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Product Commercialization, Going Beyond Demand Generation

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Historically pharmaceutical manufacturer's ability to generate demand with providers and patients was all that stood in the way of drugs realizing blockbuster status. During this large-market brand era the market was dominated by primary care drugs, where compelling direct-to-consumer (DTC) campaigns and prescriber detailing drove product prescribing demand, patient requests, and large-scale market adoption.

Today, the pharmaceutical market has rapidly evolved and is now comprised of high cost, complex specialty drugs, intended for specific rare and orphan disease as well as cell and gene therapies. Many of these new specialty drugs offer hope for previously untreatable conditions and greatly improve patient quality of life and in the case of cell and gene therapies, potential cures. However, the pharmaceutical landscape, and the requirements and knowledge needed to successfully commercialize these new specialty drugs, has grown increasingly complex and focus on narrow patient populations and indications. As a result, pharmaceutical manufacturers can no longer rely solely on their Sales and Marketing organizations for share of voice, reach and frequency, and brand messages for commercial product success.

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To put it simply, in today's world it is too often the case that health care providers are not able to treat everyone they want with a given specialty product – market access dynamics that limit product access can be very challenging and are critical for success. A direct corollary of this situation is that product demand is not typically the reason for a specialty drug's poor adoption. Adoption is now dependent on successfully configuring complicated supply chain, distribution and dispensing channels; navigating the utilization management controls payers have introduced to manage access and reduce category spend; and educating patients on the benefits of a complex therapy and the means to access new treatments; such as Qualified Treatment Centers. In the case of cell and gene therapy pharmaceutical manufacturers must address sophisticated supply chain capacity constraints, complex manufacturing, and cold-chain distribution hurdles that were previously unheard of.

As a result, commercial specialty product success has become increasingly dependent on strategic and operational levers rather than purely through demand generation tactics. Yet it is often the case that pharmaceutical manufacturers have not evolved their drug's commercialization and market access strategy to this new reality. We still observe launch strategies that place too much emphasis on Sales and Marketing at the expense of other critical operational factors which may have greater importance in successful specialty product commercialization.

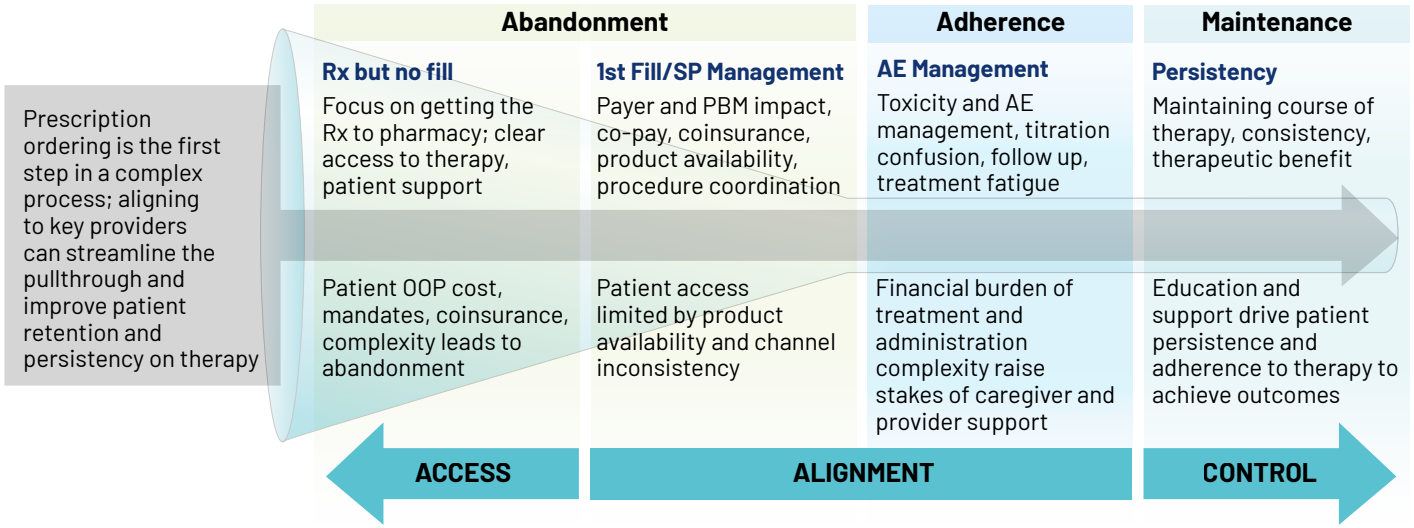
In this article we discuss how the pharmaceutical market has evolved, how this evolution has added complexity to the requirements for successful drug commercialization, and the means by which these

requirements can be understood and planned. Adapting to this new market requires a comprehensive understanding of all the factors that can influence product adoption. This includes the key stakeholders – payer, prescriber, patient, pharmacy, and distributor – as well as the competitive landscape and product pipeline. It is critical that pharmaceutical manufacturer has a detailed knowledge of the patient journey – from diagnosis to administration to long-term adherence.

First, let's explore how the requirements to successfully commercializing a drug have changed. As the scientific gains provided by research from the pharmaceutical industry have leapt forward, new and significant layers of complexity have been added for patients and providers to access these drugs:

- Specialty drugs ushered in the initial landscape shift and established new requirements for commercialization. These products dramatically shifted the pricing paradigm in the dust, with the WAC prices for these drugs setting new highs in increased pressure on limited distribution models, product procurement economics, patient cost share, and payers' processes to manage policy and contain costs. Payers met this challenge by implementing utilization management hurdles that hadn't existed in the days of oral and "non-specialty" branded medications. These hurdles introduced by the payers now required pharmaceutical brands to not only develop a clear value proposition to providers and patients, but also to payers. Payer coverage had suddenly become a rate limiting factor in revenue for a pharmaceutical product. In addition, patient out of pocket costs became a key consideration, forcing manufacturers to implement programs to ease the financial burden of coinsurance and out of pocket expenses for patients.
- As rare and orphan drugs with six-figure prices entered the market, payers increased their utilization management controls and as a result the time from prescribing to patient access lengthened. The precision and price of these products, and resultant payer actions, again shifted the landscape. Patients now need extensive education support, and stewardship throughout the process of being diagnosed and treated. Patient abandonment, meaning prescribed patients who never fill the product prescription, became a sales rate limiter. Finally, demand generation became more complex as patient identification became a clear hurdle to market development for many of these orphan and rare disease products.
- During this commercial evolution, distribution, dispensing and product administration models went through significant configuration changes ushering in the era of specialty distribution and specialty pharmacy solutions. Today, there is a great deal of sophistication in clinical and commercial supply chains and limited distribution networks focused on detailed product handling and service requirements to meet end customer needs. Specialty distribution requirements need to include careful considerations in channel cost containment, unproductive product discounting approaches impacting product average sales prices, as well as considerations for specific authorized sites of care and REMS requirements certifying administration sites and data requirements.
- Today we find ourselves in the complicated world of cell and gene therapies. In addition to sophisticated payer requirements for approval, need for extensive administration site requirements, patient and provider education, patient coordination, stewardship and financial support, the manufacturing of cell and gene therapy products often requires collecting cellular source material from the patient to begin the cellular modification process constituting commercial product production. In some cases, the patient has now become the source of raw material at the beginning of the supply chain. Lacking sophisticated cellular manufacturing capacity, cellular production throughput, and an error-free supply chain solution have now become significant points of failure for allogeneic and autologous gene therapy archetypes.

As the pharmaceutical marketplace has evolved the relative importance of sales and marketing demand generation in a drug's commercialization strategy has decreased. For new products, other considerations like payer contracting for access, patient genetic identification and education, cost, and supply chain precision now emerge as critical factors in a drug's successful commercialization. A helpful tool to understanding and addressing these critical implications and new considerations when bringing a new drug to market is the commercial patient funnel.



Below we offer an outline of the key patient funnel questions we believe are imperative to answer when designing a drug's commercialization strategy in today's world.

- **Top-line Demand (Diagnosis and Treatment Decision)** Will the patient or provider demand for our drug be problematic? What are the barriers to getting providers to see the clinical value in our drug? Am I launching into an existing market, or do I need to shape a market to help providers identify patients and drive disease state awareness? It remains important to get the patient to the mouth of the funnel, but how does one strategically plan to accomplish that in this new world?
- **Access (Financial and Physical)** What are the barriers to payer coverage for our drug, and ensuring our drug is not disadvantaged? How will manufacturers and provider sites of care contract with payers to ensure timely access to product? What will the patient out of pocket cost be and how can I ensure that isn't a barrier? What distribution channels will I need to configure to ensure every site of care who wants to treat a patient can administer the product effectively without economic constraint?
- **Last mile pull-through** Once the treatment decision is made, what factors could cause the patient to abandon therapy before they start? What patient access and support services do I need to ensure that the patient remains confident and willing to initiate treatment? What supply chain and logistics challenges could prevent the drug from being available to the patient in a timely manner for administration?
- **Adherence and Persistency** For orphan and rare or specialty chronic therapies, how can I ensure that a patient stays on therapy? What obstacles do I need to understand (e.g., transportation to lab testing) to ensure continued access? What are the reasons a patient might stop treatment against the advice of their physician? How can I mitigate this risk?

Being able to design a product specific patient journey funnel requires, at a minimum, a clear understanding of the product's label, formulation, clinical and economic value proposition, patient population, provider characteristics, health plan approval requirements, point of access, and competitive landscape. It also requires a highly collaborative and cross-functional commercial product launch team to review and align on key attributes. If these conditions are met, the patient funnel can be an effective tool for both unifying the commercial team around key strategic imperatives and prioritizing those imperatives. Moreover, functional leads from areas such as Market Access, Trade, and Brand Marketing can gain a clear line of sight toward the key determinants of success within their respective functions vis-à-vis the team's overall vision for the product.

Moving through this exercise and key considerations can prevent a commercial team from overinvesting in DTC campaigns and underinvesting in payer strategy or supply chain design, or distribution channel strategies for a product whose demand is dependent upon precision, operational efficiency, and strategic configurations. Understanding and designing strategies that optimize the patient funnel can ensure that investment will be aligned with the highest impact components of the strategy rather than with functional leads who have the most influence or the loudest voices.

In conclusion, when launching a new specialty drug, consider the complexities of today's market and the relative importance of sales and marketing positioning. When developing the drug's go-to-market strategy, take a holistic view of the patient funnel with an appreciation for all its layers of complexity including market access (financial and physical), last-mile pull-through, adherence and persistency. Using the patient funnel approach can be a powerful tool to optimize resource allocation for launch planning and ensure investment aligns with impact. Be open to the idea that demand generation may be the easy part. The payoff for such a coordinated approach allows manufacturers to not only maximize top-line demand but also optimize long term patient pull through and product persistency, and commercial success.

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