ASCO 2015—Searching for Value in Cancer Therapies
Outcomes of the annual Accenture-US National Cancer Institute panel

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As our understanding of human biology progresses, pharmaceutical companies are developing breakthrough drugs that radically change our life expectancy. We are seeing significant advances in our ability to treat even the most difficult and historically unresponsive cancers. Although these developments are encouraging, the potential scope of application and treatment models are challenging some countries' ability to pay; no longer are therapeutics hitting 1 percent to 3 percent of the total population but rather a third to a half. And an increase in combined treatment approaches only complicates matters. This is particularly germane to cancer treatments where a paradigm shift in disease management risks putting an insurmountable financial burden on public and private health insurers.

In this context, Accenture and the US National Cancer Institute held an event at the ASCO Annual Meeting to debate the cost and value of current and future therapies. Co-chaired by industry and academic leaders, two parallel workshops debated these issues in depth. The first workshop focused on understanding and defining the value of cancer therapies present and future, while the other group delved into finding ways to ensure access to high-value drugs as treatment costs grow. Both workshops drew leaders with cancer expertise from the industry, payers, academia and regulatory agencies. These conversations are summarized in the following pages.

Determining value in cancer therapy

Until very recently, value has always been a highly difficult concept to address as it depends on the entity looking at a therapy's benefit. Whereas a patient will consider a drug's value as its ability to save his or her life, a payer will see it as a cost-effectiveness equation, factoring a patient's fees for private insurance or the patients' differential contribution to GDP in the case of single public payers like those in Europe. Public and private payers can also take opposite positions; private payers have at best a three-year horizon in their evaluation while public payers may be able to consider long-term outcomes. Finally, physicians' take on value will yet again be different as they focus on balancing medical benefits with potential side effects and toxicity for their patients.

Despite these differences, parties need to engage in a dialogue to understand if current drug costs are justified, if they can be controlled, and how those dynamics might change over time. Currently, drug prices only dramatically decrease once they lose patent protection and are switched for generics. A better approach, however, might be to provide an updated value of the drug, comparing it regularly to existing alternatives as well as associating a specific price tag to a particular drug/indication combination. The latter could be helpful for drugs with multiple disease indications since they do not automatically work with the same effectiveness for each indication. Therefore, providing a blanket price covering all indications would not be effective or fair pricing.

Overall, experts can determine a path forward by examining value through two lenses: patients or society as a whole. With cancer, patient-focused value should concentrate on survival criteria, but this can no longer be addressed in absolute terms. Quality-Adjusted Life Years or QALY should be the norm in developed countries when evaluating the interest of a new therapy for a patient. Although this is currently used by a subgroup of rich countries, this approach should be used as a universal starting point when defining future drug values. Societal value, however, is much harder to define. While the patient may want a cure at any price, society as a whole assesses value by looking for drugs with fewer complications or lower cost with the goal of putting people back to work faster or for a longer period of time, therefore contributing to GDP. Even in countries with a single public payer, deciding who should pay for the societal component of a drug's value is far from obvious. And the fact that society has yet to determine how much it is willing to pay for the wellbeing of its citizens makes it even more complicated.

As innovation and science breakthroughs lead the way towards better drugs, examining the value associated with novelty and rarity becomes unavoidable. It requires quantifying the role that risk plays in innovation, and factors the R&D failures into the price of successful and truly innovative drugs. Payers acknowledge this risk in their willingness to pay beyond simple production costs. Experts will also need to assess:

- The willingness to pay from non-consumers, who share the overall burden of these expensive therapies
- The enormous value given to an extra month of life in terminal care settings or cancers currently considered as incurable
- How much society and individuals are willing to pay before one's own diagnosis? What level of insurance premiums is society willing to pay before and after such an event?
Ensuring access to high-value therapies in an era of high-priced drugs

Despite having similar GDP per capita ratios and comparable quality of life metrics, developed countries are not equal in their access to cancer therapies. Even within Western Europe, patients in Germany might have access to different drugs and treatment regimens than in France or the United Kingdom. Cancer treatment is not only linked to the type of cancer but also to where patients, prescribers and payers live. These differences can be explained by a number of factors:

- From marketing authorization to product reimbursement and availability, time to market can be vastly different between countries. These differences are all the more striking when considering the discrepancies between similar countries regarding off-label usage. Even if some countries tolerate off-label usage—giving them earlier access to some novel medications—other countries consider this alternative completely illegal.

- In an effort to gain market share and make their drugs more accessible, pharmaceutical companies offer rebates and other discounts for their most expensive drugs. When added to country-specific situations such as the relatively unregulated prices on the U.S. market, it is difficult for society to identify list prices vs. actual sales prices. Local regulations on such matters make bringing a unique pricing approach to all countries highly complex and unlikely.

- In this era of high-priced specialty drugs, innovative pricing schemes have often been seen as a cost-effective solution for payers. However, these pricing caps (by drug, patient, the drug's real-life performance, etc.) are hard to implement. The criteria used to validate such deals are often complex, and payers rarely have the infrastructure to follow through with such contracts. As deals based on innovative pricing schemes hang on a country's healthcare infrastructure analytics capabilities, they can also become a source of disparity among countries.

Finally, countries have different levels of reimbursement\(^1\) for the same drugs, and drug affordability can become a geographical issue. Whereas European single public payers might be in a position to limit the cost of future drugs, competing private U.S. payers do not work collaboratively to offer clients protection from increasing prices. Although the United States stands alone among developed nations in not having a single public payer system, its market has a dramatic impact on global decisions. The economic models and regulations associated with a decentralized, private healthcare market (no end price for drugs, payers competing to raise their market share of patients, etc.) combined with its size leads to ripple effects in other developed nations. These include cross-border pricing and trafficking across the USA-Canada border, limiting the Canadian government's ability to push prices downwards, as well as the general impact on base prices in international markets. Many developed countries use the United States among others as reference country when determining the weighted average price of a drug across comparable nations, so its higher drug prices directly influence prices in other countries.

With these factors in mind, how can payers, industry and reimbursement entities pay for highly expensive drugs while supporting long-term economic stability? First, experts will need a common understanding of that medication's value. The industry needs to investigate Quality of Life (QoL) and other proxy metrics more rigorously when filing for reimbursement as these are more important to the holistic value of a therapy than traditional endpoints such as progression free survival (PFS) and overall survival (OS). Canada, for instance, made clear that reimbursement requests that fell short on or did not provide high-grade QoL studies would most likely be denied in years to come.

In addition, payers, industry and reimbursement entities must address the total cost of the disease together. To accomplish this, healthcare providers will need to provide clear cost breakdowns for alternative therapies while pharmaceutical companies demonstrate a drug’s value using the information shared in the drug access partnership. Building a common access approach is the only way that cost-effective drugs will keep being financed while ensuring payer solvency.

Such arguments about how best to counter ever-increasing drug prices have been echoed in recent publications and petitions around the world. What is clear is that global payers would not be able to sustain the upward trajectory, leading to the bankruptcy of most healthcare payer systems in the short or medium term. As new drugs become increasingly hard to discover and manufacture for more specialized and limited patient populations, pharmaceutical companies will have to find a way to share the associated R&D costs or risk turning one of the most profitable industries into one of the least profitable ones.

If the pharmaceutical industry is forced to lower drug prices, then governments and regulatory bodies must strongly consider the possibility of granting longer use periods without generic competition. This can be achieved through various mechanisms, such as smaller, more focused pre-approval studies followed by more post-approval regulatory and real-world studies to substantiate value and expand the benefitting patient populations based on real-world evidence. All stakeholders need to find a way to bring value and access together or risk slowing the advance of life-saving drugs through the pipeline—and their availability to patients.

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