



ONCOLOGY TRENDS **IMPACTING THE** PATIENT EXPERIENCE

WHAT MANUFACTURERS NEED TO KNOW.

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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.**

The five trends shaping oncology delivery today:

1



For the pharma brand team, the ability to gain access to — and spend meaningful time with — oncologists is harder than ever.

2



Oncologists are facing greater burdens due to the increased prevalence of different value frameworks and clinical pathways.

3



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

4



Patients have higher or different expectations when it comes to their healthcare and treatment options.

5



Having the right data is more important than ever, but turning data into actionable insights is challenging.

With insights from our oncology, practice administration, product launch and commercialization experts, we've provided specific recommendations for the design and deployment of commercialization strategies and programs that effectively address all stakeholder needs, ultimately resulting in a better patient experience.



TREND 1

The ability to gain access to —
and spend meaningful time with —
oncologists is harder than ever.



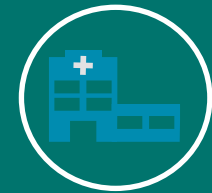
The ability to gain access to — and spend meaningful time with — oncologists is harder than ever.

Medical professionals have increasingly limited time to spend with pharmaceutical sales representatives. Physicians today — and oncologists in particular — are busier than ever, and the relentless demands on their time and energy mean less time and less willingness to interact with pharma sales reps.

Not only are most of today's oncologists treating larger numbers of patients, but given the complex nature of today's coverage landscape, the entire practice staff is also spending more time managing the administrative and logistical requirements associated with helping patients gain access to, and remain on, high-cost specialty medications.

Though many oncologists have less time to meet with knowledgeable pharma sales reps, their need for the types of support they can provide is stronger than ever. Each novel treatment option that emerges brings a new set of clinical and safety considerations, as well as complex reimbursement requirements and challenges, creating more demands on oncologists and their staff throughout the practice. Without sufficient information and support from the makers of these advanced therapy options, many prescribers find it difficult to manage all of the associated clinical and reimbursement complexity. And as the complexity continues to rise, a strong paradox has emerged: Reducing face time with pharma brand reps can make the work of the oncologist (and his or her office staff) harder, not easier.

HOW MANUFACTURERS CAN MAKE AN IMPACT IN THE ONCOLOGY PRACTICE BY:



Creating programs that enable an effective total office call:

bringing reimbursement and clinical expertise into the practice to improve the patient's experience.



Extracting value from GPO and specialty distribution partners:

leveraging their reach, designing awareness programs, fostering dialogue through educational programs and reinforcing sales efforts through consistent, branded messages and product promotion to the practice.

Reimagining the traditional pharma sales call.

“The typical pharmaceutical sales rep can no longer just drop into the practice and expect to get any personal time with the oncologists or office staff — at most, they may be able to set an appointment for two to four times per year,” says Brian Ansay, Senior Vice President, Sales and Corporate Services, for ION Solutions, which provides group purchasing and practice efficiency services for oncology practices. “As a result, today’s pharma sales reps must bring value to every interaction with the oncologists. It’s no longer enough for the pharma sales rep to just detail the features and benefits and safety aspects of the product. Rather, all brand representatives must be subject matter experts, equally well-versed on details related to clinical, reimbursement and contracting considerations of the product.”

Brand teams now must work harder than ever to create impactful, authentic and compliant ways to share clinical and safety information about their products and answer questions that healthcare professionals and billing specialists may have about everything from safety, efficacy and administration to reimbursement. Manufacturers must also share information about patient support and adherence programs both to and through the provider. The goal is to remove all foreseeable barriers in order to meet the clinical and financial objectives of all stakeholders — prescribers, patients and payers — while supporting the business objectives of the brand as well.

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The pressure is on.

“One of the biggest obstacles for drug manufacturers in oncology today is the fight for share of mind,” says Amy Grogg, PharmD, Senior Vice President, Strategy and Commercialization, for AmerisourceBergen Specialty Group. “As oncologists are treating larger numbers of patients every day and they are stressed with their practice’s financial viability, more and more physicians don’t want sales reps just walking in and interrupting them.”

Another paradox arises due to the fact that “oncologists and other physicians are increasingly being held accountable for the clinical outcomes that result from their

prescribing decisions, as commercial payers continue to scrutinize healthcare costs and explore a variety of outcomes-based incentives — such as the pay-for-performance and episodes-of-care payment models — which link reimbursement or payments to the patients’ clinical outcomes,” says Matt Sarnes, PharmD, Senior Vice President, Commercial Consulting for Xcenda, a managed markets consultancy.

As oncologists are increasingly held accountable for the clinical outcomes their patients are able to achieve, the pressure is on for brand teams to find ways to be as creative and impactful as

possible. This means helping physicians navigate all potential barriers that could undermine optimal use of the product, as well as helping patients access — and remain adherent to the therapies they need.

Meanwhile, “independent oncology practices — which use the buy-and-bill model for the medications administered to patients — take on a considerable amount of financial risk themselves, so they have more skin in the game,” says Sarnes.

Making every minute count.

In the face of stronger resistance from oncology practices, innovative pharma brand teams are exploring a variety of strategic initiatives to raise awareness of the product and clarify all prescribing and reimbursement requirements throughout the full life cycle of the product. “Brand teams should strive to improve both the focus and the caliber of their outreach communications and support materials — constantly asking themselves, ‘What more can I provide?’ — to make best use of the limited face time they are able to secure with prescribers,” says Rick Lozano, Executive Director, Corporate Accounts for ION Solutions.

This is true at time of product launch and throughout the product life cycle — for instance, to help sustain awareness and proper use as new label indications are approved, as extended-release versions or improved options to ease administration or reduce side effects are introduced, or as the product matures and faces

increased competition. To keep the messaging valuable and fresh, it must keep pace with what’s really going on in the industry.

“Against a backdrop of time and attention constraints, it can be very impactful to present deep and rich content to larger, consolidated audiences that include many physicians,” adds Grogg. “Allow these prescribers to hear and then discuss the content with key opinion leaders (KOLs) in their field.”

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So whether the information is presented to oncologists in the office setting or at another centralized location (such as a medical meeting), the brand team must strive to make sure the materials presented are valuable and authoritative.

"We host eight live meetings per year in the U.S. to bring oncology practice leaders together with pharma brand manufacturers," says Ansay. "The programs developed for these targeted audiences may focus on the specific challenges

associated with prescribing oral oncolytics, or may help physicians make sense of information that was recently presented at larger industry conferences or the meetings may focus on clinical to raise awareness of specific products."

GO LIVE

What are practices learning at GPO-led live meetings?



Key clinical findings on specific tumor types, as presented by their peers



Regulatory updates



Practice marketing tips and tools



Industry trends and expert perspectives

The ability to present targeted, useful programming to a larger audience of prescribers at such centralized meetings helps to reinforce and disseminate the critical knowledge or messaging throughout the broader oncology community.

Such centralized meetings can help manufacturers gain access to many prescribers at the same time while mitigating roadblocks or restrictions that may limit their ability to secure in-office meetings. “Many oncology practices look to us to serve as a nexus between physicians and pharma brands, to enable sound educational support and not just branded messaging,” says Lozano.

“Whether the information developed by the brand team is to be shared in meetings with oncologists and their staffs in the clinical setting, or in a broader setting, such as a medical meeting, it must be relevant and timely,” adds Lozano. “For instance, if a particular regulatory or dispensing issue or trend has emerged among some private payers or Medicare and it is impacting oncologists, the brand team should develop informative, tutorial-style

outreach to address this larger issue, and then tie in examples using their own product. This can really help oncologists to understand the challenges, and figure out ways to manage the barriers at the point of care.”

Similarly, Ansary notes that Provider Education representatives can actually empower and advocate for practices and patients by working with partners to contribute greater perspective to industry discussions. “By way of example, by developing a deep understanding of how national and regional payer policies are impacting the practice, how the sequester impacted the ASP+6 model and how the Center for Medicare and Medicaid Innovation (CMMI) Oncology Care Model will affect practices, we can work alongside brand teams to help the practice navigate potential roadblocks that are keeping them from providing the best, most autonomous patient care.”

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To overcome access barriers associated with today's high-cost specialty medications, savvy brand teams deploy specially trained field reimbursement experts, who provide direct assistance to address and remove reimbursement and access barriers for both prescribers and patients. Specifically, these highly trained professionals help prescribers and their office staffs to navigate the complex prior authorization and step therapy requirements associated with prescribing the medication, navigate specialty distribution models, manage the complicated coding requirements and

protocols needed to seek reimbursement, and handle coverage denials for high-priced medications that are purchased, administered (or dispensed in-office as with oral medications) and billed through the oncology practice's buy-and-bill model.

"Today's field reimbursement support team must be able to anticipate and address the needs of the practice manager, billing/reimbursement staff and financial counselors — all of whom play an important role in ensuring a great patient experience at the point of care — to help them

navigate coding, coverage, prior authorization and step therapy protocols, and to understand the procedures for investigating denied claims," explains Wade Hubbard, CMCO, Vice President, Field Reimbursement for Xcenda.

Many manufacturers use contract field reimbursement specialists to ensure OIG compliance, help patients overcome access barriers and assist physicians with navigating reimbursement. Contract field reimbursement specialists can support brand teams with:



Product launches and
new indications



Long-term
engagements



Temporary gaps in
staffing



Geographic gaps in
existing teams



Training for full-time field
reimbursement associates
or other staff

Derive strength from GPO and specialty distribution partnerships.

One proven strategy for brand teams to stay abreast of industry-wide best practices and to benchmark their efforts against those of competitors in the same clinical space is to work closely with their trusted partners, such as the group purchasing organization (GPO) or specialty distributor (SD) that helps to connect the product with oncology practices in the field. Specifically, both the GPO and SD — as a result of the partnerships they maintain with numerous pharma manufacturing companies and oncology practices — have both immense reach and knowledge of industry trends, data and anecdotal evidence.

Thus, both the GPO and SD bring unique customer insight and perspective to the table, which can be extremely useful for brand teams as they develop their strategies for interacting most effectively with time-constrained oncology practices. Pharma brand teams can and should

leverage their relationships with these partners, both to hone the outreach messaging and improve the delivery mechanisms in order to focus on those that are most welcomed by today's busy oncology practitioners.

“We’ve built a strong infrastructure around clinical and patient education — bringing a blend of web-based outreach, in-person outreach and other forms of high-tech and high-touch programs for a large number of pharma manufacturers. Similar programs can be customized in a number of different ways, for instance, based on the given therapy or disease state, according to the need for a companion diagnostic test,” says Ansay. Such customization can help to optimize the positioning opportunity, given the limited time and access to busy oncologists that may be available.





Meanwhile, given how limited the face time option may be with busy oncologists, brand teams should not overlook the potential value of developing targeted outreach messaging and materials for other clinical and office staff within the practice. For instance, developing clinical- and reimbursement-oriented support programs that are explicitly aimed at infusion nurses, nurse-practitioners, billing/reimbursement personnel and office managers, all of whom ultimately support both the prescriber and the patient, can help to ensure unimpeded access to the prescribed therapy.

“Through creative program design, the goal for any drug manufacturer should be to effectively disseminate all of the key clinical information, reimbursement support and affordability support,” says Lozano. “When you effectively educate and support oncologists and their colleagues throughout the practice, you have great impact on the overall patient experience.”

The impact on the patient experience.

Not surprisingly, branded and unbranded support to oncology practices has the potential to create a direct, positive impact on patients. The more the oncologist and office staff know about the many high-tech and high-touch support programs that are available from the brand, the better the experience will be for the patient. This is particularly true when it comes to managing coverage and reimbursement hurdles and addressing affordability challenges.

Well-informed practitioners are able to make the most appropriate clinical decisions and initiate therapy as quickly as possible for the patient. And when the support staff can take advantage of the brand's field reimbursement support programs — to reduce hassle, streamline benefit verification and explore other forms of financial support available to assist the patient — it engenders increased goodwill among both prescribers and patients. The cumulative result is the right patient on the right medication at the right time.

“Prescribing choices always have out-of-pocket cost implications for patients, especially if the prescribed therapies have less-favorable formulary tier status or placement in clinical pathways,” says Grogg. “When physicians and their staffs are well-informed, they can work closely with their patients to review all of the clinical and financial implications associated with a given therapeutic option, and then decide together if it’s worth it. With greater knowledge, they can both explore competing options that are clinically appropriate and evaluate the various types of cost-support opportunities that may be available to help offset the out-of-pocket impact for the patient.”

Increasingly among those options are oral oncolytics. Because of their staggering non-adherence rates (up to 80 percent in some cases) and high cost, orals demand an added layer of outreach and education. The fact is, getting a patient on the appropriate therapy and over



affordability hurdles for the first dose, although critical, is just the beginning. The provider — and thereby the manufacturer — must also consider whether the patient can afford to remain on the full course of treatment.

The stakes are higher than ever for brand teams as they work to develop the most effective and impactful programs and outreach methods. “In all cases, the messaging developed by the brand team must be directly relevant to the physician, to the patient or to the other target stakeholders — not just relevant to the brand team,” says Lozano.

¹“Crossing the Threshold: More than Half of Physicians Restrict Access to Sales Reps.” ZS Associates, 2 Sept. 2015. Accessed 12 May 2016. Available online at <http://www.zsassociates.com/about/news-and-events/crossing-the-threshold-more-than-half-of-physicians-restrict-access-to-sales-reps.aspx>

²Roshan Rahnama, Aileen Soper, “Oral Oncolytics: New Reimbursement Opportunities in a Shifting Landscape,” Oncologistics magazine, Fall 2014.



TREND 2

Oncologists are facing greater burdens due to the increased prevalence of different value frameworks and clinical pathways.



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As the cost of care continues to rise, scrutiny on the cost-effectiveness of treatments is stronger than ever. Manufacturers, payers, physicians and patients are united through the common goal of improving clinical outcomes. To achieve that cost-effectively, physicians are under pressure to defend their clinical decision-making and prescribing practices through a more stringent lens, while pharmaceutical companies are expected to provide more evidence to demonstrate the overall value (and justify the cost) of their specialty medications.

A variety of clinical oncology value frameworks, as well as clinical pathways that are developed and published by various commercial entities, could play a much larger role in determining which therapeutic options oncologists can prescribe at the point of care. Critics claim that such restrictions limit physician autonomy and patient access to the most clinically appropriate treatment options.

HOW TO IMPROVE THE PATIENT EXPERIENCE BY:



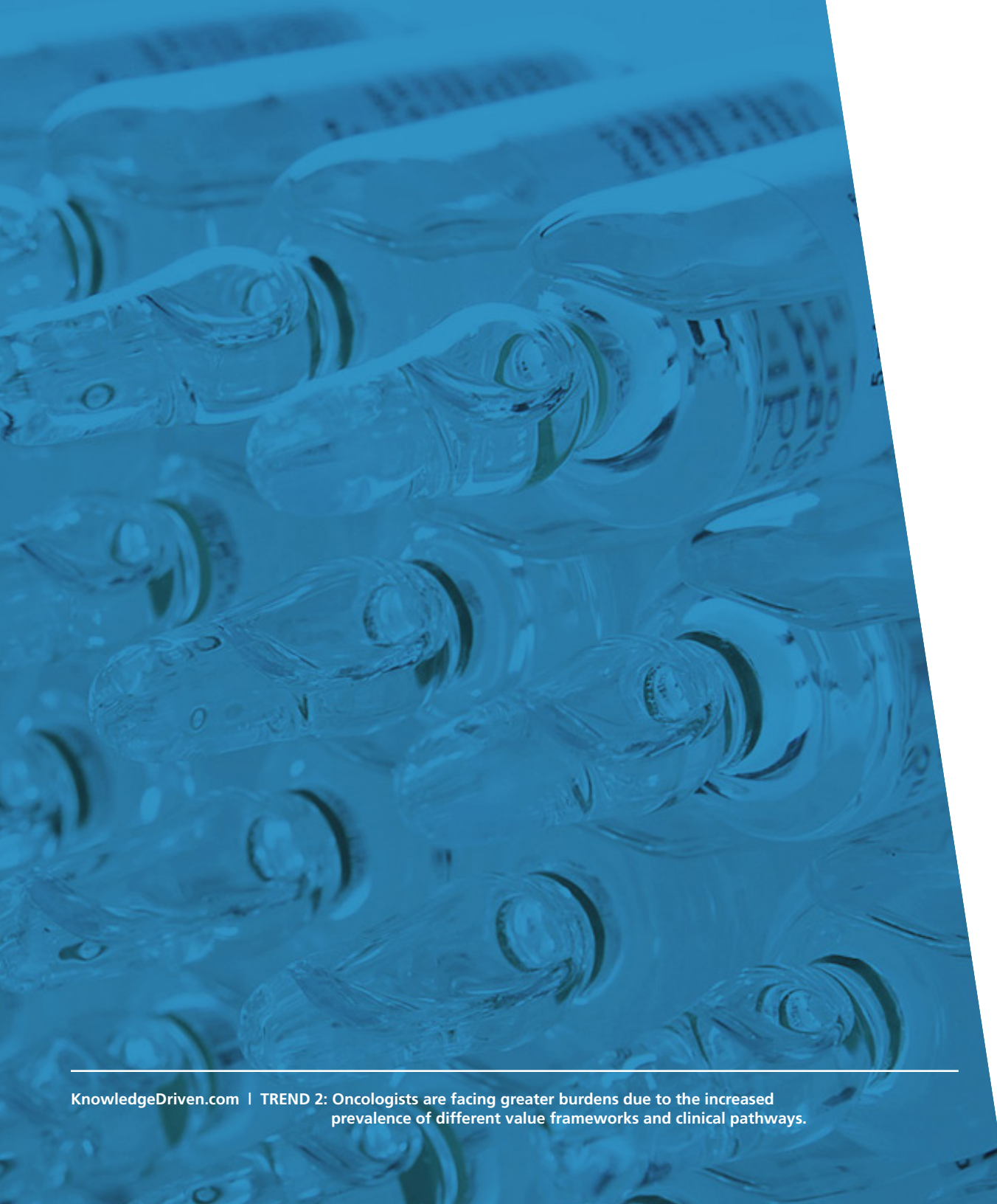
Leveraging real-world evidence and data beyond clinical trials



Proactively communicating product value



Developing partnerships to support prescribers



Understanding what's at stake when prescriber autonomy is restricted.

“Imposing strict guidelines or restrictions on prescribing practices becomes especially complicated — and in some cases counter-productive — in oncology, because in many cases, ‘easy tradeoffs’ among competing therapeutic options do not exist for a given patient with a distinct disease status,” says Barry Fortner, PhD, President of Oncology Supply, a distributor of oncology products to community oncology practices.

Advocates of published oncology guidelines and pathways say that they can help to improve clinical outcomes for the patient and reduce costs for both the payer and the patient by encouraging greater standardization at the point of care and steering physicians toward prescribing decisions that are guided

by evidence. Supporters also argue that such clinical guidance is especially important in clinical indications for which multiple treatment modalities or numerous therapeutic options may be available.

But critics fear the long-term impact that such restrictions on autonomous prescribing will have in terms of patient access to the full complement of therapy options. They argue that oncologists are uniquely positioned to recommend the most appropriate treatment modalities and medications, but their ability to act independently is increasingly being curtailed by concern over the variance among pathway tools. This can often drive increased administrative burden, which ultimately gets in the way of the physician/patient relationship. In fact, most physicians prescribe most of the time within guidelines — those published by National Comprehensive Cancer Network (NCCN), for example, which are strictly evidence-based.

“While the detailed prescribing information on the FDA label for any given product and various clinical guidelines from NCCN and others provide a nice set of parameters to educate

clinicians, the commercial clinical pathways movement has yet to show compelling evidence that it improves outcomes and reduces costs by limiting clinical choices beyond that provided by the label and available clinical guidelines,” says Fortner.

“Experience shows that there are often unintended consequences associated with such restrictions, including extended delays in treatment, reductions in adherence, reduced patient access to viable and appropriate treatment options, increased patient burden and greater need for providers to communicate limitations in the therapeutic options to patients,” adds Matt Sarnes, PharmD, Senior Vice President, Commercial Consulting, Xcenda, a managed markets consultancy. “There needs to be a continued focus on the use and development of innovative payment models and decision support tools that allow the physician and patient to collaboratively determine the path to timely, convenient, cost-effective care.”

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programs, patients may never know that there was another option available to them. This may be especially important for pathways required as part of a payer-oriented program, where cost may be a central value over quality” says Fortner. “Removing treatment options through pathways further thwarts the central value of the patient-physician relationship and the autonomy of the prescriber.”

“Oncologists must be able to continue to make the most appropriate clinical decisions on a patient-by-patient basis, weighing all of the relevant factors involved. The tools in the practice should help, not hinder, the physician in weighing the multitude of factors involved, given the increasing number of therapies available,” says Vicki Albrecht, PhD, Senior Vice President and General Manager for ION Solutions, which provides group purchasing and practice efficiency services for oncology practices.

One of the biggest challenges associated with the use of clinical pathways is that oncologists are routinely faced with the added burden

of considering numerous clinical pathways. “Physicians everywhere are struggling with clinical pathways and formulary issues — and they don’t have just one set of rules to follow; rather, oncologists in various practice settings often have to deal with multiple pathways and multiple formularies, based on the patient’s insurance,” explains Amy Grogg, PharmD, Senior Vice President, Strategy and Commercialization, for AmerisourceBergen Specialty Group.

Since many of the competing pathways are published by different commercial payers and other stakeholder groups — and the clinical requirements or restrictions are never totally identical or harmonized for any disease state — oncologists must follow different ones for different patients throughout the course of every single day. This adds further administrative burden and potential confusion to the prescriber’s workflow and invites further variability and inconsistency in patient care and clinical outcomes from patient to patient.

Sadly, this unintended consequence is in direct opposition to the stated goal of the clinical

PATIENT ADVOCACY GROUPS WEIGH IN ON:



Pathways and personalized medicine



Transparency



Patient access

The National Patient Advocacy Foundation (NPAF) contends that pathways should be held to the same transparency standards as clinical guidelines, arguing that the ability to take full advantage of ongoing advances in personalized or precision medicine “may be incompatible with clinical pathways that are not thoughtfully constructed, or don’t take into account detailed patient characteristics.”

At the end of the day, “patients need to have confidence and faith that pathways will not simply be a hidden tool to steer them to a limited range of treatment options pre-selected by their insurance provider,” the group says.¹



pathways concept, which is to streamline operation, standardize clinical care and reduce costs, notes Fortner, adding: “Different patients with different payers but with the same type of cancer and being treated by the same oncologist may end up receiving different forms of care, largely based on the payer’s required pathways program.”

“Transparency around clinical pathways remains a concern among many stakeholders in oncology. The physician-patient relationship should remain paramount,” adds Albrecht. “Of particular interest is not the question of whether clinical pathways can bring some value to oncology; it is concern over the fact that not all pathways are created equally — so the important consideration is really knowing the intent and decision criteria behind a given set of commercial pathways.”

Meeting the value challenge.

Manufacturers must be proactive when it comes to effectively and efficiently communicating the value of all of their products. “Brand teams must find strategic ways to keep both physicians and payers apprised of any new evidence that becomes available, to be sure they understand the full value proposition of the product,” Grogg says.

Similarly, Sarnes adds that “to ensure the most appropriate and advantageous position of their products as they are being considered by the pharmacy and therapeutics (P&T) committees of commercial insurance plans and pathways publishers, drug manufacturers must understand how each of these prevailing value frameworks is set up, in terms of the underlying methodology and the types of evidence each framework uses to articulate its clinical recommendations.” He says pharma companies are limited in the ways in which they can convey their findings and evidence to key decision makers in value frameworks and insurance formularies.

Specifically, when it comes to insurance formularies, drug companies must remain mindful of the requirements set forth in FDAMA Section 114, which restricts the type of information that may be communicated proactively between drug developers and formulary decision makers. Instead, Sarnes notes “drug developers should be cognizant of this guidance when designing outcomes studies to increase the ability to communicate this critical data proactively. In addition, the proactive communication strategy should be coordinated with publication strategy. Publishing data in peer-reviewed journals and presenting studies and findings at professional meetings gets that information in the public domain for use by decision makers who shape each value framework.”

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Data, data and more data.

For high-cost oncolytics and other specialty medications to have the best opportunity to achieve favorable recognition within clinical pathways (and gain the most advantageous placement within various insurance formularies), they must have a strong body of evidence available. Today's drug manufacturers must continue to develop, disseminate and publish meaningful evidence that not only confirms the safety and efficacy of the product under real-world conditions, but seeks to demonstrate its value within the overall scope and total cost of patient care. Relevant information includes real-world outcomes data, patient-reported data and other forms of pharmacoeconomic data that could help to position the brand most favorably in the eyes of crucial gatekeepers that include the medical and pharmacy directors at public payers and P&T committees at health systems.

"It is essential for manufacturers to have a solid evidence-generation strategy in place as early as possible," adds Sarnes.

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The historical types of data that the pharma industry is used to developing — for instance, clinical trial data to verify the clinical value of the new therapy — are no longer enough.

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Rather, pharma innovators must really explore the role and performance of their new therapies in terms of real-world settings. "They must ask 'what do episodes of care look like, even during clinical trials? What does the complete resource-utilization picture look like — even in one arm of a clinical trial versus another?'" says Sarnes. "The ability to build a strong, evidence-based story to support these questions sets the stage for the product to receive the most favorable placement in evidence-based pathways or formulary tier assignments that aim to balance cost against overall value."

SOURCES OF UNSTRUCTURED DATA



Open text fields
in EMRs



Social media



Patient support
programs



Collaborating and communicating — early and often.

For any brand team, working closely with strategic commercialization partners — for instance, the group purchasing organization (GPO) or specialty distributor — can provide strong strategic opportunities beyond just that of managing flow of product to oncology practices. First, with such broad reach into numerous pharma companies and numerous oncology practices, the GPO or distributor is in an ideal position to share key insight on the trends that are impacting prescribing habits related to the medication or the disease state, and often provides an effective point of entry to help the brand team gain access to busy, distracted physicians (this is discussed in [Trend #1](#)). Additionally, the GPO “is often ideally positioned to help the brand team effectively share value messaging and evidence about the product because they have a long relationship with — and are viewed as a trusted partner by — so many oncology practices,” says Grogg.

There's another benefit to developing good data as early as possible in the process. Today, an accelerated approval process is available for certain investigational drugs — especially those that show particularly promising clinical advances and unmet need. "It is oftentimes not feasible for pharma companies to support their full story at launch," says Sarnes. "However, capturing some resource utilization and outcomes data during clinical trials, coupled with better defining the overall cost of care for their target patient population, better enables them to have an educated value discussion out of the gate. Setting the foundation for a purposeful, evidence-based value story that will evolve over time puts the manufacturer in the best position to achieve common ground with payers and optimal access."

Involving decision makers that control access to therapies early in the development process can bring other advantages. "By letting payers in on the clinical trial process, the study design can be geared not just toward the FDA's needs (in terms of demonstrating clinical efficacy, safety and tolerability) but toward the payer's needs,

too, and this may pay dividends later, when formulary tier status is being evaluated," says Sarnes.

And while it may require a different mindset, pharma companies must be bold in their outreach to payers and regulators. "Too often, pharma companies tend to shy away from early conversations with payers and regulators, but it's important to keep those lines of communication open and begin sharing data and information as early as possible," says Sarnes.

"It is up to the pharma companies to make sure payers are informed as early as possible and not be caught by surprise; this gives the payers the chance to sit with the information for a while and allow them to understand the pricing implications of the new therapy in terms of how many patients will actually be impacted and the overall cost to the plan," says Fortner. "In recent years, this approach has proved to be to be helpful for some drug manufacturers."

The fact is, payers need as much information as they can get about what is coming to

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market and at what price in order to plan for the impact on their patient populations.



Understanding the impact of innovation on the cost of care will help all stakeholders better plan for navigating cancer as a chronic disease.



“Drug manufacturers must use available clinical endpoints and health outcomes-related data to prepare payers sooner rather than later in the launch process — so payers can begin to understand and digest it as early as possible,” adds Fortner. “Strong evidence about the overall value of the new therapy may help payers be more receptive when it’s time to discuss drug pricing.”

One caveat, according to Sarnes, is that comparative effectiveness studies, which aim to measure the new therapy’s performance against the standard of care, must be timed appropriately and reevaluated on an ongoing basis, keeping in mind that the standard of care at the time of testing may not be the same as the standard of care at the time the product finally receives FDA approval and is launched.

COMMUNICATING ACROSS THE CONTINUUM

What to articulate to physicians and payers.



The value of the product within the overall continuum



Tips for managing the disease or side effects



Additional indications



Support program availability

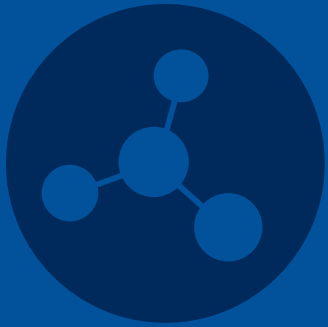
“Brand teams should deliver such information through every possible channel — high-tech and high-touch — for instance, meetings and programs with physicians and their office staff and tools that payers can use to see the impact among their insured populations.”



Supporting the patient journey.

Today's patients are receiving their cancer care in two general types of settings: Smaller, privately owned community oncology practices and larger clinical settings that are owned by hospitals or larger affiliated health systems. Not surprisingly, the patient experience can vary significantly between community and hospital-based oncology settings. Staff size, patient support capabilities and insurance coverage accepted are all major differences. In fact, where a patient receives care is often dictated by which site accepts a particular type of coverage. No matter the site of care, manufacturers must make sure they are reducing accessibility barriers for all customers. Ultimately, product access means patients benefit.

¹ National Patient Advocate Foundation (NPAF). Clinical Pathways: barrier or benefit to patient access and personalized medicine? July 2015. Accessed 18 May 2016. Available online at <http://cqrcengage.com/npaf/file/tTiSOowxuVB/Clinical%20Pathways%20White%20Paper%20July%202015.pdf>.



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 2024.¹ 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.

HOW MANUFACTURERS CAN IMPROVE THE PATIENT EXPERIENCE BY:



Understanding the challenges providers and patients face as therapeutic options expand



Leveraging the full breadth of support programs and specialty pharmacy partner solutions



Meeting the innovation challenge.

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.”

MOTIVATIONAL INTERVIEWING



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

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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.

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“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 of 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.

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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 of the life-saving medication. The need to combat this mindset is yet another challenge for physicians and pharma manufacturers.

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“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.”

¹American Cancer Society. Life After Cancer: Survivorship by the Numbers. 2013. Accessed 20 May 2016. Available online at <http://www.cancer.org/acs/groups/content/documents/image/acspc-043793.pdf>.



TREND 4

Patients have higher or different expectations when it comes to their healthcare and treatment options.



Patients have higher or different expectations when it comes to their healthcare and treatment options.

Empowered by the ease with which they can access information, today's patients seek a deeper understanding about their diagnoses, underlying diseases or health conditions and potential treatment options, as well as the financial implications of clinical decisions made by their prescribers.

But what does it all mean for pharma? In this era of greater healthcare information, transparency and easy access, manufacturers can find success by engaging patients at an individual level. It's time for true patient-centricity.

DESIGNING AND DELIVERING PATIENT-CENTRIC SUPPORT SERVICES:



Maximizing services vs.
maxing out patients



Addressing patients
holistically



Balancing high-tech with
high-touch

The empowered patient.

In the last two years alone, healthcare has made big strides in closing the digital gap between patients and their providers. According to a report from Accenture, nearly 20 percent more patients have used electronic health records (EHRs) to access their records than in 2014, and the number of consumers that do not know what data is available to them has gone down by more than 25 percent.¹ What's more, 92 percent of patients surveyed believe they should have full access to their EHRs.²

Even more remarkable is the use of mobile health apps and wearables, which has doubled over the last two years, with 36 percent of patients using symptom navigators and 12 percent using medication trackers/reminder apps.³ Among those surveyed, 90 percent of healthcare consumers were willing to use wearables to share health data with physicians or nurses.

This data is more than promising. It tells stakeholders across the continuum that patients are now more likely than ever to become highly engaged in their healthcare and treatment decisions, not only seeking more information but using that knowledge to enable more meaningful discussions (and ask more well-informed questions) during their treatment journeys.

THE APPETITE FOR DIGITAL HEALTHCARE⁴



Nearly 20% more patients are using EHRs to access their records than in 2014



25% more patients now know what data is available to them in EHRs



92% of patients surveyed believe they should have full access to their EHRs



The use of health apps and wearables has doubled over the last two years



36% of patients use symptom navigator apps and 12% use medication trackers/reminder apps



90% of healthcare consumers are willing to use wearables to share health data with physicians or nurses

Meeting the challenge of patient-centricity.

Empowering the healthcare consumer with the right information is critical for outcomes. As such, “the pharmaceutical industry is moving ‘beyond the pill’ to focus on patient-centered solutions — **enhancing the patient experience** by proving product value, resolving barriers to access, designing empowering adherence programs and offering physicians, health systems and pharmacies solutions to improve efficiency and enhance patient care,” says Amy Grogg, PharmD, Senior Vice President of Strategy and Commercialization for AmerisourceBergen Specialty Group. However, this movement can create greater challenges for pharma brand teams as they are expected to support more avenues for effective communication tailored to the varied needs and preferences of individual patients. But more *effective* outreach by pharma companies also has an enormous upside for both patients and prescribers.

Which services improve patient engagement, and which just add more noise to the conversation? In 2013, *Harvard Business Review* encouraged healthcare entities to learn from other service industries — like the hospitality industry — how to deliver better patient-centered care. Their assessment was that current approaches used focus groups and surveys to assess general patient preferences, and as a result, the industry had “a misguided focus on the needs of the average patient.”⁵

The fact is, a number of factors influence the patient experience, from therapy itself to socioeconomic issues, and all of those factors must be taken into account as brand teams map the patient journey. Manufacturers who fully commit to addressing patients holistically, and according to their individual needs and priorities, are those who are accomplishing true patient-centricity.

FACTORS INFLUENCING THE PATIENT EXPERIENCE



Therapy (cost, complexity, fear of side effects)



Socioeconomic status (transportation, language barriers, caregiver support)



Poor care transitions (access barriers to care and medication)



Conditions (depression, anxiety, substance abuse, etc.)



Beliefs/behaviors (lack of insight or belief in benefit)



Balancing high-tech with high-touch: the branded hub platform.

Because managing the patient's treatment experience is so important, many of today's high-cost specialty medications provide a centralized branded hub platform, which is typically set up by the brand team and, in many instances, operated by a third-party supply chain partner. The hub platform associated with any branded medication provides a streamlined point of entry for patients and physicians, allowing them to seamlessly access all of the diverse programs that are available to support proper use of the complex medications in the field, and to address the affordability issues that so often limit access for patients and payers.

A well-designed hub program typically provides a mix of two elements:

Automated services

These include online access to medical and product information, the ability to electronically

review payer policies, verify benefits and check on reimbursement status, online access to coupons and voucher programs that may be available to help offset the out-of-pocket costs for the medication and more; and

High-touch services

These include streamlined access to call center professionals, such as nursing, pharmacy and coaching experts who can provide remote yet immediate phone-based or online support. Such clinical experts are available to answer questions about the medications or the disease state, to assist with proper administration procedures or help the patient manage side effects (all of which helps to increase adherence to therapy). Similarly, on-call reimbursement specialists can provide a range of essential support services to help the patient manage the complex administrative and financial implications of today's high-cost medications. For instance, such reimbursement specialists can help both patients and physicians navigate the complex requirements of the patient's insurance program (in terms of helping the physician's office to manage Prior Authorization and step therapy

requirements), and assist eligible patients and their loved ones to access coupons and vouchers available for the medication and enroll in Patient Assistance Programs (PAP) that can provide the medication at little or no charge.

"When a given manufacturer establishes a single, branded hub to support all of the drugs in its oncology portfolio, the company can gain greater visibility and the brand is able to support both the physician and patient experience in an enriched and fulfilling way," says Rick Lozano, Executive Director, Corporate Accounts for ION Solutions, which provides group purchasing and practice efficiency services for oncology practices.

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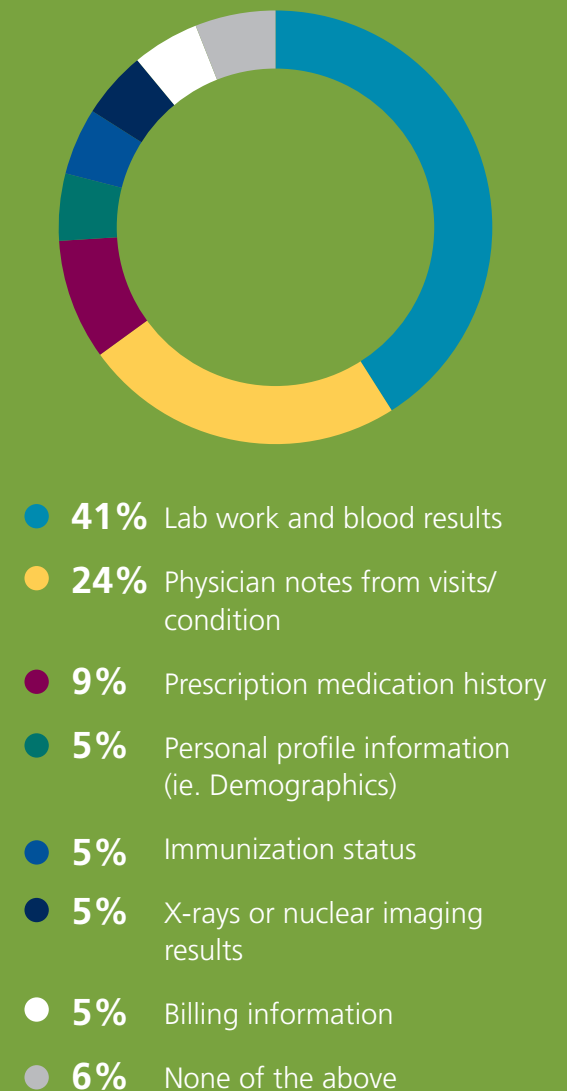
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Creating a patient support strategy to provide all of the specific forms of information, automated services and high-touch support and make them easily accessible from a single, online point of entry through the branded hub is a key element of the brand's success in the marketplace.

A centralized repository of information and on-call support services gives brand teams a great way to help address the many clinical and financial barriers that so often thwart proper adherence to therapy among patients. "There's not necessarily a right or wrong way to do it — once the patient makes contact with someone in the call center (whether it is a tele-health nurse or a reimbursement specialist), these trained professionals are able to start a meaningful conversation and draw out the patient to uncover a variety of issues that may be providing barriers to access or adherence," says Loreen Brown, MSW, Senior Vice President, Product Strategy for Lash Group, a patient support services company. "That conversation can then be used to direct the patient to other appropriate program offerings within the hub."

Similarly, taking advantage of today's electronic capabilities and patients' overall appetite for greater access and involvement in their healthcare decisions, many large oncology practices are also establishing online portals, which provide seamless access to many integrated aspects of the patient's overall treatment continuum. Such portals allow both physicians and patients to access records related to, for instance, diagnostics and lab results, billing and claims information and prescriptions.

DATA THAT PATIENTS WITH EHRs FIND MOST HELPFUL⁶





Patients who are not as motivated need support, too.

While many patients are highly motivated and empowered, others may not be as motivated — yet these patients cannot be left behind. Brand teams must grapple with the age-old problem of how to properly inform and motivate those patients who do not take an active role in optimal healthcare and commitment to adherence goals. Similarly, brand teams must devise appropriate outreach strategies to support patients who struggle with medical literacy issues, affordability issues and others barriers that could reduce both access and adherence to potentially lifesaving medications.

To ensure the best clinical outcomes and optimal performance of the therapy under real-world conditions, forward-looking manufacturers are no longer taking a one-size-fits-all approach to the design of their educational and support services. Rather, they are tailoring their outreach to meet different levels of health literacy requirements, and are targeting interventions to address different levels of patient engagement and motivation.

Looking at patients in three dimensions: segmenting and stratification.

For brand teams, the ability to segment specific patients to better understand their capabilities and motivations provides a powerful opportunity to focus resources and tailor specific types of outreach so they will be most impactful. “Segmenting your patients is so important, because not every level of patient needs the same type or amount of assistance,” says Brown. “These interactions provide great insights, and help the pharma brand team to focus its outreach and spending in ways that will yield the best outcomes for their patients, providers, payers and themselves.”

“All patients are motivated by a variety of internal and external factors, and every patient has a different level of education and a different comfort zone when it comes to medical education. So all outreach materials provided by the brand team must be not only easily accessible through the hub, but truly easy to comprehend,

no matter what the patient’s educational or socio-economic status may be,” Brown adds.

“Making the effort to really learn which factors are at play influencing individual patients (in terms of their capabilities, motivations and limitations) helps the brand team to meet the needs of both highly motivated and empowered patients, and those who may need various types of additional intervention and support as they confront the many challenges that follow a cancer diagnosis,” Brown continues. “For instance, most patients have a clear preference for either high-tech or high-touch forms of support. By understanding the patient better using proven patient-assessment methodologies, the brand team (via the hub program’s offerings) can provide and tailor more meaningful interactions, and time them appropriately to coincide with critical moments during the patient’s treatment journey.”





Patient stratification in the real world.

Brand teams can use a number of different methods or approaches to assess patient engagement or empowerment. For example, a quick survey can be administered online, by phone (using trained telehealth associates) or in written format. “It provides a score that tells how empowered the patient is with his or her healthcare journey (a score of 1 means less motivated; a score of 4 indicates a highly engaged patient, with gradations of 0-10 within each of those scores, so the patient could be characterized as a ‘high-2,’ a ‘low-4’ and so on).” explains Brown, adding: “Having assessed the patient in this way, in collaboration with the clinical program experts, the brand team can then create a more tailored, more meaningful care plan and set of support tools with that individual patient — understanding and validating where weak spots or pain points may be, and work with patient to establish goals and achieve reasonable milestones.”

The prevailing wisdom is that more highly engaged patients tend to enjoy better adherence to prescribed therapies and improved clinical outcomes. “If a patient is highly engaged, you can contact them less frequently, and those patients tend to be very self-sufficient, able to find what they need online and perhaps only requesting occasional reminder text messages,” says Brown. “On the other hand, a patient who is characterized as Level-1 may not improve, and this can help to inform the brand team in terms of how much high-touch intervention can be justified in terms of the return on investment.”

“Typically, the brand teams get the best outcomes when working closely to support Level-2 and Level-3 patients, as these are patients who have the potential to overcome obstacles and barriers with access to the right types of support materials or personal interactions or interventions,” says Brown.

“In the long run, making the investment of time and effort to undertake patient-stratification efforts pays off,” says Brown. She notes that there really is no one-size-fits-all option when it comes to helping individual patients get the most out of

their experience in terms of the use of specialty medications, and allowing the therapy to perform best under real-world conditions, in terms of safety and efficacy, tolerability and affordability. But failure to adhere to prescribed therapies is a sure-fire way to undermine the benefits of the medication, the ability to help the treatment achieve remission (or prolong current state) and both optimize and justify the use of healthcare expenditures in oncology. Brown concludes, “Efforts to segment patients using a specialty medication can also help the brand team to spot trends, in terms of identifying which patient groups need what, when and how.”

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Getting it right ... or what?

By creating new ways to connect patients, families and caregivers with the right mix of clear, accessible information and on-call support services, brand teams can help today's patients to become more engaged and empowered in managing their treatment. Armed with the right resources, patients are better able to meet challenging adherence goals, stay on complex prescribed therapy regimens and improve overall clinical outcomes. Similarly, greater collective effort and tailored strategies by pharma brand teams (and their many partners throughout the supply chain) are also helping to engage patients who may have lower medical literacy, which can make it challenging to digest today's increasingly complex clinical information.

In this era of higher expectations among all stakeholders, it is critically important to do it well. "If, during commercialization and launch, a pharma company stumbles on the patient-support piece — for instance, if some element is inconvenient or confusing, the team just does

not do a good job at educating the physicians and staff in the practice, or there is any bump in the road in terms of how the various programs assist patients — this can create very big frustrations among all parties, and this can undermine adherence among patients and brand loyalty among prescribers," says Barry Fortner, PhD, President of Oncology Supply, one of the nation's largest distributors of chemotherapy drugs and supplies. "With all of the barriers that can delay initiation of treatment, restrict a patient's access to a given therapy or raise the patient's out-of-pocket costs, pharma companies have to anticipate all of the potential pitfalls and be much more diligent than they ever had to be in the past when developing and deploying all of their brand-support programs."

¹"Patients Want a Heavy Dose of Digital." Accenture, 2016. Accessed 6 June 2016. Available online at https://www.accenture.com/t20160226T105643_w_us-en/_acnmedia/PDF-6/Accenture-Patients-Want-A-Heavy-Dose-of-Digital-Infographic.pdf

^{2,3,4,6} Ibid.

⁵ Powers, Brian, Amol S. Navathe, and Sachin H. Jain. "How to Deliver Patient-Centered Care: Learn from Service Industries." Harvard Business Review. 19 Apr. 2013. Accessed 07 June 2016. Available online at <https://hbr.org/2013/04/how-to-deliver-patient-centere.html>





TREND 5

Having the right data is more important than ever, but turning data into actionable insights is challenging.



Having the right data is more important than ever, but turning data into actionable insights is challenging.

For years, the concept of “big data” has conjured images of endless possibilities throughout the healthcare arena. But far more important than amassing impressive caches of data from various sources is the ability to make sense of the data and recognize trends that can inform and support the pharma brand team. The ability to turn data into actionable information serves all stakeholders. It allows both pharma and physicians to continue making advances in patient care by making decisions that improve outcomes.

Despite the staggering amount of data generated on a daily basis in healthcare, considerable challenges remain. The sheer volume of the potential data assets that are available today — from oncology practices, payers, supply chain partners, the list goes on and on — creates a daunting scenario for brand teams. And it’s not just disparate data sources; further complicating

the oncology data picture is the complex nature of the disease itself and the precise nature of approved label indications for so many of today’s approved oncology agents.

For manufacturers, the feeling of data overload is very real. How can pharma find the right data, from the right sources and integrate it in the right way to power product performance and patient outcomes?

HOW MANUFACTURERS CAN BREAK DOWN BIG DATA BY:



Identifying the
right data ...



... from the
right sources ...



... and integrating it in
the **right** way.

Data, data everywhere.

Big data is a big deal, and it's certainly a good thing for healthcare. But what does big data really mean? Even among players in the same industry, what the right data means for one stakeholder is very different for another. For example, data that helps payers reimburse may not offer insights for manufacturers. Even for pharma organizations, the usefulness of certain data sets varies based on where a product is in its life cycle.

And since data is so abundant, the right information can be difficult to harness. "The concept of 'big data' is alluring among all stakeholders in healthcare, and there's always a hunger for more and more data — but for pharma manufacturers, the challenge is to use different sources of data in appropriate ways that can truly advance the objectives of the brand," says Vicki Albrecht, PhD, Senior Vice President and General Manager of ION Solutions, which provides group purchasing and practice efficiency services for oncology practices.

In addition, oncology has unique challenges. "Because you often cannot compare treatment data in oncology to treatment data in other disease states, and you often cannot really compare treatment data from one form of cancer to another, you end up creating lots of unique subsets of data. This makes it much harder to extrapolate limited data sets to identify broader trends and patterns," adds Shishir Desai, Director of Client Analytics for Lash Group, a patient support services company.

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The challenge and promise of EMR data.

As brand teams seek to identify and capitalize on various sources of useful data, one of the most frustrating disconnects within oncology relates to the data seemingly locked within electronic medical records (EMR) systems. “Data gathered in community oncology settings is often siloed or isolated by fractured systems and inconsistent utilization, and while overall use of EMRs has been growing steadily throughout healthcare, there are many disparate systems from competing vendors in the marketplace, and these systems tend to not be geared well for optimal use in oncology,” says Matt Johnson, Chief Operating Officer for ASD Healthcare, a specialty pharmaceutical distributor.

Largely driven by financial incentives and penalties under Meaningful Use guidelines established by the Health Information Technology for Economic and Clinical Health (HITECH) Act, many oncology practices have adopted out-of-the-box EMR solutions that are ill-suited to the specialty practice.¹ And though widespread

EMR adoption has made it easier than ever to collect and organize different types of data related to the patient’s health and treatment, the physician’s prescribing practices and clinical outcomes, the spectrum of different systems from numerous vendors and the overall lack of standardization reduces the opportunity for all stakeholders in oncology to effectively mine what many would argue is the richest source of patient-centric data available related to ongoing care. This creates an enormous missed opportunity for all stakeholders.

Fortunately, the tools to analyze data are evolving almost as rapidly as the data is produced, and this is an area where EMRs hold promise in terms of producing cost and time savings for pharma. Before EMRs, brand teams that wanted to dig deeper into reasons for non-adherence, therapeutic dropoff and more would work with health outcomes research partners to conduct chart review studies — expensive projects using



nurses and physicians to pore through piles of paper charts. Now, those same partners leverage innovative algorithms and tools like natural language processing to mine the open text fields in EMRs. These EMR studies produce more accurate data from the reality of the way physicians use EMRs. The studies can be both supplemental and validating, and they're just one way pharma is using **innovative sources of unstructured data**.

Meanwhile, analyzing trends related to how specific therapies are being used in the

marketplace is also challenging because of where and how specific therapies are prescribed. Specifically within oncology, the treatment setting varies by practice type (for instance, community versus hospital-based oncology setting, or acute care versus ambulatory setting), and this creates further fragmentation of valuable data resources, limiting how and where relevant data can be accessed and studied to better understand the trends, says Susan Weidner, Senior Vice President of IntrinisiQ Specialty Solutions, provider of the leading clinical information system for medical oncology. "Even the way different practices

organize specific data fields — something as simple as writing 'milligram' versus 'mg' versus 'Mg' can impede effective data extrapolation when the brand team is looking to identify or quantify trends across the entire data set."

Albrecht adds: "Ideally, to be most useful, the data should be collated into a big data warehouse, so it can be cleaned up and harmonized and thus truly mineable. Only then can you actually measure what you think you are measuring."

EMR CHALLENGE

Generic EMRs ill-suited for oncology

Physicians enter data outside of fixed EMR fields

EMRs show prescription was written, but not if it was filled

POTENTIAL SOLUTION



Specialty and oncology-specific EMR solutions



Studies that integrate EMR and other data, including mined data from free text fields

Looking for trends in real-world data.

With payer scrutiny on specialty medications at an all-time high, and growing interest in defining the clinical and economic value of specialty products, pharma manufacturers are increasingly looking toward dispensing data and clinical outcomes data to better characterize how a product performs post-launch, under real-world conditions. “It’s important for drug manufacturers to use real-world data that is coming out of oncology practices, and increasingly, we are seeing pharma companies working more closely with practices during Phase III and IV clinical trials,” says Weidner. Collaborating with practices directly, manufacturers are increasingly able to improve speed and accuracy in their understanding of how new products can perform in a diversity of settings. Moreover, the data gleaned from GPO partnerships — through contracting/purchasing as well as predictive analytics around utilization and reimbursements — can be valuable as manufacturers develop support programs.

“From the drug manufacturer’s perspective, the more integrated the sources you can access, the better, in terms of accessing and evaluating data related to not just the clinical experience, but the patient experience,” says Amy Grogg, PharmD, Senior Vice President, Strategy and Commercialization, for AmerisourceBergen Specialty Group. “Integrating data related to all of these different perspectives will help brand teams to develop a better understanding of which patients best received the therapy, and which cases provide the best value for payers.”

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It's that integration that is so critical for getting to the *right* data. Insurance claims and reimbursement can provide insight to support the brand's business objectives; however, Johnson notes that you can't always take such data at face value. Rather, a nuanced approach is often needed to make best sense of it. "You may know that the drug was administered and the claim was paid, but you may still not know if the drug was used for an approved/billable indication or used off-label (and recoded). Nor do you necessarily know if it was used as the first-, second- or third-line therapy, alone or in conjunction with another therapy, in accordance with the dosing on the label or using different dosing instructions (per the doctor's discretion)."

Where can manufacturers get real-world data? It may be closer than they think. "Patient support services providers have a deep level of engagement with patients and providers, so the data that is captured and the insights that are provided by these partners are incredibly important to the manufacturer," says Desai. "As manufacturers gain these

insights and commingle it with the rest of the data they have within the organization, and external sources as well, they're able to better understand and create targeted data-driven strategies to help improve patient outcomes and product performance."

"You have EMR, genetic testing and biomarker-related data, patient-reported health data, drug-effectiveness and outcomes data, cost data associated with individual drugs (in terms of pricing, reimbursement and patient out-of-pocket costs), adherence-related data," Grogg adds. "Integrating all this data helps brand teams gain a complete understanding not just of the clinical efficacy, but also the patient experience, the provider experience, the payer experience."



The impact of patient support program data.

“We are able to help oncology manufacturers look at different patient populations — in terms of the various forms of support services the patients actually used — in order to evaluate which particular mix of services led to better outcomes,” says Desai. “Such trends can be identified by subsets of patients or services, and then the insight can be turned into actionable items that physicians in the practice can implement, to help the patient stay adherent to

therapy.” He adds: “The goal for both oncology practices and brand teams is to help patients start treatment faster, stay on treatment longer and manage cost issues. Using data analytics effectively can help to advance these objectives for both parties.”

When grappling with both the abundance and imperfect nature of available data resources, it's wise to ask a lot of questions. “Specific insight

can be gained by challenging the various data sources to answer the right questions,” says Johnson. “Useful investigational prompts may include such questions as ‘who is prescribing our drug? Is the patient receiving other therapies along with our drug? What is the patient’s site of care and does this impact access to therapy or long-term adherence? What is the reason that a given patient may suddenly fall off therapy (is it cost-related or clinical in nature)?’”

THE FOUR QUESTIONS YOUR DATA SHOULD ANSWER:



1: Who is prescribing our drug?



2: Is the patient receiving other therapies along with our drug?



3: What is the patient’s site of care and how is it impacting access or adherence?



4: What are the reasons for drop-off?



“As centralized hub platforms have become more sophisticated — providing aggregated access to all of the various [high-tech and high-touch services](#) the brand provides to support proper prescribing, use and reimbursement of the specialty medication — they provide a natural opportunity to gather a large variety of important data metrics,” notes Loreen Brown, MSW, Senior Vice President, Product Strategy for Lash Group.

The ability to use better data analytics capabilities to understand and influence the patient piece of the equation “is really a game changer,” adds Desai. “At the end of the day, all of the various programs and support services offered by both the brand team and oncology practice come down to shaping the patient experience, improving clinical outcomes and reducing costs, so the ability to both verify the impact and carry out mid-course corrections, guided by data-driven insights, is invaluable.”

Data and your distribution partner.

“The industry has become quite adept at tracking the flow of product through different protocols, but still struggles when it comes to pulling that data through to other operational and strategic functions,” adds Kevin Hallinan, Senior Vice President of Strategy, Global Sourcing and Manufacturer Relations for AmerisourceBergen.

Combining product distribution data and patient support services data remains an area where the value of a more integrated view is just now beginning to be fully uncovered. “In our role as a pharmaceutical wholesaler, we generate many sources of useful data throughout the lifecycle of a distributed product,” says Hallinan. “By analyzing our data, we can measure the success of various branded programs that are available to improve patient access to therapy (by ensuring faster starts and reduced dropoff). We can also track the success of the brand’s efforts to improve affordability — for instance, by connecting patients with available co-pay assistance and

PAP programs, and offering programs that are designed to promote long-term adherence by connecting patients with registered nurses who have subject matter expertise to help patients manage complex drug regimens, recognize and manage side effects and more.”

“The more you are able to drill down a bit more into the data — to not just know whether the drug is being used, but to know how it is really being used — the more you will be able to impact and improve your overall strategy, decision-making, messaging and troubleshooting efforts,” says Johnson.

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“Fortunately, an array of new analytical tools are available to improve data analytics,” says Hallinan. “It is now possible to relatively easily add a user-friendly dashboard to various data sets, allowing users to access and analyze real-time data elements in an intuitive, strategic way.” Using such an approach, he adds: “You no longer have to wait for quarterly reports to arrive and keep making decisions based on something that happened months ago.”

By way of example, such a dashboard can be created to track the effectiveness of a given brand’s call center activity. “This allows the brand team to very quickly collect and analyze the most relevant data metrics, and operationalize the new insights to improve both call center performance, and the patient’s overall experience with the call center,” says Hallinan.

“Similarly, when you analyze data that is routinely collected by the pharma field sales force, you have an opportunity to leverage that data to make more informed decisions about future resource allocation,” says Terrence Jones, Director of Strategic Manufacturer Services for ICS, a

provider of third-party logistics for specialty pharmaceutical manufacturers. “You’re able to see how field education and promotional efforts tie to sales, variances in regional performance, trends in sales tied to contracts or changes in reimbursement strategy.” In fact, the data that is now possible from 3PL providers goes well beyond inventory on hand to include product penetration by buyer, product and more — the channel analytics that matter most to manufacturers.

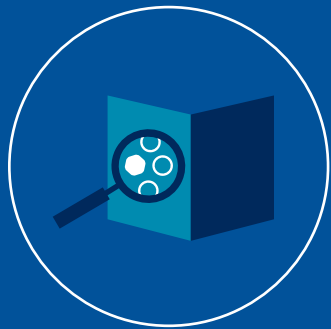
As pharma brand teams continue to search for various sources of potentially useful data and grapple with the challenges associated with data mining and data analytics, they should work closely with strategic partners whose industry reach means they play a key role in unlocking insights from sources across healthcare.

¹ Office of the National Coordinator for Health Information Technology, [ONC Data Brief No. 21/Physician Motivations for Adoption of Electronic Health Records](#). Pub. December 2014.



Oncology Delivery Tomorrow

In a field that holds so much promise when it comes to R&D, it can be disheartening for pharma to face such access barriers as those that exist in oncology. That's why manufacturers have to be innovative outside of the laboratory, too, with commercialization programs that ensure the right therapies reach the right patients. Brand teams can ensure that happens by:



Making an impact in the oncology practice with education and support that eases the burden on providers



Articulating product value to payers and providers — early and often



Fully understanding the access and adherence barriers that come with emerging therapies —and aligning support programs with them



Embracing true patient-centricity in the design and delivery of patient support



Accessing, using and integrating the right data in the right way

The most successful manufacturers will master these activities to build the commercialization programs of tomorrow, today.

Featured Experts

Brian Ansay

Senior Vice President
Sales & Corporate Services
ION Solutions



As Senior Vice President, Sales and Corporate Services at ION Solutions, Brian Ansay leads the organization's GPO initiatives, playing a pivotal role in the formation of ION Solution's oncology commercialization strategies. Additionally, Mr. Ansay has responsibility for the organization's upstream and downstream sales teams. Before joining ION Solutions, Mr. Ansay was with Johnson & Johnson for more than 15 years in several sales and sales leadership positions.

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.

Shishir Desai

Director, Client Analytics
Lash Group



As Director of Client Analytics at Lash Group, Shishir focuses on data-driven consultation and deliverables to deliver actionable, predictive and prescriptive data analytics to help manufacturers better understand their patient population, provider base and overall business.

Featured Experts

Barry Fortner, PhD

President
Oncology Supply



Barry Fortner, PhD, serves as President of Oncology Supply, one of the nation's largest distributors of chemotherapy drugs and supplies. Dr. Fortner previously served as President of ION Solutions. While at ION Solutions he had responsibility for leading the development and launch of an integrated, actionable payer strategy and the procurement of valuable member resources. Dr. Fortner has over 200 scientific publications and conference presentations. His more recent work addresses health and patient-reported outcomes, psychometrics, pharmacologic and health economics, quality improvement and oncology therapeutics and supportive care. His scientific work also includes published statistical innovations regarding treatment induced deterioration, practice efficiency, opportunity costs and clinical pathway compliance.

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.

Kevin Hallinan

Senior Vice President, Strategy
Global Sourcing and
Manufacturer Relations
AmerisourceBergen



As Senior Vice President of Strategy, Global Sourcing and Manufacturer Relations at AmerisourceBergen, Kevin Hallinan is focused on driving enterprise-wide commercial transformations for global pharma and life sciences manufacturers to deliver business value, and position manufacturers to take advantage of near- and long-term market opportunities. Prior to joining AmerisourceBergen, Kevin held roles at Merck, GSK and IMS Health.

Wade Hubbard, CMCO

Vice President
Xcenda



Wade Hubbard, CMCO, is a Vice President who leads multiple field reimbursement support teams for specialty pharmaceutical and biotech firms. Mr. Hubbard leads engagements that facilitate patient access and promote appropriate reimbursement of novel therapies. Prior to joining Xcenda, Mr. Hubbard led the financial planning and analysis units of both Aetna, Inc. and Prudential Healthcare.

Featured Experts

Matt Johnson

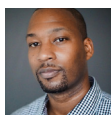
Chief Operating Officer
ASD Healthcare



Matt Johnson joined ASD Healthcare in June 2012 as Chief Operating Officer after serving seven years as Vice President of Strategy at AmerisourceBergen Specialty Group. With a decade of experience in the specialty pharmaceutical business, his areas of expertise include strategic planning, informatics and technology. Mr. Johnson holds a bachelor's degree in mechanical engineering from Northwestern University, a master's in mechanical engineering from California Institute of Technology and an MBA from Auburn University.

Terrence Jones

Director, Strategic
Manufacturer Services
ICS



Terrence Jones serves as Director of Strategic Manufacturer Services for ICS, where he works with manufacturer partners to deliver strategic healthcare logistics solutions that engage more broadly with their commercialization requirements. Mr. Jones also leads the organization's analytics and product serialization strategies, serving as a trusted advisor to manufacturer partners and internal account management teams. Prior to joining ICS, Mr. Jones served in several strategic roles across AmerisourceBergen Specialty Group, focused on developing and delivering technology solutions.

Rick Lozano

Executive Director,
Corporate Accounts
ION Solutions



Rick Lozano serves as Executive Director, Corporate Accounts for ION Solutions, the country's leading group purchasing organization for community oncology practices. In this role, Mr. Lozano leads ION Solutions' corporate services teams, which provide consultation with manufacturers through solutions, services and technology. Prior to joining ION Solutions, Mr. Lozano spent more than a dozen years in the pharmaceutical industry, leading sales, trade relations and market access functions for Dendreon, AMAG Pharmaceuticals and Ortho Biotech.

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.

Featured Experts

Matt Sarnes, PharmD

Senior Vice President
Commercial Consulting
Xcenda



As Senior Vice President of the Commercial Consulting practice at Xcenda, Dr. Sarnes focuses on helping manufacturers develop innovative strategies and tactics to overcome barriers to product access and ultimately to use their market access and reimbursement expertise to improve global health.

Dr. Sarnes has consulted for numerous manufacturers, managed care organizations and health systems, and has led the commercialization strategy for both new and in-line products across several therapeutic areas. Dr. Sarnes' expertise is founded on more than 15 years of experience across disciplines including market access, health economics, reimbursement, quality improvement, marketing and distribution strategy. He has authored more than 50 scientific publications and book chapters on healthcare technology valuation.

Susan Weidner

Senior Vice President
IntrinsiQ Specialty Solutions



As Sr. Vice President of IntrinsiQ Specialty Solutions, Susan is responsible for IntrinsiQ Analytics, the company's data and analytic solutions business focused on specialty care segments, including oncology. Susan also leads our strategic efforts associated with community-based research and precision medicine. Susan has over 20 years of healthcare experience, including all aspects of drug development and commercialization. Leveraging her expertise in clinical and outcomes research along with health economics, she has assisted pharmaceutical companies, payers and providers in demonstrating the value of their product(s) and/or their organizations.

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 [amerisourcebergen.com](https://www.amerisourcebergen.com).



Where knowledge,
reach and partnership
shape healthcare delivery.