FROM LIMITATIONS TO EXPANSIONS:

HOW PRIORITIZING PATIENTS' SPEED TO THERAPY DRIVES THERAPY ADOPTION

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Launching a new product into the marketplace presents numerous inevitable challenges for manufacturers. No amount of experience, preparation and forethought can eliminate every unforeseen circumstance that will create major and minor obstacles along the way. In fact, manufacturers spend approximately \$200 million on commercialization in the years leading up to launching a new product, but only 33% of those therapies meet launch expectations.

The question manufacturers and their commercialization partners must examine is how to avoid the pitfalls that plague so much of the industry. Why are so many consistently missing the mark? We believe at least part of that answer involves a lack of understanding of how to address evolving trends and patient expectations.

Strategies that previously worked for some products likely will not work with economic changes, against emerging competitors, in conjunction with advances in technology and modern patient and provider expectations, etc. Additionally, the ability to adapt to unanticipated hurdles and underperforming strategies is a necessity. Failed strategies do not guarantee irrevocable damage to a product's potential for success, but an inability or unwillingness to adjust those strategies will diminish it every time.

The case study below recounts a recent example of how the EVERSANA COMPLETE Commercialization® model boosted the trajectory of a new product launch and accelerated speed to therapy by addressing a common challenge: limitations.

Diabetic Gastroparesis: An Agonizing Path to Diagnosis and Treatment

Diabetic gastroparesis is a horrifically debilitating disease that causes the body to have complications properly digesting due to a damaged nerve that controls the emptying of nutrients from the stomach into the small intestine. The symptoms can be so severe that patients have trouble maintaining employment, having active social lives, completing common everyday tasks and are often forced into extended hospital stays. For example, one patient spent 143 days in the hospital in one year and experienced a dangerous weight loss of over 130 pounds due to complications caused by the disease.

Gastroparesis can be difficult to diagnose, and patients are often inaccurately told there is nothing medically wrong with them. On average, it takes five years and five

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gastroenterologists to correctly diagnose these patients. This not only delays treatment and prolongs physical pain, but it can also cause extreme mental anguish and cost significant amounts of money while searching for answers.

Another harmful element sometimes linked to diagnosing and treating diabetic gastroparesis is the discriminatory stigma some physicians attach to these patients. This common bias unfairly blames the individual for their condition and can cause serious mental and emotional anguish.

Once a patient is properly diagnosed, speed to therapy is of paramount importance to help relieve their symptoms and hopefully return them to a more normal and manageable lifestyle. As these patients have commonly been waiting years for a diagnosis, once they receive it, they want treatment immediately, and at a low out-of-pocket cost.

Market Access and Pharmacy Network Limitations Stall Onboarding

For 40 years, there had been no new FDA-approved drugs to treat diabetic gastroparesis. Evoke Pharma, a small biotech pharmaceutical company in San Diego, sought to change this and worked for over a decade to bring a new drug to market that would bring these patients rapid and affordable relief. Evoke is a small organization, which made it exceedingly difficult to manage every aspect of their product's pre-launch phase. They did not have the capacity to spend adequate time on pre-commercialization efforts or speak with payers and key opinion leaders to gain beneficial insights.

EVERSANA was brought on board a few weeks prior to the PDUFA date and had approximately 75 business days to make a plethora of key decisions including pricing strategy, distribution strategy, establishing a commercial team and more. To add another layer of complexity, this was all done during the COVID-19 pandemic, meaning these efforts were largely executed virtually.

The product launched with sales representatives about three and a half months after the PDUFA date, then launched with a limited network (single pharmacy) and a full-service hub three weeks later. Various factors went into making that decision such as what was thought to be plausible in the limited time frame and what would be most practical for physicians and patients.

Over the following months, we determined patient onboarding of new therapy was being stalled by:

- ▼ The manual process for completing enrollment,
- ✓ Issues with no reimbursement and coverage, and
- Payers' lack of providing clear criteria for how to obtain product approval.

These factors forced a need for prior authorizations and letters of medical necessity to obtain approval through an exception process.

Because this was the first FDA-approved product on the market to treat gastroparesis in 40 years, and it was in the form of a nasal spray allowing the medication to bypass the gut and avoid causing nausea, physicians recognized its value and knew it could be hugely impactful for patients. However, analyzing weekly script data revealed retail leakage, in part because prescription orders were being sent to local or large chain pharmacies outside the limited network initially launched.

Strategic Overhaul Paved a New Path to Success

Once challenges negatively impacting the product's commercial performance and keeping it out of the hands of individuals who needed it were identified, it was possible to devise a strategic plan to course correct and achieve a successful ROI and, most importantly, bring relief to patients more rapidly and effectively.

EVERSANA, Evoke and our partners made the decision to transition the model from its initial phase by removing some of the burden from the front end. Patients were waiting an average of 24 days to receive therapy, which was deemed unacceptable. To combat this, we chose to move away from the manual enrollment form and adopted an automated process through a digital pharmacy, and almost immediately saw that wait time reduced to 11 days.

This change was piloted in six geographies where both patients and physicians embraced the updated process, resulting in a significant increase in prescription volume and decrease in abandonment. Three months later, the new model expanded to our entire commercial team to increase brand reach. Evoke's confidence in this new strategy allowed us to mitigate risk with added operational expenses.

An additional key component included the utilization of EVERSANA's direct-to-patient model launched in 2022. Because this patient population often faces uniquely challenging obstacles, such as having to see multiple specialists before receiving an accurate diagnosis, increasing their avenues for convenient access to specialists was a significant priority.

Leveraging the direct-to-patient model streamlined onboarding processes and opened the door to telehealth options that expanded accessibility to a healthcare provider and accelerated the path to diagnosis and treatment. As a result, Evoke saw an increase in brand adoption, accelerated patient onboarding and an overall improved experience for patients and HCPs.

While not every challenge was solved, there were significant improvements from the second to third quarter:

- Prescriptions at the top of the funnel: 37%
- Prescriptions dispensed: 55%
- Net revenue: 80%

The third quarter also saw 77% of these prescriptions being reimbursed.

Improve Product Performance Through Tailor-made Solutions and Collaborative **Partnership**

The guiding force that enabled us to resolve limitations and change performance trajectory was a consistent focus on keeping the patient at the center of every decision. Manufacturers must understand their patients' journeys to best meet their needs and create success for their products.

What are the symptoms? How do patients typically attempt to self-medicate before seeing a physician? What does the diagnosis journey look like? What are the physical, mental, emotional and financial tolls befalling these patients? What does obtaining coverage look like? How are pharmacies playing a role in optimizing access to the therapy?

Discovering the answers to these questions is essential to inform decision-making for how to best serve patients and providers, and how to adjust strategies that are not working as initially expected. Modern science is achieving incredible advances in medical care every day, but without proper strategies and resources to foster robust access, affordability and adherence, countless patients will never reap the benefits of those scientific breakthroughs. EVERSANA COMPLETE Commercialization connects the science to the patient in a holistic approach that elevates standards of care and ultimately changes and saves lives.

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