COVID-19 Part 4: Redefining Product Launch Strategy After COVID-19

The COVID-19 pandemic is causing tremendous shifts in both supply and demand for the Life Sciences industry. Manufacturers are gearing up for these changes, while trying to meet the needs of a suddenly changed market. For manufacturers imminently planning product launches in these turbulent times, adjusting strategies for these changes will be critically important.

In light of the massive uncertainty surrounding the COVID-19 pandemic and its far-reaching effects, accurately understanding the nuanced impacts on the costs associated with participating in Government Pricing (GP) programs, has become increasingly important. At Riparian our mission is to provide clarity to complex issues by thinking more deeply about potential challenges and their implications and by presenting novel solutions to those challenges. This article is part of a multi-part series examining topics relating to the COVID-19 pandemic. In the prior installments we focused on macroeconomic shifts, changes in market segmentation, and potential initiatives to support COVID-19 relief efforts. In this current and final installment, we will tie together these concepts as they apply to manufacturers planning to launch a new product in the coming year.

Getting product launches right is always a challenge. A great deal of time and effort is put into developing pricing strategies, forecasting sales, and predicting all the downstream impacts on Gross to Net. The science of developing accurate predictions about a new product's financial viability is based on an accurate understanding of the new product's market. But for manufacturers that have a product set to launch in the next year, many of the factors that previously formed the basis of those predictions may have changed dramatically. A successful launch will be predicated upon a manufacturer's ability to understand how macroeconomic changes, market segmentation, and disease response efforts affect the underlying metrics of their strategy and their ability to pivot to the new reality.

Many manufacturers approaching launch during these turbulent times are asking themselves the challenging questions about how the product will fare in the newly changed market and how that differs from pre-COVID-19 market expectations and forecasted utilization:

- Is your product likely to be used in caring for COVID-19 patients?
- Is your product potentially helpful to treat downstream symptoms associated with COVID-19 or recovery?
- Is your product used for elective or mandatory procedures?

- Is your product targeted towards a dwindling patient population, or a declining channel?
- Conversely, will your drug be impacted by an unexpected increase in demand?

In our first installment, we discussed that in the near term the market will experience significant volatility. Accurate forecasting of Medicaid liability will depend on the estimated Unit Rebate Amount ("URA") and Medicaid utilization. As we discussed previously, macroeconomic indicators and utilization may be extremely volatile right now, and this can have a dramatic impact on lifetime Medicaid liability for new products.

Generally, Medicaid liability for all future periods is tied to the pricing offered in the first full quarter of sales for branded drugs and the fifth quarter of sales for generics. The calculated Average Manufacturer Price ("AMP") in the initial period is called the Base AMP, and it sets the base price for benchmarking all future AMP values for the purpose of calculating inflation penalties. The inflation penalty is the mechanism in Medicaid used to penalize manufacturers for increasing drug prices faster than inflation (measured through the CPI-U), and is calculated by comparing the current quarterly AMP to the Base AMP increased by inflation (i.e. CPI-U). The incremental increase in quarterly AMP greater than the inflation-adjusted Base AMP plus is added to the rebate (Unit Rebate Amount, or "URA"). For this reason, it is imperative manufacturers carefully plan initial pricing strategies with an understanding that steep increases in AMP after the initial Base period will lead to additional Medicaid liability throughout the product's lifetime.

Essentially, this means long-term Medicaid liability levels are governed by a combination of the measure of CPI-U growth and Medicaid utilization changes over time, both of which may experience extreme changes in the near term as a result of COVID-19. For branded drugs, the focus for planning at launch is the first full quarter of sales (the base quarter is the quarter following launch, unless the product is launched on the first day of the quarter). Consequently. for branded launches, forecasting accurate price points in the early quarters will be crucial to the long-term success of the product and these manufacturers need to be much more cognizant of the nuanced impacts COVID-19 will have on their market. For generics, the focus for forecasting and controlling price increase penalty liability comes a year later, in the fifth quarter, and manufacturers will have more time to see the fluctuation of COVID-19 ease and have more time to adjust.

According to SSR Health, net prices in the first quarter of 2020 fell by 2.6%.[1] *While analysts predict that net prices may increase slightly in the coming quarters, it is important to note that product launches may be entering a base AMP period with downward pressures on prices which may result in larger future Medicaid liability. COVID-19 has shifted focus away from drug prices and more on development of treatments, but drug pricing is still a priority of the current administration, exacerbating the uncertainty of the product launch.*

[1]See https://www.fiercepharma.com/pharma/fiercepharmapolitics-net-prices-decline-first-quarter-but-political-threat-returns

As an example, consider a new branded product that is targeted as a non-urgent, non-COVID-19 related condition. Manufacturers should be considering if the product has a unique sensitivity to near-term fluctuations in demand due to COVID-19 treatment, or due to the delay in treatment because of COVID-19 precautions. If this is a first product, the manufacturer may be financially dependent on early market success. While it is appropriate to rethink market entry price levels to address near term fluctuations and early market access, the launch team also must be mindful of any long-term impacts noted above as well. Lowering the price to accommodate the volatile current market with an eye toward steeper increases as demand stabilizes may have the unintended consequence of long-term increases in Medicaid liability. Catch-up price increases will be compared to that lower Base AMP, creating an artificial multiplier to price that has nothing to do with macroeconomic indicators. In essence, by adjusting the market entry price in response to COVID-19's environmental changes to the market, manufacturers are introducing a third metric that may increase long-term Medicaid liability. In the perfect storm, CPI-U may decrease creating an artificial price increase, and for some products, Medicaid utilization may spike after the COVID-19 dust settles when the need for routine, non-COVID-19 treatments can be addressed.

Additionally, in our second installment, we addressed market segmentation changes, and more specifically the likely impact to 340B sales. We noted that the changes in treatment focus at safety net hospitals (disproportionate share hospitals or "DSH") may result in fewer inpatient services for covered patients. As predicted, lawmakers have raised concerns to Congressional leadership that shifts in treatment focus at DSH hospitals due to COVID-19, are leading to their loss of 340B eligibility, noting that many of these hospitals are shifting to outpatient care to boost bed capacity for the most critical COVID-19 patients.[2]

Last year, Walgreens announced the closure of almost a thousand stores in 2020. While not caused by COVID-19,this could have an impact on patient access; the 340B contract pharmacies as pharmacies "operating in underserved areas, particularly ones serving primarily low-income, uninsured, or publicly insured patients, were most at risk of closing."[3] The proximity in timing to the COVID-19 driven market segmentation may have a significant impact on demand for products that serve the related demographics.

Lawmakers are considering adding elements in the next relief bill that will protect DSH 340B status during the pandemic response. Consequently, products that were predicted to have a significant 340B patient population may experience more extreme shifts in sales and GP discount liability as compared to original forecasts. Manufacturers preparing to launch a product targeted at a 340B patient population should consider these shifts when adjusting their forecasting scenarios.

[2] See, "House lawmakers want new flexibility to ensure hospitals don't lose 340B eligibility due to COVID-19 response," FierceHealthcare, April 29, 2020, by Robert King.

[3]See, https://www.pharmacytoday.org/article/S1042-0991(20)30208-5/fulltext

Manufacturers launching products in today's market need to consider all of these factors when attempting to accurately forecast future sales and downstream impacts to GP and Gross to Net line items. Understanding how the market has suddenly and drastically changed will allow product sponsors in the company to manage these volatile changes and quickly adjust forecasts. Now is the time to go back through underlying assumptions, and pivot to the changed environment.

About the Author

Susan Dunne

Senior Director, Consulting and Managed Services, Riparian LLC

Susan Dunne is the Senior Director and a member of the Riparian leadership team based out of the Virginia / Washington D.C. area. Susan is a licensed attorney with over 25+ years of experience working with life science manufacturers providing support for their interactions with federal pricing programs. Susan focuses on GP compliance solutions and strategic decision-making and has long-standing relationships with industry leaders in government, law firms, and industry executives from large, medium and small pharma.

About Our Contributors

David S. Chan

Co-Founder & CEO, Riparian LLC

David S. Chan is the Co-Founder and CEO of Riparian LLC, which provides software, outsourcing and consulting solutions to Life Sciences manufacturers. David has overall responsibility for the strategic direction, product development, sales, operations and specific client initiatives. David brings 20 years of experience leading revenue management and contracting teams in the life sciences.

Cynthia Hwang

Co-Founder & Senior Vice President, Riparian LLC

Cynthia Hwang is the SVP of Consulting and Managed Services and one of the Co-Founders of Riparian. She has two decades of experience advising a variety of clients in the life sciences industry – including generic drug manufacturers, "traditional" brand drug manufacturers, and manufacturers of specialty therapeutics (including gene therapies). Cynthia is a regular on the speaking circuit covering a variety of operational and compliance matters. Her responsibilities include overseeing the execution of the majority of Riparian's consulting and managed services projects, maintaining high client satisfaction, providing product direction and design, and growing sales.

Contact Us

Email: info@riparian.com
Website: Riparian.com
Phone: 646-809-4201