



Building an evidence-driven framework for greater access

Authors: Muna Tuna, Jason Boller and Wendell Miranda

In a market driven by cost pressures, integration, and a push for transparency, what strategies can biopharma companies develop to gain and improve market access?

Executive summary

A Market Access executive is speaking with a pharmacy director of a national health plan about a recently approved product. "Our new anti-epileptic therapy can reduce seizure incidence by X percent per year and budget impact models show that the cost of this innovation will only increase your pharmacy per member per month by Y percent," he says. The pharmacy director replies, "What gross and net price does that assume? Where do you expect market share to move from? Is the market growing bigger or is share moving from other drugs? How does this compare to alternative therapies? Have you done a comparative effectiveness trial?" As the conversation continues, the pharmacy director

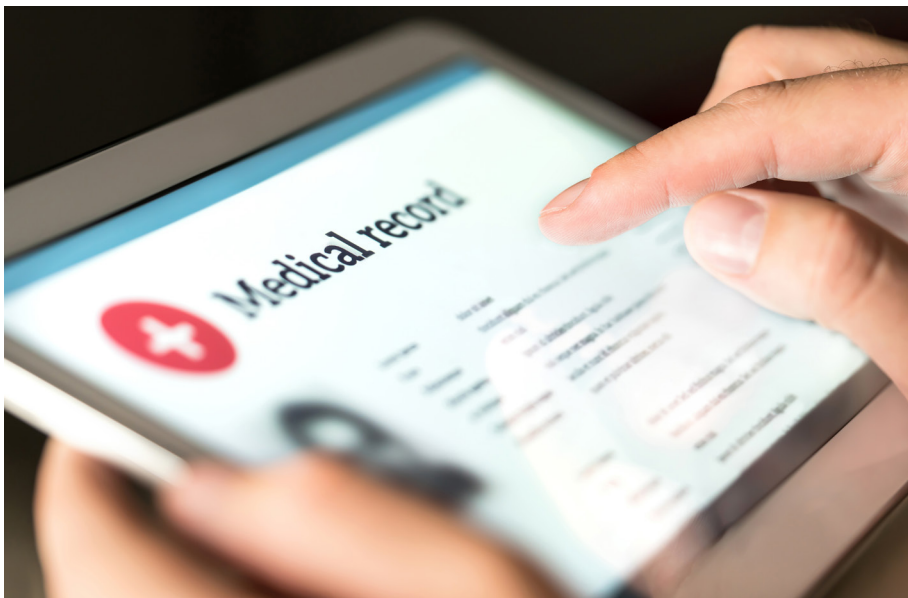
probes further asking "Do you envision this as a first line therapy? How do you justify the price point? Is it reducing costs and how does that value impact my fully insured versus self-insured populations? Are there any unique sub-populations which have different outcomes during your clinical trials?"

As this scenario shows, for biopharma companies, the orthodoxy "If we build it, they will buy it" is no longer relevant. Cost pressures, vertical integration between large payers and pharmacy benefit managers (PBMs), and the push for greater transparency, quality, and better health outcomes per dollar spent are all accelerating the volume-to-value transformation.

In this increasingly constrained landscape, how do biopharma companies develop successful market access strategies? To understand how health care stakeholders approach coverage and placement decisions and how this is evolving, the Deloitte Center for Health Solutions surveyed health care executive decision makers and found that:

- ✓ As more metrics and tools to analyze the total cost of care become available, most decision makers (78 percent) expect cost-effectiveness to have more of an influence on coverage.
- ✓ There is a need for more transparent exchange of clinical, economic, and financial data related to a product before a launch.
- ✓ Real world data (RWD) is likely to increasingly complement clinical trial data in access decision making.
- ✓ Two thirds of the executives we surveyed expect an increase in value-based contracting to address uncertainties around product value, particularly in oncology, neurology, and inflammatory disease areas.
- ✓ But less than 40 percent say their organizations are investing in building internal capabilities to generate real world evidence (RWE) and power value-based contracts (VBCs).

In response to these trends, biopharma market access strategies should evolve into a more consultative process. Engaging in dialogue with access decision makers can help drive a deeper understanding of value drivers unique to individual health plans, health systems, and PBMs. Biopharma should also engage early with access stakeholders and present compelling evidence of value earlier in the product lifecycle. Tailoring evidence-generation plans to value drivers will likely be crucial to crafting customized evidence-backed value stories for greater access.



Impact of COVID-19

We conducted our research before COVID-19 had made a significant impact in the United States. Biopharma companies are working with governments around the globe to address the public health emergency, from supporting the development of vaccines to developing treatments, all while planning for changes in the supply chain. Market access and other commercial customer-facing teams that are usually out in the field, are working from home. Priorities have shifted, and the teams are appropriately scaling back outreach, recognizing the demands on healthcare resources.

As we recover from the crisis, this experience could point to innovation in commercial models to make more efficient use of non-personal engagement channels. We could see more companies revisit traditional models of work. And for biopharma, there could be an acceleration to new commercial models that allow companies to thrive in periods of significant disruption.

But regardless of what our new normal looks like, biopharma market access strategies should evolve. Engaging health plans, health systems, and PBM decision makers with tailored solutions and messaging supported by evidence will likely be critical to ensuring patients' access to their therapies.

Introduction

US spending on prescription drugs has climbed from \$783 per capita in 2007 to \$1,025 per capita in 2017. The Centers for Medicare and Medicaid Services (CMS) project that such spending will continue climbing to \$1,635 per capita by 2027, an increase of 60 percent.¹ Specialty drugs accounted for two percent of total prescriptions, but 50 percent of total drug spend in 2018.² Traditional drugs represent the other 98 percent of prescriptions, but half the spend. As specialty drug spend grows, payers and providers could find it increasingly challenging to contain health care costs. With rising drug prices there

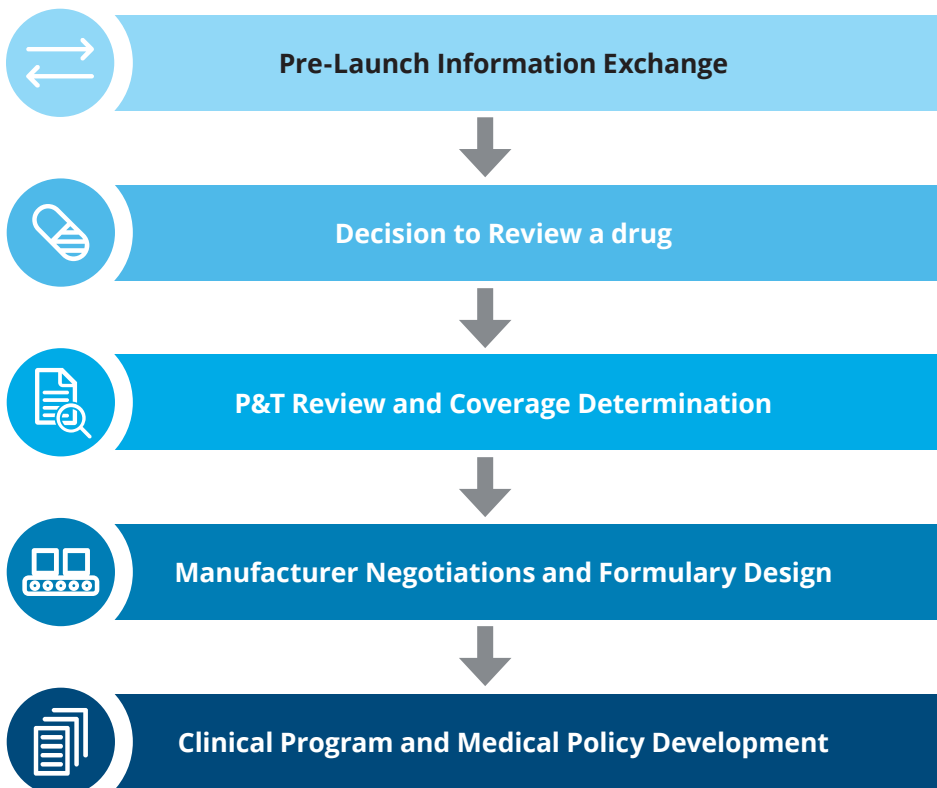
is more scrutiny on value. The growing costs of developing new drugs, increasing competition, and shortening times to peak sales make it imperative for biopharma companies to get their commercialization strategy right. Prior Deloitte research shows that 36 percent of drugs launched between 2012 and 2017 missed their launch forecasts, over 50 percent of which were due to failures in achieving market access.³

At the same time, the increasing payer and provider system-wide focus on improving health outcomes per dollar spent is helping drive the need for a more holistic view of

health care spending. Consolidation in health care is one of the trends that could support such a view. Convergence across payers, PBMs, specialty pharmacies, and care providers to manage costs could lead to more well-rounded care delivery and a focus on total cost of care by analyzing integrated pharmacy and medical benefit data.⁴

In this evolving environment, access decisions are moving away from individual prescribers or physicians toward a more centralized process through pharmacy and therapeutics (P&T) committees. These committees at health plans, health systems, and PBMs evaluate a drug for inclusion on an organization's formulary. In some cases clinical and financial data can be examined together, while in other cases clinical decisions are made by the P&T committee, and other committees must separately determine placement and formulary design. P&T committees can also make recommendations on utilization management tools such as step edits and prior authorization.

Figure 1: Baseline access decision-making process



Source: Deloitte Consulting

Research methodology

In early 2020, the Deloitte Center for Health Solutions surveyed 80 health care decision makers including pharmacy and medical directors, chief medical officers, population health directors, and others involved in formulary design and access decision making. They were from health plans, health systems, PBMs, and integrated delivery networks. Survey questions revolved around triggers for drug reviews, factors impacting coverage and placement, formulary design and management, and value based contracting. We also interviewed 10 decision makers to better understand their approaches to market access decisions.

Research findings

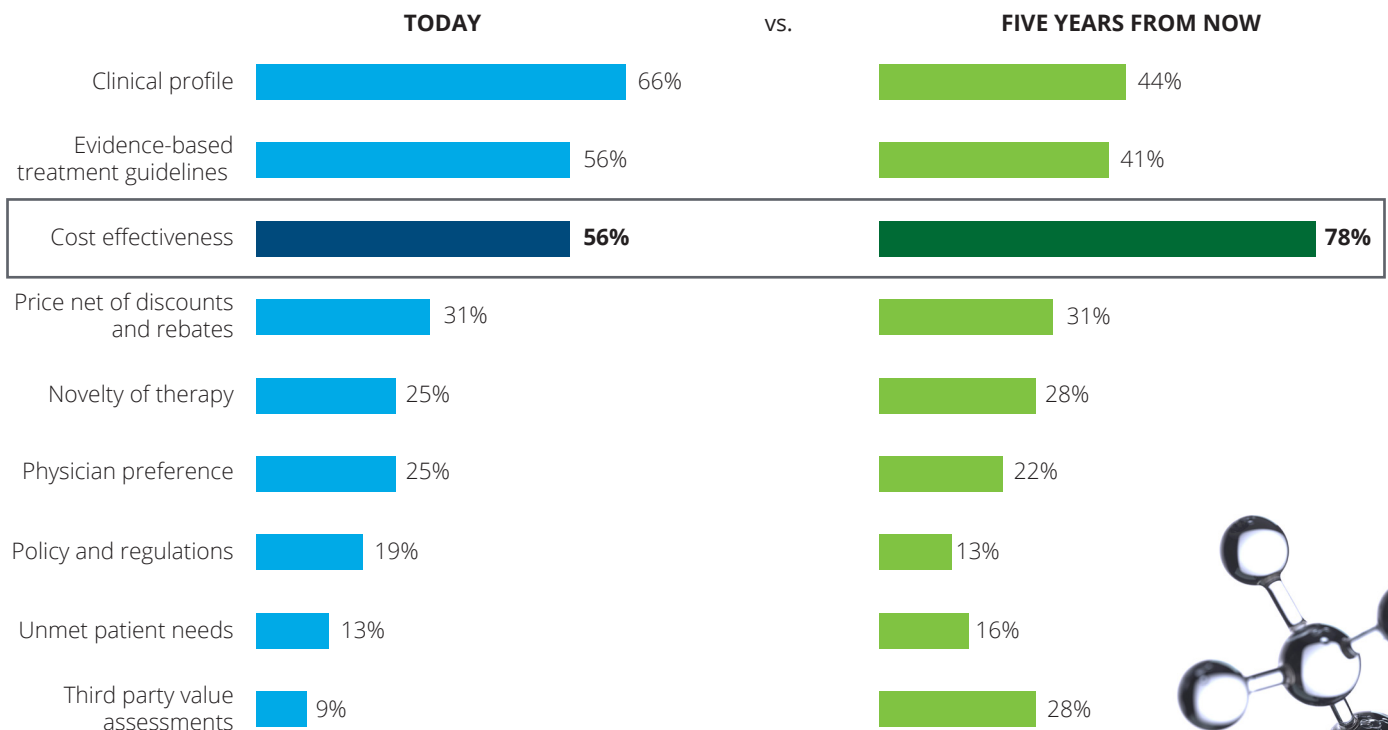
Our research highlights how trends in access decision making are likely to change in the next few years and its implications for pharma companies.

Cost effectiveness will influence coverage to a greater extent

While two-thirds of respondents said that a drug’s clinical profile is the biggest influencer in coverage and placement today, 78 percent of health system respondents believe that in the next five years, cost-effectiveness could grow in importance for formulary decision making. Decision makers are likely to have access to a wider arsenal of tools and metrics to assess a drug’s clinical and cost effectiveness. Metrics such as total cost of care, health care resource utilization, and a drug’s budgetary impact assessment, indication, or impact on particular patient populations could influence decision making to a greater extent in the future.

Our research also shows that few organizations currently take a holistic approach to coverage decision making, considering such factors as length of hospital stay, patient productivity, or quality of life. Most organizations focus on direct drug cost and impact on the pharmacy budget. Our interviewees pointed out that most P&T committees rarely consider indirect costs as well as medical budget impact while making decisions. Survey data also shows that less than a fourth of organizations model indirect health care costs and quality-adjusted life years to help formulary decision makers.

Figure 2: 78 percent say cost effectiveness will influence coverage to a greater extent in the next five years



As PBMs and health plans become more integrated, decision makers are likely to become more interested in the total cost of care while making coverage decisions. This shift will likely require marrying medical and pharmacy data through sustained investments in interoperability and analytics. Most interviewees emphasized the need for executive leadership support to encourage a more integrated approach to decision making.

Our interviewees pointed out that third-party value assessors (e.g., Institute for Clinical and Economic Review) who take a more holistic approach to evaluating treatments are beginning to influence coverage decision making informally. Assessments and recommendations from such organizations could be used to a greater extent to evaluate the clinical and financial value of therapies in coming years.

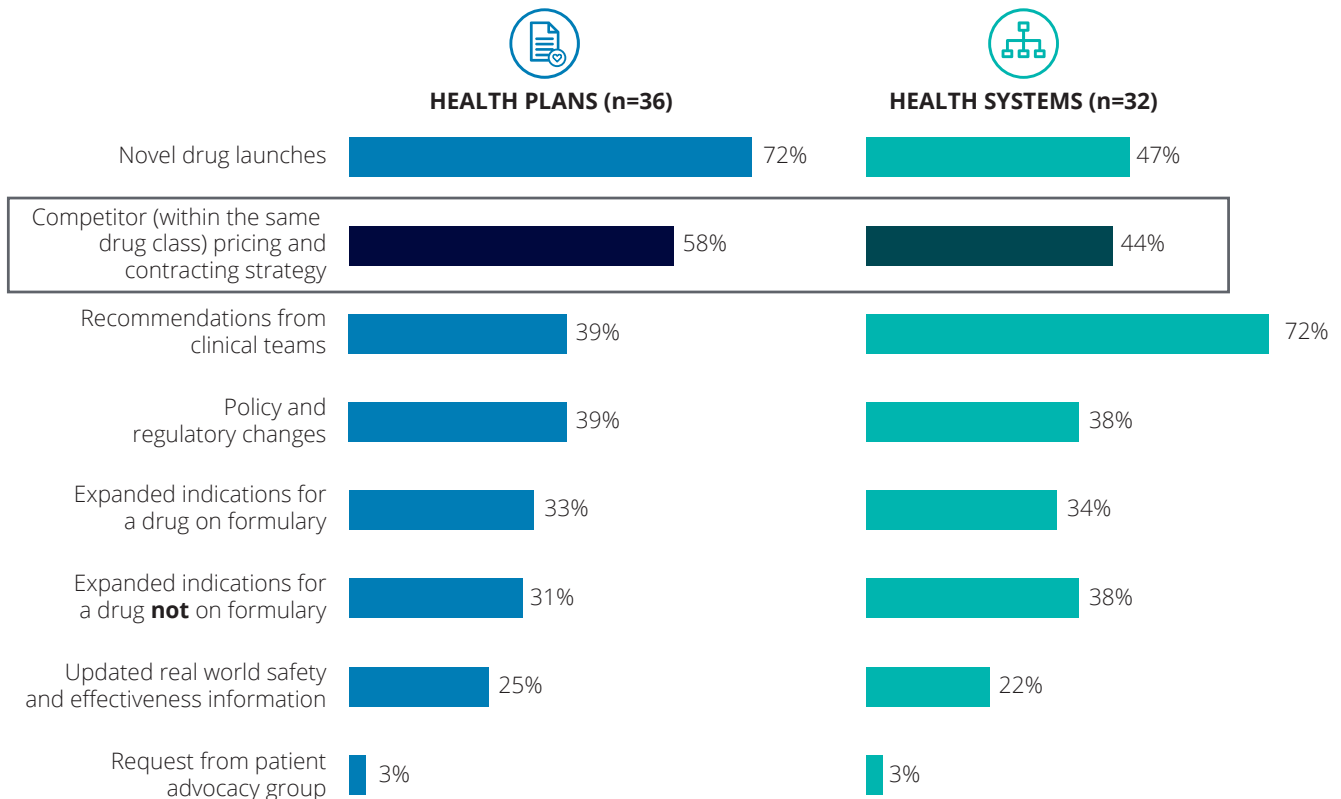
“Decision making is still siloed, where pharmacy is concerned with not breaking the pharmacy budget, but not the medical costs.”

Pharmacy policy director at a large integrated delivery network

Competitive dynamics are playing a bigger role in review decisions

At health plans in particular, competitive dynamics are increasingly triggering reviews of new drugs or those already on the formulary. Survey data shows 58 percent of health plan respondents reported competitor pricing and contracting strategies commonly trigger drug reviews for coverage and placement as compared to 44 percent of health systems respondents. Our research shows payers are using increasing competition within classes to revisit past decisions to get more benefits from manufacturers.

Figure 3: At health plans competitive dynamics more often trigger drug reviews



Please note figures indicate frequency of being ranked among the top 3 choices

“We tend to move a drug in response to rebates/discounts that match the monumental effort of reshuffling the formulary.”

Pharmacy director at a national health plan

Decision makers want to see much more data before launch

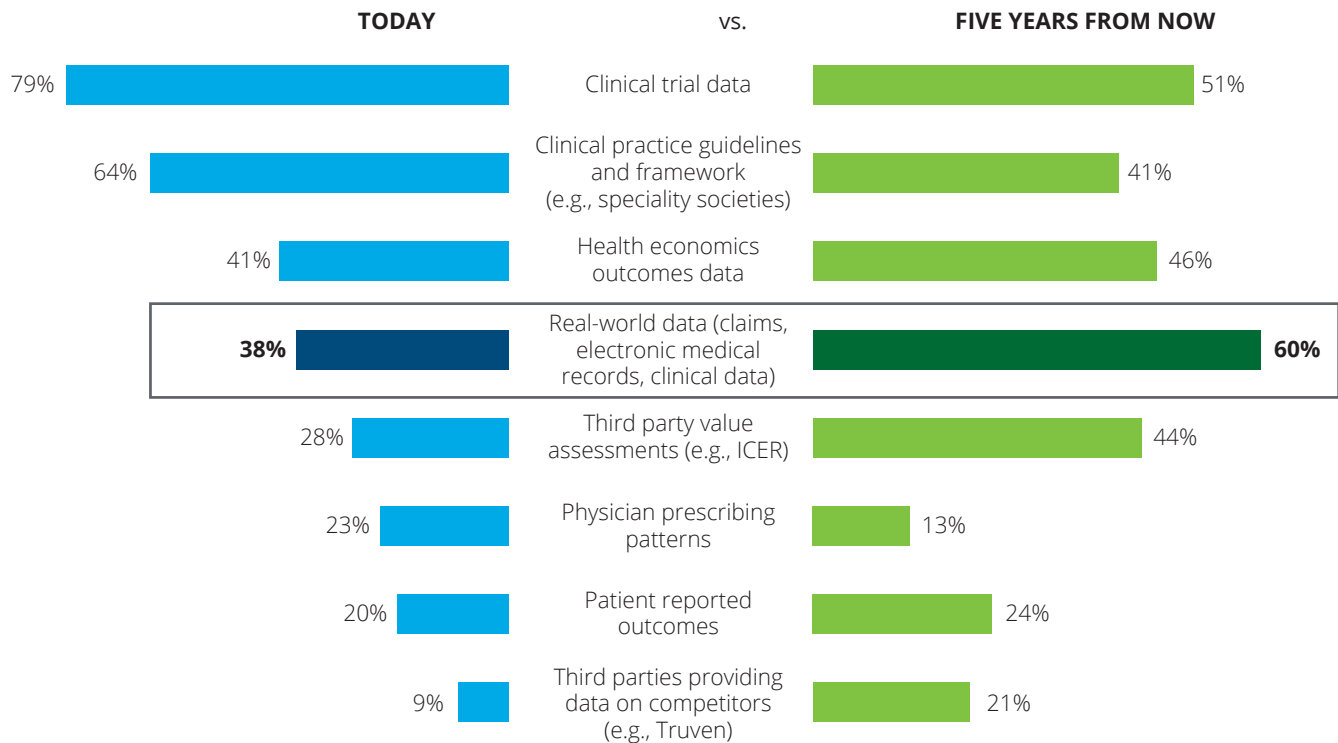
Interviewees stressed the need for access to more transparent and factual product data as early as possible in the development cycle. The US Food and Drug Administration (FDA) guidance resulting from the 21st Century Cures Act allows manufacturers more flexibility to communicate health care economic information in advance of receiving marketing approval.⁵ This has opened the door for more pre-launch information exchange. Manufacturers can now share factual data on product indications and clinical trial design (including sample sizes and patient cohorts), expected timelines for approval, patient utilization projections, and pricing estimates. This could go a long way in enabling better planning and budgeting to help ensure patient access to new therapies.

RWD could increasingly complement clinical trial data for access decision making

Our interviewees pointed to a growing interest among organizations to look beyond data collected during clinical trials for access decision making. At a few organizations, real world data (RWD) and real world evidence (RWE) are already being presented during P&T meetings as a part of evidence reviews whenever available and appropriate. Sixty percent of survey respondents predict the use of RWD will increase for review and coverage in the next five years (see figure 4).

Health plans and systems are becoming increasingly open to the use of RWE for decision-making. Many large health systems and health plans are already collecting patient-reported outcomes or analyzing their own patient or member data to create evidence-driven

Figure 4: Sixty percent believe RWD is likely to have greater utility for coverage decisions



Please note figures indicate frequency of being ranked among the top 3 choices

Total Responses=80

protocols (see case study 2). Deloitte's prior and ongoing research on RWE shows biopharma companies are investing in platforms and partnerships⁶ to generate and share RWE on product safety, comparative effectiveness, and impact of their products across patient subpopulations. Such analysis could serve as a source of differential economic and clinical evidence on a product to aid access decision makers (see case study 1). Third party data vendors such as Flatiron Health and COTA are also providing payers and providers access to richer real world data sets tailored for ease of decision making and analysis.

Case study 1: RWE to demonstrate economic evidence to accelerate adoption of new therapies⁷

A biopharma company received accelerated approval for its drug based on a single arm phase 3 trial to treat urgent bleeds associated with Factor XA inhibitors (FXai's) use. This limited the ability to produce comparative effectiveness models owing to lack of data for comparison at launch.

Comparing EHR data from patients treated with its drug and 4-Factor Prothrombin Complex Concentrate (4F-PCC), the standard of care, the company demonstrated in-hospital mortality was 4 percent for patients treated with its drug as compared to 10 percent with 4F-PCC across all bleed types. This includes intracranial hemorrhage, gastrointestinal bleeding, and bleeding due to trauma. Also, analysis of three years of patient data from a patient registry in the United Kingdom showed 30-day mortality was 14.6 percent for patients treated with the company's drug versus 34.1 percent with 4F-PCC across all bleed types.

Analyzing claims and utilization data, the company demonstrated treatment with its drug resulted in lower hospitalization costs as compared to 4F-PCC. Such results could help demonstrate the clinical and economic benefit of the company's drug in the absence of definitive head to head clinical trial data, and minimize the barriers for utilization and adoption.⁸

Case study 2: Building evidence-based protocols to encourage off-label prescribing

Analyzing internal prescribing and claims data helped a large integrated delivery network to generate evidence on the economic and clinical effectiveness for the off-label use of drug X to treat macular degeneration. Evidence-based protocols were then put in place to encourage ophthalmologists to prescribe drug X to accountable care organization patients instead of the much higher-cost alternatives. For patients covered by other plans, the integrated delivery network acknowledged the challenge of enforcing its outpatient formulary. However, options to align affiliated physician incentives e.g. network participation, are being explored. Ultimately we need to soften the network participation threat.

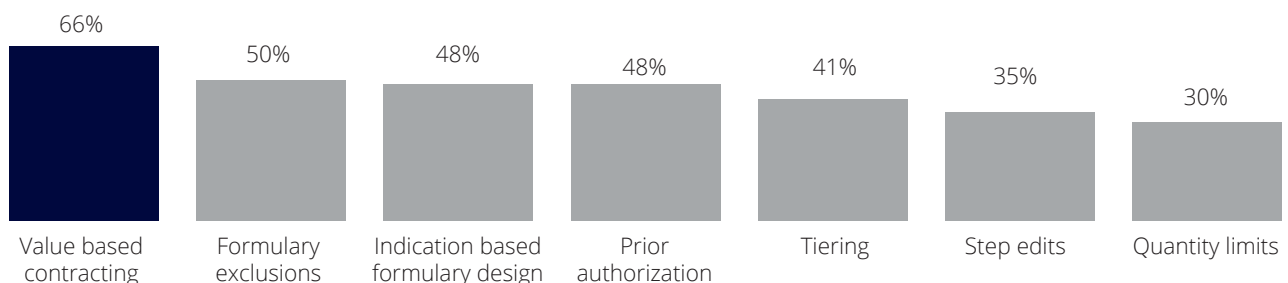
Decision makers expect value-based contracting to increase

To address uncertainty around value, health plans and health systems believe value-based contracts that allow them to share risk with manufacturers are useful. Two-thirds of survey respondents expect use of value-based contracting to grow in the next five years.

Publicly available data shows 19 value-based contracts were signed between pharma and payers and providers in the United States in 2018 compared to only five in 2011. Our interviewees are optimistic that certain barriers to value-based contracting are steadily fading away. For instance, some see advances in sensor technology and apps as well as interoperability making it easier to capture patient-reported outcomes to enable more patient-centric value-based contracts. However, most admit moving the needle on contracting requires data standardization, agreement on what constitutes value of a therapy, and greater trust between stakeholders.

In the next five years, survey respondents expect value-based contracting to expand the most in oncology, neurology, and inflammatory diseases. More targeted and expensive cancer therapies hitting the market such as CAR-T might trigger more innovative risk-based contracting and alternative financing models. Interviewees believe expensive one-time curative therapies could be

Figure 5: Two thirds of respondents expect use of value-based contracting to increase



feasible for contracting arrangements as determining the impact of a treatment is easier.⁹ Value-based contracts also offer an opportunity for biosimilars (such as those for inflammatory conditions) to gain momentum by demonstrating similar outcomes as originator products at a lower cost.

Few organizations are building capabilities to leverage RWD and value-based contracting, presenting opportunities for biopharma

Our research suggests there is opportunity for biopharma to collaborate with health plans and systems to build tools to leverage the increasing volume of patient data for decision making. Survey data shows fewer than 40 percent of organizations are investing in internal tools and talent to capture patient-reported outcomes and analytics to map patient journeys and treatment pathways (see the sidebar, *Mapping the patient journey in rheumatoid arthritis to support treatment decisions.*)

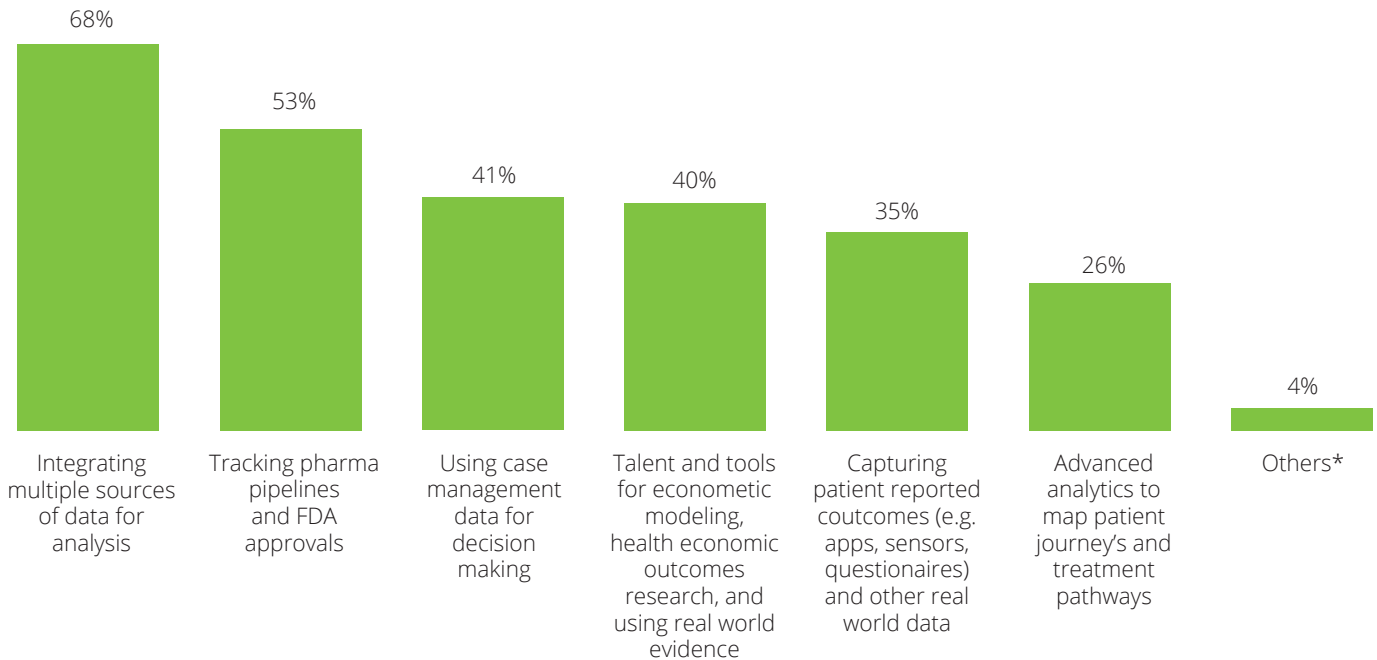
Our interviewees pointed out that this may be due to most health plans and providers leveraging third parties to provide safety and efficacy data and comparative effectiveness research for evidence

reviews. This also shows that while most organizations see the potential of RWD and value-based contracting to aid decision makers, few are investing to build internal capabilities to harness these for formulary design and cost containment.

Mapping the patient journey in rheumatoid arthritis to support treatment decisions

In the United States, an integrated delivery network is combining EMR, claims data, and physician prescribing patterns with patient-reported outcomes on pain, fatigue, and other parameters from rheumatoid arthritis (RA) patients. By analyzing these data points the organization was able to determine whether treatment decisions such as using biologics vs. disease-modifying anti-rheumatoid drugs (DMARDs) lead to reduced emergency room visits, better functional responses, and higher self-reported quality of life. Analyses like this help decision makers justify the choice of a more expensive biologic as well as determine the impact of a treatment choice on the total cost of care.

Figure 6: Investment areas to aid formulary design and management



Note: Others includes machine learning models to create formularies and "No" investments

Pharmaceutical companies should consider evolving their strategies to engage with decision makers

Our research demonstrates it is now more critical than ever for biopharma companies to rethink the way they approach and communicate product value to access decision makers. Our research also helped us identify steps biopharma companies should consider when crafting a compelling value proposition for their products:

1. **Engage early:** Pre-launch information exchange can help pharma companies engage with access stakeholders prior to launch. Exchanging clinical, safety, economic, and financial data as early as possible can make it easier for health plans, health systems, and PBMs to plan and budget for new products.
2. **Understand value drivers:** Identifying or defining value drivers unique to individual payers and providers and understanding how these are assessed could help develop an intimate understanding of how key customers define value from therapies. These value drivers could include reducing disease burden, optimizing health care resource utilization, or meeting unmet patient needs in one or more patient sub groups. Value drivers could also differ within organizations depending on line of business (Medicare/Medicaid or commercial) and across therapy areas. Assessing value drivers could also help identify if opportunity exists for access through innovative arrangements such as indication or value-based contracting.
3. **Align evidence generation plans with value drivers:** There is a need to incorporate United States access stakeholder value drivers into global evidence generation plans. Cross-functional alignment on the desired value claims, proof points, and approaches to address priority evidence gaps can help achieve this. Such alignment can also help generate insights and make consistent strategic choices while communicating with access decision makers.
4. **Craft customized value stories:** Pharma companies should craft customized value stories that resonate with access stakeholders' definition of value.¹⁰ Such stories should incorporate clinical, economic, and humanistic perspectives on product value that adequately reflect pricing.
 - a. **Clinical perspective:** RWD can be analyzed to identify care gaps and inefficiencies in care delivery to position products to fill these gaps. Leveraging RWE to demonstrate proof of a particular product's clinical superiority versus the next best alternative or standard of care in specific populations and bolstering this data with RWE on long-term safety and outcomes could provide an edge for favorable placement.
 - b. **Economic perspective:** Pharma companies can gain an advantage by customizing budgetary impact assessments at the population or cohort level. Supplementing budget impact models with cost effectiveness models allows the pharma company to communicate the overall value of their therapy relative to the standard of care, other therapies within its class, or non-drug interventions. Incorporating market-access endpoints such as overall clinical cost offsets into clinical trials can help differentiate the economic value of a therapy.
 - c. **Humanistic perspective:** For novel products approved based on limited clinical information (e.g., rare disease treatments), pharma companies could share evidence beyond clinical trial endpoints including patient reported outcomes, details on patient support programs, and implications of the product on quality of life for patients suffering from the disease.
5. **Be more data driven:** Sustained investments in analytics will power risk-based value modelling, identifying target reimbursable patient population and other analysis to build customized value stories. Analytics applied to RWD can also help identify potential value drivers. For example, actuarial analytics applied to RWD on disease burden can help identify new sources of clinical and economic value to be incorporated in value stories.
6. **Be transparent:** The health plan decision makers we interviewed indicated they are more interested in draft models with transparent parameters/assumptions provided by pharma companies, rather than black box budget impact models. Sharing rationale and assumptions earlier and as transparently as possible can cement trust between pharma and other stakeholders.
7. **Collaborate more:** Pharma companies could enter into strategic partnerships with payers and providers to exchange data and build tools to map the patient journey and generate RWE. Working with technology companies can also help access advanced analytics capabilities to analyze the growing volume of patient data.

To scale value based contracting, pharma manufacturers could collaborate with other stakeholders to build shared utility platforms and tools to collect, validate, and analyze RWD. Pilots focusing on improving outcomes, rather than financial risk, could help stakeholders develop an early value-based contracting roadmap. Once a quality-focused model has been developed, the shared savings and risk-sharing components can be added. Involving a neutral third party to manage the data could help contracts build trust and be more palatable to all participants.

Achieving these objectives requires a robust market access strategy development capability consisting of an end-to-end market access strategy framework and effective cross-functional teaming to help ensure alignment on strategic choices. This framework should inform the strategic choices required to engage access stakeholders with differentiated and tailored value propositions supported by evidence obtained from answers to the following questions.

Where to play?

- What are the sources of value in the disease state and where in the disease burden can we make an impact for our prioritized patient populations relative to our closest competitor or standard of care?
- Who are our priority access stakeholders, what are their unmet needs, what drives their decision making, and which external stakeholders influence their decision making?

How to win?

- What are the value claims and proof points that will align our value proposition with our customers' definition of value and what is our plan to address any evidence gaps?
- How do we quantify the value of our therapies in terms that resonate with our customers?

How to execute?

- How do we organize internally and engage our customers with tailored solutions?
- How can we become agile and anticipate and respond to material changes in the access environment?

Ultimately, biopharma companies should be asking themselves: how do we measure our ability to capture the value we create and adjust our strategies to reflect our learnings and changing market conditions?

Authors



Muna Tuna
Managing Director
Deloitte Consulting LLP



Jason Boller
Senior Manager
Deloitte Consulting LLP



Wendell Miranda
Senior Analyst
Deloitte Services LP

Project team

Sarah Thomas provided invaluable guidance on helping to scope and shape the research. Casey Korba managed the research project, led survey development, conducted interviews, and wrote up multiple sections in the report. Chris Amador, Jeffery Weiss, and Nikhil Maheshwari provided their expertise, support, and guidance to make this whitepaper more insightful. Madhushree Wagh assisted with survey data analysis and creation of charts.

Acknowledgements

The authors would like to thank Joe Coppola, Tom Yang, George Van Antwerp, Patrick Santavicca, Ramani Moses, Regina DeSantis, Claire Cruise, Natasha Elsner, Sonal Shah, and Laura DeSimio who contributed their ideas and insights to this project.

Endnotes

- ¹ *Why Are Prescription Drug Prices Rising And How Do They Affect The U.S. Fiscal Outlook?*, Peter G. Peterson Foundation, November 2019, <https://www.pgpf.org/blog/2019/11/why-are-prescription-drug-prices-rising-and-how-do-they-affect-the-us-fiscal-outlook>, accessed April 15,2020
- ² The IQVIA Institute, *Medicine Use and Spending in the U.S.*, May 2019, <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>, accessed April 15,2020
- ³ Deloitte Center for Health Solutions, *Key factors to improve drug launches: Why drug launches miss market expectations and what to do about it*, March 2020, <https://www2.deloitte.com/us/en/insights/industry/life-sciences/successful-drug-launch-strategy.html>, accessed April 15,2020
- ⁴ Thomas Beaton, *Cigna to Acquire Express Scripts for \$67B to Expand Consumer Value*, August 2018, <https://healthpayerintelligence.com/news/cigna-to-acquire-express-scripts-for-69b-to-expand-consumer-value>, accessed April 15,2020
- ⁵ Peter J. Neumann and Harry Weissman, *The FDA's New Guidance On Payer Communications: Implications For Real-World Data And Value-Based Contracts*, HealthAffairs, July 2018, <https://www.healthaffairs.org/doi/10.1377/hblog20180712.816686/full/>, accessed April 15,2020
- ⁶ Deloitte Center for Health Solutions, *The future of real-world evidence: Biopharma companies focus on end-to-end, AI-driven, internally developed solutions*, June 2018, <https://www2.deloitte.com/us/en/insights/industry/life-sciences/2018-real-world-evidence-benchmarking.html>, accessed April 15,2020
- ⁷ *New Data Demonstrates Andexxa® Can Provide a Net Cost Reduction for the Treatment of Intracranial Hemorrhage Associated with Oral Factor Xa Inhibitors*, Portola, March 2020, <https://investors.portola.com/2020-03-05-New-Data-Demonstrates-Andexxa-R-Can-Provide-a-Net-Cost-Reduction-for-the-Treatment-of-Intracranial-Hemorrhage-Associated-with-Oral-Factor-Xa-Inhibitors>, accessed April 15,2020
- ⁸ *Portola Pharmaceuticals Announces Results Demonstrating Andexxa® was Associated with Lowest Rate of Mortality in Patients with Multiple Types of Factor Xa Inhibitor-Related Bleeds*, Portola, March 2020, <https://investors.portola.com/2020-03-16-Portola-Pharmaceuticals-Announces-Results-Demonstrating-Andexxa-R-was-Associated-with-Lowest-Rate-of-Mortality-in-Patients-with-Multiple-Types-of-Factor-Xa-Inhibitor-Related-Bleeds>, accessed April 15,2020
- ⁹ *Neurology market to see an increased focus on rare diseases*, Pharmaceutical technology, April 2019, <https://www.pharmaceutical-technology.com/comment/neurology-pipeline-2019/>, accessed April 15,2020
- ¹⁰ *Various Factors Help Payers, Pharma Agree On 'Value,' Enter Into Value-Based Deals*, Managed Markets Insight and Technology (MMIT), June 2018, <https://www.mmitnetwork.com/member-content/various-factors-help-payers-pharma-agree-on-value-enter-into-value-based-deals/>, accessed April 15,2020

This publication contains general information only and Deloitte is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This publication is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor. Deloitte shall not be responsible for any loss sustained by any person who relies on this publication.

Deloitte.

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee ("DTTL"), its network of member firms, and their related entities. DTTL and each of its member firms are legally separate and independent entities. DTTL (also referred to as "Deloitte Global") does not provide services to clients. In the United States, Deloitte refers to one or more of the US member firms of DTTL, their related entities that operate using the "Deloitte" name in the United States and their respective affiliates. Certain services may not be available to attest clients under the rules and regulations of public accounting. Please see www.deloitte.com/about to learn more about our global network of member firms.

Copyright © 2020 Deloitte Development LLC. All rights reserved.