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by Valeris

Alternative Channels

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Alternative Channels: Noise vs. A Real Strategy?

Alternative access models have begun to emerge to challenge the traditional PBM-rebate pricing structure that has historically governed how patients access medications in the US market. Whether in response to the shifting policy landscape or as an independent indicator that the GTN bubble was becoming unsustainable, these models offer increased transparency and more choice in accessibility to therapy. But do they really unlock additional access or represent a shift in how manufacturers should think about gross-to-net? Reading between the lines, are these channels "noise" in an ever-complex market access environment or do they realistically open a new strategic lever for manufacturers?

As previously discussed in this series, there are occasionally dichotomous incentives around pricing created by recent policies in the US (e.g., high list high rebate strategies supported by Part D Redesign while lower list lower rebate strategies are incentivized by CMS Negotiations and MFN models). While the dichotomy around pricing strategy remains, these alternative channels potentially enable manufacturers to meaningfully execute on 'lower list, lower rebate' strategies that previously faced barriers given the importance of the PBM relationship within the value chain.

This paper will explore three alternative channels and the potential considerations to evaluate before pursuing each: Cost Plus Models, Direct-to-Patient (DTP) Models, and Direct-to-Employer (DTE) Models.

Cost Plus

The concept of Cost Plus Pharmacies emerged (e.g., Mark Cuban Cost Plus Drug Company) prior to many of the policies reflected in our white paper series to-date, reflecting the challenges emerging with drug pricing and the implications for many patients (i.e., high OOP based on list pricing when paying with insurance). Cost Plus models focus on transparent pricing using a cost plus set fee model that is available to the consumer. While this model has improved access to therapy for many patients with high-deductible plans or uninsured patients, there has been limited traction in the branded drug market, leaving the newest therapeutic innovation available through standard channels and subject to the GTN bubble. In a "net first" world, there may be more incentive for manufacturers to engage with Cost Plus Pharmacy models to offer their products to patients at the same price they are contracting with insurers.

Cash Pay and DTP

While cash pay is not a new concept within the pharmaceutical industry (patients have long been able to acquire certain therapies – those that are deemed lifestyle or non-covered – at cash prices), there has been an increasing focus and utility of the cash pay channel in the past 12 months. The market was likely primed for increasing cash pay options given growing GTNs, evolving pharmacy models, and the rise of punitive plan tools such as accumulators and maximizers. The cash pay and DTP emergence was further fueled by recent policy and executive orders (e.g., MFN pricing, TrumpRx, Letters to Large Pharma).

DTP models represent a broad umbrella of prescribing and distribution approaches that ultimately enable a patient to pay cash for their prescription therapy without submitting a claim to their insurance. Additionally, DTP often, but not always, involves integrations that have empowered patients to own their healthcare decisions (e.g., consumer-like telehealth platforms).

With the increase in DTP demand, the capabilities (e.g., prescribing & telehealth, pharmacy, cash transactions) to efficiently execute these models have rapidly expanded. Some pharmaceutical companies have built internal capabilities to facilitate components of DTP access. Even the

government has become involved, launching TrumpRx, a federal aggregator of "MFN" drug prices that often links patients to either coupons or cash pay sites for their prescription therapies.

A key component to explore when evaluating cash pay / DTP feasibility will be the underlying population readiness to engage in these channels and the implications for volume/price trade-offs. Further, there may be downstream implications on reducing volume through traditional insured channels in favor of DTP (e.g., PBM/plan push back on lack of visibility, limited member continuity, and reduction in rebates as manufacturers shift resources to build DTP infrastructure). As it stands today, the DTP channel may be most feasible for a targeted set of product archetypes or an alternative strategy that is triggered later in the product lifecycle.

Direct-to-Employer

A more novel access model has recently emerged, led by some of the obesity therapy manufacturers, to offer Direct-to-Employer platforms. For this innovative access channel, manufacturers partner and contract directly with employers to bypass the PBM model altogether. The intent of these models is to reduce costs and drive price transparency for the employer, particularly in higher cost or highly prevalent categories.

These models could enable more predictable pharmaceutical spend for employers in certain categories and avoid the temporal component associated with rebates that are passed through by the PBM in the traditional model. Similar to DTP, this model has substantial nuance in how it can be deployed and there are still outstanding questions that remain as this model emerges. For example, how will member cost-sharing influence deductibles? And what are the downstream implications on the PBM-Employer relationship?

Alternative Channel Considerations and Implications

Despite the fervor surrounding alternative or innovative access strategies, it remains to be seen if these models offer a real strategic path to decrease US prices by removing intermediary rebates or ultimately serve as increasing complexity and noise in the marketplace. For example, as you evaluate the therapies that have been offered as DTP or cash prices to-date, they are overwhelmingly therapies that fit into a few product archetypes:

1. Medications without meaningful insurance coverage (e.g., obesity and fertility medications)
2. Medications towards the end of the product life cycle offered via cash pricing as a life-cycle management or share preservation option
3. Medications with existing high GTN spread where the product can be offered at the current net price as a cash price to patients with little additional concession

At this point, it will be important for manufacturers to critically evaluate if and when alternative channel strategies are worth the investment. Further, manufacturers may have to be willing to place bets on more novel pricing strategies (i.e., lower list, lower rebate) to optimize use of alternative channels to drive patient access.

For example, manufacturers must meaningfully consider the cost and volume trade-off that arises when pursuing these alternative access avenues for products that do not fit into the above archetypes (e.g., launch brands, limited GTN erosion). Reasonable cash prices for the manufacturer may still result in higher OOP exposure than most patients are accustomed to, reducing demand. Further, DTE arrangements could have negative

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implications on PBM-Manufacturer relationships and contracting if these arrangements and platforms expand into a meaningful share of the PBM business.

While these channels do create meaningful additional avenues to unlock patient access, we at Triangle Insights Group believe these channels must eventually be combined with continued meaningful pricing and PBM reform to truly drive change in the marketplace and genuinely unlock 'low list, lower rebate' pricing strategies. Until those market factors align, these additional channels are likely to remain as alternatives for specific product archetypes.

In the absence of major market reforms (e.g., PBM reform), we could also envision these channels serving to further fragment the US market. For example, manufacturers may start to consider multiple channels throughout the lifecycle of a therapeutic to manage GTN or coverage depending on their relevant patient population(s).

We'll be watching for market signs that suggest these access channels (DTP, DTE) unlock meaningful strategic value across more product archetypes but in the meantime, these channels may be self-limiting to a smaller set of product categories.

In summary, for manufacturers exploring alternative channels, it will be critical to evaluate the product and market characteristics to determine if these channels unlock access or create complexity.

Manufacturers should have solid expectations of anticipated coverage and GTN over the product life cycle to determine if (and when) new-to-market brands should invest in these alternative channels and which channel will be most meaningful. Connect with Triangle Insights Group to define realistic, strategic, and actionable access channel strategies.

Strategic Considerations

1. As manufacturers consider investing in alternative channels for new product launches, they should carefully consider the cost and volume tradeoffs that may result.

2. The implications on stakeholders across the value chain should be carefully integrated into alternative channel planning (e.g., PBM/plan pushback, potential lack of impact on deductible for patients when pursuing DTE)

3. Careful review of the underlying product, market, and patient characteristics to determine readiness for engagement with alternative channels.

4. Execution considerations should be tailored to the product and patient population to bring an alternative channel strategy to the market (careful consideration of required tech platforms, partnerships, integrations with existing infrastructure, and data demands)

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