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Achieving Differentiation in the Complex Oncology Market

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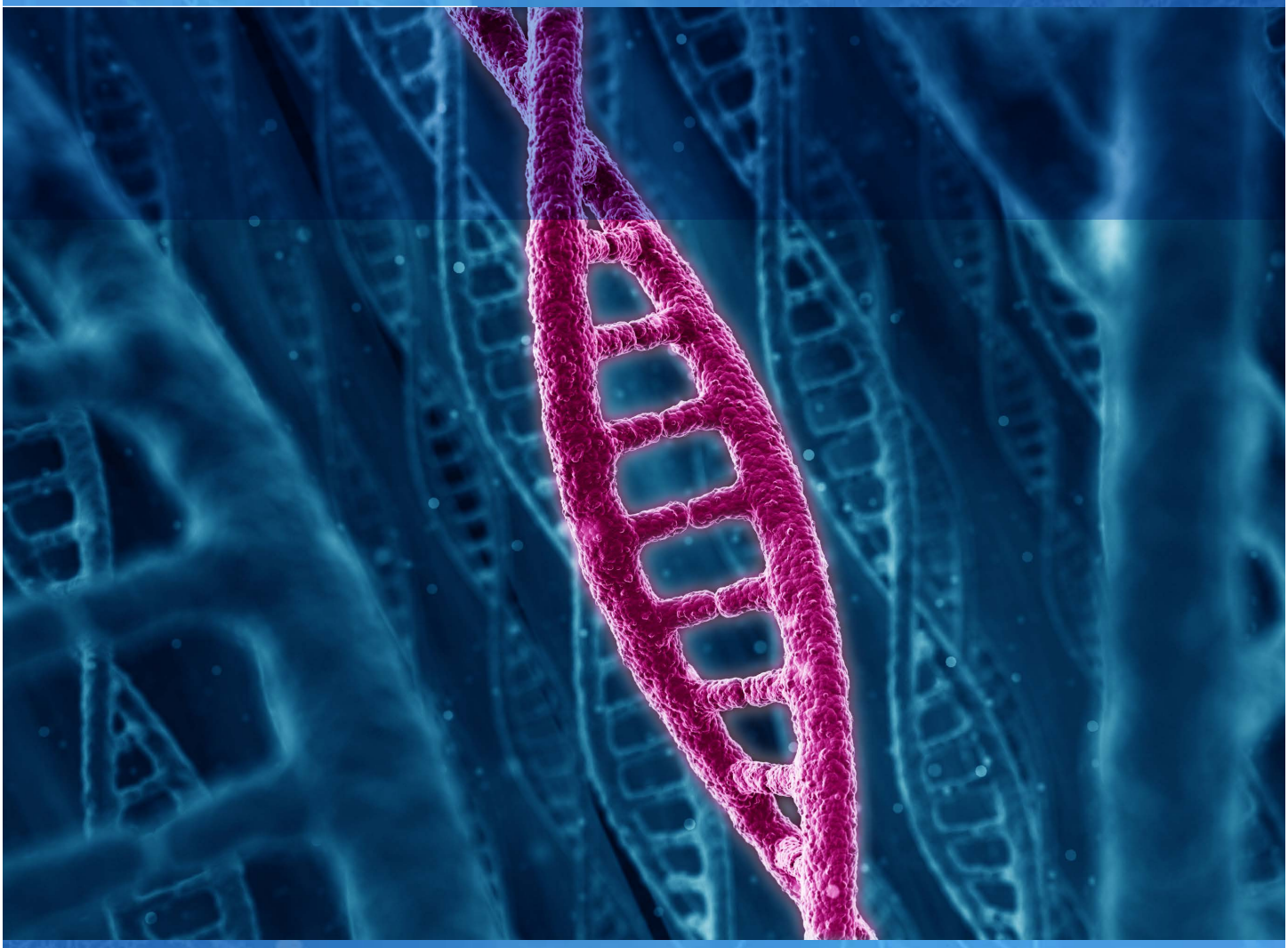
White Paper



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Achieving Differentiation in the Complex Oncology Market

Introduction: A Challenging Market Influenced by Diverse Stakeholders

Nobody would use the word "easy" to describe the oncology marketplace. For one thing, it's characterized by a complex array of stakeholders, all of whom can influence treatment decision-making, and have different needs and challenges. For biopharmaceutical companies operating in the space, understanding and engaging the needs of all of those stakeholder groups can be a daunting task.

An added complication is the increasingly competitive dynamic in the oncology market. Launches are occurring more frequently, largely due to massive investments in research and development and a rapidly evolving knowledge of disease biology. Many indications are becoming more complex, segmented, and competitive, with approved molecules acting across a broad range of pathways and mechanisms. This trend will certainly continue for the foreseeable future, driven by an increased understanding of underlying cancer biology and approaches to personalized care.

As a result, it's getting harder to demonstrate clear clinical differentiation in oncology. Data for agents within the same mechanistic class—or from different classes—may look similar and/or be difficult to compare (e.g., through use of different endpoints or by having data at different stages of maturity). In addition, more frequent launches mean that commercial teams typically have less time to entrench their brands prior to the entrance of new competitors.

In this challenging environment, companies must find other means to differentiate outside of clinical data. One way is for a company (or a brand) to differentiate based on how it engages with all of the customer groups that are relevant to it. A company can do this by maximizing the end-to-end experience each group has with the product: from understanding the disease to treatment selection, all the way through administration, reimbursement, monitoring, and follow-up.

In this paper, we explore the key stakeholder groups that biopharma companies most often engage with in oncology. We describe their typical needs and challenges and outline a process that companies can use to address them head-on. The goal is to develop a type of "roadmap" that companies can use to differentiate products based on stakeholder experience, providing an extra measure of differentiation when the clinical data alone just aren't enough.

Key Stakeholder Groups

The complex array of stakeholders that biopharma companies must engage range from oncologists to nurses to payers to patients and more, each with its own set of needs and challenges.

Oncologists remain the most important group with regards to treatment decision-making. However, other stakeholders are increasingly:

- Affecting the range of available treatment options (e.g., pathways, group purchasing organizations [GPOs], and payers)
- Influential in defining the unmet need and shaping the perceived value of various therapeutic options (e.g., advocacy groups, government affairs)
- Contributing to treatment decision-making (e.g., patients, caregivers)

Together, these groups form a complex ecosystem of decision making for patient care that biopharma companies must

- Deeply understand: What are their needs? What are their roles? How do they relate to each other?
- Determine how best to engage: How can biopharma companies address their needs, build trust, and add value?

Oncologists

Oncologists are still the most critically important stakeholder group to engage, given their continued lead role in treatment decision-making. However, the dynamics are changing for oncologists, and this has implications for commercial decision makers in pharma.

First, oncologists today are bombarded by data. The sheer speed of innovation in oncology is significantly increasing the amount of information that oncologists have to absorb. These data include:

- Extensive clinical data required to support regulatory approval, across a growing number of clinical assets
- Emerging data sets, such as real-world evidence (RWE), generated from multiple sources such as electronic health records, claims data, patient / disease registries, patient-generated data, and investigator-sponsored trials
- New guidelines and pathways (detailed protocols for delivering cancer care), as they continue to proliferate (for example, there are now over 100 ASCO Clinical Practice Guidelines)

The large number of oncology-focused conferences and congresses is evidence of the sheer volume of information that's becoming available to oncologists. The American Society of Clinical Oncology (ASCO) now holds no fewer than 10 major symposia and congresses per year. The European Society for Medical Oncology (ESMO) has 15, plus a range of smaller meetings.

Second, much of this data is being adjudicated through a growing number of entities who develop these guidelines and pathways, such as the National Comprehensive Cancer Network (NCCN), ASCO, integrated delivery networks (IDNs), and an array of other vendors.

As oncologists consolidate into group practices and corporate networks, they are increasingly being required to incorporate treatment guidelines and pathways into their treatment algorithms. As a result, their clinical decision-making power is being reduced. For example, according to ASCO's 2017 *State of Cancer Care in America* report, 58% of oncology practices surveyed use clinical pathways. Furthermore, 46% indicated that they were required by health plans or other outside entities to comply with more than one pathway.

With these market dynamics in play, biopharma companies must find ways to "cut through the noise" and connect with oncologists despite the significant volume of data that's vying for their attention, and the limited access biopharma companies sometimes have to key decision makers. In addition, companies must find strategic ways to inform those who develop guidelines and pathways about the value of their products. For products that are not on guidelines or pathways, uptake will likely be more limited and companies will need to double down on finding channels that will lead to trial use (e.g., develop champions and/or generate additional data).

Key Opinion Leaders (KOLs)

KOLs have always been important to biopharma companies, and not just in oncology. However, within today's oncology market, there are several key dynamics that biopharma companies must remember.

First, KOLs often sit on the committees that develop treatment guidelines and pathways. Because their ability to influence the development of these tools is significant, it's important for biopharma companies to cultivate solid relationships with these KOLs and ensure that they're able to appropriately communicate the clinical and economic value of their therapies.

Second, KOLs can be very helpful in providing an objective opinion that summarizes the treatment impact of many related datasets. In multiple tumor types, top-tier KOLs from leading institutions hold significant sway in shaping treatment decision-making, an effect that is magnified by their ability to communicate broadly, not just from the podium but also through social media (e.g., Twitter, OncologyTube).

Finally, regionally-focused KOLs are also influential within their own specific health system or by their attendance and advocacy at regional conferences and events. When developing their KOL strategies, biopharma companies should seek to include both regional and national-level KOLs, as each influences treatment decision-making at the community level in different ways.

Advanced Practice Providers

Advanced practice providers (APPs), which includes nurse practitioners and physician assistants, are important stakeholders due to their critical roles in assisting with decision making, managing the logistics associated with administering complex treatment regimens, and helping patients deal with adverse events (AEs) and compliance challenges.

They are becoming an increasingly important stakeholder group:

- The expansion of combination therapies is making therapeutic regimens more complex and harder to track, manage, and administer. Today's more complex regimens may involve a combination of infused, injected, and oral medications, all dosed on different cycles.
- As individual therapies launch into new indications, their dosage regimens may vary from one indication to another, which can make it even harder to stay on track.
- APPs need to stay abreast of new developments while also ensuring that varying treatment regimens (even for the same product) are properly administered for each patient. Like the oncologists, they also face information overload.

To engage successfully with APPs, biopharma companies need to offer solutions that will reduce their burden and help them do their jobs more easily. As an example, Abbvie and Genentech provide starter kits for VENCLEXTA in chronic lymphocytic leukemia (CLL). These kits contain color-coded blister packs to help with the dose ramp-up schedule. Other means of support include providing reprints from medical journals outlining AE management strategies, clinical nurse educator teams that focus on direct engagement with nurses, and more.

In addition, pharma companies can provide clear guidance on how APPs can direct patients to support programs for dealing with side effects or AEs and getting emotional support. These types of offerings directly address the challenges APPs face.

Practice Managers

Within oncology clinics, Practice Managers focus on running the office, dealing with finances, and addressing issues related to therapy access and reimbursement. As the access and reimbursement environment for oncology products gets more complicated, the role for Practice Managers in turn becomes more critical. For example, Practice Managers are increasingly responsible for:

- Directing patients to the relevant financial / reimbursement support programs.
- Effectively engaging with insurance companies on behalf of patients.
- Ensuring business efficiencies for the practice.

As clinical differentiation between competing regimens continues to become more elusive, factors such the ease of obtaining reimbursement become more relevant to treatment decision making, all other things being equal. In such situations, biopharma companies must work with Practice Managers minimize the challenges associated with getting—and keeping—patients on therapy. This means providing robust information and support regarding their challenges and questions, primarily regarding reimbursement.

Distributors, Specialty Pharmacies (SP), Hub Services Providers

Aside from stakeholders working in the oncologist's office, specialty pharmacies, hub services providers and similar stakeholders are often the first points of contact for many patients. These entities are often engaged in providing a range of value-added services to patients:

- Facilitate patient access
  - Benefits investigations
  - Appeals
  - Dispensing / triaging to co-pay assistance
  - Shipping of drugs to patients (including starter kits, in the case of SPs)
  - Call center services to address and triage patient questions on access & reimbursement
- Facilitate compliance and persistence (depending on manufacturer program design and contract with hub or SP):
  - Deployment of manufacturer-designed and -sponsored programs such as custom communications, materials, starter kits through multiple communication channels (mail, email, phone, text, etc.)
  - Nurse call center to address and triage patient questions on dosing, administration, and AE management

These stakeholders can provide a critical link from biopharma company to patient, and often, in the case of SPs, have the most direct role in providing a positive patient experience. Biopharma companies must develop and maintain strong strategic relationships with specialty pharmacies, distributors, and hub companies, and ensure their contractual arrangements with these parties meets the needs of their products and businesses.

Also, due to the increased number of oral oncolytics in development (representing approximately 25% of the oncology pipeline), biopharma companies will increasingly have to address the unique challenges associated with these molecules, including distribution strategy (e.g., closed vs. open network), adherence challenges, and patient financial challenges.

Integrated Delivery Networks, Group Practices, Health Systems, & Similar Entities

Corporate entities—such as group oncology practices, integrated delivery networks, and health systems—are becoming more important in oncology. These entities are:

- Instrumental in establishing and/or leveraging treatment guidelines and pathways, reducing the decision-making power of oncologists (but enabling therapies included within the guidelines to be "pushed down" to clinics).
- Focused on cost-control and understanding the value of therapies.

To engage with these corporate customers effectively, pharmaceutical companies must clearly understand their needs and field highly competent key account teams. Additionally, they must appropriately leverage health economics and outcomes research (HEOR) data and RWE to create and communicate relevant value arguments.

Patient Advocacy Groups

Patient advocacy groups (PAGs) often have the most direct connections to the patient community. As a result, they deeply understand the nature of the unmet needs and challenges for patients and caregivers. They play vital roles in advocating for new research, better treatment options, and favorable access. They also provide a forum to establish the voice of the patient. This make PAGs a critical part of the oncology ecosystem.

While engagement with PAGs can be less direct and more restricted than with other stakeholder groups, it is critical for manufacturers to be aware of their influence, establish a supportive working relationship, and provide information to support patients in navigating their treatment journeys.

Payers

The rate of innovation in oncology has been phenomenal in recent years. Indeed, 14 of the world's largest pharmaceutical companies have at least one-third of their late-stage R&D activity focused on oncology, and around 700 organizations have at least one oncology drug in late-stage development.[1] Some of the most exciting innovations continue to emerge in immuno-oncology (IO), such as PD-1/PD-L1 checkpoint inhibitors and CAR-T therapies. Approximately 40 companies are currently developing new CAR-T therapies alone.[2] As promising as these therapies could be, they represent a series of challenges for payers.

First, the latest wave of therapies in oncology are expensive. This is understandable, given their high levels of innovation and complexity. Many of these therapies are personalized to each specific patient and have very complicated manufacturing processes. Add in that many offer a curative potential, and the resulting prices can climb into the hundreds of thousands of dollars.

As new therapies are developed, some cancers become chronic or curable—rather than fatal–conditions, more high-priced combination regimens emerge, and deeper cost-effectiveness data become broadly available, payers will further refine how they manage their oncology businesses. This will likely include tighter management practices and new reimbursement models (e.g., outcomes-based payments, risk sharing agreements, etc.).

Patients

No discussion of stakeholders would be complete without addressing patients. There is a continuum of ways in which biopharma companies can directly connect with patients. At a high level, the key points on that continuum can be described as:

- No Outreach – This has been the traditional approach in most places, and generally considered the lowest risk, particularly in oncology.
- Direct-to-Patient (DTP) – DTP outreach can range from brochures placed with primary care physicians, to online ads targeting people who search using terms related to certain malignancies, to other forms of direct patient engagement.
- Direct-to-Consumer (DTC) – Long a staple in the US in many therapeutic areas, DTC is newer in oncology, not widely deployed, and not without controversy. For example, Bristol-Myers Squibb encountered a backlash after they ran DTC ads for OPDIVO in NSCLC, as related in the New York Times in August of 2016 *(Cancer Drug Ads vs. Cancer Drug Reality)*.

DTP and DTC outreach can be effective in getting patients to ask about a specific therapy when in their oncologist's office, which can be a critical determinant in treatment decision-making, especially in tumor types with limited clinical differentiation between competing therapies. As patients seek to play an increasingly significant role in their health and treatment decision-making—driven in part by the use of wearables and mobile devices—companies should consider them an increasingly important stakeholder group with whom to interact.

Given the range of options, biopharma companies must consider their own business situations and determine how best to engage with patients. As time progresses, rising competition in oncology might demand that companies increasingly deploy DTC marketing in specific instances. In addition, DTP / DTC might help newer therapies get usage, thereby working around pathways that might not include them. While oncologists often must follow one guideline or another, they are usually given the flexibility to deviate from those guidelines for a certain percentage of patients. For newer therapies, DTP / DTC outreach may be one mechanism for helping encourage trial.

Exploring the Implications for Biopharma Companies

To engage with the stakeholder groups mentioned above—and drive commercial success—biopharma companies must understand the needs and determine the priority of each stakeholder for their specific therapy, and then develop strategies, messages, and programs specific to those needs. For those stakeholders most focused on understanding product value and controlling costs, biopharma companies must move beyond messages and collateral, and focus on new ways to leverage emerging data sets data to make compelling value arguments.

In most cases, those strategies will ultimately be implemented by companies' field forces, which can encompass a range of commercial functions (Sales, Marketing, Payer Marketing, Account Management, etc.), as well as Medical Affairs. Now more than ever, it is critical to ensure that those field forces are properly organized, sized, equipped, trained, and integrated.

Doing this well requires solid analysis, articulation of business goals, and understanding of trade-off decisions. To succeed, decision makers must answer a range of questions, such as

- What is the optimum organizational approach for our customer-facing teams? Is it a structure that uses numerous highly specialized roles, with each focused on a specific area of expertise? Or, is it better to use an approach that emphasizes cross-training, so that fewer roles can handle more tasks, leaving only a subset of the most challenging cases to a small cadre of specialists?
- What's the best way to foster effective cross-functional coordination across these teams?
- How can we maintain compliance in an era of increased coordination between commercial and medical teams?
- How can we simplify how our customers understand and navigate our services?

Five Requirements for Creating a Positive Stakeholder Experience

As stated earlier, differentiation through clinical data is often not enough: Companies must differentiate based on how they engage with their stakeholders. They can do this by working to maximize the positive experience stakeholders have with the product. Creating this positive experience requires five things:

1. The ability to think holistically across the end-to-end use of the product – The company must identify the stakeholders (and their respective roles) that are involved in selecting, using, and administering the product.

2. A deep understanding of the needs and challenges of each stakeholder – This understanding must be temporal in nature, as it must account for how needs, challenges, and expectations for different groups will change over time, pre- and post-launch.

3. Strategic and tactical approaches for addressing those needs and challenges – For any given therapy, the company must decide which stakeholders to prioritize, what beliefs and behaviors they want to establish in those stakeholders, and how they will achieve that end.

4. The operational excellence to put strategies into action – This includes cross-functional coordination in planning and implementation. Many teams (e.g., commercial and medical) will—to an extent—share some stakeholders (e.g., KOLs). While companies should be careful to ensure compliance firewalls between these two teams (and these frequently vary on a company-by-company basis), they also need to ensure that the information stakeholders receive is aligned to the extent possible.

5. The technological capabilities to optimally leverage emerging solutions – This includes using tools such as innovative digital non-personal promotional channels to engage stakeholders, synchronizing digital engagement with follow-up emails and rep visits, and using data analytics companies to generate and communicate relevant data beyond the clinical data package.

A Framework for Differentiating on the Basis of Stakeholder Experience

Identifying the End-to-End Steps in Using the Product

To begin the process of differentiating on the basis of stakeholder experience, a product team must identify the end-to-end steps that are involved in using the product. The typical steps are listed below. While these steps can vary somewhat from product to product, this list is representative:

1. Disease Understanding
2. Diagnosis
3. Treatment Selection
4. Treatment Administration
5. Access and Reimbursement
6. Patient Monitoring and Follow-Up

For some of these steps, the set of stakeholders involved will be product-specific. Consider some examples below.

Diagnosis for some tumor types (for the purposes of informing treatment selection) can be relatively simple and made on the basis of imaging (e.g., glioblastoma), whereas for others there is a need for biopsies and more clearly characterizing the molecular profile of the tumor (e.g., NSCLC, not only for histology but also for genetic mutations). This might require breaking diagnosis into several steps, each with potentially different stakeholders. Even when limited to staining and microscopy, this still introduces pathologists as an additional stakeholder to consider.

However, tumor genetics are increasingly being assessed via next-generation sequencing (NGS), which frequently involves samples being shipped off-site to central labs operated by specialist companies such as Foundation Medicine and Guardant Health. This introduces an additional process step. In these situations, factors such as turnaround time and the quality / clarity / breadth of information provided to the oncologist can become important determinants of treatment selection decisions.

The list of stakeholders influencing treatment selection can shift across tumor types and across products. Clinical decision support pathways, for instance, are active in some tumors and not others. In addition, some therapeutics have more problematic adverse event profiles, increasing the level of focus placed on nurses.

Developing a Strategy to Maximize Stakeholders' Experience at Each Step

Within each buying process step, the objective is to identify how to make the experience as positive as possible for all stakeholders who take part, within the context of the company's capabilities and launch resources. To do this, the product team must:

1. Identify the stakeholders that are most impacted by—or that are most influential in—the process step.
2. Understand each stakeholder's key challenges and needs related to that step.
3. Determine which tactics or programs would best address those needs.

In most cases, product teams must make prioritization and trade-off decisions across buying process steps. Not all unmet needs and/or challenges are equally important, and these may vary for each launch. In addition, not all tactics are equally effective. Teams frequently don't have the resources to optimally address the needs of all stakeholders across each process step, so they should carefully consider the resource requirements (both financial and team bandwidth) and likely benefits before making decisions.

Using the Framework: Some High-Level Examples

The process of identifying all buying process steps and the stakeholders in each, as well as their key needs and tactics for meeting those needs, can be complex. It's beyond the scope of this paper to provide a comprehensive example. However, we can explore some high-level examples across specific process steps.

Example Buying Process Step: Disease Understanding

The overarching goal is to ensure access to the information needed to understand and recognize the disease, facilitate a diagnosis, and initiate the disease management process. Key stakeholder groups may include the following, each with somewhat different needs:

- Medical oncologists or hematology oncologists must have the latest information on the disease and available treatment options. They must also have the tools and information available to properly educate their patients and address their questions. This is particularly important for tumors with relatively low-incidence, where they may only see a handful of patients per year and the disease will rarely be top-of-mind.
- Patients need access to trustworthy educational materials about the disease and treatment options to advocate for their best interests. For some diseases (HER2+ breast cancer in particular), patient advocacy is very strong and there is a wealth of useful information available to help inform patients. However, for others (e.g., bladder cancer), things are much less developed: quality is often variable, and the degree to which the information is conflicting leads to an overwhelming experience.
- Caregivers may need information on what to expect and how they can help, especially for tumors where the age of diagnosis is older (e.g., prostate, pancreatic) and/or patients have higher comorbidities, meaning patients are generally less able to gather their own information.
- Payers need to understand the disease epidemiology and the relative clinical and health economic impact of disease progression (for example, hospitalization rates).

Within this buying process step, a pharma company's programs and tactics may lean heavily toward:

- Disease state education for MedOncs, informing them of key population-level aspects of the disease (e.g., etiology, epidemiology, prognosis) as well as key mechanisms underpinning the development of the disease and therapeutic approaches—both current and in development
- Patient-focused educational tools to facilitate oncologist and APP communications with patients, such as brochures, key statistics, and locations of additional resources (e.g., advocacy organizations)
- Educational resources for patients and caregivers, specifically designed for accessibility and easy communication of key facts

Example Buying Process Step: Administration

Once a treatment regimen has been selected, specific stakeholders need to be engaged to ensure optimal administration of the therapeutic. For example:

- APPs must be able to optimally administer the regimen and educate patients and caregivers on how to manage side effects, as well as ensure adherence and compliance.

• Patients and caregivers must be educated on what to expect from the therapeutic and how to minimize and/or manage any side effects.

Within this buying process step, a pharma company's programs and tactics might typically include:

• APP-specific messaging, guidance, and tools to aid administration and patient adherence and compliance – This can be carried out by oncologist-focused reps as part of a total office call, but also by APP-specific field teams and/or call center representatives, who are often ex-nurses themselves and understand the terminology and attitude to use that will be most effective.

• Patient education materials and tools on adverse event identification and management

• Compliance support programs—executed by specialty pharmacies—to ensure patients have the necessary information on managing side effects and understand the importance of staying on therapy

Failure to use the right programs and tactics at this step can negatively impact the patient and nurse experience, causing them to push back on the treatment choice. In situations when other therapeutic options are available with little or no clinical efficacy drawback, this may be enough to influence oncologist prescribing preferences.

The Framework Overview Table

Table 1 provides a high-level look at a typical / potential product buying process, highlighting:

1. Range of buying process steps
2. The key stakeholder groups in each step
3. Key needs for each stakeholder
4. Types of strategic and operational approaches pharma companies might employ

Table 1: Example Buying Process with Key Stakeholders, Needs, and Tactics at each Step

Process Step:	Disease Understanding	Diagnosis	Treatment Selection	Treatment Administration	Reimbursement	Patient Monitoring & Follow-up
Impacted Stakeholders	**Patient, Caregiver, Onc, Payer**	**Onc, Pathologist**	**Patient, Onc, Pharmacy Director, P&T, Pathways**	**Patient, Onc, Patient Navigator, Nurse, Pharmacist**	**Patient, Reimbursement Manager, Payer**	**Patient, Caregiver, Nurse, Patient Navigator**
Example Stakeholder Needs	• Access to resources/ information to educate on disease, unmet need, and key areas of development focus	• Onc understands diagnostic options available and how to use preferred option (incl. how to use NGS, if applicable) • Pathologist understands how to optimally execute on a requested diagnostic test	• Onc has clinical and non-clinical information to make optimal treatment decision • Patient informed to appropriately engage in treatment selection discussion • Pathways understand clinical and economic value of available treatment options	• Nurses know how to optimally administer regimen, manage side effects, and educate patients on what to expect • Patients and caregivers minimally negatively impacted by taking therapy • Pharmacist able to accurately dispense therapy and educate downstream stakeholders	• Reimbursement managers have resources to obtain timely reimbursement, with support on hand to address issues • Payers understand value of product and have relevant data analyses • Patient has manageable financial impact and ready access to financial support services	• Patient navigators able to anticipate and meet patient needs • Patient non-compliance and non-adherence is minimized
Example Strategy and Tactical Approach	• Commercial, medical affairs, PR, advocacy provide aligned and consistent messaging and information on the disease, including pre-approval disease education and post-approval patient materials	• Pathologists are trained on timely and accurate interpretation of diagnostic test results • (Note: Degree of biopharma involvement varies depending on their relationship to diagnostic test manufacturer)	• High-belief KOLs identified to advocate on behalf of the product and cascade out belief, with compliant coordination across medical and commercial • Oncologist engagement with digital properties coordinated with emails and rep visits	• Nurse-focused field teams train nurses on how to optimally administer and manage patients • Patient convenience maximized through use of transport services to get to infusion centers or use of mobile ambulatory infusion centers	• Practice managers have single point of contact call center able to handle multiple different requests • Reps cross-trained to resolve common reimbursement issues, with mechanism in place to triage difficult cases to dedicated reimbursement support team	• Patient archetypes identified based on their likely compliance and adherence challenges and support materials and services developed to meet the needs of each
Potential Problems If Sub-optimally Addressed	• Patient lack of information or support mean that they are not able to effectively advocate for their best interests	• Extended test turnaround time considered prohibitive, especially in acute situations where oncs need to make a rapid treatment decision	• Oncologist doesn't have full understanding of clinical and non-clinical product attributes and selects a different treatment option	• Nurses find treatment burdensome for patients and communicate this to the oncologist	• Clinic throughput negatively impacted by time-consuming reimbursement process, leading to pressure to select alternative treatment option	• Patients have a sub-optimal experience and outcome – real-world experience starts to diverge from clinical data-based expectations

Implementing the Framework

Implementing a framework like the one above begins with a strategic evaluation to determine the relevant steps, stakeholders, and their needs and challenges. To inform that effort, the product team needs to answer a range of questions, including:

- What is the level of patient education and/or advocacy support?
- Is this an oral or infused agent?
- Where will it be prescribed? Hospitals (including in-patient or out-patient) or clinics? This is critical to understand as it informs the reimbursement pathway and associated challenges as well as the importance of site-specific stakeholders such as pharmacy directors and P&T committees.
- Will it be used primarily in academic centers or community sites of care?
- Will there be a diagnostic associated with the product? If so, will this be single gene testing or comprehensive genome profiling / NGS?
- What will be the level of clinical differentiation?
- What will be the level of competition? Incumbent vs. future?
- How tightly will it be managed by payers? Do pathways seek to manage access?

Also integral to this process is determining how to operationalize it. Once all stakeholder groups are designated, their needs analyzed, and potential tactics or programs are identified, the company must:

1. Understand its level of resourcing and organizational capabilities

2. Prioritize programs and tactics, incorporating any necessary trade-offs

3. Understand its ability to successfully execute, including identifying any capability gaps and developing plans to mitigate them

4. Optimize compliant cross-functional alignment and cooperation

Proper planning and implementation of this approach is recommended for products launching into intensely competitive environments. Aggregating marginal gains with stakeholders across multiple buying process steps can lead to meaningful points of non-clinical differentiation. It's sort of like building a structure, one small piece at a time. No single piece is a game-changer by itself, but when all added together, they result in something very meaningful. For an oncology product in a highly competitive market with limited clinical differentiation, this may be the only pathway to true commercial success.

Notes:

1. IQVIA Institute for Human Data Science, Global Oncology Trends 2018, Innovation, Expansion, and Disruption, May 2018, p. 3, accessed 19 September 2018 at https://www.iqvia.com/institute/reports/global-oncology-trends-2018

2. Jill Condello, Andrea Favaro, Martin Lachs, Rebecca Walker, "Access and Reimbursement for Adoptive T-Cell Transfer Drugs", *Pharmaceutical Executive*, vol. 37, issue 12, 11 Dec. 2017, accessed 13 December 2018 at http://www.pharmexec.com/access-and-reimbursement-adoptive-t-cell-transfer-drugs

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