BUILD MORE ACCURACY INTO YOUR FORECAST

How to Modernize Your Approach to Predicting Formulary Coverage

FAST

Close gaps and gain more control over your brand's success by challenging traditional approaches to market access assessments

We want to change launch failure trends

In 2020, Deloitte published findings related to drug launch success, looking at actual and forecast sales for novel drugs approved in the United States between 2012 and 2017. Among the findings: 36% of all drugs failed to meet market expectations, while 26% far exceeded expectations.

Why is there such wide variability?

In a November 2020 survey by Precision Value and Health of 40 pharmaceutical executives, 73% of respondents said that unrealistic forecast expectations were a moderate to significant contributor to unsuccessful launches, while 53% also blamed unsuccessful payer access strategies. (Contact us for details.)

Brand marketers are evaluated against goals based on market access assessments and cumulative forecasts, but often these predictions simply aren't realistic. While some forecasts underestimate expectations, others overestimate. The data points to a clear need for more accurate predictions.

In this guide, we will bring to light common yet risky gaps in typical market access strategies and then show you how to fill those gaps. You will find out how having a deep understanding of your brand's future market access can give you more sophisticated insights, empowering you to strengthen multiple facets of your brand's market access strategy through the entire product lifecycle.

Pharma execs point to top culprits of unsuccessful launches

73%	53%
Unrealistic Forecast Expectations	**Unsuccessful Payer Access Strategy**

Question assumptions about how to predict your brand's market access

While it's widely known that market access is a critical factor in determining how well a brand performs, pharma has traditionally relied on high-level assumptions, rules of thumb and cursory analogue assessments to inform their market access strategies. The result: launches that fall short of market expectations, disappointing GTN models and diminishing returns.

This scenario might sound familiar:

- As a brand leader, you are likely the person responsible for hitting market access goals and securing profitable payer contracts, but you also rely on other people to reach those goals and negotiate deals.
- You might hire a vendor to develop the forecast that guides your decision- making. If the vendor doesn't understand the payer or rebate piece, you might unknowingly approve an inadequate forecast and then go to market with it.
- The CFO and CEO then manage you against goals set according to that forecast, which becomes part of your performance metric.
- In the end, you are responsible for the product's Profit and Overhead. How confident are you that you have done everything you can to optimize P&O?

When you have a truly deep assessment of your drug's formulary coverage possibilities and threats, you can make decisions more directly tied to hitting launch goals and staying competitive.

Ask yourself:

- *What if you could confidently report what your expected coverage will be and know which factors will have the most — and least — influence on your brand's market access?*
- *How would you use that information to guide where and how you invest resources?*

As the latest innovative product from PRECISIONxtract, FAST makes it possible to much more accurately predict your drug's formulary coverage possibilities and threats. You no longer have to rely on one-dimensional insights and subjective reasoning to try to understand why a drug is rejected or covered. Through FAST's leading-edge algorithm, you can discover the market dynamics that lead to those coverage decisions. And when you know the root cause of a coverage decision, you can influence the effect.

Read on to learn more about the FAST approach and how you can use it to support your brand's goals.

Closing these four gaps will immediately improve your market access assessments

A team of data scientists, analytics consultants and solution architects developed FAST to uncover critical gaps in traditional approaches to predicting a product's formulary coverage. Closing these gaps gives you a more a transparent, complete picture of access to gain alignment across all stakeholders.

GAP NO. 1

Missing key variables that explain payer coverage decisions

In addition to trends, identifying payer-specific variables and including them in your market access assessments can give you an advantage in contracting negotiations and goal setting. Consider how the following examples of market access intelligence could arm you to work smarter:

1. **Competitive Landscape** — the number of products currently in the market for the specific therapeutic area and manufacturers with multiple products in their portfolio
2. **Generic Competition** – data shedding light on how an available generic can lead a priority payer to apply restrictions on branded products before they will approve (i.e., how does generic competition impact payer decisions if the client's product has the same class of MoA or a completely different MoA?)
3. **Order of Entry to Market** — evidence of how a priority payer will behave when a product enters the market (depending on the payer type)

Do you know if the people working on formulary coverage predictions and forecasts for your brand are considering these types of variables and how they interact with each other?

In addition, brands often overlook qualities of their own product that can impact coverage. Payers might respond differently if your brand has a new RoA (Route of Administration) or MoA (Mechanism of Action). Knowing these nuances and how payers are responding to them — as risks to or opportunities for your brand — makes it possible for you to emphasize your product's optimal qualities with payers.

Incorporating these key variables allows you to more clearly understand your value proposition relative to other alternatives on the payer's formulary, and its value merit weight as you contract with payers. Without this intelligence, you will likely under- or overestimate the contract value, and under- or overpay during contracting.

In all of these cases, the key is to understand why payers behave the way they do — why these key variables lead to more positive or negative market access.

Close the gap by identifying and considering often-overlooked variables when predicting access.

GAP NO. 2

Using history without understanding trends

Looking to the past to predict future market access can provide valuable insights, but only if you dig deep. Pharma teams typically consider what a payer did over the past few years as a gauge for what they will do 12 or 24 months in the future, while account managers tend to underestimate access to help manage internal stakeholders' expectations.

The pervasive gap in this approach — one that leads to inaccuracies — is the tendency to let economic and policy-related trends guide market access predictions without fully understanding how these trends impact coverage behavior.

Will a high-level historical review answer these kinds of questions?

- *How do rising tariffs abroad impact a big US insurer's belt-tightening and its coverage of your new specialty product?*
- *Will a new federally mandated policy designed to combat obesity change a payer's rebate decisions when it comes to your diabetes drug?*

While you have no control over federal health policy and the global economy, you can identify changes in coverage behavior as a result of these trends. Employers and the federal government are buying the coverage, so incorporate how trends influence these buyers as you work to predict future market access for your brand.

Also, a payer's coverage behavior isn't limited to what they have done by therapeutic class in the past — another false assumption. Looking at management behavior at the drug class level is also important. For example, if you have an oncology drug, look beyond how a payer has covered oncology drugs in the past. If they restricted a growth hormone drug recently, this could indicate a pattern of increased specialty drug restrictions — cost cutting — across therapeutic areas. Your product could be the next to be restricted.

Close the gap by finding a way to identify changes in coverage behaviors.

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GAP NO. 3

Insufficient payer detail to support GTN

Gross to Net (GTN) modeling is complex and challenging. Having the right access insights and a good understanding of different beneficiary populations can help prevent your GTN results from disappointing shareholders, managers … and you.

All too often, brand marketers have to rely on sweeping generalizations regarding access for patients covered by Medicare, Medicaid and commercial insurance carriers. But this approach creates gaps that will hurt your GTN model.

These three populations and their circumstances vary widely. A whole different set of government policies related to best price and discounting must be followed for Medicare and Medicaid. Some Medicare populations are subsidized vs. not subsidized, a "donut hole" finance teams underestimate or involve populations they don't know how to split effectively. Plus, commercial carriers have regional variations to factor in.

If you don't get these access buckets right for each beneficiary population, you will be unable to achieve the end goal of shareholders' end goal, measured simply by profit.

Close the gap by making access predictions that inform GTN forecasts.

GAP NO. 4

Using the wrong analogues

Brand marketers rely on analogues to help them predict what their product's formulary coverage will be. Getting these predictions right is essential because pharma's optimistic C-suite teams often impose lofty goals to measure a brand's success. A better approach is to reach for realistic goals, which is more likely to happen when your forecast includes a more realistic market access assessment.

Analogues play a major role in the process. Unfortunately, most vendors and consultants choose these seemingly analogous products based on just a few general criteria — therapeutic area is most common — when they should be looking at multiple variables across a range of products for different reasons.

These examples might sound familiar:

- Say you're launching a new product for women that treats urinary tract infections, and you want to predict your market access as part of your access forecast. You hire a vendor to help with the task. Although your product is a one-dose pill for UTIs, your consultant presents analogues that have nothing to do with UTIs. In fact, they're birth control pills. The overarching similarity is that OB/ GYNs are the primary prescribers of the analogues, like with your medication.
- Or perhaps you're marketing a new birth control pill that is a combination product, so it contains two or more active ingredients. Even if you narrowed your analogue options to just other birth control pills, your product's combination status makes it difficult to just choose a birth control pill at random to use as an analogue. Moreover, if a birth control pill has the same mechanism of action as four other generic drugs, you have to use an analogue of a fifth drug in a series of four generic drugs with the same Mechanism of Action (MoA), as opposed to just birth control pills.

Getting your analogues right can be complicated, but getting them wrong can lead you to missed launch expectations. Using just the prescriber type or just the therapeutic area as a leading factor in analogue choice won't give you an accurate prediction of your own market access. The right analogue is one that looks at multiple variables.

Close the gap by identifying the right analogues.

With accurate formulary coverage predictions, your brand can excel

When you fill these gaps in traditional approaches to predicting market access, you will connect data that was previously disconnected. You will see more clearly the intersections, networks of influence and relationships among variables that impact your brand's success.

Being able to pull each variable lever and see how it influences the other variables is powerful. This process of running different scenarios gives you a view into the future and its different possible threats and opportunities. As a result, you can build more accurate forecasts, develop more robust launch and access strategies, and use resources more wisely.

The depth and breadth of data and FAST's underlying analytics are more than one individual could access, integrate and implement on their own. To simplify these otherwise complex insights and make them useful for brand marketers, FAST uses a 100-point index (FAST Market Access Strength Scores).

Brand marketers who more accurately predict their market access challenges experience the advantage of FAST's market access intelligence. A full understanding of market access — the right combination of data and insights — can empower you to carry out the following capabilities.

CAPABILITY NO. 1

Manage the dynamic forces that are mostly likely to affect you at launch

You don't have the luxury of launching your product into a vacuum. To varying degrees, unexpected variables can and do interfere with even the best laid plans, shifting the landscape in an instant. In some cases, outside forces lead to a surprise advantage, but perhaps more often they catch brand marketers off guard, hurting their chances at hitting launch goals.

For these reasons, contingency plans need to be as relevant and reliable as possible.

A comprehensive understanding of your predicted market access position brings to light the specific variables that are most likely to impact your brand's launch so that you can plan for them months before your actual launch date.

Understanding the likely launch dynamics and how they can change at different times can give you a leg up. For example, say a competitor launches a product at the same time as yours, or a drug in the same therapeutic area goes generic at the same time as your launch. How valuable would it be to understand the potential impacts of these events? How would you manage these kinds of scenarios?

In the case of a simultaneous launch, having a better assessment of what your access will be can prepare your for the possibility that payers' Pharmacy and Therapeutics (P&T) committees will group your brand together with a new competitor to determine market access, leading to dog-fight like discussions. On the other hand, a simultaneous launch can have a positive impact on your outlook if you have more than one product on the market, which allows you to make a stronger portfolio play.

For brand marketers, being able to predict the impact of such outside forces and events on your product launch empowers you to establish more accurate launch expectations.

USE CASE

Two Rivals Launching at the Same Time

PROBLEM: As a brand marketer, you're typically aware that a new competitor could come on the market around the same time period as your product's launch date. But reliance on a general awareness of this possibility is insufficient. The related question to answer and prepare for is:

"If the competition's launch date is close to ours, how will it affect our launch success?"

SOLUTION: Up to 12 months before your launch date, consider how a new competitor launching alongside you would make a difference. Test out scenarios across different points in brand maturity (e.g., 3 months post launch, 6 months post launch, and beyond) to determine if an overlap in launch time is indeed meaningful, and prepare accordingly.

CAPABILITY NO. 2

Choose the most advantageous stories to tell to encourage pull through

In an effort to engage payers and P&T committees making decisions about your product's availability, you develop stories and invest resources to amplify your brand's value proposition.

- *How much do you rely on gut feeling when determining which messages to develop?*
- *How does data drive which stories you tell?*

Historically, brand marketers have relied too much on comparisons to similar products or marketing "best practices" to craft their stories. But you can avoid this trap of generalities.

Through the process of running different scenarios around your specific brand's market access outlook, you will discover which value propositions are most advantageous for your brand.

When you can see which influences (e.g., cost, clinical novelty, competition) are actually impacting your projected market access and in what combination, you discover the most powerful positive and negative drivers of market access.

These positive drivers become critical to your brand's story, its value proposition and what your payer discussions should focus on.

USE CASE

Being a Brand in a Sea of Generics

PROBLEM: Say you're launching a branded topical product that treats a specific skin condition. Currently, there are other topical creams and lotions used for spot treatment of this same condition and other general skin inflammations. Therefore, a key question to answer and prepare for is:

"How can we get a foothold in the market when there are multiple generics already available?"

SOLUTION: Widen your focus from primarily a therapeutic comparison to a more holistic assessment to uncover ways to talk about your brand in a way that sets it apart from generics and other competitors.

In this use case, you might learn that payers don't put a lot of value in generic steroidal creams, but they do value approved products for specific conditions. It is your product's unique MoA — approved for a particular indication — that sets it apart and becomes your compelling value proposition, showing payers you are more than just a branded version of a generic product.

Knowing what payers value gives your brand the power to step into conversations to say, "Yes, I know there are generics to treat this specific condition, but they aren't approved. Ours is the first approved product."

CAPABILITY NO. 3

Be prepared to address future threats to brand differentiation

No brand is safe from the threat of competition. On the upside, competition is a huge driver of innovation in drug development. But, even if you're the first entrant in your therapeutic space, if a dozen other drugs follow on, your stronghold on the market will weaken.

Fortunately, a deep assessment of your predicted market access allows you to develop competitor scenarios that help you prepare to stay on top in a more crowded market.

As you develop your brand's formulary coverage insights, dialing up or down the brand saturation variable makes it possible for you to see how much new competition will increase payer access risk one or two years in the future. You can then use this insight to improve forecasts and strengthen access strategies.

For example, by running scenarios that involve varying levels of brand saturation — in combination with other variables — you might discover that continuing to tell a story of "innovation" will serve you well when new competition emerges. Or your brand's convenient route of administration (RoA) might be the story to maintain and promote in payer discussions. By increasing brand saturation and then playing with some of the other variables that affect market access, you can start to see what can help you even if brand saturation is high.

USE CASE

A Novel Product Gets Competition

PROBLEM: Six months after your launch, a competing drug launches into your product's market. While you might have enjoyed a few months of hitting launch goals, even one year out, you can be at risk of losing coverage because of the more crowded marketplace. The key question to answer and prepare for is:

"What do I do if this new competition is a viable threat?"

SOLUTION: First, find out how much of a threat they really are by running an applicable scenario. If increasing brand saturation drives your market access score down, prepare for this scenario. If you don't have other products on the market, which could hurt your chances to make a portfolio play with payers, consider other tactics. Work to lock in your existing position and interact with payers to safeguard your future position. Either that or be prepared for payer rebates to be a big factor in the future.

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CAPABILITY NO. 4

Dial in on specific payers' behaviors

No two payers are alike. Each values some product attributes more than others, and decides which drugs to include in their formulary based on those values. So in the process of evaluating different scenarios to uncover your formulary coverage, should you assume your market access score is the same for all payers, driven by the same attributes? Should the value propositions and stories you deliver be the same for every payer?

Evaluating the multiple variables that impact market access is the first step to dialing in on specific payers' behaviors so you can personalize access strategies for priority payers. (FAST is currently developing a payer behavioral segmentation tool to achieve this level of payer specificity.)

As you run different tests to predict market access, your score will creep down in some situations, indicating that the risk of problematic coverage is increasing. When you can determine why this is happening and understand the layers that make up your overall risk, you will be able to consider tactics to correct or manage the root of the problem.

USE CASE

Pre-Launch Payer Targeting

PROBLEM: It's pre-launch time, and you are handed a goal of 80% market access coverage. Of course, your strategy includes payer specificity. Resources are limited — and you want to hit or exceed your goal — so you have to work smart. The question to answer and prepare for is:

"Which payers should we prioritize?"

SOLUTION: Dialing in on payer behavior early in the process and as comprehensively as possible helps you spend your resources where they will make the most impact. By peeling back the layers of your predicted market access, you determine which payers will be low-risk open access types and which are likely to block your product. Focus on the payers you should spend time talking with to reach that 80%.

CAPABILITY NO. 5

Know how much the cost of your product really matters

Rethink the argument that perception is reality. When it comes to a product's cost and its true impact on market access, data is reality.

Unlocking a deep assessment of your drug's formulary coverage possibilities and threats can bring to light just how much and in what ways cost impacts market access position. It allows you to see pressure points and inflection points, which can be drastically different from a generic market to a fully biologic market.

For some drugs, there is actually little cost sensitivity despite perceived cost sensitivity. Your $300 product might perform just as well as a $500 product. When you're aware of the difference between actual and perceived cost sensitivity, you're better able to hone your own launch and access strategies.

The key is to measure the impact of a product's cost in conjunction with other product attributes. Factors such as manufacturer portfolio, type of RoA and whether it's a biologic treatment play key roles in how important the actual cost of a product is to payers.

USE CASE

High-Cost Product Rethinks Access Strategy

PROBLEM: The product you're launching costs a hefty $900 per unit. You have your work cut out for you to hit high market access goals. The question to answer and prepare for is:

"While I can't change the cost of my product, what can I do to maximize its market access?"

SOLUTION: Influence what you can. As you pursue a deeper understanding of your predicted market access, adjust up and down the annual treatment costs for your product and relevant analogues to see how price fluctuations affect payers' propensity to cover them. Often there's an unexpected tipping point, and scores won't always move in a predictable way. You might see a high-cost product with really good coverage. As a result of what you discover, you may consider higher discounts or rebates to help secure coverage. Often, payers bake rebating into their process, so be prepared.

Make your next move

If you choose to take a deeper dive into market access intelligence, you will uncover and close gaps that otherwise would prevent you from reaching your potential for your brand's launch success and its sustainable growth. Armed with more realistic formulary coverage expectations, you can pursue more achievable goals — and reach them.

- *What are you doing now to unlock the deepest, most realistic assessment of your drug's formulary coverage possibilities and threats?*
- *Where are the gaps in your approach and how would closing those gaps give you the capabilities to excel?*

Contact PRECISIONxtract to find out how FAST can unlock the industry's most comprehensive and rigorous assessment of your drug's future formulary coverage.