Aligning Access Investments to Today's Payer Realities

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Establishing market access and reimbursement for new pharmaceuticals is perhaps harder today than at any point in the industry's history. Manufacturers can leverage rebates, price protection contracts, and co-pay assistance programs to achieve access goals but must make and time these investments carefully to avoid unsustainable erosion of profit that is challenging to reverse.

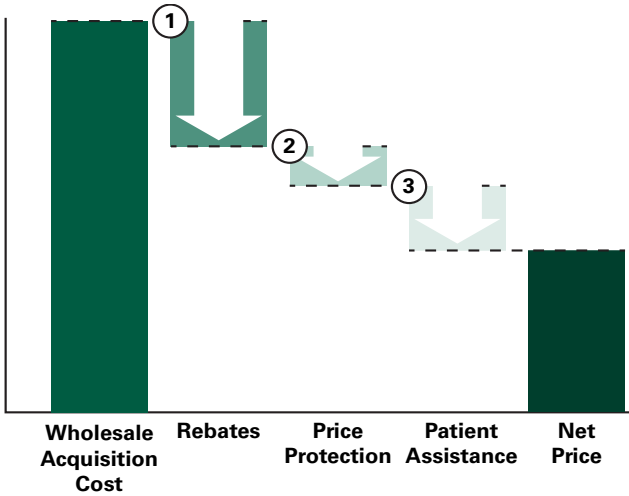
In the early 2000's, the pharmaceutical industry's "golden age" of primary care blockbusters was reaching a pinnacle when several drugs eclipsed $5 billion in annual sales. Pfizer's Lipitor reached $13.7 billion in peak sales in 2006, while AstraZeneca's Nexium and Bristol-Myers Squibb's Plavix reached peak sales of $5.2 billion and $9.3 billion respectively in 2007 and 2011. In this environment, payer consolidation was just picking up steam and PBMs remained largely focused on negotiating rebates rather than aggressively implementing utilization management controls. In turn, manufacturers of market-leading products were able to offer moderate access rebates for stable, favorable formulary access, while simultaneously and predictably increasing prices.

By the turn of the decade a number of trends converged to rapidly change the U.S. market access landscape. Opportunities in large chronic diseases became increasingly scarce and highly competitive. Manufacturers turned to rarer, more complex conditions and developed biologic and specialty drugs at prices that often exceeded $25,000, and sometimes $100,000, per year. Specialty care became the fastest growing category in healthcare spending and payers found themselves, consequently, under growing financial pressure and needing to more actively manage use of these specialty drugs.

At the same time, major consolidation was occurring among payer organizations along with benefit restructuring that created more sophisticated utilization management controls and shifted greater costs to patients. Payers were establishing greater influence across the healthcare market and realizing a more direct impact on physician prescribing and patient demand. In turn, payers used this leverage with manufacturers to demand deeper rebates and establish price protection contracts. Furthermore, payers' narrowing of formularies and cost-shifting to patients accelerated prescription affordability challenges and the expansion of manufacturers' co-pay support programs. These forces have collectively reshaped the access landscape for innovative pharmaceuticals in ways that critically impacted the cost of establishing access.

As manufacturers grapple with the evolving access landscape, it has become critical to think about rebating, price protection contracts, co-pay support, and government program exposure as an integrated access investment. Each of these factors plays a unique role in the widening gap between gross and net sales for pharmaceuticals (Figure 1). Understanding the evolving nature of each of these factors is critical for manufacturers to develop and balance strategies that focus on achieving commercial goals while avoiding unsustainable profitability erosion.

FIGURE 1 Gross-to-Net (G2N) Factors and Their Impact



In certain circumstances, the combination of these three investments can result in >50% impact on profitability

1. Rebating, particularly in competitive categories, typically has the greatest impact on net sales
2. Price protection terms will impact net sales when price increases exceed negotiated ceilings
3. Co-pay cards, coupons, and free trial offers significantly impact net sales especially when exposed to HDHPs* and/or limited long-term persistence

*HIGH DEDUCTIBLE HEALTH PLANS

Rebates Expansion: Risks & Unintended Consequences

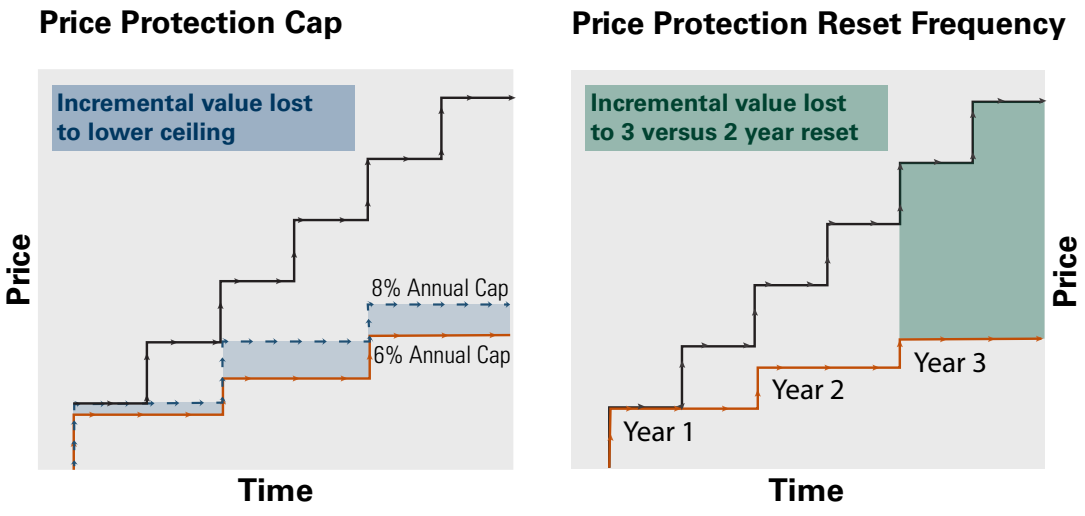
Rebates are one of the most common concessions made by manufacturers to establish favorable access. However, over the past decade, the magnitude of rebates has dramatically increased with a predictable impact on profitability. In March 2018, Johnson & Johnson (J&J) released their 2017 transparency report, which disclosed that J&J paid a staggering $15 billion in discounts and rebates that year. J&J is not alone. From 2007 to 2014, Sanofi saw concessions on wholesale prices increase from 20% to 40%. AstraZeneca saw concessions expand from 30% to 60%. As this trend is expected to continue, it is critical for manufacturers to reevaluate the expected value of formulary access, identify strategies for insulating against deepening rebates, and account for expected profitability loss by "right-sizing" other access investments, such as co-pay support programs.

While rapidly expanding rebate depth reflects the general trend in the industry, the magnitude of rebates can vary greatly by drug class and level of in-class competition. AstraZeneca and Sanofi's portfolios, for example, index highly on large, chronic disease drug classes (e.g., COPD, diabetes) with modest clinical differentiation and significant competition, enabling payers to easily alternate between preferred drugs in order to drive deeper rebates. On the other hand, companies focused in less competitive or more severe conditions like oncology or orphan diseases often maintain more stable margins with lower rebates. For example, Celgene, with portfolio revenue driven predominantly by the oncology drug Revlimid, has maintained aggregate rebate levels under 15% from 2009 to 2014. Forward looking manufacturers must strike a delicate balance between development risk and market saturation in order to manage rebate impact at the portfolio level.

Limits to Price Protection Contracting

A typical price protection contract may cap annual wholesale acquisition cost (WAC) growth at 6-7% which can delay or prevent the financial value of taking pricing increases above this ceiling. Contract lengths vary depending on the type of payer. Commercial payers may seek price protection contracts for two to three year terms while Medicare plans will often negotiate terms of one to two years. At the end of a contract, when WAC typically resets, large MCOs and PBMs will often attempt to negotiate a portion of the cost of the WAC reset into the next cycle's base access rebate, offsetting revenue gains from the price increase (Figure 2).

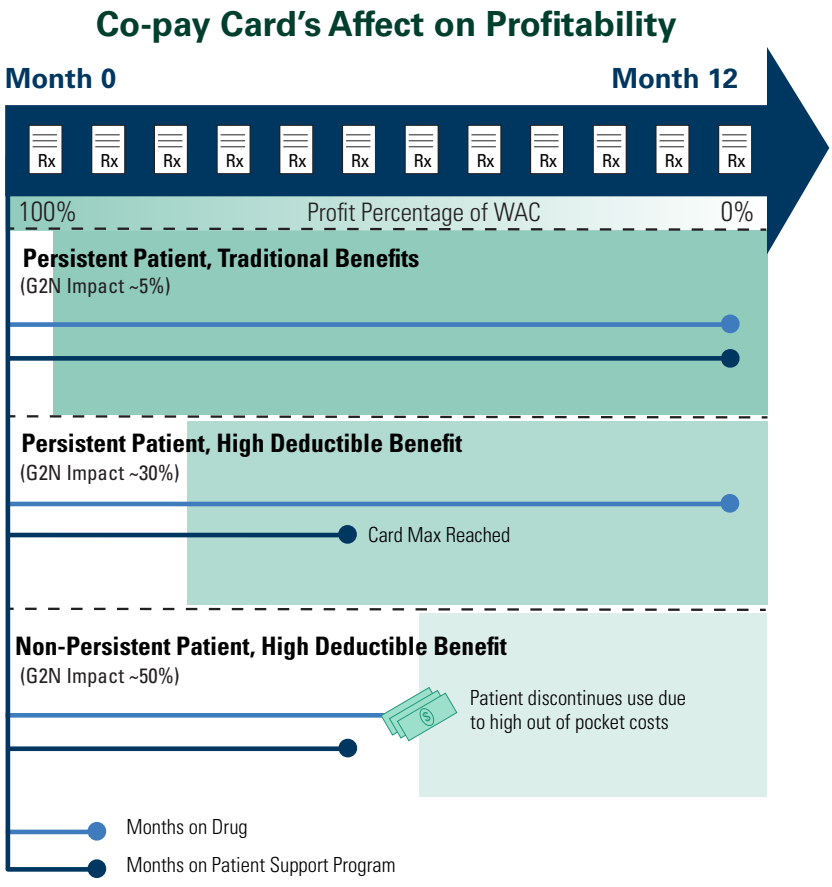
FIGURE 2 Avoiding a lower price protection ceiling can allow greater capture of value from annual price increases. Avoiding longer (e.g., 3 year) reset freqency is also critical to capturing value from annual price increases.



The ability to set and raise drug prices has historically represented a key lever for manufacturers to address business objectives. Manufacturers, for example, may have historically launched new products at price points that optimized access, knowing price increases could be leveraged to accelerate revenue growth in conjunction with volume growth. It is clear, however, that such control over price may not be achievable today.

Where possible, manufacturers should strive to establish price protection terms that have a high ceiling (e.g., >10%) and one or two year reset frequency. These terms should be customized to the manufacturer's specific brands, rather than across portfolios, in order to maintain greater flexibility in customizing list price changes to the realities of each brand's market position.

FIGURE 3 Co-pay assistance programs can become more considerably more expensive when patient persistence is low or coverage extends to patients in a deductible period



When market-leading payers demand significantly more aggressive price protection terms, manufacturers must now consider the combined cost of price protection and rebate concessions on longer-term profitability. The volume gains anticipated through more favorable access may be insufficient to justify the impact on profitability. Consequently, maximizing launch price and temporarily or permanently selling through access barriers may be preferable to offering payers deep rebates and stringent price protection terms that are now often needed to establish unrestricted formulary access at launch.

Patient Affordability: Smarter Patient Assistance

A number of factors have combined in recent years to increase the overall demand for patient assistance programs. The shifting design of health benefits, rise of high-deductible health plans (HDHPs), and increasing rates of co-pay assistance redemption can each exert pressure on the cost of manufacturers' patient assistance programs, creating uncertainty regarding the total impact to net price. While commercial co-pay assistance and Part D donut hole rebate programs represent important access support for many patients, they can represent a substantial impact to profitability. Exposure across these programs should be tracked carefully to predict their financial impact when combined with access rebate and price protection exposure.

Along with evolutions in benefit structure come new concerns around how co-pay programs impact the bottom line (Figure 3). Co-pay card utilization has grown steadily in recent years, with competitive markets seeing utilization rates in excess of 60%. The net impact to profitability that co-pay programs represent is a function of patient out-of-pocket (OOP) costs. Consequently, co-pay card value for patients enrolled on HDHPs, or those with blocked formulary access, may run into the thousands of dollars range if the card value has a high monthly and/or annual ceiling.

As co-pay exposure increases it is critical that manufacturers carry this consideration forward into rebate negotiations in order to protect profitability. To that end, manufacturers must have a robust understanding of how lives segment across benefit structures for key accounts. HDHP pharmacy coverage that is being heavily subsidized by commercial co-pay assistance should not be rebated at the same rate as more "traditional" benefit structures. Understanding this dynamic regarding benefit structure is critical to ensuring access and costs are balanced for HDHP lives.

A clear understanding of patient persistence and average time in the deductible period is also important when designing co-pay support programs (See "Persistency Impact on Co-Pay Assistance Costs). If patient retention is poor outside the time period over which a co-pay program is in effect, the program's true impact to net price may be higher than anticipated. Understanding patient behavior and treatment persistence on an annual basis enables manufacturers to set co-pay card savings length and depth to support prescription fulfillment while also making business sense.

Manufacturer Considerations

Each of the access investments highlighted can have a significant impact on profitability, particularly when not clearly tracked or regularly adjusted to the address evolving commercial goals.

In addition to being the most common WAC concession, rebate contracts typically represent the greatest impact on net price. Rebates at launch for products in competitive and chronic disease areas may start in the 20-30% range and grow over the product's life cycle. Price protection contracts, while new, now represent one of the most common access concessions. Price protection contracts may vary significantly, but can represent an additional 5 – 10% cut to gross price. The impact of co-pay and donut hole assistance programs is ultimately a function of the distribution of pharmacy claims across formulary tiers, overall utilization, and the benefit structures for key accounts. When not carefully designed, co-pay assistance programs can cause prescriptions filled by patients in Commercial HDHPs to generate little or no net revenue (and may represent a net loss in revenue when combined with rebates and price protection concessions).

Ultimately, the combined investments of rebate, price protection, and co-pay assistance can easily expand to represent a 50% or greater impact on net revenue. With this context, it is clear that manufacturers' brand and market access teams must develop strategies with the long view in mind. Only by thinking critically at launch about how gross-to-net considerations are likely to change over time will products have the best prospects of achieving net revenue growth expectations.

Persistency Impact on Co-Pay Assistance Costs

As HDHPs proliferate, traditional co-pay card benefit structures increasingly expose manufactures to profitability risks. Patients on HDHPs using co-pay assistance programs pay the difference between the card value and the drug cost until they meet their deductible limit. For co-pay assistance programs with high monthly or annual maximums, the program contribution during the deductible period can dramatically reduce the value of each HDHP prescription.

Furthermore profitability can be negligible, or negative for HDHP patients who stay on therapy for only a few months or who hit their deductible late in the year. It is therefore critical that manufacturers adapt co-pay program depths and lengths to their specific markets through an understanding of patient utilization and retention dynamics.

Cross Team Coordination

The total impact of access investments on profitability may not always be clear because different functional teams may be responsible for price changes, payer negotiations, and patient assistance. Therefore, teams that lack an integrated understanding of all core gross-to-net considerations run the risk of significantly over- or under-investing in one component. For example, profitability goals may not allow both deep payer rebates and extensive co-pay card distribution. Additionally, price increase levels may need to be reconsidered if they will cause a significant expansion of access rebates where payers refuse to absorb the impact of a price protection reset.

Price growth may not represent the driver of profitability it once did. Robust evidence planning for payers should occur early in the clinical development process to ensure a compelling payer value story exists at launch in order to support higher launch pricing and/or lower rebate requirements to optimize formulary access.

Selling through restrictions and accepting lower initial prescription volume may be necessary to optimize long-term profitability and net revenue. In these instances, it is particularly important that teams align internally around uptake expectations and prepare accordingly. Support services for patients and physicians that help navigate access barriers become critical in these instances, and are most effectively implemented when the entire team is on the same page.

Conclusion

With the present landscape of deepening rebates, stringent price protection terms, and growing impact of patient assistance, it is more challenging than ever to ensure that access strategy can support field sales efforts while also delivering predictable, long-term margin stability. Furthermore, payer consolidation and persistent public scrutiny will only continue to challenge manufacturers' ability to achieve their prescription volume and revenue growth targets. In this new world, success will require marketing, sales, and market access teams to align and make difficult trade-offs between access and profitability goals. The most successful teams will have a clear view of the impact their pricing, access, and patient affordability investments have on profitability and strategies that balance both near and longer-term brand goals.

About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life sciences sector. The firm combines international industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medtech and digital, and diagnostics companies worldwide.

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