

Front & Center

Utilizing an Integrated, Multi-Channel Approach Can Improve Access for Oncology Products

How biopharma companies can pursue multiple channels to enhance access to segmented markets.

Market access for a new oncology product was once a straight line from successful Phase 3 trials to FDA approval, payer coverage, formulary placement, and growing uptake by prescribers. This model began to shift as the first therapies with specific tumor indications were approved and specialty pharmacies emerged as key players in the oncology market. The growth of highly targeted, highly segmented patient populations defined by biomarkers such as BRAF and PD-L1 status further complicates the progression from FDA approval to product access and uptake in the marketplace—and with personalized medicine and cell and gene therapies on the rise, oncology stakeholders should anticipate the changes to continue.

McKesson explored an evolving strategy—using a multi-channel approach to support oncology market access—at the 12th annual CBI Oncology Market Access Strategy Summit in San Francisco. Four access specialists focused on ways biopharma companies can, and should, pursue multiple channels to enhance access to increasingly segmented markets.

“The oncology world has changed,” said Sarah Alwardt, PhD, Vice President of Data, Evidence & Insights Operations for McKesson. “We have competitive products, biosimilars and novel molecular entities that are in the

same disease states and therapy lines. The value proposition that biopharma stakeholders need is very different today. It is more complex and has more sophisticated customers.”

Distributors are well-placed to understand the changing dynamics of new agents, new coverage requirements and new distribution channels.

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Distributors also grasp increasing complexities at the provider level as prescribers deal with a growing universe of therapeutic options and biomarkers that may not even have existed during their medical education.

Patients are increasingly sophisticated in their approach to treatment and their online connections to other

patients and third-party information sources. Prescribers, payers and biopharma companies are recognizing that patients play a key role in therapy. Prescribers and payers have a part in treatment decisions, but the patient is the ultimate decision maker in whether or not they pursue treatment and adhere to treatment regimens.

“Where patients want to receive their treatment is a key factor and a key decision point for biopharma companies,” Alwardt said. “Do they offer their product in a hospital setting or an academic center where patients would have to travel? Or are they making products available in the community oncology setting, which might be closer to home?”

Early Access Considerations

Just as biopharma teams have begun laying the groundwork for private and public payer coverage during product development, they can prepare prescribers for new products before approval. Clinical education may begin with an overview of available therapies, focusing on gaps that could be filled by new products. Starting those educational conversations early can prepare prescribers for approval, said Anne Hoang, Senior Vice President, Network Operations, The US Oncology Network.

FDA-approved labeling will largely guide early use of any new product, she said, but disease state education and pipeline updates can encourage prescribers to think about what might be coming and how a novel therapy might benefit specific patients.

There may be more early adopters among US Oncology Network prescribers because so many are also trialists, she continued. Once an agent is approved, they may already have clinical trial experience or have been exposed to information through colleagues who have used the agent. But in terms of clinical education, Phase 3 trial plans should include a broad prescriber awareness component.

Late-stage development is also the time to begin working on payer approval, said Chris Wixson, Vice President, GPO Services, McKesson Pharmaceutical Solutions and Services. Should the new agent be rolled out immediately after approval? Is it better to accept a summary J-code or wait for a unique J-code?

These strategic decisions need early attention, Wixson said. Waiting until the product is approved with the final label is too late to begin payer discussions. Not having early discussions is a missed opportunity that can delay coverage and limit market access opportunities at product launch.

The Move to Oral Oncology Drugs

Not long ago, nearly all oncology products were infused at a hospital or a prescriber's office. When such drugs were administered in the hospital or the office, there was no question as to whether the patient got their treatment.

As more novel oncology drugs arrive in oral formulations, adherence is a patient decision, noted Morgan Gruye Olson, Senior Director, Pharmacy &

Dispensing, McKesson Pharmaceutical Solutions and Services. Of note, many studies show that most patients are not appropriately adherent to their regimens, whether they simply forgot to take a pill, they didn't feel well at treatment time, it was too expensive or other reasons.

Recognizing that adherence is the number one factor in clinical outcomes, prescribers and payers are searching for more effective methods to engage patients in their therapy. Those methods range from intensive patient education and clinical support to nurse navigators, triage specialists and other advanced practice nurses who proactively reach out to patients on a regular basis to track and encourage adherence—whether it be through the physician's office or a specialty pharmacy who is managing the patient's oral prescriptions.

The move to oral oncology therapies has financial implications as well given that infused or injected agents are generally covered as a medical benefit. Oral agents however are covered under Part D, which has encouraged many practices to open dispensing operations (vs. relying on a specialty pharmacy provider to manage their patients). A prescriber's in-house pharmacy can be convenient for patients and profitable for the practice. It can also add financial shock to the treatment when a 25% coinsurance charge is due and payable in the office rather than being billed several weeks later. Biopharma companies must balance the potential financial toxicity of dispensing at the point-of-care against patient convenience as compared to specialty pharmacy dispensing when considering their product distribution and network strategies.

The Distributor in the Middle

The distributor is in a unique position to understand what is happening with patients across their entire cancer treatment journey. That position can provide insight into real world performance of a new product compared to clinical trial performance.

“Only 3–4% of any disease population is qualified for a clinical trial,” Alwardt said. “When the drug is approved, you suddenly have the other 96% or 97% taking your agent. All of the different comorbidities, backgrounds and patient features that were not included in the clinical trials can become meaningfully important.”

Payers are paying increasing attention to that kind of real-world evidence of both safety and effectiveness, she continued. When biopharma companies are building their value story, real-world evidence plays an important role.

Real-world evidence can also inform commercialization strategies. The distributor has a direct view on treatment and utilization patterns nationwide, where a new product is taking off, where it is lagging behind existing treatments.

“Techniques that have been used in other ‘ologies’ are coming to oncology,” Alwardt said. “Biopharma companies must start thinking differently on how they commercialize. There are a number of shifts that have to take place to power decisions. Having partners that link all those elements will be more important than ever before in deciding which channels to leverage at which stage of your product development, launch and life cycle. Product success today depends on using multiple channels at the right time and in the right sequence to maximize market access.”