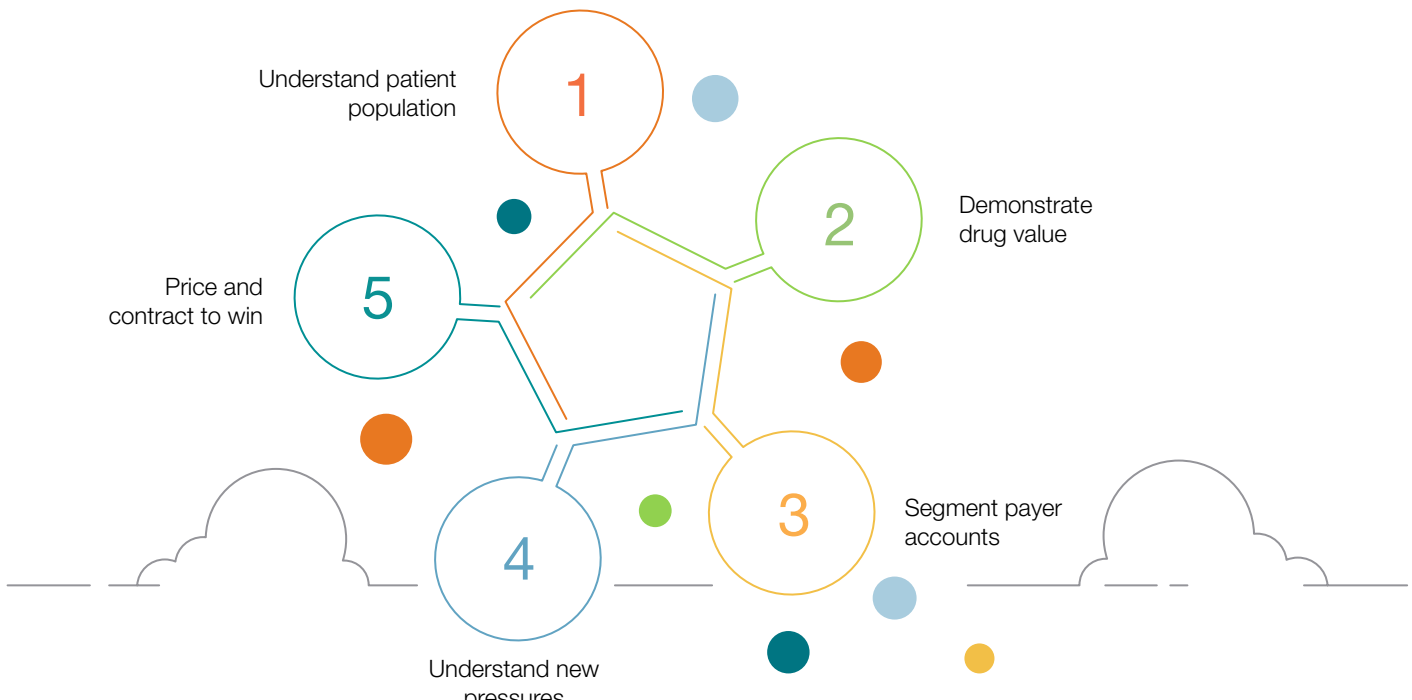
When talking “value” is no longer enough: Five steps to ensure your evidence and access strategy is fit for the future



Introduction

While spending on global healthcare has long been a topic of discussion, pharmaceutical pricing has never been more in the spotlight of public discourse than it is today. Payers, providers, patients, and most recently politicians, are engaged in very complex and at times emotional debates about how to address this growing issue. While many European and global markets can reasonably be archetyped and classified based on their proposed approaches to this issue, the US continues to stand out as a market struggling to balance the drive for innovation with budgetary realities.

In recent years, a number of potentially disruptive national and state-level policies have been proposed and/or implemented by policymakers in the US. In figure 1 on page 3, we highlight a select list of such policy solutions.

In addition, a number of independent groups have sought to address the concept of value in pharmaceutical pricing. Of note is the Institute for Clinical and Economic Review (ICER), which is now working with several US payer organizations, including the Veterans Affairs, Express Script and CVS/Aetna in assessing a drug’s value, based on cost per Quality Adjusted Life Year (QALY) to help determine patient access.

While most of these highlighted situations drive toward the concept of value-based care and getting what you pay for, implementing value-based solutions at scale can be extremely challenging. Indeed, “value” is truly in the eye of the beholder, so such solutions need to be tailored to support the desired outcome for ***each*** customer type. In other words, what is valuable to a patient may not be valuable to a payer – a truth not just relegated to the US. Therefore, success in this area will require global launch strategies that are nuanced enough to capture value across stakeholders, supported with the right evidence at the right time, and fit for a variety of future scenarios.

Introduction

Figure 1: **Proposed and ongoing reforms impacting access in US**

Removal of Rebate Safe Harbor Policy
Would eliminate safe harbor, allowing Medicare to receive volume-based rebates, with potential spillover effects to commercial payers

Medicare Part B Reform
A number of proposed policy changes are focused on increasing Medicare’s ability to negotiate, particularly for Part B products

International Pricing Index (IPI)
A novel Medicare payment model to decrease Part B drug costs by linking prices to an International Pricing Index

Widespread co-pay law and co-pay accumulator programs
Payers will not count manufacturer-supplied financial assistance toward patient deductible or OOP max, reducing ability of PSPs to offset payer-mandated cost sharing

Integration of Pharmacy and Medical Benefit
Payers are exploring ways to manage IV, SubQ and orals using tools typically reserved for Part B, such as tiering and simplified PA/SEs

Increased Scrutiny by Independent Groups Like ICER
Assessing a drug’s value based on cost per Quality Adjusted Life Year (QALY) to help determine patient access

Five steps to be fit

Connecting evidence and access strategies to support agile launches fit for the future

In order to prime your launch strategy for this ever-changing environment, global evidence and access strategies need to be tightly connected to promote agile solutions that hold weight with customers. This white paper proposes five steps that HEOR and market access teams can take to ensure their launches are fit for the future:

1. Generate evidence to understand your patient population
2. Generate evidence to demonstrate the value of your drug
3. Segment payer accounts, including the likelihood/ impact of adoption of evolving “value” tools
4. Understand new pressures being placed on HCP, pharmacist and patient customers
5. Price and contract to win in a variety of future scenarios

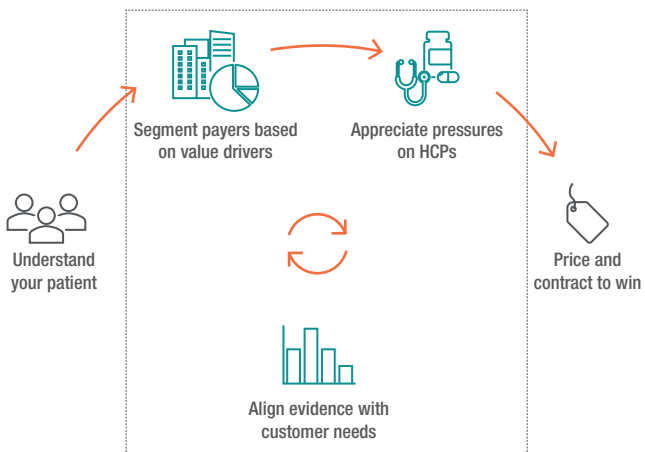


Figure 2

Let us flesh out these five steps to understand the compelling “value” their guidance can bring for launches that are fit for the future.

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Step #1: Generate evidence to understand your patient population

Pharmaceutical companies need to leverage both primary and secondary research to generate evidence to understand their patient population.

Key questions include:

- **What is the patient burden?**

  - Primary and syndicated research with stakeholders to assess the impact on health-related quality of life and indirect economic costs
  - Retrospective database research to understand the pharmacy utilization patterns and outcomes

- **What is the unmet patient need?**

  - Primary research to assess unmet patient need with current treatments from a physician and patient perspective
  - Chart reviews to understand the HCP perspective on existing treatments

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Step #2: Generate evidence to demonstrate the value of your drug

At the end of phase 3, pharmaceutical companies need to ensure their registration trial design will generate efficacy evidence – how a drug performs in a highly controlled setting – to support their drug’s value (benefit/cost) proposition for discussions with health technology assessment (HTA) and payer groups.

Three key decisions include the selection of relevant comparators, endpoints and patient populations. To effectively make these decisions, it is critical to engage regulators, HTA groups, payers and patient advocacy groups to seek their perspective.

In phase 4, it is critical to demonstrate the real-world effectiveness of a drug, how the drug performs in a non-controlled environment.

- Retrospective research assesses the utilization patterns and outcomes associated with a drug, to help define its value and place in therapy
- Primary research with patients, caregivers and HCPs is critical to understand the “why” that drives the retrospective research results, to provide insights for potential adjustments to a brand’s strategy or tactics
- Chart reviews to understand the HCP perspective on the use and experience with the drug in comparison to other treatment options

Step #3: Segment payer accounts, including the likelihood/ impact of adoption of evolving “value” tools

When it comes to your payer accounts, not all of them will be early adopters of the various value tools being discussed. Private/subnational payers, in particular, are likely to adopt the components that fit within their own strategic objectives, and this variation among accounts and therapeutic areas means a singular approach to value will fall short. Because of this, it’s critical that you segment your payers in a similar fashion to your HCP and patient customers – based on their personal motivations and decision drivers.

We recommend four key steps in a payer segmentation approach:

- Secondary research into press releases, policy document and HTA reports to set a baseline for each key national, regional/subnational and local payer
- Primary and syndicated research with a representative sample of key payer accounts, focused on therapeutic area(s) of interest
- Rigorous internal workshopping and simulations to define variables and tailor a segmentation framework around Ipsos’ client’s objectives
- Deliver a final segmentation framework which allows for future modification based on market changes (including competitive changes) and emerging players

Step #4: Understand new access pressures being placed on commercial stakeholders, including health systems, HCPs, pharmacists and patients

Access strategy doesn’t end with reimbursement. The individual purchaser is a critical customer that must be engaged to better understand what value means to them in the current climate. For example, a national payer success story may very well include an attractive price for the manufacturer and listing consistent with the approved label. However, local hospitals may struggle to find room for this new innovation without further negotiation focused around budget impact, while pharmacists and patients may feel other alternatives offer better value for the money, given contracts and personal preferences, respectively.

We recommend an approach that ensures that the voices of all your access customers come to light:

- Engage with practice purchasers, dispensing pharmacists and other procurement professionals to understand the role of your product in practice economics
- Expose HCPs to access realities, including more rigorous prior authorization, step edits, exclusions and patient cost-sharing
- Layer cost-sharing and other access-related expectations into ongoing patient research to identify price sensitivities based in reality

Step #5: Price and contract to win in a variety of future scenarios

As discussed earlier in this paper, pharmaceutical pricing is one of many things competing for center stage in the public discourse globally. This creates new threats and opportunities for pharmaceutical pricing at launch and continuing throughout a product’s lifecycle. A successful pricing strategy must therefore be tailored not just based on the market, but also based on stakeholder type within that market, and any true value-based pricing strategy is predicated on the first four steps outlined above (see figure 2 on page 4). Furthermore, contracting and negotiation will continue to play a major role in the net/purchase price for all stakeholders, so pricing strategies need to be further augmented to succeed in these conversations.

We advise an approach that leverages a variety of pricing research methods, tailored to your needs:

- **Secondary research:** Review past analogues to understand accelerators and barriers to access at different price points within your therapeutic areas of interest (or ones similar to yours).
- **Qualitative/semi-quantitative research:** Engage directly with relevant access stakeholders to maximize achievable price, optimize access and mitigate barriers.
- **Quantitative Conjoint/Discrete Choice Modeling (DCM):** Measure the impact of both clinical and access variables on HCP prescribing allocations, adjusted for any potential bias, to create a revenue-optimizing, price-volume tradeoff curve.

Given the disparate potential solutions and the subjectivity involved with defining “value,” evidence and access strategies need to be tightly connected to promote agile solutions that resonate with customers. And understanding that no one size fits all, only by tailoring a pricing strategy to a specific stakeholder type and to support your desired outcome, can you ensure your evidence and access strategy is fit for the future.

Summary

In this white paper, we’ve explored the need for interconnecting evidence and access strategies, shared how you can capture value across stakeholders supported by the right evidence at the right time and touched upon the need for the voices of all your access customers to come to light. We invite you to advance the dialogue with Ipsos’ HEOR, real-world evidence and market access teams to understand how you can adapt and leverage our evidence-based strategies to deliver an agile and successful launch that’s ready for any future scenario – from 2022 and beyond.

Let’s start the conversation!

Richard Tolley, MD, Market Access (Europe)

Richard.Tolley@ipsos.com

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