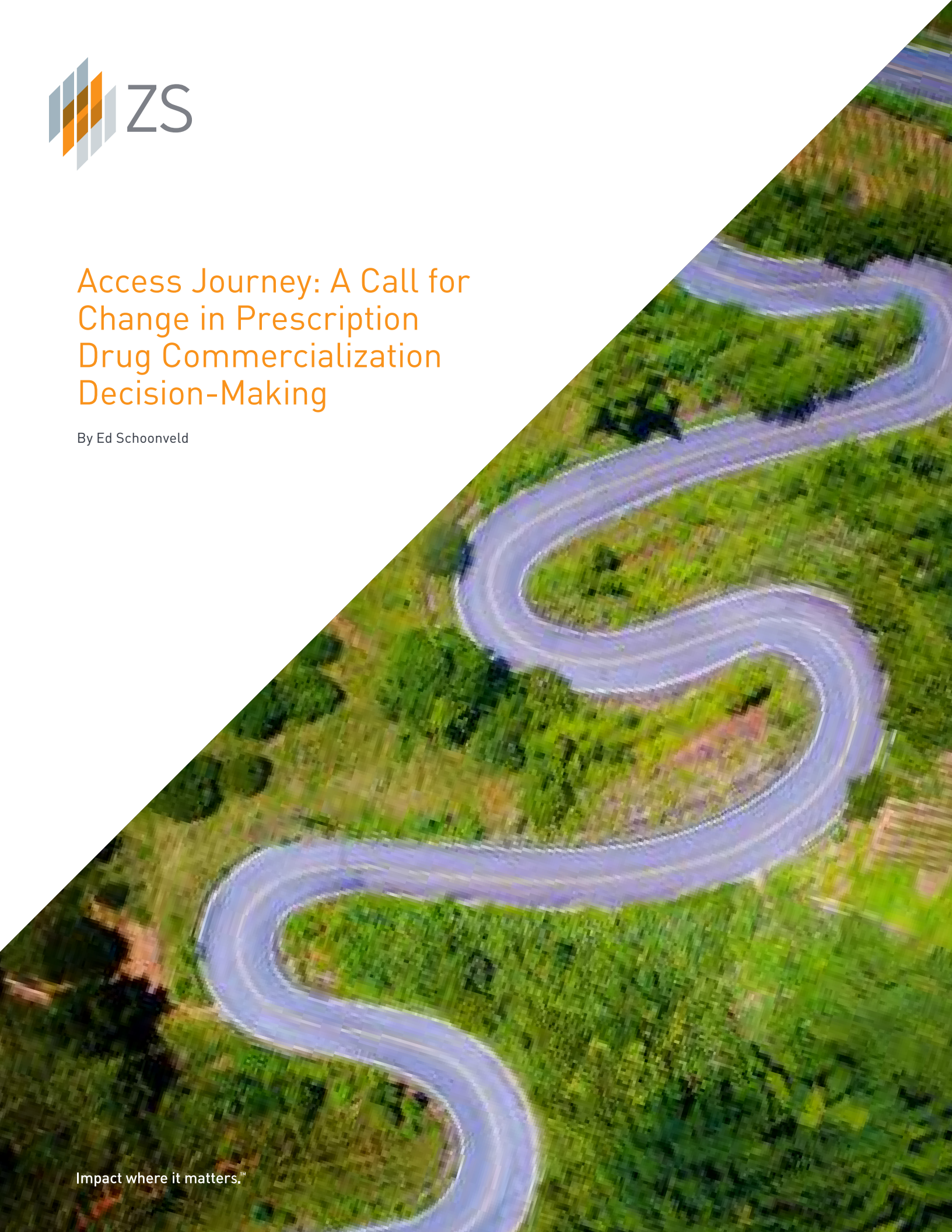
ZS

Access Journey: A Call for Change in Prescription Drug Commercialization Decision-Making

By Ed Schoonveld



Impact where it matters.℠

Access Journey: A Call for Change in Prescription Drug Commercialization Decision-Making

By Ed Schoonveld

CONTENTS

EXECUTIVE SUMMARY

Until recently, commercial success for a prescription drug mainly involved getting the drug on payer formulary and creating pull-through with sales force efforts toward physicians. Success was defined as securing full, unrestricted access and building significant share through share of voice. The rapidly rising cost of healthcare, new emerging pharmaceutical technologies with breakthrough potential, public concerns over drug pricing, and a gradual shift from fee-for-service to value-based payment models are transforming the pharmaceutical market. Today's market is much more complicated, as public and private payer management is more restrictive, medical communities are more willing to engage in value vs. cost trade-offs, and providers are taking a more holistic and integrated health care delivery focus.

The current environment is perhaps best described as the "world of value and affordability." Demonstrating patient value is crucial but not sufficient to gain broad market adoption in the global post-Sovaldi prescription drug market where payers have been empowered more than ever to say no.

Success in this new payer-empowered world of value and affordability requires two fundamental changes in pharma companies' corporate decision-making:

1. **Drug development decision-making and evidence development** must evolve to one that is based on a **more robust trade-off analysis** between revenue potential, clinical risk, investment needs and launch timing, thoroughly incorporating the impact of success at various **"access journey"** decision points such a price, payer access, clinical guidelines, provider formulary, prescribing, patient fulfillment and adherence.

2. **Commercialization and value communication activities** need to recognize the revenue impact and evidence needs of a **broader set of stakeholders in the ecosystem**, and they need to reach beyond physician promotion and payer account executives. A coordinated value communication program needs to include the medical communities, provider organizations, patients and their influencers.

Most pharma companies have been hesitant to recognize the need for change as creating evidence of a compelling outcomes claim usually also involves a higher risk of clinical failure. However, bringing a drug quickly to market that does not address the needs of critical decision makers can hardly be a recipe for commercial success. Companies that lag in making this adjustment are likely to underperform and see their share prices decline as real revenues don't match their earlier forecasts.

Many professionals within the innovative pharmaceutical industry are aware of these trends and a need for change. Some may indeed be very well structured and equipped to tackle the challenges and devise optimal strategies that address all of the complex trade-offs in consideration. However, from experience, it has been proven hard to change actual decision-making in large organizations with vastly differing functional objectives and complex trade-offs. The intent of this paper is to raise urgency and to provide a structured approach to drive trade-off analyses and consensus-building within the organization.

THE AGE OF VALUE AND AFFORDABILITY

The global prescription drug market, and the U.S. market in particular, have transformed under the influence of a combination of healthcare budget pressures, increased pharmaceutical innovation and public concern on drug pricing.

Healthcare cost has continued to rise at a faster pace than most other products. The mortgage crisis-induced global recession and the Euro-crisis highlighted rapidly growing healthcare budgets as an unsustainable problem. While cost rises are primarily caused by insufficient planning for the increased healthcare needs of an aging population with often unhealthy lifestyles, European governments have held a tough stance on pharmaceutical spending. The emergence of much needed hepatitis C cures, promising immuno-oncology agents such as PD-1s, and the emergence of gene therapies such as CAR-Ts have further increased budget pressures. In the United States, drug pricing and price increases have come under unprecedented scrutiny. Price increase outliers, such as by "pharma bro" Martin Shkreli for Turing Pharmaceuticals' Daraprim and Mylan's Epipen have sensitized the public further beyond an ongoing critique on pharma price increases for prescription drugs in oncology and hematology indications, such as multiple myeloma.

Change in Environment

The global healthcare environment has been subject to significant change as a flux of drug innovation and healthcare budget pressures force tough trade-offs for public and private health insurance agencies. Pressures related to high drug cost for curative treatments in hepatitis C and emerging immuno-oncology drug combinations have subjected the pharmaceutical industry to a lot of public and political criticism across the political landscape. This trend, together with emerging value-based payments models, have mobilized the medical community to focus on specific outcomes measures related to (re-)hospitalization and disease-area-specific outcomes. Particularly in cardiovascular disease and diabetes, accountable care organization (ACO) quality metrics and other formal outcomes metrics are driving provider organization decision-making. In oncology, ASCO, NCCN and ESMO are among the organizations that have created value frameworks to help treating physicians with tough trade-offs as patients are increasingly exposed to high co-payments and deductibles. While these value frameworks themselves don't have a lot of "teeth" in payer and prescriber decision-making, they can inspire treatment pathways, which, through physician incentives, have started to have some impact.

The Institute for Clinical and Economic Review (ICER) has been publishing cost-effectiveness analyses that have provided payers additional arguments to critically assess the value of high-cost treatments. In some cases, ICER evaluations have been quoted by payers and some manufacturers as a rationale for price or contracting agreements. CVS announced a willingness to offer formularies to employers that exclude drugs that exceed $100,000 per QALY. However, whether and how cost-effectiveness-based formularies will be accepted by the medical community, employers and patients is still a large question mark.

Gilead's launch of Sovaldi has had a long-lasting impact on the global prescription drug environment. Not only has it provided many patients with a cure for their hepatitis C infection and its devastating health impact, but it has motivated payers worldwide to more firmly link price to the cost of treating an eligible patient population. Japan introduced formal price cuts linked to revenue volumes. Many other payers use less specifically communicated approaches. Pricing of innovative drugs and drug combinations continue to be an area of focus for many payers. New payer initiatives to manage them with respect to affordability are highly likely.

Payer Empowerment

Concerns over the high cost of new drugs and perceived excessive price increases for drugs in the United States have been widely communicated through the media and have upset the public worldwide. Politicians across the political spectrum and the medical community have undertaken various initiatives to address the issue. Examples include many U.S. state legislative initiatives, triggering disclosures related to price increases and legal action against some excessive cases, such as Turing Pharmaceuticals' Daraprim, and European price negotiation alliances.

In this environment, we have seen an increasing confidence from payers in making tough decisions. In the United States, Express Scripts set a precedent through its inclusion of one of two hepatitis C drugs in its drug exclusion list, thus extracting significant discounts from AbbVie but denying access to Gilead's Sovaldi to its members. CVS's successive exclusive choice of Sovaldi in its drug list further marked the market power of pharmacy benefit managers (PBMs) and the empowerment of this payer category that has often been accused of not adding value and being overly focused on extracting rebates rather than patient benefit versus societal cost.

The launch of PCSK9's Repatha (evolocumab, Amgen) and Praluent (alirocumab, Regeneron/Sanofi) posed a challenge to payers as the use of this highly efficacious new treatment at a relatively high cost was not clearly defined in the eligible patient population. The medical community did not strongly support a broad use within label, thus offering opportunities for payers to impose effective prescribing hurdles to physicians without any serious backlash. The PCSK9 case clearly demonstrates the criticality of securing strong support from the medical community for a new drug's positioning in clinical practice.

Public concern over drug pricing and healthcare costs, poor handling of public communications by pharma companies, and some highly publicized price increase excesses have empowered payers worldwide to act tough on drug prices and patient access.

The Growing Influence of the Medical Community

Treating physicians increasingly find themselves in a position where they feel conflicted between bringing the medically most appropriate treatment to patients and the impact that its cost may have on patient affordability and the broader healthcare budget. Over the past few years, we have

seen a higher willingness of physicians to take treatment cost into active consideration in both formal treatment guidelines and in individual patient prescribing decisions. The actual impact will vary across the payer systems and degree of patient cost sharing.

In the United States, the cost of healthcare has become an increasingly heavy burden on federal and state governments through programs such as Medicare and Medicaid, employers and employees through insurance premiums, and individual patients through deductions and co-payments. As a result of broad awareness of healthcare cost concerns, the medical community is increasingly willing to consider ways of limiting the use of high-cost treatments to those who will have a clearly demonstrated benefit.

In the cardiovascular area, cholesterol-lowering agents are a good example. The American College of Cardiologists has issued hypercholesterolemia guidelines that emphasize the broad use of statins and severely limited the use of PCSK9s to a very narrow patient population. This set the stage for challenges for PCSK9's that were highlighted in the previous section.

In Europe, payer coverage decision-making has always involved guidance by the medical community, albeit by specifically recruited individuals for review committees rather than by independent medical associations. Tightening of requirements and scrutiny on high-budget impact drugs has been a more gradual further evolution from what was already a very restricted access environment.

The oncologist community has been very vocal over their concerns regarding "financial toxicity" (the impact of substantial patient co-payments on patient ability to afford the treatments that they need). Value frameworks, such as by ASCO, NCCN and ESMO, as well as Memorial Sloan Kettering's "Drug Pricing Lab," have added to the debate on oncology drug value and pricing, although it has been hard to specifically measure impact on payer management and physician prescribing behaviors. In the future, these could become more important when used as a basis for treatment pathways and other payer management techniques.

The Evolving Role of Provider Organizations

Particularly in the United States, there has been a strong push to shift payment models from traditional fee-for-service payments to value-based payments (payments that are linked more to clinical outcomes and less to individual services provided). Payment schedules between health insurance and provider groups, such as integrated delivery networks (IDNs), increasingly include performance-based elements as payers want to shift risk to providers.

The Institute for Health Improvement (IHI) developed the "Triple Aim" framework to optimize health system performance through 1) Improving the patient experience, 2) Improving the health of populations, and 3) Reducing the per capita cost of healthcare. CMS healthcare policy and initiatives have embraced the Triple Aim objectives. Under the Patient Protection and Affordable Care Act, ACOs were incentivized to share in joint savings. In addition, the Centers for Medicare & Medicaid Services (CMS) engaged in many pilot programs to explore further progress in this area.

Under this push for value-based payment reforms, provider organizations have focused to organize themselves to take advantage of ACO and similar payment incentives and adjust their business model to optimally align with the new payment structures. In addition, as local healthcare markets increased in their significance, provider organizations have further increased scale to gain a competitive edge over local competition, further drive efficiencies and attract patients to their practices.

As a result, the U.S. healthcare market has transformed into a large number of local healthcare markets that can be distinctly different from each other. Some markets may be heavily payer-dominated, others could be provider-dominated in terms of control in prescribing practices. This characteristic can have a significant impact on local medical practices. For prescription drugs, the impact of provider organizations is most prominent in therapy areas where outcomes metrics are included in payment models, such as for cardiovascular disease and diabetes. Another area of impact may be in oncology, where provider organizations may demand rebates for the formulary inclusion of high-cost prescription drugs in highly competitive markets where drugs may be deemed interchangeable.

The Voice of the Patient

Patient centricity is a hot topic, and what matters to the patient is a large part of "pharma talk." While the patient treatment outcomes are deemed highly important, that does not mean that the patient "voice" is always directly considered. We need to distinguish between decisions where the patient interest is central from the ones where they make the actual decision.

Patient outcomes are central in decision-making on pricing, market access, clinical guidelines and provider formularies, but patients tend to not be at the table in many of these decisions. As a typical example, European pricing and reimbursement decision bodies, such as the Joint Federal Committee (G-BA) in Germany, have a single patient representative who has no vote. Payers and regulators are highly critical of patient opinions and patient preference studies unless they are carefully designed and validated. At the same time, however, payers are increasingly interested in the demonstrated impact of drug treatments on the patient's quality of life in an unbiased way. Patient-reported outcomes (PROs) that are obtained through carefully designed and validated patient questionnaires are increasingly used by regulatory and payer agencies worldwide to validate patient outcomes claims for use in label and market access discussions with payers. It is therefore crucial to consider PRO studies in every case where patient outcomes are highly valued by payers and providers.

When considering prescribing, fulfillment and treatment adherence, the actual patient voice is more apparent. Many physicians discuss drug options with patients and listen to specific requests for a drug. Whether the patient ultimately picks up the prescription in the pharmacy and adheres to the treatment when a co-pay is problematic or side effects are experienced is decided by the patient under guidance of the physician, pharmacist and others in the patient's direct environment. However, communications on patient-reported outcomes are highly regulated by the FDA/EMA and other regulatory agencies. Unless regulators approve these PRO claims and their underlying PRO instrument, we are extremely hampered in our ability to communicate on patient benefits to physicians and patients.

The above is critical in deciding where we need to do a formal PRO study and what evidence we need to reach out to the patient through DTC advertising, patient information leaflets or indirect communication through physicians.

SUCCESS IN A PAYER-EMPOWERED WORLD

As we have entered a payer-empowered world for prescription drugs, one may wonder how this should impact the pharmaceutical industry. What do you do when a payer says no and asks questions after? Will it help to provide the payer with more evidence of value? Yes and no. Let's analyze.

1. Payers are generally very careful to ensure that their sometimes-tough trade-offs between value and cost are well-supported by the medical community and are evidence-based.

2. Increasing willingness of the medical community to make value trade-offs offers opportunities to payers to tightly manage high-cost treatments to patients that extract the highest demonstrated value. Well-designed clinical treatment pathways can build a bridge between evidence-based clinical practice and payer cost-containment objectives.

3. Value-based payment initiatives and the evolving role of provider organizations are likely to further enable focus on outcomes and outcomes-based contracts, not only between payers and providers but also between payers and pharma and perhaps providers and pharma

In this more complex environment, we need to consider the interactions between payers, providers, clinical opinion leaders and other influencers to assess where our efforts have the highest impact on a host of decisions that each of these groups engage in.

Figure 1 shows the "dinner for three" analogy, which is illustrative of how the prescription drug decision-making process is different from a typical consumer product. Rather than a simple buyer/seller transaction, this involves a complex tripartite communication between the physician, the payer and the patient. It's as if we go with three people to a restaurant where one orders the meal (prescribing physician), another one consumes the meal (the patient) and a third party (the payer) pays for the meal. In the current environment, we not only need to consider this complex process between payer, physician and patient but also need to include the influence of a host of other stakeholders and influencers such as medical associations, patient groups and employers. In addition, provider organizations are increasingly influencing the behaviors of individual physicians (often their employees now) through treatment guidelines, outcomes metrics and incentives.

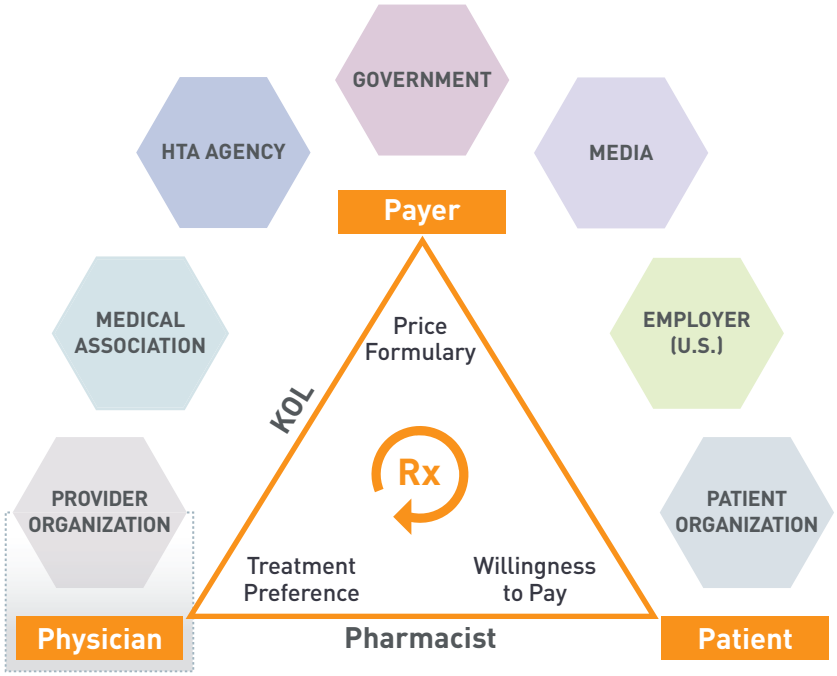


Figure 1: Key stakeholders in the prescription drug market

As we assess the impact of each of these stakeholders and influencers on treatments and drug choices, and ultimately the revenues of these drugs, we need to consider:

1. Which decisions and underlying processes do these stakeholders make or influence?
2. What are the decision-making criteria for these decisions? What unmet needs and benefits are most important, and what constitutes a relevant improvement to the decision maker?
3. What evidence is required to convince decision makers that the claimed benefit is real?
4. What are the implications on drug development and commercialization?

Optimizing the commercial potential of the prescription drug portfolio requires communications between the commercial and development teams in the company that go far beyond the FDA and EMA considerations that are often still the cornerstone of clinical trials' design decisions.

Given the importance to the company, imperfect alignment between team objectives, and the complexity of the trade-offs, it's critical to use a structured analytical approach to support trade-off analyses by a cross-functional team. The remainder of this paper provides such an approach.

THE ACCESS JOURNEY

Ensuring access for patients to a prescription drug that has gained market authorization from the U.S. FDA, European EMA or another regulatory agency requires many considerations as many hurdles and endorsements will impact actual prescribing and patient use. Most of these decisions are influenced by list and net price in the context of specific patient needs and other available treatment options.

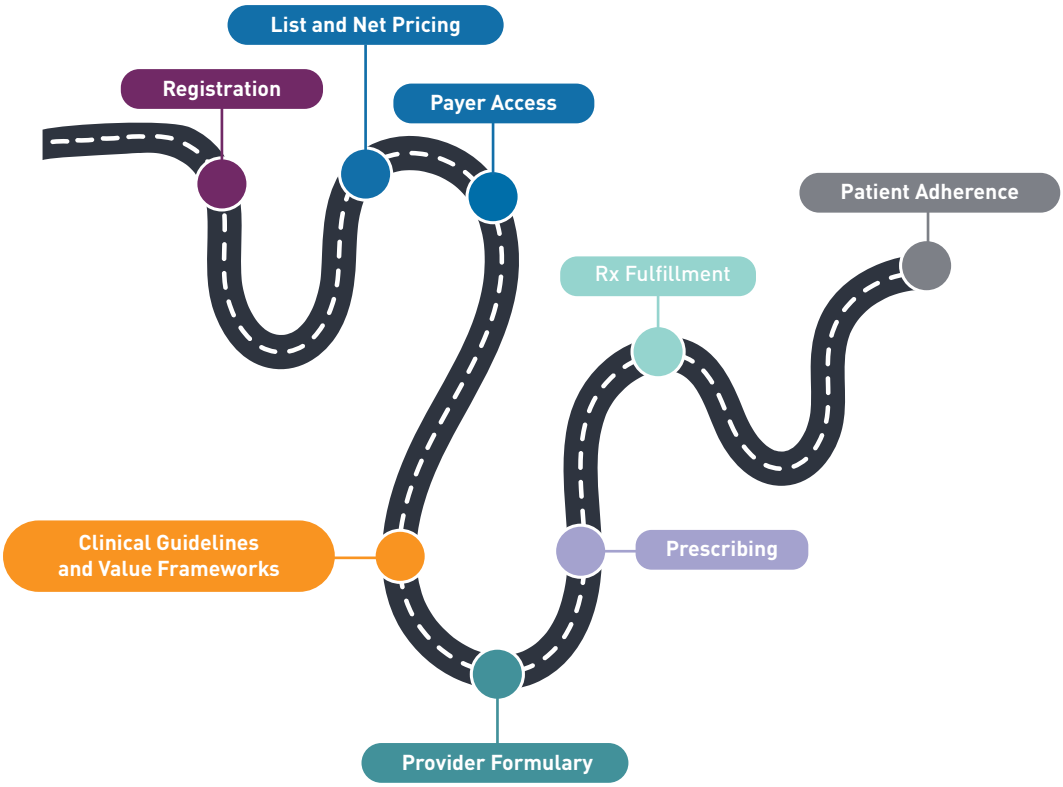


Figure 2: The access journey

Consider the "access journey" in Figure 2 as a sequence of hurdles that need to be addressed to optimize the commercial success of a drug through broad and extended use at an attractive net price. Each of these steps can be considered a financial risk equivalent of a dangerous curve

on a mountain road. Every "miss" results in loss of patients and revenue from what's formally authorized through the approved label. For each of the access journey steps, we need to consider a different decision maker with different values and preferences, which we will discuss in more detail.

The impact of imperfect value demonstration on net revenues is illustrated in Figure 3. While it's not realistic for a drug class or treatment to be used in all patients within label, minimizing losses from the narrowing of the funnel is essential. Each of the access journey steps may influence each other, and decisions aren't necessarily taken in a sequential order.

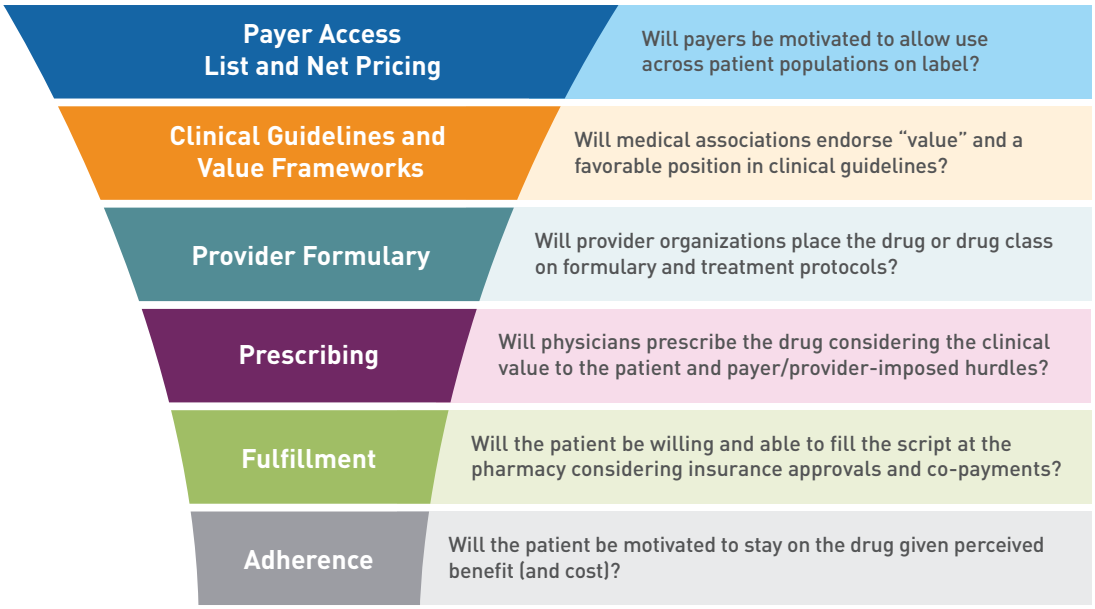


Figure 3: The access journey's impact on revenue

How do we best shape our development program so that each of these steps in the access journey are considered—with respect to their impact on the funnel—so that we limit restrictions and ultimately retain a large share of eligible patients? How do we ensure a proper trade-off between results and the underlying investments, clinical risk, and impact on timeline with the forecasted revenue? Doing so requires a structural evaluation of each of the steps on the access journey.

List and Net Pricing

Differences between official list price and actual net price can be substantial, particularly in highly competitive therapy areas. In the United States, PBMs and MCOs can extract significant rebates when choices are deemed sufficiently interchangeable by the medical community knowing that exclusion lists and co-payment differences can substantially shift prescribing behaviors. Figure 4 shows how list and net prices have changed over the 2011 to 2015 period, illustrating an increasing divergence between list and net pricing since 2012.

U.S. pharma companies spend well over $100 billion on rebates annually—more than twice all other selling, general and administrative expenses. As rebates are confidential between manufacturer and payer, it's hard to provide exact insights by drug or therapy area, but we know that many rebates in diabetes and hepatitis C exceed 50%. In other areas, where there are few similar options, rebates may be very small or non-existent.

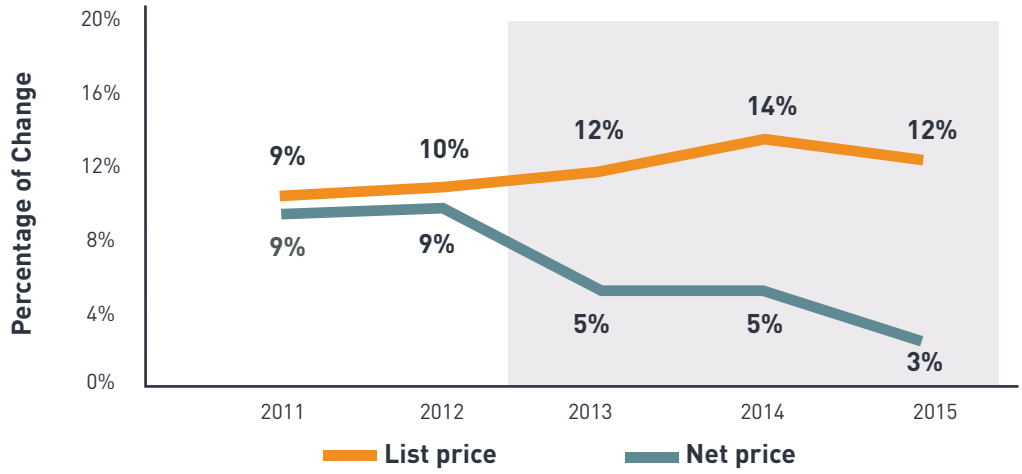


Figure 4: U.S. gross and net price growth for all branded drugs (source: IMS data)

In other countries, discounts can be agreed upon, usually on a basis of confidentiality. For example, in France, periodic negotiations between the French government and pharmaceutical companies often include confidential rebates and contractually agreed upon further rebates when, for example, certain sales revenues are exceeded. In Germany, the government insists on transparency of net prices. The future will tell how this debate will further evolve in the United States.

Payer Access

Formulary adoption by public and private payers is obviously a critical step in reaching a patient. In price-controlled markets, this is essentially an all-or-nothing event, where the outcome is largely driven by the provided evidence of benefit over the existing treatment standard at the time of negotiation. Criteria for approval are different by country, but the critical issue is usually whether the demonstrated patient benefit is deemed significant by payer accepted standards. Approval criteria have gradually become more stringent over time, particularly in terms of head-to-head comparisons with standard of care and demonstrated benefit across the label population.

In the United States, the stakes have increased as payers are no longer routinely putting new drugs on a third formulary tier with a higher co-payment. Large PBMs and many MCOs often exclude new drugs from formulary until closer review or on a more permanent basis when it is placed on an exclusion list, favoring similar drugs with better rebate terms.

Provider Formularies and Treatment Pathways

Provider organizations include a large range of integrated healthcare systems, specialty clinicals, hospitals and physician groups that put policies in place that influence treatment and prescribing behaviors of its associated physicians in varying degrees. Payment mechanisms and performance metrics are important drivers of provider organization preferences and related decisions.

Provider performance metrics are increasingly visible to the public and can influence the ability to attract patients, as well as directly impact reimbursement rates. Hospitalization rates, re-hospitalization rates and cardiovascular outcomes metrics are among the most commonly monitored metrics but more detailed Healthcare Effectiveness Data and Information Set (HEDIS), ACO and other metrics are increasingly used in payment decisions. Broader public awareness of health outcomes performance of provider organizations and their individual physicians is likely to further

evolve. In the age of TripAdvisor, it may soon only require a few clicks to access specific statistics such as hospitalization rates and cardiovascular event rates and direct patient feedback on each institution and physician.

Treatment pathways have emerged to encourage efficient use of resources in the treatment of patients. Pathways have been primarily used to optimize treatment and thus improve outcomes efficiently in cancer care. Treating physicians get a payment depending on the degree of adherence with the treatment options that are specified in the pathway guidelines. Some pathways, such as AIM (part of Anthem), select specific drugs within a recommended class. The actual impact of pathways on physician prescribing is still not fully clear. However, we expect that payers and providers may seek economic opportunities to make choices between options where they are deemed medically interchangeable.

A slightly different variation of the pathway is found in Germany, where regional physician groups agree on "quota," dictating that the least expensive drug option in a class is used for a specified percentage share of diagnosed indication. One of the earlier examples was the mandatory use of risperidone in 85% of patients with a need for an atypical antipsychotic. Quotas have proven to be an attractive tool where physicians claim to need discretion for a different option for some patients.

Funding for new technologies, including drugs, is often a challenge for providers in cases where a capped reimbursement rate, such as a diagnosis related group (DRG) rate, is resulting in institutional losses. New technologies can sometimes qualify for additional payment, such as the new technology add-on payment (NTAP) in the United States and the equivalent Neue Untersuchungs und Behandlungsmethoden (NUB) in Germany, but qualification has very high hurdles. Reimbursement payments are usually adjusted over time, but in cases where the treatment involves a substantial share of patients, providers will look to limit treatment numbers or move patients, where possible, to an outpatient setting with often different reimbursement mechanisms.

Clinical Guidelines and Value Frameworks

Medical communities have provided clinical guidelines to the physician community for many years. In recent history, these guidelines were purely clinically oriented and rarely included treatment and drug cost considerations. As an illustrative example, the American College of Cardiology (ACC) and the American Heart Association (AHA) published the ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures. It states, "The need for greater transparency and utility in addressing resource issues has become acute enough that the time has come to include cost-effectiveness/value assessments and recommendations in practice guidelines and performance measures."

Oncologists have been most vocal on the impact of cost and affordability on patients. Various value frameworks by the American Society of Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO) and the National Comprehensive Cancer Network (NCCN), as well as the "Drug Pricing Lab" by Memorial Sloan Kettering Cancer Center's Dr. Peter Koch have attempted to measure and communicate benefits of drugs, or lack thereof, in relation to its cost. While the value frameworks have sensitized physicians and the public on drug cost, they have not provided clinicians with clear guidelines on when to use what treatment option.

In heath-economics-driven markets, such as the U.K., Canada and Australia, health technology evaluations provide a basis for price or reimbursement. These cost-effectiveness-based guidelines provide payers significant control through direct linkage to price or reimbursement decision-making. The Institute for Clinical and Economic Review (ICER) is using a similar method to communicate cost-effectiveness of drug treatments in the United States. However, both methodology and financial perspective are not well aligned with U.S. PBM and MCO

decision-making. The question is whether and how ICER cost-effectiveness reviews will be adopted by payers, and whether these initiatives will be endorsed by the medical community and patients.

In the United States, a more likely scenario through which the evolving value frameworks may impact prescribing is through a linkage with treatment pathways and reinforcing incentives. This way, treatment value is better linked to a specific treatment stage and its related choices rather than for a drug overall.

The evolution of value frameworks and their impact on prescribing will continue to be an area of uncertainty for some years to come.

Prescribing

The actual physician prescribing decision will continue to be the central factor in the market adoption of any drug. No drug will perform well without the physician's endorsement of its value in treating individual patients. As such, the prescribing decision is the resulting transaction under influence of decisions and communications provided by medical communities, payers, provider organizations, and other potential stakeholders and influencers.

A lack of demonstrated value can have a strong negative impact on prescribing due to payer-imposed restrictions in addition to the direct impact of a less compelling message to prescribers. Commercial success may not be achieved by merely passing minimum hurdles to gain market access. In the United States we may gain FDA approval for an undifferentiated drug with a placebo-controlled study. However we will subsequently be forced to offer either significant rebates or intensive co-pay offset programs in the commercial market to overcome patient co-payment hurdles and related hesitance of physicians to prescribe.

A key question is whether we adequately represent the impact of demonstrated value, or lack thereof, on the forecasted physician prescribing. Forecasts are only as good as the options that we consider in predicting performance. Unless we explicitly consider the impact of multiple value proposition options on peak market share and forecasted revenues, decision-making teams will typically favor adhering to the minimum FDA requirements.

Prescription Fulfillment

What happens when the patient leaves the doctor's office? Will the patient go to the pharmacy to pick up the prescription? What if there is a substantial co-payment? If so, was the patient made aware of any coupons that may offset the co-payment? As co-payments have been rising in the United States and some other markets, prescription fulfillment is an increasing area of concern.

Pharmaceutical companies have been offering an array of patient support services to help eliminate paperwork, cost and co-pay hurdles that payers have instituted to limit access to high-cost prescriptions drugs. Payer adoption of new management strategies such as drug exclusion lists and recent co-pay accumulators require adjustments in brand strategies.

Patient Adherence

Does the patient adhere to the drug treatment over time and how is this different across patient populations? Adherence is strongly dependent on efficacy and the safety/tolerability profile and can also be impacted by patient co-payment and the associated financial burden. Particularly for non-symptomatic, chronic conditions, adherence can be a major challenge.

DESIGNING A VALUE STRATEGY

As a pharmaceutical company, our commercial success is hinging on our ability to optimize each of the elements of the access journey. It does not help us if after a favorable FDA approval, payers restrict drug access, medical associations don't recommend it on their guidelines, providers don't place it on formulary, physicians don't prescribe, or the patient decides not to pick it up in the pharmacy or ends the treatment early. Therefore, it's essential that we closely evaluate each of the access journey steps to determine what it takes to secure success. Who is the decision maker and what development strategy and resulting evidence will positively influence that decision?

As illustrated in Figure 5, each of the access journey steps involves a different set of decision makers with different value preferences and needs. Payers are generally focused on long-term outcomes and related economic impact. They tend to put limited significance on direct clinical metrics unless it has a sustained and long-term health impact. Provider organizations are likely to want to see an impact on quality metrics, such as (re-)hospitalization rates, other outcomes metrics and patient satisfaction. These differences may not seem fundamentally large, but they can have a significant impact on clinical development programs. For example, whether measuring a tumor response rate, progression free survival or overall survival has large implications on trial design, investment need and probability of success. Similarly, HbA1c management in diabetes and low-density lipoprotein (LDL) control in hypercholesteremia may be accepted metrics for success to a clinician, but payers and provider organizations may want to see additional evidence of long-term impact on outcomes and related cost.

Even where stakeholders are aligned on a meaningful metric, the level of evidence required can be very different. Payers typically require head-to-head trials versus an appropriate long-term endpoint. Provider organizations prefer real-world evidence that demonstrates improvements on meaningful outcomes metrics in their specific population. Patients want to feel a response, improvements in their symptoms and confidence in the long-term prognosis.

	WHO TO INFLUENCE	WHAT THEY VALUE
List and Net Pricing	+ Government and Private Payers + PBMs, GPOs, Trade	+ Demonstrated long-term outcomes + Limited budget impact, rebates
Payer Access	+ Government and Private Payers + PBMs, GPOs, Trade	+ Benefit/value evidence vs. unmet needs + Economic and budget impact
Clinical Guidelines and Value Frameworks	+ Medical Associations + Compendia, Pathway Companies	+ Clinical and outcomes evidence + Appropriate place in therapy
Provider Formulary	+ Provider Organizations + Hospitals, Treatment Centers	+ Impact of treatment on relevant outcomes metrics + Impact on organization's financials
Prescribing	+ Physicians	+ Address patient clinical and humanistic needs + No access hurdles/hassle, patient affordability
Prescription Fulfillment	+ Patients/Caregivers + Pharmacies	+ Patient understanding of value across options + Address deductibles, co-pays
Patient Adherence	+ Patients	+ Managing side effects + Address patient affordability

Figure 5: Decision makers and preferences for each access journey step

Focus on Differentiating Benefits

Understanding what drives decisions for each of the access journey elements is of critical importance when devising a development plan and ultimately a launch marketing strategy. We use our benefits analysis methodology to systematically assess priorities to stakeholders in each of the benefit domains shown in Figure 6.

BENEFIT DOMAIN	DESCRIPTION	EXAMPLES
Clinical	Efficacy, safety and tolerability measures	HbA1c in diabetes, tumor response rate (PR/CR) in cancer
Humanistic	Health-related quality of life metrics, patient-reported outcomes, social functioning	Patient ability to function, perform daily activities
Economic	Economic impact from the decision makers' perspective, value for money	Cost-effectiveness, budget impact through, for example, reduction in hospitalization cost, reduced nursing time
Organizational Excellence	Impact on organizational reputation	Formal quality metrics (HEDIS, ACO metrics), patient-satisfaction-related statistics
Public Health	Global- or national-level health-statistics-related improvements	Reduction in disease incidence, disease-specific survival rate, reduced stroke mortality, reduced absenteeism

Figure 6: Description of benefits domains

Figure 7 shows a typical, high-level example of a benefits analysis for an oncology drug where we:

1. Identify potential improvements in terms of benefits in the specific disease category

2. Rate the importance of each of these benefits to key stakeholders

3. Rate potential or proven differentiation versus one or more comparators for each of the benefits

In this simplified example, we only consider 12 benefits across the various benefit domains. For each of the benefits, the importance of any improvement claim is rated from the perspective of payers, physicians and patients. In real practice, we may want to consider more stakeholders as well as specific segments within the payer or physician community. Overall survival (OS) and related life expectancy expectations are rated highly for all stakeholders, but tumor response rates are rated much higher by clinicians than by payers. Physicians see a response rate as a direct measure of progress with the patient that raises expectations with respect to the prognosis, but payers are more skeptical and require direct evidence of overall survival. Progression-free survival (PFS) outcomes have been subject to a lot of debate. PFS improvements have not been demonstrated to lead to guaranteed OS benefits. A notorious example has been for Avastin in breast cancer, which was accepted into clinical standards for many years on the basis of PFS improvement data until the confirmatory Phase III trial showed no difference.

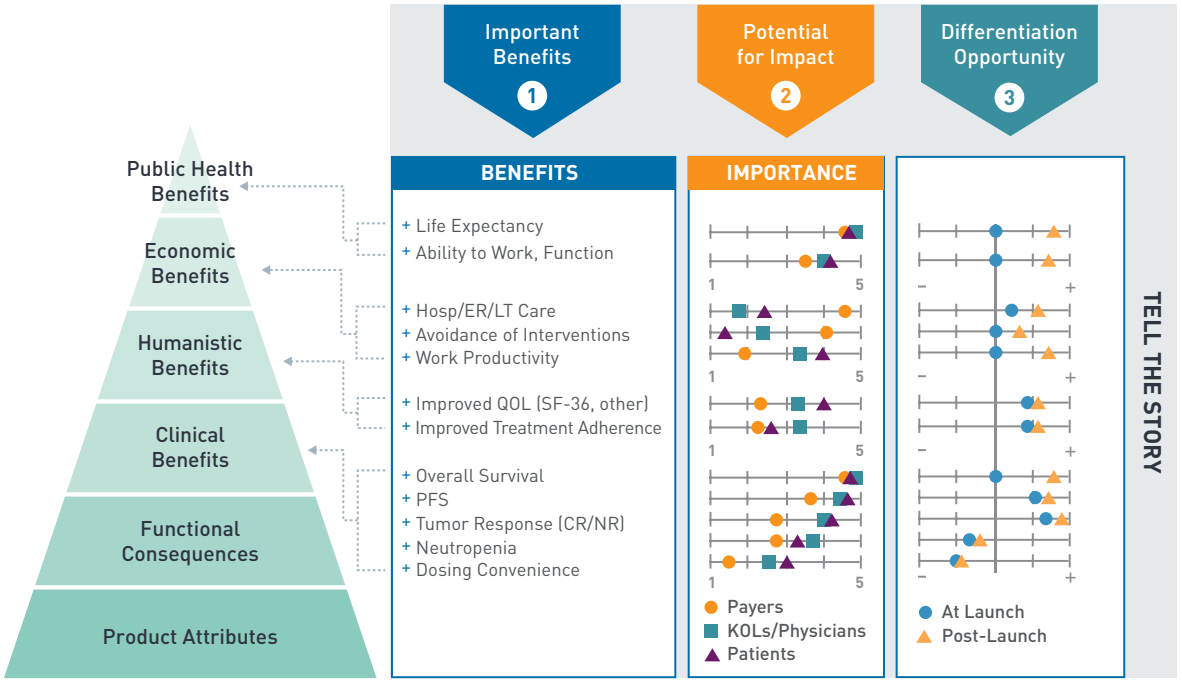


Figure 7: Benefits analysis for an oncology drug

In the example in Figure 7, we indicated differentiation opportunities at launch as well as post-launch. We often talk about "aspirational" value propositions, which can excite teams but are not claims that can be made at launch. For this reason, it's important to consider specifically what can be claimed at launch when first negotiations take place and the price is set versus later in the life cycle when additional long-term outcomes data and real-world evidence may be available. Our example illustrates a fairly typical situation where OS data is not available at launch and we need to negotiate with PFS and tumor-response improvements claims. Absent of OS data, HRQOL data is essential to support the value of PFS improvements. Most payers require that new drugs with PFS improvements should at least not lead to a further deterioration of HRQOL, as well as a commitment of post-launch confirmation of OS improvements.

In Figure 8 we see an example of a benefits analysis for a hypothetical diabetes drug. The benefits analysis in this example is particularly focused on the perspective of provider organizations, such as IDNs, in contrast to payers and individual physicians. The most important benefits for providers are indicated in blue. They involve economic and organizational-excellence-related benefits, which are the benefits that are most closely tied to the organization's business performance. Important clinical metrics, such as HbA1c in diabetes, are particularly important in addressing physician needs and their willingness to prescribe, but the providers want to see the ultimate impact on metrics, such as HEDIS and ACO scores, as well as direct (reduced hospitalizations, etc.) and indirect (through outcomes metrics) impact on economics. In this case, the clinical benefits are important antes for the provider (to satisfy physician needs), but the economic and organizational excellence benefits are the important differentiators, provided that the appropriate evidence is delivered.

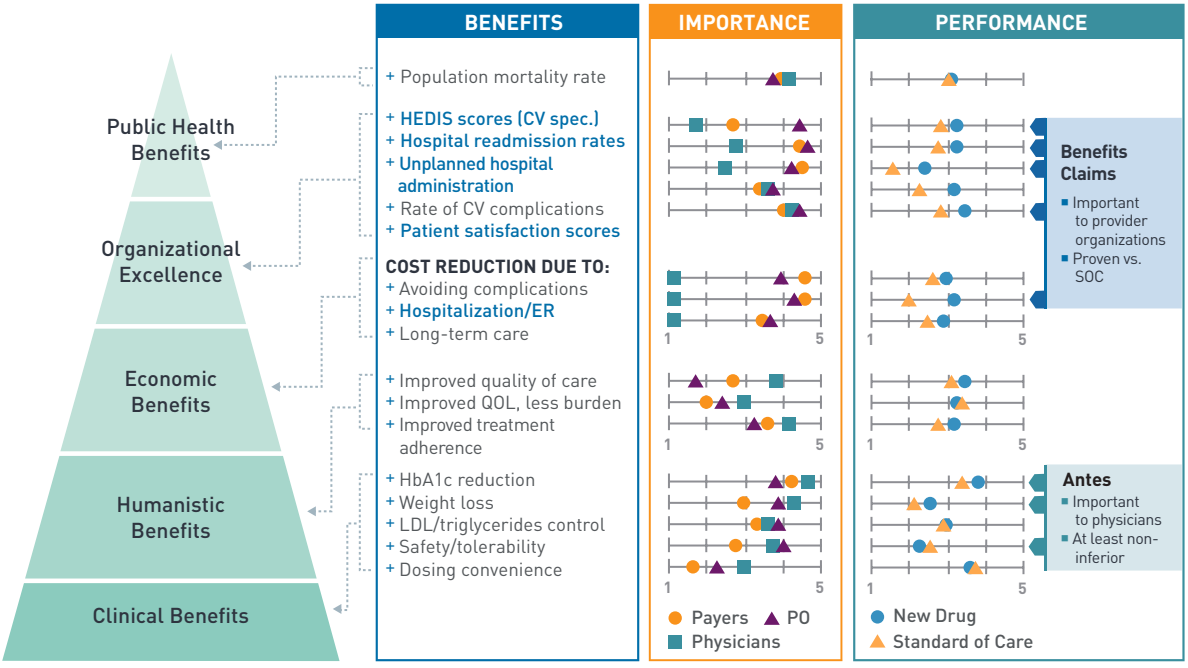


Figure 8: Benefits analysis for a diabetes drug

Figure 9 is summarizing the differences in benefits preference and hence evidence needs for FDA/EMA, payers, provider organizations, prescribing physicians and patients. This is merely a high-level illustration of typical differences in perspectives on value between stakeholders. For individual drugs, a more comprehensive analysis is warranted, which should include a larger set of potential benefits, a complete set of comparators, and all-important stakeholders and their segments. It does, however, illustrate the need to customize value claims and supporting evidence to each of the stakeholders individually.

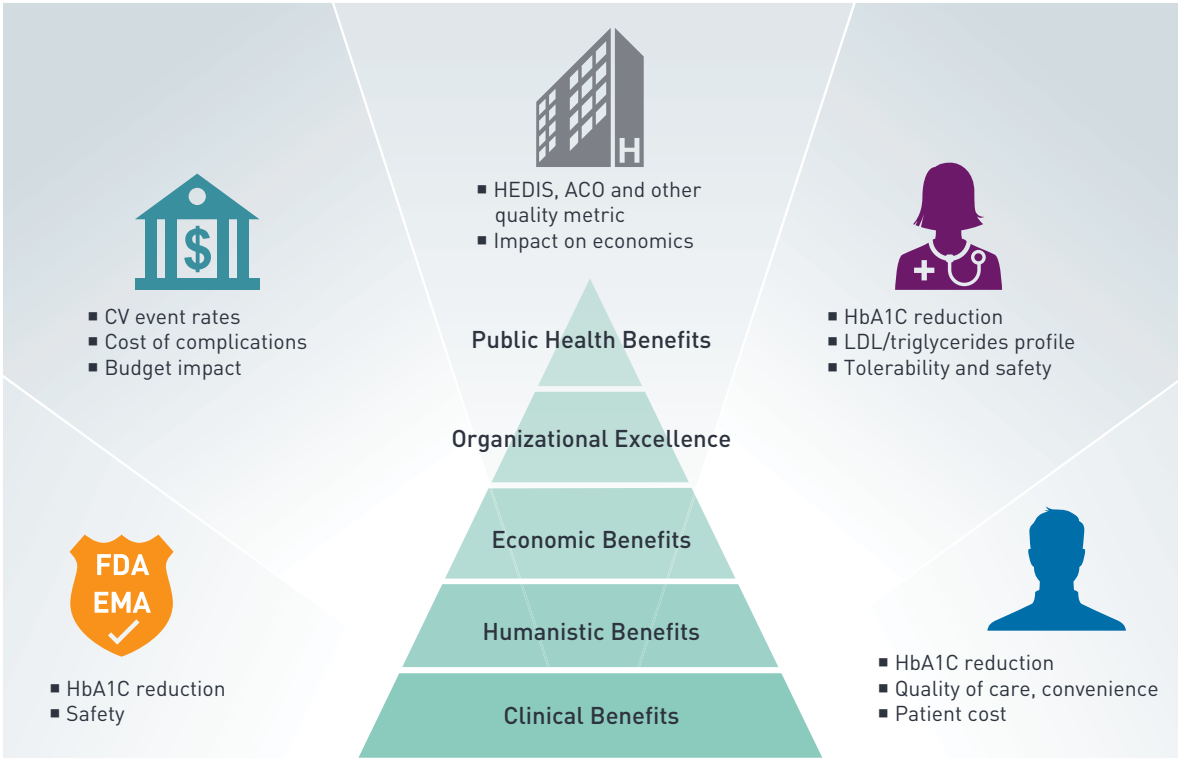


Figure 9: Illustrative view of improvement priorities across stakeholders

"Designing" a Commercially Successful Product

How do we develop our drug to maximize risk adjusted net present value to our organization?

Not long ago, clinical development programs were mainly designed based on FDA and EMA requirements. Meeting minimum requirements for market authorization secures a launch on paper but does not guarantee endorsement of the treatment by the medical community, funding within each of the payer systems around the world or prescribing to a broad range of patients by practicing physicians.

To secure a reasonable price that makes the drug development commercially viable, we can essentially either offer a stepwise or "incremental" improvement at a price level that is similar to the current standard of care or offer a clinically substantial or "breakthrough" improvement that warrants a higher price than the existing price levels. Figure 10 illustrates this in a simplistic way.

Where the current standard of care is at low cost, we can only expect a drug to be commercially successful when we address a substantial unmet need that is recognized and endorsed by the medical community and accepted by payers.

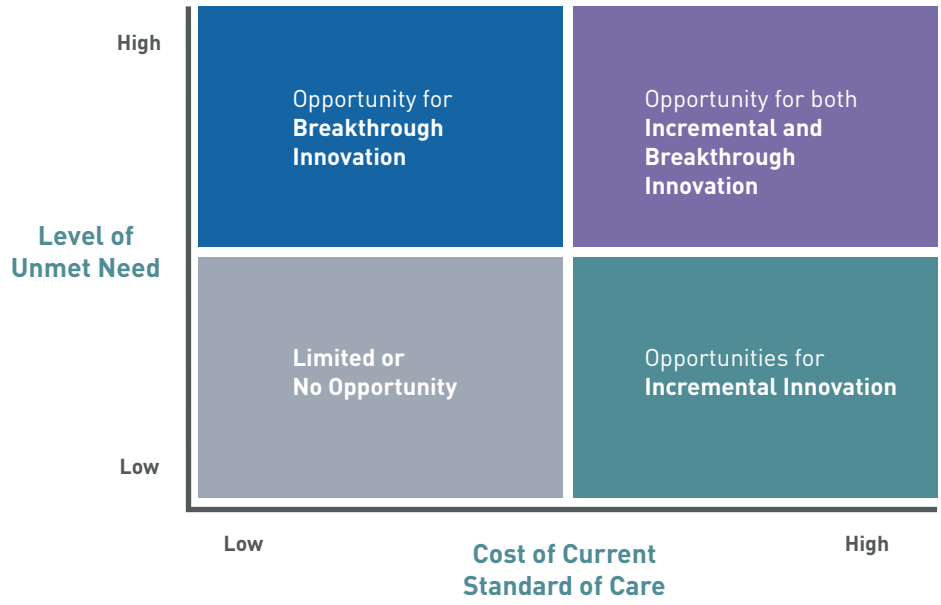


Figure 10: Breakthrough vs. incremental innovation opportunities

The large majority of new product launches are incremental innovations, commanding no or small price premiums over the standard of care. Provided that the price level of the standard of care is acceptable, commercialization or reaching blockbuster status is certainly possible, as history has shown. The problem arises when development is pursued for new drugs, where the standard of care is a low-cost generic and the planned evidence does not yield significant value in the eyes of the medical community and, ultimately, the payers.

Breakthrough Innovation

Whether a new drug constitutes a breakthrough innovation may be judged substantially differently between the scientific community and government or private payers. While a new mechanism of action may offer great promise and excitement from the clinical community, the adoption in treatment practices and formal guidelines needs to be generally based on substantial evidence on relevant clinical end points. Payers tend to take it a step further and will more typically require head-to-head clinical data for the relevant endpoints and long-term outcomes implications within the appropriate patient populations. The benefits analysis across stakeholders, as described earlier in this paper, will help to analyze the impact of various development strategies on commercial success. However, it is essential that a cross-functional team, bridging commercial and R&D, is aligned on the analysis and its conclusions.

Treatment efficacy is the primary innovation that is valued in the market. Long-term effectiveness and patient outcomes are the primary focus of payers, where the medical community is generally more willing to accept surrogate measures of treatment effectiveness. In oncology, the dichotomy between overall survival, progression-free survival and complete or partial tumor response rate

is a classic but still highly relevant example. As illustrated in Figure 7, payers and oncologists typically have a different view on the significance of each of the benefits. This can have large implications for the design of our pivotal trials.

Another factor to critically consider is how the potential benefit of our drug varies across patient populations? For example, given existing treatment options, will it best add value in earlier lines of therapy for a broad population or as a more focused later-line option for later-stage patients? Also, after market authorization, will the drug be reimbursed and prescribed across the label or mainly in sub-populations where the benefits are most pronounced? In some cases, biomarker tests help to identify specific patients with the highest benefit and can be used in reimbursement decision-making for individual patients.

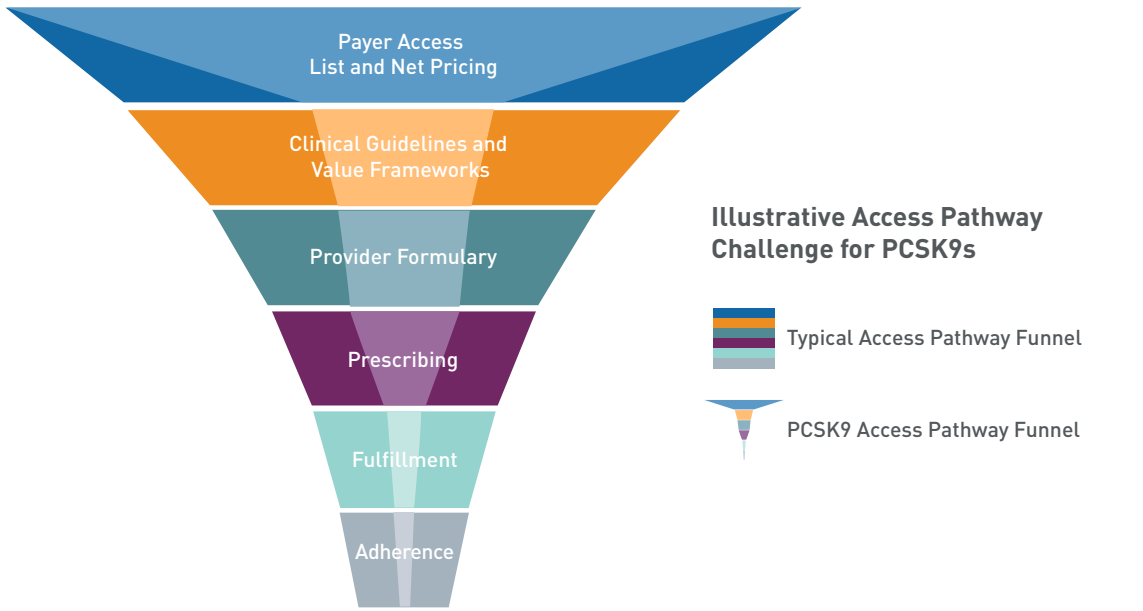


Figure 11: PCSK9 access journey challenges

An obvious example of a mismatch between the label patient population and the population for which the medical community sees its highest value is the PCSK9 category. Because of this issue, uptake is much narrower than the indicated label. Figure 11 illustrates the issue. This example will be further discussed under the header "access diagnostics" later in this paper.

Incremental Innovation

Most meaningful product improvements are not considered "breakthrough." First, products in a therapeutic class are often improved upon with later launched products with the same mechanism of action. These subsequent market entries can have great market potential but do not command a substantial price premium over the existing standard of care. Therefore, it's critical that the prevailing price levels for the therapy are sufficient to warrant commercialization.

Incremental innovations need to meet two essential criteria for successful commercialization. First, they need to be somewhat compelling for a payer to at least allow access. Provided that the payer can be convinced that the drug does not hold significant concerns with respect to its efficacy

and safety profile, that hurdle may not be insurmountable as added cost to the payer should be limited or nil. Second, the benefits of the incremental innovation should be important enough to the medical and provider community to drive physician prescribing.

Here are some examples of clinical strategies to explore benefits from incremental innovation:

+ In some disease areas, it may make sense to introduce a different efficacy metric as the existing one may not accurately reflect improvements. An example is plaque psoriasis, where PASI 90 can be used as a more patient relevant end point instead of the classical PASI 75 for treatments that provide better skin clearance.

+ Tolerability improvements, which can be highly rated by physicians and patients, often qualify as an incremental opportunity as well. The drug industry is often claiming outcomes improvements through improved adherence and compliance, but the required evidence is usually hard to obtain. Even in HIV/AIDS, where treatment adherence is considered a critical problem, single tablet formulations of two or three drugs have not led to price premiums.

+ In some cases, substantial patient sub-populations have additional concerns that can be addressed. Cymbalta (duloxetine), for example, addressed depression and pain associated with depression. For diabetes, managing weight and cardiovascular risks have become increasingly important.

Convenience-related improvement examples include:

+ Oral administration in a category where only IV/IM options are available and the frequency of administration of an office-administered drug are good examples of innovations that may have some impact on cost but are largely focused on patient convenience

+ Devices, such as insulin pens, pumps, patches and similar devices that allow for easy patient administration of a drug, can be very important for patients

Besides innovations that are directly related to the drug or its delivery system, we can think of other value-added programs that may not allow us to charge a substantially higher price but that can give us a competitive edge—provided we have gained at least a level playing field with respect to market access.

Beyond-the-Pill Programs

As developers and marketers of prescription drugs, we are focusing on the role that each drug can have in the context of the broader treatment challenges that providers may face. FDA, EMA and payers worldwide evaluate clinical data, mostly generated in a randomized controlled trial setting, to evaluate efficacy and safety across the appropriate patient population. However various gaps result from that perspective, which can create doubts about the real-world effectiveness of

the treatment. Beyond-the-pill (BTP) offerings to our customers to address these gaps can help us to positively differentiate ourselves from the competition, albeit mostly at a similar cost to the customer. BTP programs can be introduced for a number of other reasons, such as creating a better patient experience or building a stronger partnership with a payer or provider.

Many pharmaceutical companies have been actively pursuing beyond-the-pill programs, but in our experience only few result in a meaningful collaboration. Payers and providers tell us that there are three main reasons for this:

1. Pharma does typically not know what constitutes "value" to a payer or a provider organization. What is important beyond the drug, and how does it impact the organization's performance and financial metrics?

2. Customers often don't trust pharma. The industry is seen as advancing its own agenda and pursuing programs in narrow support of that, which stands in the way of collaboration.

3. Logistics in terms of effort required to collect and analyze data, as well as legal compliance/ data privacy process hurdles are often overwhelming to make a program practically viable and attractive.

There are several successful programs in place, but many do not go beyond a single company-payer or company-provider deal. In a world where contractual agreements between payers and provider organizations—linking payments to population health performance—are more commonplace, there's likely to be much more opportunity to be successful with these programs. An important success factor in designing a BTP program is to identify an important client business need or concern where our product can play a role in resolving that. A partnership with the client can help to resolve that challenge or to overcome any concerns that the client may have in using the product. Some examples of potentially successful BTP collaborations are:

+ Partnerships that help patient compliance with treatments, including patient information, handheld devices with patient self-management information and alerts

+ Real-world data generation that can help provide more evidence on effectiveness of treatment approaches and for sub-populations

+ Outcomes-based contracts that link payment to long-term patient outcomes. These programs should link directly to payer- or provider-relevant performance metrics and should be relatively simple to implement

ALIGNING R&D AND COMMERCIAL ON EVIDENCE NEEDS

How do we best address customer evidence needs in support of our strategy through our drug development program? How do we make the right trade-offs between evidence needs and required investments, impact on development timelines and probability of clinical success? Pharmaceutical companies typically have a formal process with involvement of many R&D and commercial disciplines to support drug development and commercialization decision-making. Decision-making is usually based on an assessment of risk-adjusted net present value (rNPV) across drug candidates and their indications. rNPV calculations include investment requirements, probability of success, and revenue projections based on target product profiles and their upside and downsides.

As with any process, the decisions are only as good as the analysis and underlying assumptions that are used in the process. Each functional discipline may have very different perspectives on what is required to claim "success." They may have different perspectives in what development program is required and may have different performance metrics. In many cases, these discussions can become emotional as generating compelling evidence may incur risk to the program and impact functional and individual job objectives. Failure to meet a primary endpoint often results in termination of a program. Whether this risk is justified in light of less risky options to prove a less compelling claim should be evaluated in an objective way from the perspective of the company's goals and results. In many cases, compromises can be found in defining primary and secondary endpoints and sequential testing.

The following steps can help to facilitate rational decision-making for the company:

1. **Define success.** Are we considering how our profile will impact decision-making beyond FDA/EMA approval? Do we capture the needs of all stakeholders in the access journey?

   Many organizations are not taking a holistic approach in considering all commercially important aspects of decision-making and impact on the revenue forecast. While most companies look beyond the FDA and consider EMA and their requirements for marketing authorization in Europe, the evolving payer requirements are not consistently considered in a robust way in many companies. Particularly in oncology, the perception of many still is that "coverage is mandatory anyhow," not taking into account that patient co-payments, KOL endorsement and the growing influence of value frameworks and treatment pathways have large implications for success today, and five years from now.

Outside of the U.S., consider how many drugs face "surprise rejections" in countries such as Germany, France, Italy, Canada and the United Kingdom. Surprises can occur as the market is sharpening its access requirements, but often it may just have been an underestimation or even denial of the signals that we picked up from payers and KOLs during the development process. In many cases, evidence that is critical to European markets would accelerate uptake and increase peak market share in the U.S. as well. Forecasts often do not address these upsides in the U.S.

While today's market requires addressing a larger set of key stakeholders and influencers, we don't believe that the evaluation process needs to be overly burdensome. An evaluation of alternate strategic options is only needed for the most important aspects of the access journey in each situation.

2. **Consider multiple development options.** Which development choices are included in the options evaluation set? Have we been willing to explore the potential of alternative development options and some perhaps riskier options with large upside potential?

   The clinical and regulatory teams tend to focus on options that satisfy FDA requirements and help the asset to gain market authorization as quickly as possible with the least amount of clinical risk. While important considerations, we need to look beyond these options to ensure that we don't get rapid approval for a drug that nobody will pay for. This is not to say that the most comprehensive evidence option should be chosen. It may not make sense to choose a more robust development plan when, for example, a competitor product will then beat us to the market and there is significant risk that our more impressive claims are declared a class-effect. A short patent life may also further contribute to a preference for a minimal program. The essential point is that we need to engage in a structured evaluation of options that go beyond the ones that are formulated from a regulatory needs perspective and address the needs from all decision makers represented in the access journey.

3. **Examine the impact of the important options on the forecast.** How do we ensure that the forecasted revenues are representing the current prescription drug environment (capture the impact of all access journey decisions)?

   Our commercial forecasts need to adequately represent the impact of development options and their implications on access journey decisions, such as the value proposition on medical community adoption in clinical guidelines and formal advice to payers, payer formulary adoption and willingness to prescribe given payer-imposed hurdles to prescribing. Most forecasts are based on a projected market share of an epidemiology-based estimated market size. Do market share projections properly incorporate the impact of our evidence program in gaining solid KOL support, and favorable treatment guidelines that compel broad access and allow for unrestricted prescribing? Or do we just assume that we can achieve a result that's similar to a previously launched drug from a different company and then minimize the investment to get a quick FDA approval? The latter is often the reality. We need to validate each of the explicit or implicit access journey assumptions on its validity considering evidence requirements for the decision maker and the impact on forecasted revenues. Examples include the impact of value frameworks, oncology pathways, clinical guidelines, ICER evaluations etc.

   Validation of forecast assumptions generally requires a mix of market research and analogue analyses. This is relatively straightforward for payers and physicians. However, assessing the impact on revenues of some newly emerging stakeholders in the United States requires recent analogue analyses, some educated projections and in some cases scenario analyses. Some examples that come to mind:

+ The impact of U.S. provider organizations, such as IDNs and ACOs, on the prescribing of a new cardiovascular drug class

+ The impact of NCCN and ASCO value frameworks on payer management and physician prescribing

+ The impact of a positive or negative ICER evaluation on payer formulary adoption

Taking access journey factors in to consideration, together with regulatory requirements, investment needed, timing and probability of success is crucial for a robust decision that focuses on a common corporate goal. How to get to a consensus decision in a multi-disciplinary team with diverging views and objectives is the next challenge.

Develop a Robust Process

Do you have the right parties at the table in the development decision process? Are insights from all the critical stakeholders represented when options are considered and impact on the commercial results validated? Can we do this in an environment that is perceived as fair and rational and that allows for sometimes tough choices?

Decision-making processes in pharmaceutical companies are often complex. Motivations and incentives are usually not aligned between R&D organizations that focus on reaching development and regulatory approval milestones and commercial teams that focus on revenue and profit. The trade-offs are also very complex and require knowledgeable input from many functional disciplines.

Having the right process in place to balance the magnitude and risk of clinical development with the strength of evidence generated is perhaps the most important determining factor in which of today's pharmaceutical companies will be the most successful over the next decade. Making these decisions in a multidisciplinary setting with strong representation of clinical, regulatory, marketing and market access is essential. Market access is not always a direct participant in the trade-off discussions. Given the generally limited direct experience in market-access-related challenges by other commercial and development disciplines, this can seriously hamper well-informed decision-making.

The typical structure of pharmaceutical company decision-making is organized by milestones or decision points (see Figure 12). At each decision point, progress and projections are reviewed and decisions are made on whether to proceed or not with many R&D and some commercial disciplines around the table.

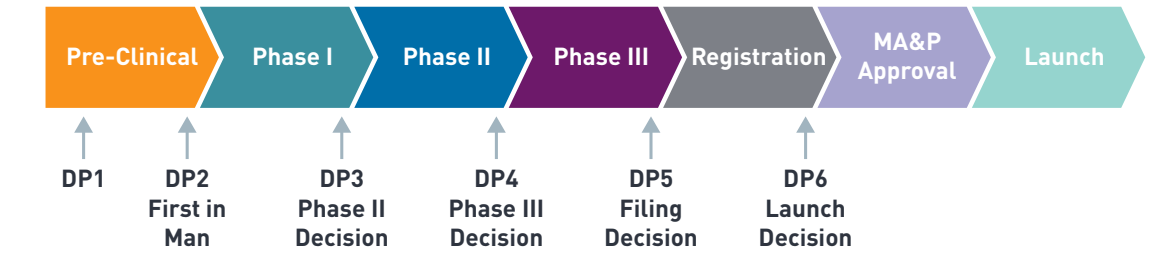


Figure 12: Illustration of typical development decision points

While the high-level decision-making process for each of the milestones or decision points, such as the Phase III decision, may be appropriate, we need to closely consider what goes into the decision. The decision can only be as good as the options and choices that are considered and analyzed. In particular, do we explicitly include multiple trial design options that address evidence needs from not only the FDA and physicians, but also the U.S. and international payers, medical societies (guidelines), provider organizations and patients? Considering the right options can serve to rationalize the decision and take emotions and gut reactions out of the equation.

	MINIMALLY ACCEPTED OR DOWN SIDE PROFILE	BASE CASE OR TARGET PROFILE	UPSIDE PROFILE
Primary Endpoint			
Secondary Endpoint			
Safety/Tolerability			
Launch Timing			
Peak Share			
Duration of Therapy			
U.S. Launch Price			
U.S. Gross-to-Net			
U.S. Annual Price Increase			
ROW Multiplier			
Peak Year Revenue			

Figure 13: Typical template for development decision-making input

As an illustrative example of how commercial forecasts are supporting the decisions, consider Figure 13, which shows a typical forecast that's used to inform decision-making. Primary and secondary endpoint information, together with statistical significance of any differentiation versus a comparator, are often included for a target or base case, a down side and an upside. While the information is all relevant, it does not provide sufficient insight into:

+ The performance of a clinical scenario on each of the access journey components

+ What other options can and should be considered to optimize journey decision-making and how do they compare with base case and upside/downside clinical scenarios

A simple schematic of the considerations that should lead to generation of meaningful development options and, ultimately, the evaluation of their impact on commercial success is illustrated in Figure 14.

Based on various agreed-upon objectives with FDA/EMA and key access journey decision makers—and trade-offs between benefit/value, clinical risk, investment and launch timing—we can evaluate risk-adjusted net present value (rNPV) of some meaningful evidence program options.

An important part of the process is to organize cross-functional discussions to reach agreement on a limited number of development options that span the trade-off between strength of value proposition, time to launch, probability of clinical success and investment required. For the prioritized options, the impact of projected evidence on the revenue forecast should be validated through an assessment of the impact on the access journey decisions.

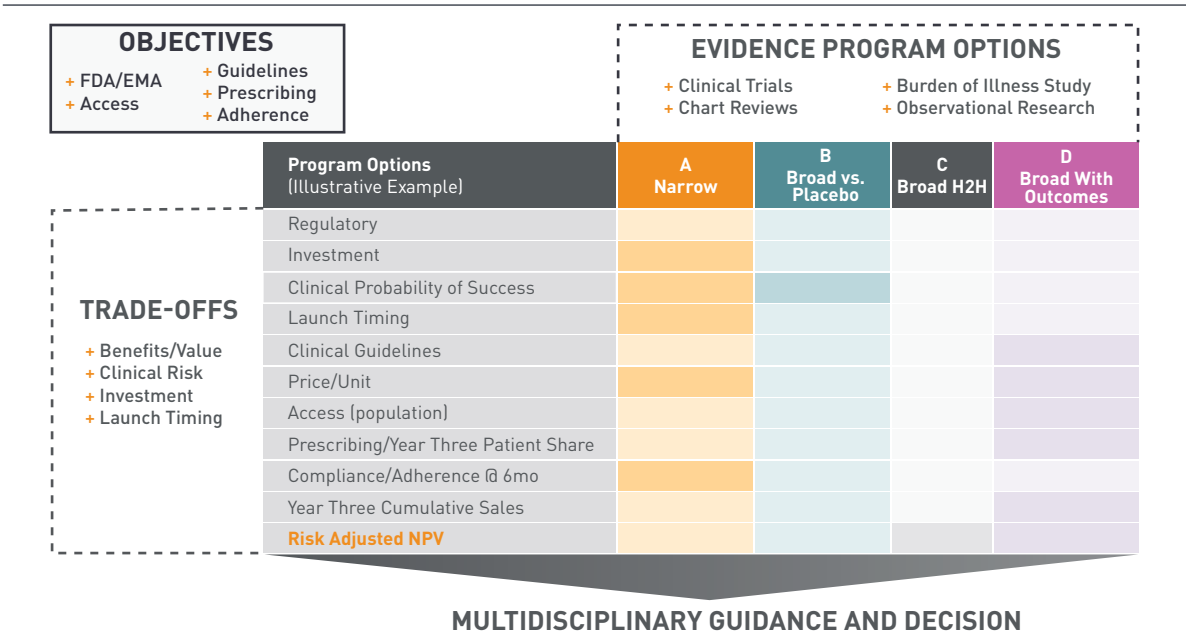


Figure 14: Development decision-making work flow

ACCESS DIAGNOSTICS

"Why is our drug not reaching the forecasted revenues that we projected when we commissioned the Phase III studies?" This is a question that is periodically and perhaps increasingly heard within pharmaceutical company C-suites and brand teams. Often, the answer is "access limitations," but identifying the actual underlying problem, as well as how to address it, requires closer examination of the situation. The access journey offers a structured framework to examine the situation and pinpoint where some of the causes of underperformance may lie.

Let's consider the PCSK9s as an example. Amgen's Repatha (evolocumab) and Sanofi/Regeneron's Praluent (alirocumab) have struggled with market uptake due to several factors that are actually closely related. Payers have put significant access hurdles in place, the medical community has not placed PCSK9s broadly on treatment guidelines, and physicians have limited prescribing to a narrow patient population. While the actual "narrowing of the funnel" may be due to payer restrictions and lack of willingness to prescribe (partly due to health insurance hurdles) by physicians, the actual underlying problem has been to convince the medical community of the value of broad use of these drugs within label. Given the view that PCSK9s play a key role in a much narrower population than included in the label has empowered payers to incorporate tough restrictions and disincentives for prescribing physicians. While payer restrictions may be seen as the primary hurdle by many, in reality, convincing the medical community of value of PCSK9s in a broad population has been the critical gap in value demonstration.

The PCSK9 example clearly illustrates the need to systematically evaluate the role of each of the access journey stakeholders and their level of endorsement of the drug therapy before deciding where the real problem lies. Payer access restrictions can be caused by a lack of demonstrated value to the medical experts and prescribing physicians. In other cases, it can be a lack of demonstrated benefit with prescribing physicians as our trials were merely powered to show non-inferiority to the FDA and gain broad access at parity or discounted pricing versus the prior standard of care.

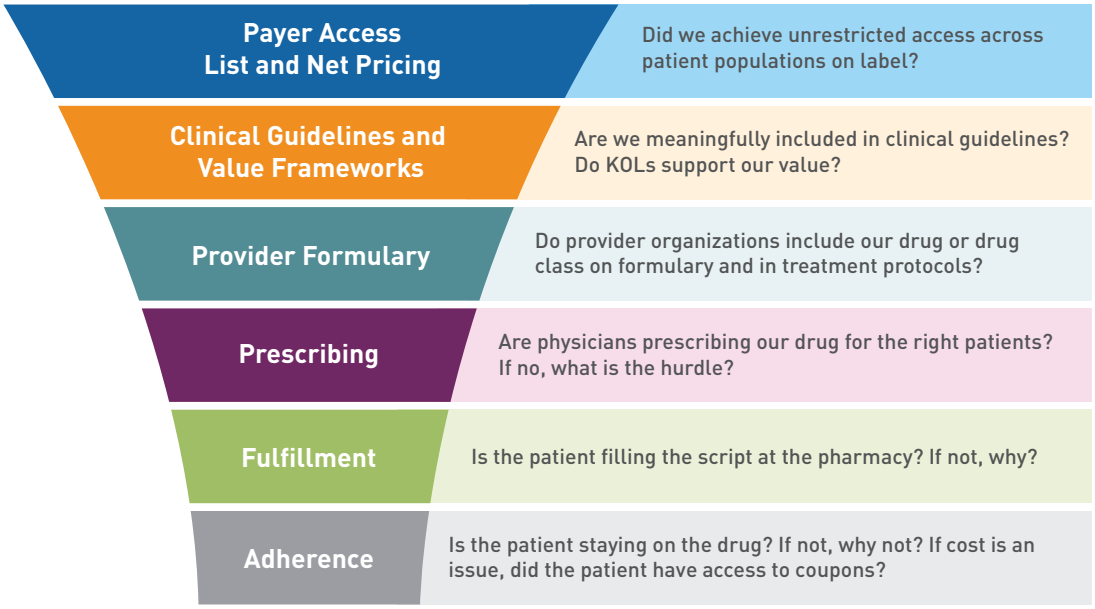


Figure 15: Access journey diagnostic questions

Post-launch, most of the access journey diagnostic questions can be answered through data analytics. Understanding cause and improvement opportunities require market research.

IMPLICATIONS FOR THE PHARMA ORGANIZATION

Pharmaceutical sales forces that target high-prescribing physicians have long been the focus of promotional activities in support of prescription drugs. Managed care account teams and their equivalent in international markets are focused on influencing formulary and coverage decision-making, and medical scientific liaisons have offered medical support in response to specific customer inquiries. In the United States, direct-to-consumer advertising has been used to create or strengthen brand awareness and encourage patients to seek treatment or ask for a new brand with the treating physician. More recently, teams focused on provider organizations or "organized customers," such as IDNs and IPPNs have been created with variable success.

An important question is whether we have evolved our marketing and sales force strategies from a sales representative focus to the needs that the current access journey requires. Payers and providers often complain that the interfacing company representatives are often behaving like classical reps rather than a partner that understands their needs and is ready for a more appropriate interaction in that setting. Materials that brand teams create are often focused on the sales rep and may not meet the slightly different needs from other customers.

Approaching the medical community with medical information and "promotional materials" is subject to significant FDA regulation and often involves the participation of the medical team. These aspects obviously need to be taken into close consideration when devising communication programs to all access journey stakeholders.

The 21st Century Cures Act has provided new opportunities to communicate with payers and formulary decision makers on value. Real-world data and patient preferences provide new opportunities to demonstrate the impact of our prescription drugs on long-term patient outcomes and economics. At a time when value and affordability are crucial components of our value proposition, we need to take these opportunities to drive our success.

A successful value communication program to our customers needs to consider the two important components:

1. What constitutes value and credible evidence of that value for each of the access pathway decision makers? What are the implications for promotional materials?

2. How do we effectively influence decision makers through other stakeholders? What are the implications for our organization and coordination across teams?

Addressing both components effectively requires a coordinated approach across customers that recognizes the differences in needs between those customers and its implications for promotional materials, team capabilities and organizational design.

Recent changes in the pharmaceutical environment forces the question of how we adjust our organization to reflect that medical societies and provider organizations limit physician choices and influence their behaviors. Have we shifted our strategies and resources to address these changes? Have we attracted the right talent to work with for example provider organizations, or did we simply shift a traditional sales force representative?

About the Author

Ed Schoonveld is a managing principal at ZS and is the leader of the firm's value and access practice area. In this role, he provides strategic consulting and research solutions to healthcare industry clients, and he's considered to be one of the world's leading experts on global pharmaceutical pricing and market access. Ed has unparalleled experience as the former head of the global market access and pricing functions at Wyeth, Lilly and BMS, and as a consulting leader at Cambridge/IMS and a number of other organizations. Ed is the author of *The Price of Global Health*, a textbook about global drug pricing and market access; the second edition was published in 2015.

About ZS

ZS is the world's largest firm focused exclusively on helping companies improve overall performance and grow revenue and market share, through end-to-end sales and marketing solutions—from customer insights and strategy to analytics, operations and technology. More than 6,000 ZS professionals in more than 20 offices worldwide draw on deep industry and domain expertise to deliver impact for clients across multiple industries. To learn more, visit www.zs.com or follow us on Twitter and LinkedIn.

For more information, please contact:

ZS
+1 855.972.4769
inquiry@ zs.com

www.zs.com

12-18