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OUT OF CONTROL: THE EVER INCREASING PRICE OF PREFERRED FORMULARY ACCESS

The pharmaceutical industry needs to use new and better data to accurately measure how much it is willing to invest in avoiding plan control

By **Mason Tenaglia**

For Big Pharma recently, the cost of achieving high-quality formulary access for branded products has increased dramatically. Factors driving the spiral include the growing ability of managed care organizations to exercise market power in curtailing product choices for patients, which manufacturers fear can lead ultimately to a loss of market share. Managing—and ultimately reversing—this trend is a key strategic challenge for the “C suite.” The burning question to tackle: How can manufac-

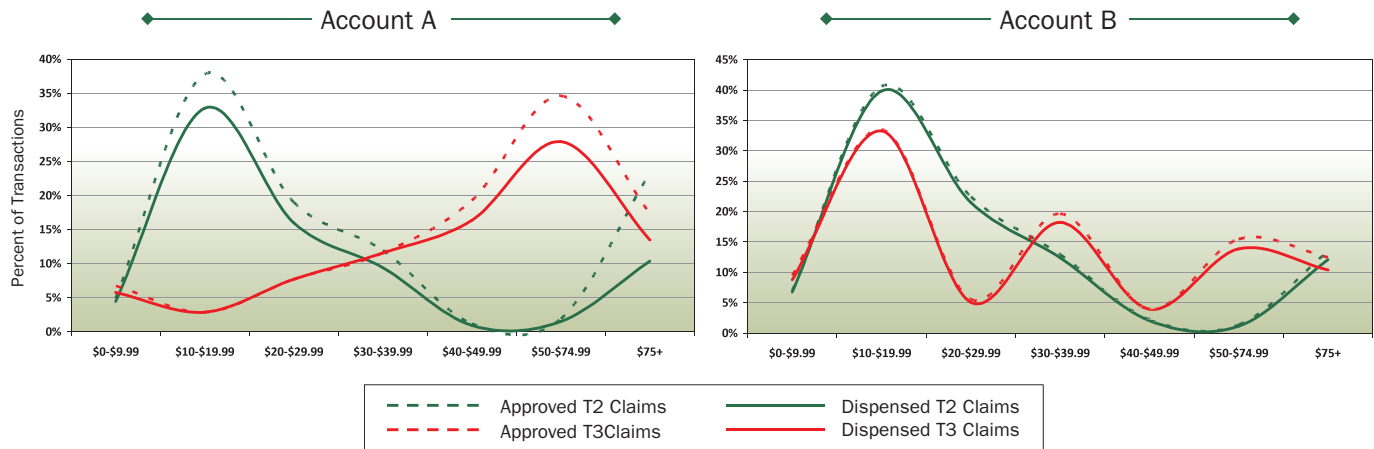
turers do a better job of quantifying payer control in order to secure more consistent returns from their access investments?

“Voluntary” rebates, those paid by manufacturers for preferred access on commercial and Part D formularies, have become the single-largest expense for promoting branded products in the US market. By our estimates, and those of investment analyst Richard Evans, ethical pharmaceutical companies will write checks back to pharmacy benefit managers (PBMs)

Table 1

Payer Ability to Control Through Co-Pay Varies Widely Across Plans

Preferred and Non-Preferred Brand Co-Pay Distribution for 2 Commercial Insurance Plans



Source: Wolters Kluwer PTD 2010

and insurers for almost \$30 billion in 2011. This is almost three times the amount that the federal Office of Management and Budget (OMB) estimated it had spent on sales forces in the US in 2010.

What is even more striking is how fast this expense has grown in the last 10 years. Access to data that we have reviewed, deconstruction of PBM and pharmaceutical financial statements, and the federal Office of Inspector General (OIG) reconciliation of Medicare Part D plan performance and “risk corridors” lead us to estimate that the price of preferred quality access is going one way: up. Over the past five years, charges for rebates and other methods of obtaining preferred tier access have risen from around 10 percent of gross US branded sales to almost 15 percent. For brands in the highly competitive classes, averages grew from 25 percent in 2005 to 40 percent in 2010. For comparison, rebates even for highly competitive products in the mid 1990s might have been at most between 10 percent and 15 percent. And in the extreme there are mature and clinically undifferentiated brands where Medicaid “best price” concerns are overcome, and where manufacturers shave as much as 70 percent off list price on each prescription back to the payers.

There are still a few therapeutic classes such as Oncology and HIV, and a handful of truly unique products that largely pay

nominal or even zero rebates for preferred formulary access. Overall, however, the growth of rebate spending and the growing gap between gross and net sales are keeping a lot of US general managers awake at night.

The Stimuli

How did the price of preferred access go up so rapidly? The short answer is that the plans have demonstrated greater power to control market share in many therapeutic classes, and the manufacturers have been more than willing to pay to be on the good side of that control, or to ensure that it wouldn't be used against them.

Three factors have given the plans more market power: consolidation, Part D, and the ability and willingness to use step edits and prior authorizations (PAs) to manage access.

The continued consolidation of PBMs and insurers gave each of them more volume under their control and better intelligence for their negotiations. More lives under management provided more leverage. However, it was newly gained information that had the greatest impact. When United Healthcare Group acquired Pacificare/Prescription Solutions and CVS merged with Caremark, one of the first actions each took was to compare the rebate contracts between their two previously independent organizations. Within only a few months,

each combined entity called manufacturers back to the table and demanded that they now get “most favored nation status” for whichever of their entities had a less-rich contract. For many large and visible brands, this led to renegotiation of contracts and five percentage points from gross sales in additional expense.

The introduction of Part D in 2006 only served to raise the value of preferred access and increase the potential cost of non-preferred status. By 2007, Part D plan sponsors began to see that substantive copay differentials were insufficient to drive utilization from Tier 3 to Tier 2 brands. In many plans, the lion's share of the volume for brands was originating from the Low-Income Subsidy (LIS) enrollment, which paid the same “out-of-pocket” for preferred and non-preferred brands and only \$2 more than generics. PBMs and insurers quickly began to employ “generic first” step edits and PAs for non-contracted brands and have continued to punish those who will not “pay to play.” Today, as a result, rebates in Part D can be considerably higher than in commercial contracts.

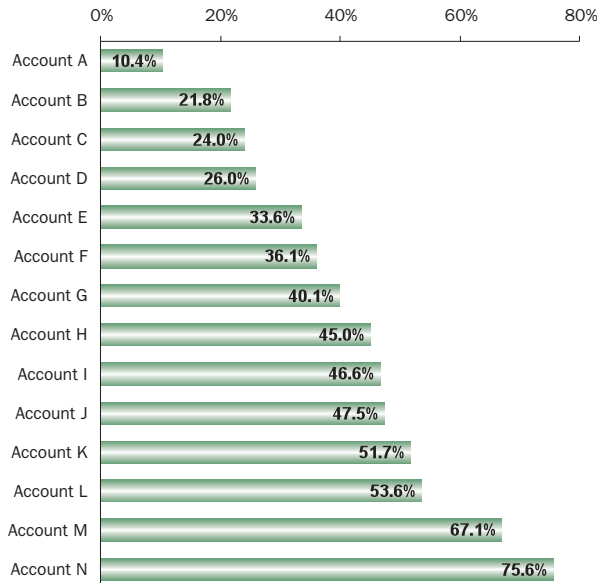
Unlike commercial drug beneficiaries, Part D patients can't turn to their employer with concerns about utilization management. Nor can they use copay offset programs to get their out-of-pocket down to the preferred (Tier 2) copay, as these programs are current-

Table 2

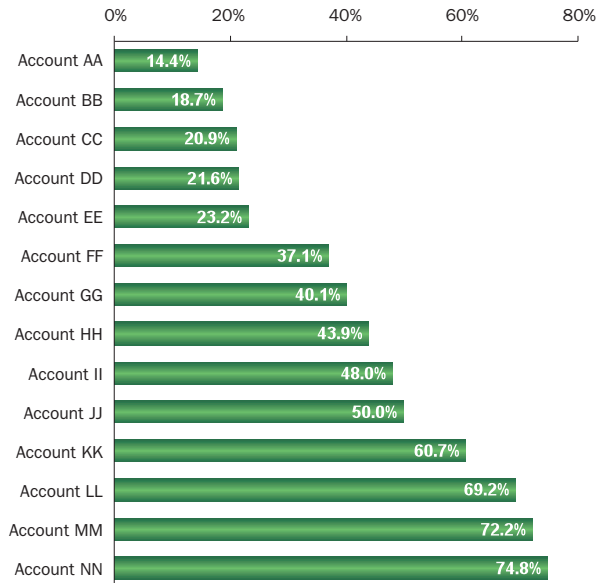
Effectiveness of Utilization Management Across Plans

While MCOs may implement low-cost ST or high-cost PA, their effectiveness varies widely from account to account, even in the same therapeutic class

% of BRAND New Patient Starts Prevented from Getting Through **ST** Restriction Within 3 Months



% of BRAND New Patient Starts Prevented from Getting Through **PA** Restriction Within 3 Months



Source: Wolters Kluwer PTD 2010

ly considered an illegal inducement by the Centers for Medicare and Medicaid Services (CMS). A Part D patient’s only recourse is to wait until the new plan year and then find a plan sponsor who has their drug of choice in a preferred position. However, there is little evidence that this kind of switching is taking place. Rather than switching plans, Part D members appear to be switching brands.

What’s Steering the Ship?

The slate of patent expirations in the last few years is the last driver that empowered commercial plans to extract higher rebates through the threat of a “generic first” step edit. The arrival of multi-source simvastatin (Zocor), omeprazole (Prilosec), and alendronate (Fosamax), among others, each gave PBMs and payers a newfound ability to move market share away from non-contracted brands. Initially, the copay differential between non-preferred brands and generics moved many patients voluntarily to the lower cost alternative. However, in many benefit designs, copay differentials were insufficient motivation for patients to abandon

their branded prescriptions. So, plans began to introduce both prior authorization and step edits through a generic before a non-contracted, non-preferred brand could be filled. Manufacturers were quick to see the potential volume loss from this tactic and capitulated to those plans that had the ability and willingness to impose these utilization control measures. In some classes, particularly those with fungible brands, even the threat of a step edit was sufficient to up the rebate ante.

In the commercial channel, manufacturers have had an alternative to contracting. Direct-to-patient subsidies, such as coupons and copay offsets, are often less expensive but also less efficient than contracting for a brand, as they will only be adopted by a fraction of those exposed to higher copays. Brands that either were unwilling or unable to contract for preferred access have developed extensive copay offset programs using e-vouchers, copay cards, and coupons to pay patients down to the Tier 2 out-of-pocket expense. Payers are taking note of these programs and are voicing their concerns about

offsets that reach down to the Tier 2 out-of-pocket, or in the case of Lipitor’s “pay no more than \$4” program, to Tier 1.

But even this option has the potential to go away. United Healthcare recently created yet another mechanism for reducing the utilization of non-contracted brands. In January, it introduced a “Special Designated Pharmacy,” which is the only means for some of United’s members to obtain a refill of 20 non-contracted brands. These can only be filled via United’s mail-order pharmacy, which, conveniently, does not accept coupons or copay offsets. United’s primary motivation, however, is to reinforce its ability to drive market share to preferred, rebated drugs and provide a return to those who invest in formulary position.

Manufacturers Speak Volumes

While the plans have demonstrated increased control, manufacturers have become increasingly willing to pay for preferred access. It is their own behavior that has driven up rebates as a result of irrational exuberance over the universally accepted value of preferred or Tier

2 access. Most executives who are currently leading pharmaceutical companies grew up in the age of the big blockbuster products, when getting on formulary at any cost was a priority. When big launches produced multibillion-dollar products, and when the price of access was 5 percent to 10 percent of gross sales, the relative cost of contracting was insignificant to the overall success of a franchise. Volume drove everything, and more volume papered over many inefficient investments in sales and marketing.

Many of today's general managers still believe that they need at least 80 percent Tier 2 coverage within 12 months of launch in order to succeed long-term. They are willing to pay nearly any price for that access. Today, however, the launch of a non-differentiated product has lower dollar potential. Generics are a reasonable alternative to many marginally innovative products. And the cost of access in many therapeutic areas can be 25 percent to 40 percent of gross sales, or even higher. The heuristic premise of gaining preferred access at any cost may no longer ensure a profitable business, and the 80 percent target is unrealistic. It can lead to disappointing net sales, gross margins, and profits.

Selective Solutions

To slow the growth of rebate spending and continued deterioration of margins, pharmaceutical manufacturers will have to be a lot smarter and more selective about where they invest their sales dollar. The current process for segmenting based on "plan control" is inherently flawed and is often based on the wrong information. Most manufacturers will segment accounts based on whether they are "high control" or "low control," with those designations being made by the historical perception of their own field organizations. They may also turn to third parties to gather data on the current formulary status of competitors in a class in their published formularies, which will quantify the difference between Tier 2 and Tier 3 out-of-pocket. However, these estimates, based on the payer's dominant formulary rarely reflect the experience for the majority of patients. Every insurer and PBM manages hundreds of benefit designs for their large and small group customers, and many of those designs don't provide the copay differential between preferred and

non-preferred tiers seen in the published formulary. Many public-sector employers, unions, and public retiree organizations still maintain open formularies with \$5 and \$10 out-of-pockets even for non-preferred brands (although this may soon change in Wisconsin). Our own experience is that most manufacturers' current contracting approach frequently results in gross overpayment for Tier 2 coverage.

A better approach for segmenting these accounts and their control is to look at an actual distribution of adjudicated claims in the class of interest. A comparison of these adjudicated claims for Tier 2 and Tier 3 products can provide a much better picture of where it may be valuable to invest in preferred access in any given payer. In Table 1, we have presented a picture of preferred and non-preferred patient cost exposures for two distinct plans in 2010. Plan A has a clear differential, which will lead to higher abandonment and more switching off the Tier 3 drug. For those who do fill the prescription at the higher copay, the brand can expect lower overall patient adherence. What a manufacturer should be willing to pay for on each of these two accounts can be calculated using those measures and is often well below the plan's asking price.

For launch planning, many manufacturers will use primary research to identify likely control characteristics of plans. Although market research firms can provide anonymity for the product in question, they also will not have any empirical evidence on which to ground responses. When they do ask, every plan says every new product is "non-differentiated" and will require at least a 30 percent rebate to get on formulary, or will be stepped or prior authorized into oblivion. Do you believe them?

Despite the threat of imposing a step edit or prior authorization, not all plans are willing or even able to implement such utilization management processes. In many therapeutic classes, more than 50 percent of commercial volume will be found in plans that don't employ utilization control in primary care products. Even those that do frequently use prior authorizations and step edits should not be taken at their menacing word. Some plans really have no teeth in their utilization management efforts.

Power of the Plan

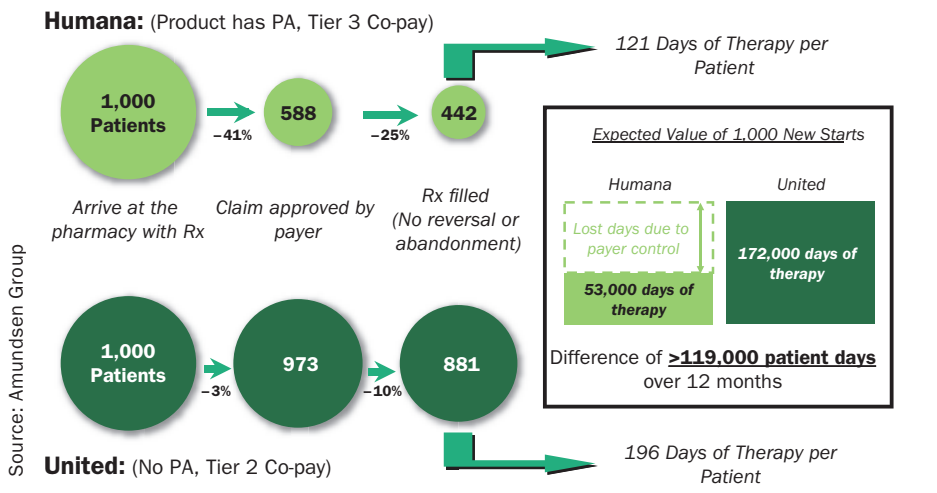
Again, empirical analysis suggests a very wide range of results across plans for how much impact each step edit or prior authorization really has on brand performance. Dynamic claims lifecycle (DCL) data has been providing manufacturers with measures of how many claims actually get rejected or abandoned for each major national and regional payer. However, this data, while directionally correct, is not necessarily reflective of the true power of the plan. By combining rejection and reversal data with a longitudinal data set, payer analytics groups can actually measure the lagged effect of utilization management techniques. Sure, some plans initially reject many transactions, but how many patients (or their physicians) manage to work their way through the administrative red tape to get their originally prescribed product? The answer can be surprising.

In Table 2, we tracked patients through step edits and PAs in both commercial and Part D accounts for a single high-volume product. We were not surprised to see that not all utilization management efforts are created equal. In fact, in that one class [from the table], there are plans where 90 percent of patients have successfully navigated through a step edit or PA and others where more than 90 percent of interventions have stuck in place. A major driver of the differences can be whether continuing patients on a non-preferred brand are grandfathered in. But equally important is whether the plan really has the ability to employ utilization management to its upstream customers. Many employers, unions, and pension plans really don't want to use these measures nor are they willing to accept the irate phone calls from their insured members. In some plans, the PA or step edit may only apply to a small fraction of the customers and formularies under a PBM's control.

By combining these two empirical measures, manufacturers can more accurately estimate the potential loss from having non-preferred status. By capturing patients' longitudinal history at a payer level, brands can get valuable insight as to the economics of a product with or without contract and similarly with or without utilization

Table 3

Case Study: Impact of PA on Product Adoption



management. As a way of normalizing these metrics across accounts of different sizes, we have quantified the value of 1,000 new written prescriptions and follow them through the adjudication process and forward for 12 months. When we present these empirical data back to clients they are often shocked by exactly how important it is for them to avoid a PA or a step edit in many of the highest control plans.

In Table 3, we have provided one such comparison for a single product. In 2008, United Healthcare had this product on Tier 2 unrestricted, while Humana employed a fairly strong prior authorization on the drug. In our analysis, this manufacturer lost over two-thirds of the potential days of therapy per 1,000 new patients in Humana as a result of the utilization management and the higher out-of-pocket expense

for those that did fight their way through the PA. These differences can also be “dollarized” to estimate the opportunity cost of losing a preferred position. Our estimates, using this approach, suggest that manufacturers should have been willing to pay much more to avoid utilization control—usually many percentage points better than their best and final offer. At the same time, however, they may be able to cut back significantly in other plans where PA and/or step edit interventions have little lasting impact.

We believe that the industry needs to use new and better data to accurately measure how much they are willing to invest to improve tier placement or to avoid step edits and PAs. By comparing the dollar value of 1,000 written prescriptions across high control plans, and across those never restricting their formularies, manufacturers can have a true empirical measure of plan control that can be used to calibrate their rebate spending. This index of payer control must be developed and then employed by the industry if the trend in rebate growth is ever to be slowed or—better yet—reversed. **PE**

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At The Amundsen Group, we believe that achieving high quality of access to prescription medications is critical to pharmaceutical brand success. Payers have become increasingly sophisticated at managing patient utilization, requiring greater concessions for formulary placement, and shifting more and more cost to both the manufacturer and the patient.

But securing high quality of access need not translate into reduced profits. With the wealth of transactional, longitudinal, and claims data available today, granular detail can be extracted and analyzed to transform a brand's access strategy. Understanding patient and physician behavior when confronted with increased cost-sharing, tougher restrictions, and other competitive threats across therapeutic classes and geographic markets, is the key to increasing product returns.

The Amundsen Group is a pharmaceutical strategy consulting firm that provides unparalleled analysis and insight to Brand, Managed Markets, and Market Research teams. We bring new insights to our clients through our:

- Extensive understanding of the US reimbursement landscape and knowledge of the payers who can influence brand performance
- Experience in measuring patient sensitivity to cost-sharing and other formulary management controls (e.g., prior authorizations and step edits)
- Expertise on geographic variations in payer, provider, and patient interactions
- Depth in linking, analyzing, and interpreting a variety of third-party healthcare data supported by our extensive IT infrastructure

Since 2004, The Amundsen Group has provided pharmaceutical clients with the critical metrics, analytics, and insights needed to ensure that their investments in managed markets and direct-to-patient initiatives generate the highest returns.



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