PRECISION
value & health

Achieving Launch Excellence:

A Novel Data- and Analytics-Informed Approach

Introduction

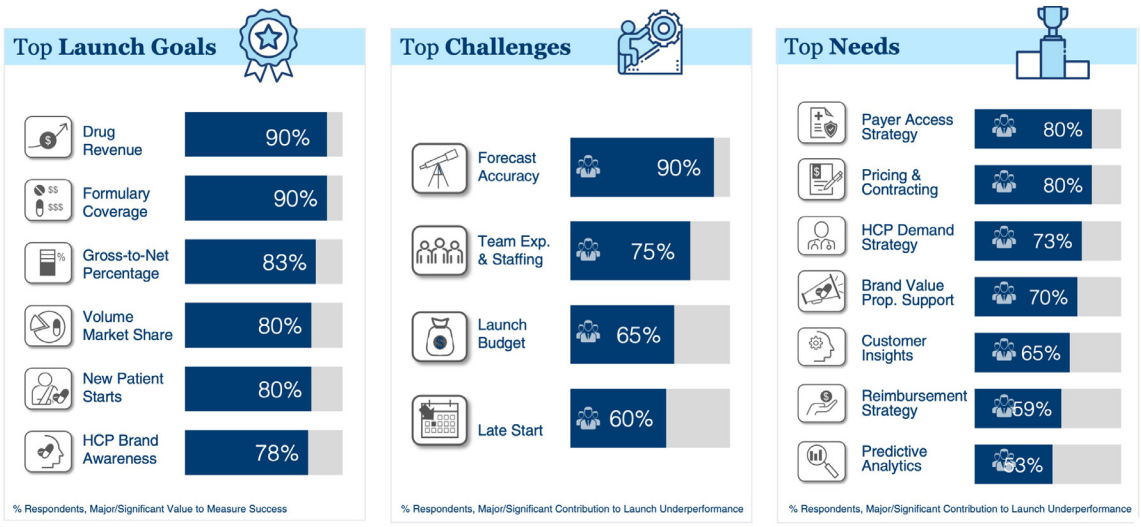
While the U.S. Food and Drug Administration (FDA) approved 53 new products in 2020 and 50 in 2021, only 16 therapies were approved in the first half of 2022. In an increasingly rigorous regulatory environment and crowded competitive landscape, product launches have become more challenging. With fewer approvals, the ability of each individual product to meet forecast targets and brand objectives is of paramount importance to manufacturers. Planning for—and achieving—launch excellence is one way to help ensure that goals are met; however, every launch is unique and it is often unclear how excellence can be obtained.

Data and analytics can help drive and inform launch preparations and support efforts to achieve launch excellence through realistic goal-setting and risk mitigation. PRECISIONadvisors works with manufacturers, helping them make key decisions—related to product positioning, go-to-market strategy, and customer engagement across payers, providers, prescribers, and patients—through data- and analytics-driven insights.

Understanding Challenges and Opportunities for New Drug Launches

In a recent survey, Precision Value & Health asked 40 pharmaceutical sales and marketing executives about their top launch goals, challenges, and needs (see Figure 1). Drug revenue and formulary coverage were the most important goals, followed by gross-to-net (GTN) percentage, market share, new patient starts, and healthcare provider (HCP) brand awareness. Interestingly, approximately two-thirds of survey respondents said they had missed at least one of their launch goals and a majority indicated they had missed multiple goals. Forecast accuracy was the greatest challenge and payer access strategy and pricing and contracting were the most pressing needs.[1]

Figure 1. **Top commercial goals, challenges, and needs for a new drug launch[1]**



Preparing for Launch

Product launches are complex and require integrated, cross-functional collaboration to ensure that all stakeholders are aligned on the goals that define launch success. The core tenets of launch preparation and launch excellence are patient centricity, speed to market, flexibility, and agility. In today's environment of targeted therapeutics and precision medicine where patient journey are more complex and personalized, product launches have become exponentially more challenging. It is now necessary to align data sources across an increasing number of stakeholders to predict how a new drug will perform post approval and identify targeted opportunities with high specificity.

Traditionally, manufacturers have approached drug launches by looking at access and demand for all stakeholders using a siloed approach. Most companies have recognized the limitations of that approach, but struggle with collaborating across workstreams and connecting information across functions to set realistic goals and develop tactical launch plans. With so many stakeholder insights to integrate, successful launches require careful orchestration of data and analytics starting as early as 36 months prior to expected drug approval.

At Precision Value & Health, we take a total market approach to launch excellence that links access and demand to brand objectives (see Figure 2). We build a data infrastructure that effectively and efficiently connects insights across all stakeholders—payers, organized providers, distribution providers, prescribers, and patients—to develop a targeted, personalized go-to-market strategy.

Figure 2. **Delivering launch excellence within a total market framework**

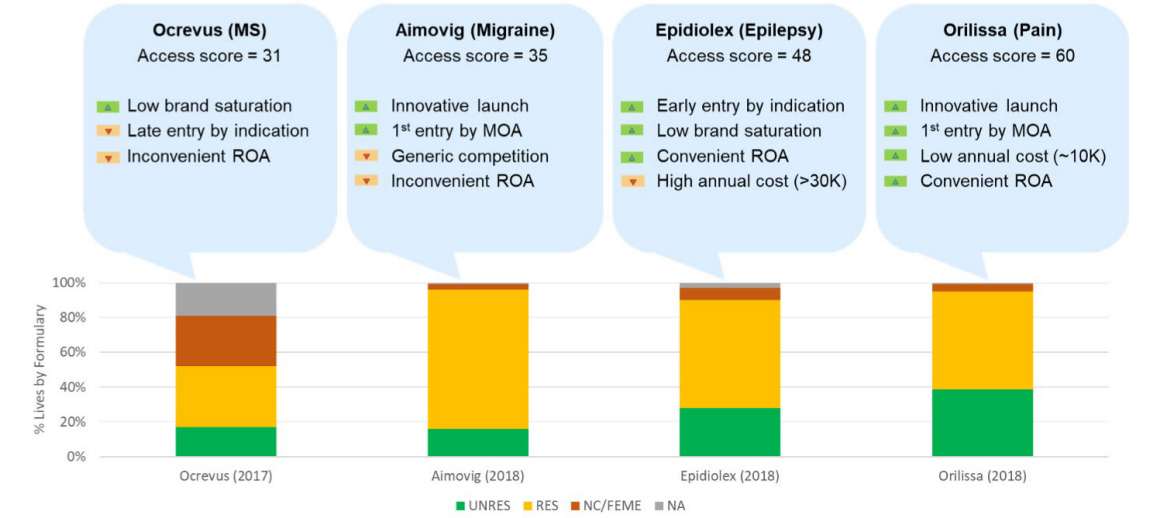
Setting Expectations with an Early Payer Access Outlook

Launch preparation begins with defining the parameters that equate to success. In order to establish these key performance indicators, it is critical to understand the potential of the asset from a payer access perspective. Early assessments of the market size, market opportunity, and competitive landscape are critical, but are often too broad. The key is narrowing the scenario range to be able to plan with more specificity and to set achievable goals.

Precision Value & Health has developed a machine learning-based access outlook modeling tool that analyzes data for over 2,000 drugs to generate a Payer Access Score for an investigational drug. Powered by a sophisticated statistical model that uses advanced network algorithms and supervised machine learning, this technology identifies lookalike analogues to the investigational drug and evaluates more than 50 features that impacted the actual access of those lookalike analogue product launches to identify factors influencing payer coverage.

These access-impacting features include both product attributes, such as therapy type, route of administration and cost, and market attributes, such as brand saturation and generic availability. The Payer Access Scores generated by this tool have been validated at greater than 80% accuracy based upon more than 3,000 observations. The access outlook modeling tool then creates a synthetic analogue based on the investigational drug's target product profile (TPP) and benchmarks it against the lookalike analogues to estimate a predicted Payer Access Score. This early read on access can be extremely useful for prioritizing or re-focusing launch preparation activities.

Figure 3. **Sample Payer Access Score Analysis**



Developing an Early Understanding of Market Dynamics Across Stakeholders

Predicting payer access is just one dimension of launch preparation. It is critical to develop an early understanding of market dynamics across all stakeholders. To do this, the Payer Access Score must be combined with available formulary and claims data to create a holistic view of both access and demand. At Precision Value & Health, we synthesize these insights for review by our internal Access Experience Team (AET), a multi-disciplinary expert panel. The output of this review is an Early Market Assessment Package that addresses key questions across the payer, provider, prescriber, and patient perspectives to inform early tactical planning:

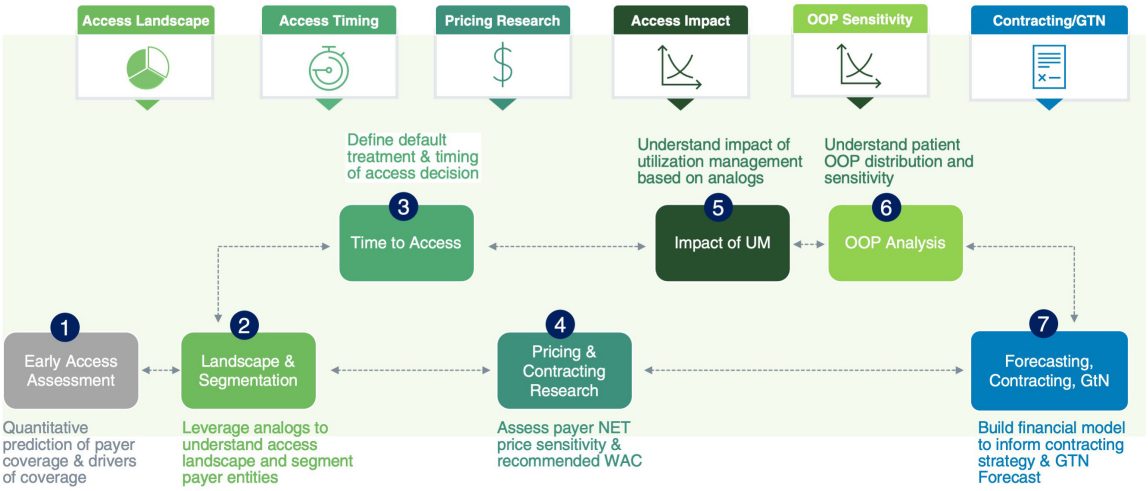
- How well is the product positioned for launch success?
- What are the key drivers and barriers impacting likelihood of success?
- What is the ideal TPP and how should the existing TPP be refined?
- Which priorities must be addressed to improve the probability of launch success?

Integrating all these data points also helps to create alignment across the medical affairs, marketing and market access functions on the target patient for the new drug, which will impact the scientific and clinical evidence that must be generated to support approval and access.

Performing a Deeper Payer Analysis

As a product progresses further down the pipeline, a more comprehensive payer analysis is warranted. Precision Value & Health's approach to integrated payer analytics creates a data- and analytics-informed framework for maximizing brand business objectives. This framework combines research and analysis on the access landscape, payer segmentation, access timing, pricing, utilization management (UM), out-of-pocket (OOP) distribution and sensitivity, contracting, and GTN forecasting (see Figure 4).

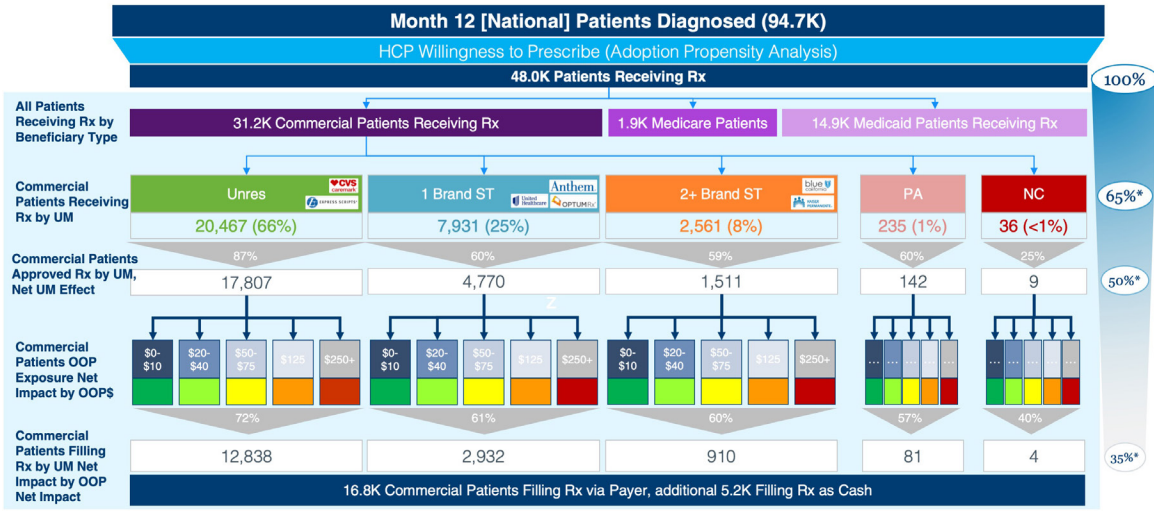
Figure 4. **Integrated payer analytics**



Integrating Access Insights to Fine Tune a Forecast

Layering these access insights into provider demand forecasts or patient funnels can help manufacturers create more specific, more accurate performance parameters for launch. Often, forecasts are built upon the total number of patients who receive a prescription for a drug. However, as seen in Figure 5, payer segmentation, utilization management, formulary position, and OOP exposure all affect access, with a meaningful net impact on the number of patients who are likely to fill that prescription. Forecasts often end up inflated when these access insights are not properly incorporated, setting the brand up for perceived underperformance out of the gate.

Figure 5. **Building a bottom-up assessment of access impact into the patient funnel**



Incorporating Access Insights at the Provider Level

Manufacturers should keep in mind that access dynamics are not limited to payers—they also exist at the provider level, particularly for oncology and specialty drugs. Provider behavior should be factored into provider and prescriber targeting, patient access, and product forecasting.

Large, sophisticated providers such as integrated delivery networks (IDNs), academic medical centers, and community-based practices have begun adopting the same tools payers are using for drug utilization management:

- **Formularies**, which are specific lists of medications that are centrally managed and approved to be stocked and prescribed, usually based on evaluations of efficacy, safety, cost-effectiveness, and other factors
- **Clinical pathways**, which define specific treatment choices by condition and line of therapy and specify a set number of treatment regimens. These pathways are generally more restrictive than FDA labeling and expert guidelines
- **Treatment plans**, which are order sets that organizations develop to manage which treatments are easily available to HCPs and exactly how those treatments are to be administered to patients

Drug utilization management at this provider level is dynamic and varies by institution or practice.

In oncology, about 30% of large practices are utilizing clinical pathways that are integrated into their electronic health records. According to Precision Value & Health research, 60% of oncology providers decide whether or not to load a new drug product into their treatment plans within the first 10 weeks of launch.

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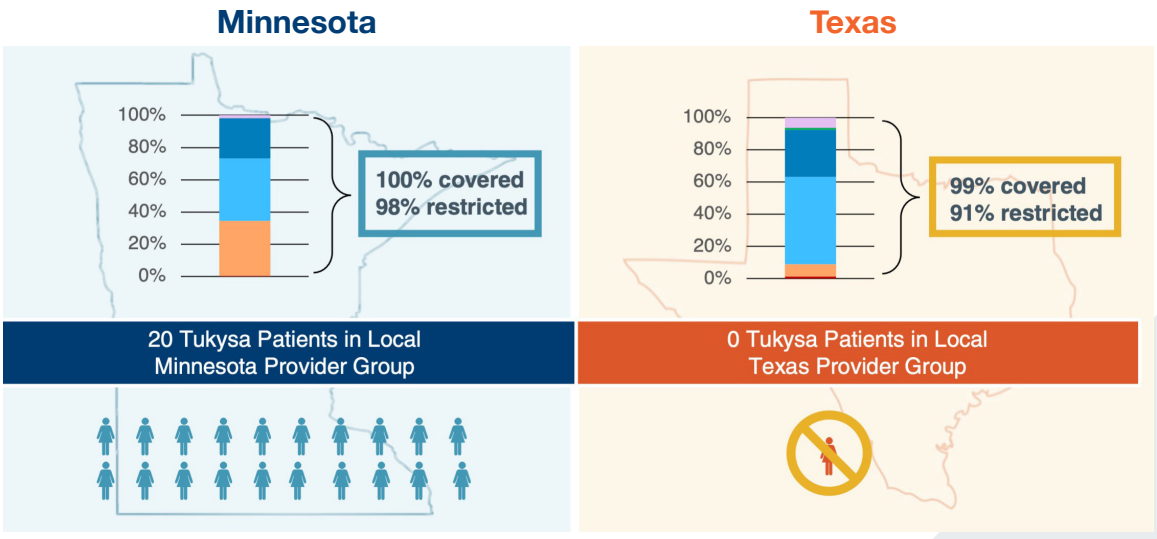
Just as with payer access, utilizing analogues for historic drug launches can inform access strategy and execution at the provider level. Using a proprietary technology called OncoGenius, Precision Value & Health can segment provider groups based on the restrictiveness of their drug management tools and the effort required to override those restrictions. This provider segmentation can help manufacturers shape provider and patient targeting during launch. Interestingly, Precision Value & Health research shows that, for oncology drugs, the beachhead for launch efforts is often provider groups with highly restrictive formularies, pathways or plans and more sophisticated processes for adding products.

Case Study: Integrating Provider Insights

In April 2020, tucatinib was approved in combination with trastuzumab and capecitabine for the treatment of patients with advanced HER2-positive breast cancer. Using OncoGenius, Precision Value & Health looked at tucatinib utilization among provider groups in Minnesota and Texas in the first half (H1) of 2021. Although payer coverage was nearly identical in the two states, utilization was markedly different (see Figure 6).

Figure 6. **Payer coverage and provider utilization of tucatinib in H1 2021**



OncoGenius can also be used to determine whether an oncology drug is included in clinical pathways or treatment plans. A closer look at utilization revealed that in Minnesota, 24% of organizations with multiple sites manage tucatinib through clinical pathways and most allow its use in the second line of therapy and beyond. Whereas in Texas, provider clinical pathways limited tucatinib to the fourth line of therapy and beyond, suggesting that a change in pathways would be required to boost utilization.

Key Takeaways

As markets grow increasingly challenging, using novel analytics-driven insights to inform and refine go-to-market strategies and expectations will become even more important for supporting launch excellence. Proactive planning and execution helps ensure that a new drug launch is as effective and efficient as possible. Analyzing and integrating diverse sources of data across all stakeholders in the patient journey creates a comprehensive view of the opportunities and challenges for an asset in the market and eliminates blind spots, enabling manufacturers to set more achievable goals for launch.

At PRECISIONadvisors, we have developed approaches for integrating multi-stakeholder insights and building data infrastructures that are both robust enough to generate actionable information and flexible enough to evolve as new data emerges or priorities change. By combining market data, evidence and engagement strategies with commercial expertise to optimize product value and maximize patient access to life-changing therapies, PRECISIONadvisors is uniquely positioned to help elevate launch excellence.

1. PRECISION Pharmaceutical Launch Experience Survey (Q3 2021) of 40 pharma sales & marketing executives (~19 years average industry experience).

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