ONCOLOGY TRENDS IMPACTING THE PATIENT EXPERIENCE

WHAT MANUFACTURERS NEED TO KNOW.
Across the oncology landscape, a confluence of factors is creating new challenges to product access, optimized clinical outcomes and commercial success. AmerisourceBergen explores those factors and trends in this ebook series, offering strategic recommendations for how pharmaceutical manufacturers can support prescribers and patients through the continuum of cancer care.
TREND 3

Advances in oncology care bring greater complexity to patient access and support.
Advances in oncology care bring greater complexity to patient access and support.

The rich pipeline of oncology innovation continues to bring novel treatment options and hope to cancer patients. Advances include an increased number of approved biomarker-directed therapies (with companion diagnostic tests), a growing list of immuno-oncology therapy options, oral therapies that can provide greater patient convenience and a pending wave of biosimilars that may offer less costly alternatives to today’s biologics.

Because of ongoing advances, earlier diagnoses and improved oncology care, more cancer patients are surviving for longer periods than ever before. According to the American Cancer Society, there are 14.5 million cancer survivors in the United States today, and this figure is projected to rise to almost 19 million by 2024. And with more patients managing their cancer as a chronic condition, the need to properly manage access and adherence in oncology has grown even more pressing.

KnowledgeDriven.com | TREND 3: Advances in oncology care bring greater complexity to patient access and support.
Before advanced treatment options and superior care can become fully accessible, a number of hurdles must be overcome. Among the biggest factors determining the success of cancer care are the patient’s ability to access, afford and remain adherent to the prescribed oncology therapy regimen. Numerous barriers routinely impact these objectives:

- Cost-control measures
- Tolerability challenges
- Cancer stage
- Co-morbidity issues
- The patient’s mental or psychological capacity, emotional state and/or motivation
- Access to transportation
- Level of health literacy, and more
“So many factors are at play when it comes to whether or not any given patient will remain adherent to their medications — including personality and behavioral traits, cost issues and the clinical effects of the drugs themselves,” says Amy Grogg, PharmD, Senior Vice President of Strategy and Commercialization for AmerisourceBergen Specialty Group. “Pharma manufacturers must develop a variety of strategies and programs to address these challenges and optimize the patient’s experience with the brand throughout the entire treatment journey.

“When brand teams are able to help patients to better understand their disease and their medications — how they work, why strict adherence to complex dosing and administration protocols is important and how to recognize and manage side effects — they are much more likely to remain adherent,” adds Grogg. “Then, further scaffolding can be provided, in terms of easy electronic access to informational resources, streamlined access to nurses or pharmacists on call and more.”

In the face of persistent barriers and challenges, many brand teams are stepping up with targeted programming and outreach to help both physicians and patients overcome the reimbursement obstacles they face. These include targeted educational materials and outreach programs and easy access to on-call clinical and financial specialists. The goal of such programs is to help patients to address specific clinical and affordability challenges.

“Oncology practices need many forms of high-tech and high-touch solutions and support to effectively manage reimbursement requirements, and swiftly address denied claims,” says Grogg. “By working closely with patients and physicians, we are able to help them understand what the patient’s out-of-pocket obligations are likely to be. And once we know that, we are able to connect patients with co-pay assistance programs that may be available from manufacturers or charitable foundations, or patient assistance programs (PAPs) that provide access to medications at no charge for eligible patients.”

Industry partners can play a major strategic role in the manufacturer’s overall strategy when it comes to supporting the patient journey and minimizing clinical and financial barriers that can restrict access, affordability and adherence.

“One effective approach for improving patient adherence to costly therapies is to provide a support program that involves interviewing the patients to assess motivational factors,” says Grogg. For example, such an interview may reveal that certain patients are very organized and proactive, and would be receptive to an app that can help them to remain motivated and organized when managing complex drug regimens. By contrast, such an interview may reveal that other patients are more highly motivated by personal support, encouragement or coaching. “This is very useful information for the brand team, in terms of targeting individual patients with the most appropriate forms of outreach or support, to help remove the clinical or cost barriers and incentivize them to stay on their medications in ways that truly resonate with the individual patient,” she adds.
Biomarker-directed therapies provide benefits — and challenges.

The industry has seen significant growth in the number of cancer medications specifically indicated for a particular subset of patients — that is, those for whom a companion diagnostic testing can confirm the presence or absence of a given biomarker or genetic abnormality. This opportunity for improved precision medicine has created tremendous excitement in cancer care, but the rise in biomarker-directed therapies also raised its share of questions.

“Diagnostics hold the promise of getting the right medicine to the right patient at the right time, but much work remains to develop a standardized system of approving, coding and covering/reimbursing diagnostic tests to ensure patient access,” says Perry Dimas, Vice President, Business Development for Premier Source, a provider of commercialization services for precision-medicine diagnostics. “While medications and dosages are routinely assigned a J-code so the payer quickly understands what it is reimbursing, the same process does not exist for diagnostic testing. Lacking an appropriate code for their tests, most diagnostic companies use a miscellaneous CPT code, which raises red flags and makes the process for being reimbursed challenging for both manufacturers and oncologists, which then blocks access to treatment and slows reimbursement.”

“Manufacturers of diagnostic tests can take steps to support standardized coding and optimal reimbursement. Acquiring the right post-launch data to demonstrate clinical utility is crucial.” For instance, Dimas notes that “payers look for observational trial data, such as how a test, once ordered by a physician, impacts patient management and affects health outcomes, and exactly how does it help.”

“This new wave of tests, while helpful, can Diagnostics hold the promise of getting the right medicine to the right patient at the right time, but much work remains to develop a standardized system of approving, coding and covering/reimbursing diagnostic tests to ensure patient access.
also be expensive,” adds Vicki Albrecht, PhD, Senior Vice President and General Manager at ION Solutions, which provides group purchasing and practice efficiency services for oncology practices. “The steep cost is punctuated by the fact that most insurance companies will only cover a portion of the test, so patients may face higher out-of-pocket costs.”

She continues: “In these instances, the oncologist faces a dilemma: Ordering the test may lead to a more precise diagnosis and better course of treatment, but that isn’t guaranteed. The test itself creates additional expense for the patient and then may call for the use of specific therapeutic options which, if they are not covered, can further add to the patient’s financial stress.”

One proven strategy is to work with a knowledgeable third-party partner, who can help secure meetings with medical directors of governmental and commercial payers to make sure data collection is aligned with what the payer wants to receive. “Proving clinical utility can help catapult diagnostic tests to widespread adoption within the payer community,” says Dimas.
Oral oncology agents change treatment dynamics and support mechanisms.

In recent years, the use of oral oncology agents as an alternative to traditional intravenously infused chemotherapy has ushered in an exciting new era in oncology. To ensure access to these potentially lifesaving drugs, though, manufacturers must provide a variety of information-based programs and high-touch support services to address all of the “financial and clinical toxicity” issues that impact the use of oral products.

“Creating programs that help remove financial barriers — which so often cause delays in the initiation of oral oncolytics — is a key role of the specialty pharmacy,” says Kelly Ratliff, DPh, President of US Bioservices, a national specialty pharmacy. “The goal is to provide a dedicated patient assistance team that can remove those financial barriers and ensure patients are able to begin therapy as quickly as possible.”

“These experts have deep knowledge of all of the financial assistance options that may be available to address the significant affordability issues that arise with so many of today’s advanced oral oncology therapies,” Ratliff adds. “They work to connect patients with copay-offset programs or early-initiation programs that can provide access to medication while insurance coverage requirements are being investigated. Financial assistance coordinators can provide connectivity to patient assistance programs sponsored by drug manufacturers or to private or charitable foundations. These experts are able to help patients manage the complex paperwork, removing another challenge for patients and their treating oncologist.”
And such support is not only important at the initiation of care. “In many cases, the patient’s financial situation changes over time, especially in clinical situations where therapy extension is needed,” says Ratliff. “To be most effective, this type of hands-on support to address the financial barriers should be available throughout the entire treatment regimen and support improved continuity of care.”

From a treatment standpoint, the ability to receive chemotherapy in pill form provides the potential for greater ease of administration and greater convenience for patients — reducing or eliminating the need to travel to the physician’s office, hospital or clinic setting for regular IV infusion sessions. However, proper at-home administration of oral oncology agents can be burdensome for many patients, and tolerability issues and potentially debilitating side effects can reduce adherence and hinder clinical outcomes if not properly managed.

“Oral oncolytics often have complex dosing protocols. These include changes in the number and frequency of administration — for instance, ‘Take 1500mg twice daily for 14 days, followed by 7 days off. Take all doses with food.’ The complexity of the regimen may cause patients to over- or under-administer drugs,” says Loreen Brown, MSW, Senior Vice President, Product Strategy and Commercialization Excellence for Lash Group, a patient support services company. “But unlike the case of a patient sitting in an IV chair with the oncology nurses controlling the drug administration, when patients have to follow complex dosing instructions at home, the doctor does not really know if the requirements or restrictions are really being followed appropriately.”

The challenge is magnified as patients are required to take not only one therapy, but often a host of other medications in a complex regimen. To address this, some manufacturers have placed more expectations and responsibilities on specialty pharmacies — particularly those that can work in a clinically integrated fashion with oncology practices. These oncology-focused specialty pharmacies then serve as an extension of the practice itself for the administration and management of cancer care to patients.

The ability to receive chemotherapy in pill form provides the potential for greater ease of administration and greater convenience for patients … However, proper at-home administration of oral oncology agents can be burdensome for many patients, and tolerability issues and potentially debilitating side effects can reduce adherence and hinder clinical outcomes if not properly managed.
“Connectivity between the oncologist’s office and the specialty pharmacy is critical,” says Ratliff. “Specialty pharmacists and nurses proactively identify and communicate with physicians on a regular basis, sharing clinical information and issues that may arise during the course of therapy. Customized technology solutions can deliver near-real-time updates directly to the oncologist. These updates can include, for example, information pertaining to medication shipment status, documented clinical notes and prescription refill status.”

It’s not only engagement with the cancer care provider that promotes success for oral oncology products, it’s also engagement with patients throughout the course of care. “Many patients do not alert their doctor to any side effect or rash, or announce that they don’t feel well, because they fear their physician might take them off the life-saving medication. The need to combat this mindset is yet another challenge for physicians and pharma manufacturers,” says Brown.

For example, Ratliff explains: “Clinical nurse outreach programs can proactively manage patients at key milestones in therapy. We start with a cadence of calls based on what we know about the medication’s profile, and the calls are then adjusted based on individual’s response to therapy and each patient’s desire to continue receiving the calls. One size never fits all.” Proper timing, touch and tone are everything. “Successful nursing-support outreach programs provide ongoing benefit to patients by serving as an extension of the oncologist/patient relationship,” she notes.

Addressing the loneliness and isolation sometimes associated with at-home cancer care using oral therapies is another area that can be addressed by clinical support programs and outreach organized between the manufacturer and specialty pharmacies. “Especially within the realm of oncology, going to the oncologist’s office or hospital for regular chemotherapy infusion sessions really does create a unique little community or family for many patients. As strange as it may seem, some patients really look forward to seeing the same nurses, and the same patients on a regular basis. These interactions can help to support the patient’s overall adherence objectives,” says Brown.

Many patients do not alert their doctor to any side effect or rash, or announce that they don’t feel well, because they fear their physician might take them off the life-saving medication. The need to combat this mindset is yet another challenge for physicians and pharma manufacturers.
“By comparison, taking your oral medications at home can be a very isolated and lonely process — you have less connection to other people in a similar situation who can offer encouragement, support and wisdom,” says Brown. “For this reason, patients taking oral oncolytics can benefit from high-touch programs specifically designed to provide a sense of camaraderie. These are highly personalized, interactive programs that incorporate communication across multiple channels — phone, electronic messaging and web portals — and can encourage sustained, appropriate adherence.”

For their part, oncology practices are also taking steps to mitigate patient challenges with oral oncolytics. Specifically, many practices have set up their own in-office pharmacies, which allow them to dispense oral chemotherapy agents directly to patients.

“There are definite advantages for patients when oral oncology agents are prescribed and managed in close proximity to the physician practice. Physicians must retain ultimate clinical oversight in terms of coordinating comprehensive treatment protocols. Collaborative relationships between oncologists and specialty pharmacists enhance the ability to quickly react to a patient’s response to therapy that may require dose adjustments, adjuvant therapies, or discontinuation,” says Ratliff. “But whether it’s in-office dispensing or through a clinically integrated specialty pharmacy, all stakeholders should remain focused on enhancing the delivery of patient care. This is possible when the patient and provider experiences are emphasized and aligned, resulting in optimized clinical outcomes, appropriate access and adherence and more effective control over the total cost of care.”

**Featured Experts**

**Amy Grogg, PharmD**
Senior Vice President
Strategy & Commercialization
AmerisourceBergen Specialty Group

As Senior Vice President of Strategy and Commercialization for AmerisourceBergen Specialty Group, Dr. Amy Grogg advances the company’s leadership and position in the pharmaceutical services industry as the preferred commercialization partner for specialty pharmaceutical manufacturers. Prior to her current role, Dr. Grogg was President of AmerisourceBergen Consulting Services where she led the growth of a portfolio of companies that included Xcenda, as well as Innomar Strategies and Lash Group.

**Vicki Albrecht, PhD**
Senior Vice President and General Manager
ION Solutions

As Sr. Vice President/General Manager of ION Solutions, Vicki is responsible for leading the expansion of Innovation Cancer as the overarching model for products and services to our oncology customers. With a background in management consulting, Dr. Albrecht has over 10 years of experience in strategy, business development and commercialization across the healthcare value chain. She received her PhD in Bioengineering from University of California, San Diego and her undergraduate in Chemical Engineering from Massachusetts Institute of Technology.

**Loreen Brown, MSW**
Senior Vice President
Product Strategy & Commercialization Excellence
Lash Group

As Senior Vice President of Product Strategy & Commercialization Excellence, Loreen Brown leads Lash Group’s Business and Product Strategy, Product Management, Business Informatics, and Performance Excellence organizations. Ms. Brown is responsible for all Lash Group commercialization and new product operational adoption and implementation efforts, as well as other collaborative, cross-functional and strategic commercialization efforts within Lash Group’s key growth areas. Currently, Ms. Brown leads the development of the adherence program, commercial co-pay and ACE services, with expanding efforts on oncology, orphan drugs, non-profit operations, diagnostics and global reach. Prior to Lash Group, she was Senior Vice President, Commercial Consulting for Xcenda, also part of AmerisourceBergen.

**Kelly Ratliff, DPh**
President
US Bioservices

Kelly Ratliff, DPh, serves as President of US Bioservices, a national specialty pharmacy, where she has held a number of leadership positions during her 20-year tenure, including COO, VP of Operations and Director of Pharmacy Operations. Mrs. Ratliff’s expertise includes pharmacy operations, clinical services, payer strategy, commercial activities and business development.

---

**About AmerisourceBergen**

AmerisourceBergen (NYSE: ABC) is one of the world’s largest pharmaceutical sourcing and distribution services companies, working alongside healthcare providers and pharmaceutical manufacturers to improve access to products and enhance patient care.

With services ranging from drug distribution and supply chain management to patient support solutions and pharmaceutical commercialization, AmerisourceBergen enables quality care and innovation in human and animal health. Tens of thousands of pharmacies, physician practices, health systems, veterinary practices, livestock producers and pharmaceutical manufacturers turn to AmerisourceBergen for the expertise they need to drive business performance.

Learn more at [americourcebergen.com](http://americourcebergen.com).
Where knowledge, reach and partnership shape healthcare delivery.