VALUE AND DIFFERENTIATION:
Planning For Successful Oncology Market Access
Oncology is a crucial driver of innovation and growth in today's pharmaceutical market. Cancer drug launches are at record levels, while annual spending on oncology therapeutics is growing in double figures worldwide.

Precision medicine, immunotherapies, cell therapies, biomarkers and genetic profiling are transforming the oncology treatment paradigm. That is good news for patients, health systems and the pharmaceutical industry. Real innovation drives competition, treatment diversity and better health outcomes.

The flipside is an increasingly crowded oncology market in which premium pricing and rising patient numbers are making payers nervous. Meanwhile, R&D pipelines remain heavily invested in immuno-oncology and other cancer drug candidates. All of this raises the stakes for successful oncology market access.
For cancer drugs addressing high unmet need with clearly differentiated added value, the opportunities are still plentiful, notes Erin Solano, Senior Engagement Manager at Syneos Health. Paul Tyahla, senior reputation and risk management strategist at Syneos Health, points out, though, that differentiation now has to be both clinical and economic, including evidence of cost offsets.

**Privileged Status**

For all the growing emphasis on managing drug costs, and the competing demands on health care resources from age-related diseases such as Alzheimer’s, oncology retains something of its traditional privileged status. “It’s not an area where payers want to limit the choices physicians have available to prescribe,” Solano says. Nonetheless, she adds, if payers “have lots of similar products, that’s an incentive for them to start to manage.”

Also changing is the relatively sympathetic tone of media coverage in the category. If an oncology proposition, for reasons of strategy or data immaturity, is built on relatively soft or surrogate endpoints, it may have problems communicating benefit. “Where you have strong overall-survival data, that’s what patients, doctors and payers want most,” Tyahla notes.

In line with these trends, cost sensitivity cannot be ignored in the oncology market-access equation, particularly with the arrival of expensive “one-shot” cell therapies such as Novartis’ Kymriah and Gilead’s Yescarta. Moreover, many of the new, premium-priced cancer drugs are used in combination. The cumulative financial impact is hampering uptake, particularly in Europe with its more restrictive single-payer health systems, Tyahla says.

This is especially problematic if marketing authorization is on the basis of progression-free survival data. “We have good clinical trials and good data; we have speedier approvals,” he comments. “But then you have to work with payers to demonstrate that there’s a value-add to the product.”

**Picking Winners**

For all that, oncology remains “somewhat protected” compared with more explicitly cost-driven categories such as diabetes, where multiple treatment options allow payers to “pick winners and losers,” Solano observes. “The payers really feel an obligation to make the right product available for the right patient,” she adds. They will look at comparative efficacy, and “if it’s likely to work, even though it’s expensive, they’re going to pay for it.”

One exception is biosimilars (e.g., trastuzumab for breast cancer), where payers do have more choice and more leverage in product coverage. “That’s an area where contracting might come into play,” Solano acknowledges. To date, though, the comfort level with biosimilars overall in the key US market remains “somewhat low,” and particularly in oncology.

Originator companies have also done “a lot of work” with physicians and payers around interchangeability. As result, Solano points out, there is “some hesitancy” about embracing oncology biosimilars more proactively. Nonetheless, the comfort level will grow as more oncology biosimilars reach the market and more data emerge on product usage, she believes. “Some plans have started to make those choices, and I think more will as time goes on.”

Precision medicine and biomarkers, with products targeted to rare diseases and responsive patient subsets, are also helping oncology products to circumvent MA barriers. “Payers do appreciate having very specific indications,” Solano comments. “The manufacturer can help the payer identify what the coverage criteria should be. At the end of the day, payers want to pay for things that are going to work.”
**Talking To Stakeholders**

From a strategic perspective, companies chasing success in oncology MA should make an early start – at least one year ahead of launch – on constructing a broad-ranging value narrative adaptable to a whole ecosystem of stakeholders. That ecosystem includes physicians, payers, regulatory agencies, distributors, nurses, caregivers and patient advocates, each with their own set of rational and emotional needs.

Payer concerns may be largely economic, for example, whereas patient advocates are more interested in access to better treatment options and associated issues such as financial support and disease awareness. These distinctions are not always fully understood, especially among fledgling biotechnology companies with innovative oncology platforms but limited experience in launching products and addressing market-access needs.

“We can lay out what that roadmap from development to launch looks like, who the important stakeholders are, when you need to engage them, what’s the right message, when you can actually go out and talk about these things,” Solano notes. “In a small company or start-up where there are a lot of things going on, not all of that information is necessarily well socialized.”

One of the more elusive stakeholder groups, Tyahla points out, is patients who do not belong to any formal advocacy infrastructure. They may represent 20–40% of the entire community, and may be an important source of information and insights as well. Since direct communications with these patients risks straying into pre-approval promotion, social-media listening and analysis can and do play influential roles in this area.

Oncology MA strategy also needs to take into account both the current and future treatment landscape. For example, a product may come to market initially as a later line of therapy, with a relatively narrow indication, Tyahla explains. Yet payers understand that there will be multiple indications to come, and that value may be demonstrated in earlier lines of treatment. Being up front about the full scope of a development program, including the cumulative cost implications, helps to define the long-term relationship with stakeholders and to “ensure those initial conversations are held in good faith,” says Tyahla.

**Alternative Contracting**

One potential game-changer in resolving tensions between innovation, cost and access in oncology is new or emerging pricing and reimbursement models, such as pay-for-performance, indication-specific pricing or value-based contracts agreed on preliminary evidence and adjusted for real-world data and outcomes. So far, though, there is a lot of “surface-level interest” in these schemes but not much traction in oncology specifically, Solano says.

Especially for payers without prior experience of alternative contracting, “there is a huge cost of capital in getting these things up and running,” she comments. That includes agreeing on measurable outcomes, as well as the duration of measurement; determining whether payers will have access to the relevant real-world data; and ensuring the necessary infrastructure is in place to adjudicate contracts.

Solano believes alternative contracting will eventually play a role in oncology market access. For the moment, though, it is more feasible in categories such as diabetes, where HbA1c levels provide an easily measurable endpoint already checked as part of routine disease management.

This is also an area in which patient relationships and patient advocacy can help to change the policy landscape. More broadly, public relations and lobbying can educate the public, payers and government about “the true burden” of cancer, “both at the individual level and at the population-health level,” Tyahla notes.
The need to raise awareness is all the more pressing as well-managed cancers become chronic diseases. These then have “sustained impacts on the health system and social services outside the system, and are not always well understood or well appreciated,” Tyahla adds.

Future Direction
Gauging the future direction of market access in oncology is difficult at a time when major markets like the US are discussing radical reforms, such as international price referencing in Medicare Part B, that could have profound implications for pharmaceutical MA and investment decisions worldwide. Japan is another country that has drawn a line in the sand, with its move from bi-annual to annual pharmaceutical price reviews, Tyahla points out.

With a rich pipeline of oncology products set to enter the market, some of which may lack compelling differentiation, “choices will have to be made,” Solano warns. Nonetheless, certain fundamentals continue to apply, such as “a really well-thought-out market-access strategy that involves all the stakeholders in the ecosystem.”

Flexibility is also critical, Tyahla observes. “The environment is changing so rapidly that companies really need to take a look at what the market looks like as they approach launch, in the first year post-launch and at the first round of payer negotiations. And they should be prepared to be nimble.”

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