perjeta, Herceptin, and chemotherapy also achieved significantly longer overall survival, compared with patients on Herceptin and chemotherapy alone. These efficacy results are paired with a side effect profile similar to that of Herceptin and chemotherapy alone. Perjeta sets a high bar for payer expectations around the impact of combined biologic therapies relative to other combination regimens.

Currently, commercial payers are experimenting with the use of clinical pathways and bundled payments, particularly in tumor types with high disease prevalence such as breast cancer. This means a significant improvement in the risk-benefit ratio will become an even more critical access driver for high-priced regimens if payers are successful at moving payments away from the traditional fee-for-service model.

Delivering Economic Value

Looking forward, it will become increasingly important to consider economic drivers. Late-line therapies may be particularly at risk in this regard. Heavily pre-treated cancer patients have not only received multiple lines of drug therapy, but are likely to have previously undergone surgical interventions and/or radiotherapy as well. Patients who have been through multiple lines of drug therapy are often extremely sick and/or have depleted their finances. As a result, these patients are more apt to cancel their appointments for cancer treatments, making the community provider more

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reticent about ordering and stocking a drug indicated for this patient population because the drug cannot be easily reallocated for use in other cancer patients. Rather than taking the risk of having to pay a significant re-stocking fee, providers are more likely to refer these patients to a hospital outpatient department for treatment.

Most hospital outpatient departments are reimbursed at a percentage of charges, which allows them to significantly mark up the price of drugs to health plans. Commercial payers are realizing that it is far more economical to keep patient care in the community practice setting than to pay for hospital-based care. As a result, payers have a vested interest to retain cancer care in the community and in the solvency of these independent providers.

The trend to shifting patients to outpatient hospital departments is one area where the interests of drug makers and commercial payers may be closely aligned. Hospitals, as institutions, have the power to influence access to prescribers and product selection, and thus represent an additional access barrier. Manufacturers should partner with payers to address shifts in site of care. By demonstrating the economic value proposition of their products, manufacturers may be able to persuade payers to maintain reimbursement rates for certain drugs and partner in other ways to retain care in the community.

Conclusion

The components of a product value proposition are not limited to the features and benefits of a product, rather cancer drug makers should consider a host of other issues. Manufacturers’ clinical and commercial teams must collaborate early in the clinical development process to define the clinical value of the product, facilitate its appropriate use, and address payer access considerations. The ability to prospectively identify likely responders and demonstrate the product’s economic value is also increasingly important from a clinical and commercialization standpoint.


OBR DAILY NEWS FLASHES

An update from our previous NewsFlash in May’s OBR green: The FDA issued a complete response letter for Merck/Ariad’s ridaroforolimus as a sarcoma treatment while Roche/Genentech’s pertuxumab was approved for HER2-positive late-stage breast cancer. (Xconomy, 6/6/12 & San Francisco Chronicle, 6/10/12)

9/11 responders finally got their due when a federal health official ruled that 50 different types of cancer seemingly related to the Sept. 11 terrorist attacks would be covered by a $4.3 billion compensatory fund. (New York Times, 6/8/12)