

Understanding the Payer Mindset Throughout the Brand Journey

Payers are the gatekeepers of product utilization. Access is what paves the way for sales.

When a physician writes a prescription, the patient's ability to fill it is uncertain as access is never a guarantee.

For example, even in categories where there is virtually no clinical differentiation between brands, formulary coverage differences can cut access by 50% (e.g., GLP-1 agonists for diabetes).¹

Consider mental health – payers have imposed access restrictions such as prior

authorization and step therapy to decrease the use of non-preferred drugs by 50%, as was shown in a recent study.²

As brands progress through their lifecycles, payers have influence at various stops along the way; for instance, when a product receives a new indication, or a competitor enters the market. The table below is a roadmap to understanding how payers can impact a brand's commercial journey.

Brand Journey Milestones	Payer Action Points	Strategic Considerations for Brand teams
01 Pre-Phase 3 Clinical Program Design	<ul style="list-style-type: none"> ■ Monitor long-term pipelines for products representing major shifts to current treatment paradigms or potentially significant cost exposure 	<ul style="list-style-type: none"> ■ Find opportunities to integrate payer mindsets and insights into trial design to <ul style="list-style-type: none"> - ensure that trials yield data relevant to the interests of payers - support coverage at launch ■ Think about the unmet need the product can fill from the perspective of value
02 Phase 3 Clinical Trial	<ul style="list-style-type: none"> ■ Monitor pipelines and assess the <ul style="list-style-type: none"> - likelihood of approval - risk profile within member population(s) - member population eligibility - likelihood of follow-on indication(s) - potential cost impact on membership 	<ul style="list-style-type: none"> ■ Seek opportunities to highlight the clinical and economic burdens associated with the disease and remaining unmet needs, in spite of current treatments ■ Help payers understand the potential impact of how to evaluate burden in less-common/ rare diseases ■ Involve KOLs, where appropriate, to support payer/HCP alignment <p>Note: Consider facilitating these conversations at a local level to strengthen impact.</p>
03 Post-Data/ Pre-Approval	<ul style="list-style-type: none"> ■ Assess budget impact by reviewing <ul style="list-style-type: none"> - Pre-approval Information Exchange (PIE) materials - Health Care Economic Information (HCEI) ■ Consider the total cost of care, including medical cost offsets (larger health plans) ■ Consider potential formulary decisions in context of the existing market <ul style="list-style-type: none"> - e.g., market share of other products ■ Consider pre-emptive actions prior to launch <ul style="list-style-type: none"> - e.g., engage with competitors to secure formularies in the category 	<ul style="list-style-type: none"> ■ Leverage the ability to connect with formulary decision makers early – prior to launch – with a purposeful focus on value (and what will help drive it) ■ If applicable, assess the risk associated with payers taking pre-emptive action to lock up formularies and consider strategies to offset risk
04 Product Approval	<ul style="list-style-type: none"> ■ Payers' Pharmacy and Therapeutics (P&T) Committee examines <ul style="list-style-type: none"> - efficacy - safety - patient population - expected provider demand/ utilization ■ P&T next considers <ul style="list-style-type: none"> - financial impact - cost of competitive drugs - total cost of care (drug costs + medical costs and related offsets) 	<ul style="list-style-type: none"> ■ Understanding the timing and required information for P&T review ■ Ensure alignment of prescriber positioning and expected payer coverage <ul style="list-style-type: none"> - e.g., if the brand is positioned as a first-line agent, but payers are covering it only after failure on 2 other agents, there will be a misalignment

Brand Journey Milestones

05

Product Launch

Payer Action Points

- Establish coverage
- Consider utilization management tools
- Negotiate rebate (if applicable) with the manufacturer
- Make a final coverage decision/policy
 - **Open access** allows patients to access the drug when it is prescribed for the approved indication (common in categories with no other approved options)
 - **Managed access** involves payers employing utilization management tools to drive use of preferred products; patients may still access the prescribed drug after they have met other requirements (common in more crowded categories)
 - **Restricted access** may require more complex prerequisite steps before allowing access to the drug, or prevent a patient from accessing it all together
- Ask questions such as
 - "How can we reduce the total cost of this disease state?"
 - "Will this product help us do that by reducing other (medical) costs?"

06

Competitive Entrant(s)

- Maintain control over the landscape as it evolves, including
 - remaining aware of how demand for each product in a category will ebb and flow based on new entrants
- Reconsider/adjust utilization management strategies as required to capitalize on the availability of multiple formulary options to drive down net costs

07

Product Extension (new formulation, etc.)

- May be skeptical of the incremental value offered by product line extensions— leading to a change in management or additional restriction (including the potential for formulary exclusion)
- May perceive the following as benefits of a product extension:
 - Better tolerability
 - Less-frequent injections or administration
 - Other clinical arguments that prove the new formulation is beneficial

08

New Indication

- Assess impact of broader patient eligibility within their membership—and impact on PMPM costs—potentially by
 - utilizing indication-based management criteria OR
 - leveraging bigger indications to drive rebate revenue stream for ALL indications

09

Sunsetting (final stage of patent life)

- Begin to evaluate the category pipeline for upcoming patent expirations
- Consider establishing policy involving the successor generic, biosimilar, etc.
- Forecast a year in advance to understand the potential impact on budget/costs in the category; begin dialogue with employers to prepare for changes and align on what comes next

10

Patent Expiration

- Consider driving utilization to
 - lower-cost options (generic, biosimilar, etc.)
 - OR
 - another product in the same manufacturer portfolio where there may be a replacement rebate stream

Strategic Considerations for Brand teams

- Demonstrate physician demand/utilization, which directly impacts payer decision making
 - e.g., payers would rather get a 10% rebate on a drug that has 50% market share than a 50% rebate on a drug that has 10% market share
- Focus on driving demand through “pull through”, the process of communicating coverage to physicians
- Seek opportunities to leverage growing share/ demand to negotiate for better coverage
- Consider a “population health” focused partnership in which payers can help identify eligible/appropriate patients for therapy (if applicable to the category)

Consider payers when crafting brand commercialization strategies, communication plans, and messaging.

Payers have meaningful influence on product utilization. As such, aligning with their priorities and developing integrated strategies across stakeholders can help drive overall commercial success.

Lumanity applies incisive thinking and decisive action to cut through complex situations and deliver transformative outcomes to accelerate and optimize access to medical advances. With deep experience in medical, commercial, and regulatory affairs, Lumanity transforms data and information into real-world insights and evidence that powers successful commercialization and empowers patients, providers, payers, and regulators to take timely and decisive action.

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References:

1. Siegal Y, Shah S. Optimizing market access: how therapeutic area dynamics could influence strategy. Updated March 14, 2019. Accessed August 6, 2021. <https://www2.deloitte.com/us/en/insights/industry/life-sciences/pharmaceutical-pricing-market-access.html>.
2. Seabury SA, et al. Patient outcomes and cost effects of Medicaid formulary restrictions on antidepressants. Forum Health Econ Policy. 2014;17(2):153-168.

Content refined with—and validated by—payer medical and pharmacy directors in current roles.