Payer Influence

on Product Performance in the

Pharmaceutical Industry

White Paper

AXTRIA
INGENIOUS INSIGHTS

Michael P. Diggin is a Director at Axtria.

This document focuses on the influence Payers (Healthplans & PBMs) exert in the Pharmaceutical marketplace and the impact on performance at a product-level.

Marketplace influences extend from prescribers to patients and are often driven, with varying degrees of effectiveness, by a payer's ability to control formulary compliance.

We will explore how tools and analytics can enable a Pharmaceutical manufacturer assess factors impacting formulary control and incorporate those findings to evaluate contracting opportunities and related decisions. These approaches can be leveraged to understand the various ways (levers) payers use to control product utilization and their direct and indirect ("spillover") impact they have on prescribing. "Levers" include various formulary access controls such as Prior Authorization, Step Edit, and Tier Position/Co-pay. A true understanding of these components can have profound implications on contracting terms, rebates, and actually extend to other areas such as Targeting, Incentive Compensation, etc.

Understanding a Payer's ability to control its formulary is an important issue and one that Pharma needs to factor into contracting decisions, allocation of promotional budgets (personal & non-personal), and other commercial areas. Without a true understanding of a Payer's level of control, Pharma may make sub-optimal decisions with regard to rebates and/or the level of resources required to effectively manage pull-through activities.

Background

In recent years numerous market forces have surfaced requiring Healthplans to adapt their business models to stay competitive. These market forces include changes in reimbursement models driven by Healthcare Reform, focus on quality-based outcomes required by employers, and the rise of Organized Customer Groups such as Integrated Delivery Networks and Accountable Care Organizations.

Payers are seeking ways to control high cost line items, including the utilization and cost of pharmaceutical drugs. The establishment and enforcement of formularies often play a key role in managing pharmaceutical costs. A formulary is a list of prescription drugs, both generic and branded, that are selected by a payer as the most effective and cost efficient way to treat a disease state. The purpose of a formulary is to steer prescribers and patients to use the preferred prescription medications. Patients will pay more for a medication that is not covered on a payer's formulary.

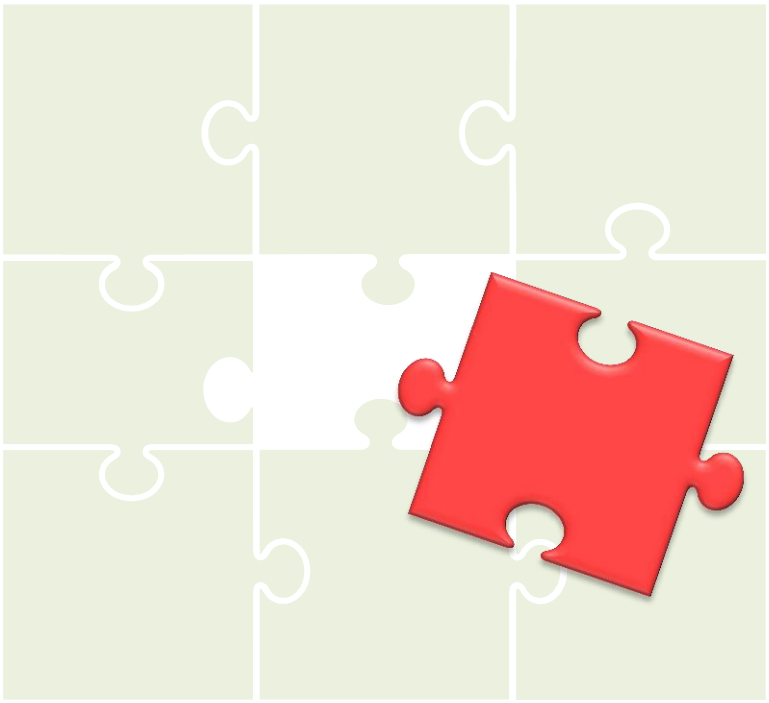
Pharmaceutical manufacturers can be involved early in the formulary process by educating healthplan decision-makers about their products. As decisions are finalized and if their product is added to formulary, Pharma may negotiate contracts with payers regarding terms and conditions related to pricing, tiers, restrictions, etc.

As noted earlier, understanding a Payer's ability to control its formulary is a key factor in contracting decisions as well as the allocation of promotional budgets (personal & non-personal) that Pharma will use to drive product performance. Without a true understanding of a Payer's level of control, Pharma may make sub-optimal decisions with regard to rebates and/or the level of resources required to effectively manage pull-through activities.

Business Gap

"The ability to control costs and enforce formulary compliance differs across healthplans, often based on size, geographic location, competition, internal policies & procedures, etc."

Rebates and Discounts represent one of the largest line items on Financial Statements of Pharmaceutical Manufacturers, yet the criteria for assessing contracting decisions often lacks the analytical rigor that match the financial exposure. Pre-deal analysis uses inputs from account managers which tend to overestimate both the benefit of contracting and the risks associated of not contracting. This is not a surprise since factors beyond Pharma's control can impact the actual results, including a payer's formulary control and related spillover impacts.



The ability to control costs and enforce formulary compliance differs across healthplans, often based on size, geographic location, competition, internal policies & procedures, etc. More controlling payers (i.e. Kaiser) have strong internal policies and operate in a somewhat defined geography. Payers exerting less control tend to operate on a national basis with numerous sub-plans. This diversity provides more opportunity for local factors to influence processes and is exhibited in the variability of formulary compliance in downstream entities of large plans and PBMs. Pharma needs to recognize these variations and use analytical models to support negotiation strategies that maximize product performance.

Further a payer's ability to effectively control and enforce its formulary may vary by therapeutic area (TA). Therefore, factors used to make a contracting decision for one TA may not be applicable across a Pharma company's portfolio.

Payer Levers

Once a product is placed on formulary, payers use a variety of ways (levers) to exert control/influence over their members and prescribers. In response, prescribers and Pharma Companies use several methods, where possible, to reduce the impact of payer levers. Examples are discussed following a brief review of each payer lever.

- Variances in Patient Co-Pay requirements, often directly associated with formulary tiers, are the most common way payers manage formulary compliance. This "lever" passes a portion of the cost for medications directly to the consumer (patient) based on the positioning of a product on the payer's formulary. Generic and preferred-branded products will have lower co-payments while non-preferred products will require the consumer to absorb a high portion of the cost.

  Pharmaceutical companies have developed a number of approaches to address this lever. Co-pay cards are commonly used to bridge the gap between a consumer's out-of-pocket cost for preferred vs. non-preferred products. Payers do not normally support co-pay cards as they drive utilization away from preferred products, potentially impacting their overall costs, including lost rebates.

- Prior Authorization is a cost-control feature directed at the prescriber, requiring additional steps (paperwork) to be completed prior to a medication being approved for coverage. As a control lever, payers use prior authorizations as a vehicle to deter utilization of medications that are not on formulary. Prescriber behavior is often influenced and formulary adherence improved as prescribers look to avoid the administrative costs of processing prior authorization requests.

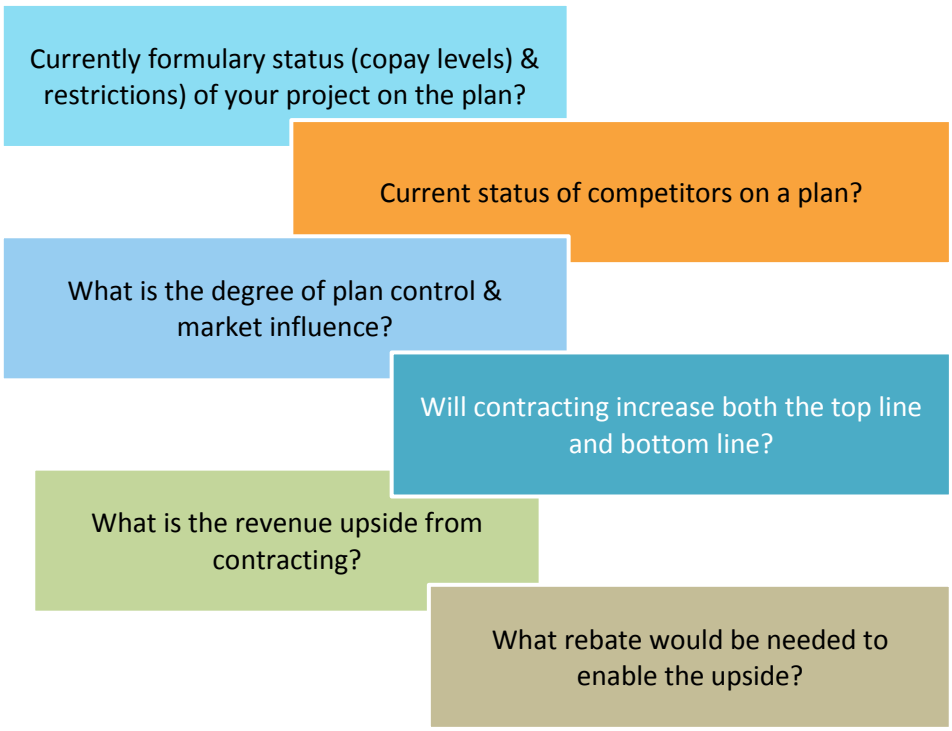
  Prior Authorizations are seen as a nuisance for prescribers, primarily from an administrative perspective. If a payer approves PAs on a regular basis and in a timely manner they may not have the desired impact on modifying prescribing habits. Further, Pharma reps often work with office staff to provide PA approval forms that a patient receives when the script is written, thereby eliminating the need for the office staff or prescriber to address the script a second time.

- Step Edits are also prescriber-focused controls requiring a patient to use a medication pre-determined by the payer as the most efficacious and cost-effective for a disease state. Other medications will not be covered unless the prior (preferred) medication proves ineffective for that patient. Double step-edits are also used which indicate the second medication that must be used should the initial one prove to be ineffective.

  Step edits are one of the most effective ways for a payer to control its formulary Prescribers have limited options until the patient fails on the preferred medication(s).

Closing the Gap through Analytics & Insight

A good process for contracting decisions needs to consider the quantitative ramifications of contracting and meet the needs of multiple organizational stakeholders. As highlighted in Diagram 1, In order to effectively implement a successful contracting strategy Pharma needs analytical tools to address several key questions related to market conditions and related variables. These include quantifying a payer's ability to enforce controls on prescribing, assessing a product's forecasted performance at higher vs. lower co-pay levels, and measuring the effectiveness of a well-designed co-pay card program. Insights resulting from this analysis can directly influence contracting decisions including terms, rebate levels, tier placement, etc.

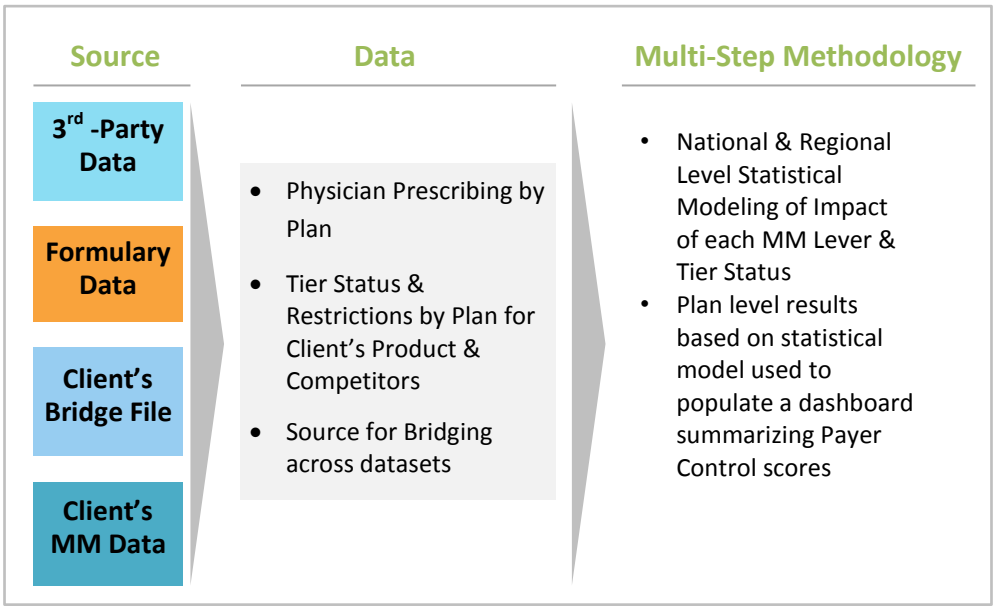


If it is determined that a payer can exert high control, the need to secure favorable formulary positioning increases. This may lead to aggressive rebating in order to secure the business and maximize product performance. Budgets allocated for pull-through may be relaxed as the payer's control will be a tremendous asset in driving product utilization.

Conversely, if analysis reflects that a payer is not effective at controlling formulary adherence, a Pharma manufacturer may pursue a less favorable formulary status (with lower rebates) and direct more resources to pull through efforts.

Ideally, analysis should focus on quantifying the direct and indirect ("spillover") impacts of payer levers on prescribing. Output should produce a control score that can be applied to each payer in total, as well as a control score for each payer by therapeutic area. As noted in diagram 1, data required to conduct this modeling needs to focus on physician prescribing by plan, payer plan hierarchy, plan level metrics, brand & competitor formulary status, share trends and rebates paid.

Further, through this analysis a plan level "What-If" tool can be developed providing a valuable, dynamic scenario planning tool for Pharma Managed Markets leaders. A tool of this nature provides analysis regarding impacts as a brand moves up or down formulary tiers, if a restriction (PA or ST) is added or removed, higher or lower co-pays are applied, etc. Assessing these impacts and various trade-offs positions Pharma with additional insights that can be applied when negotiating contract terms.

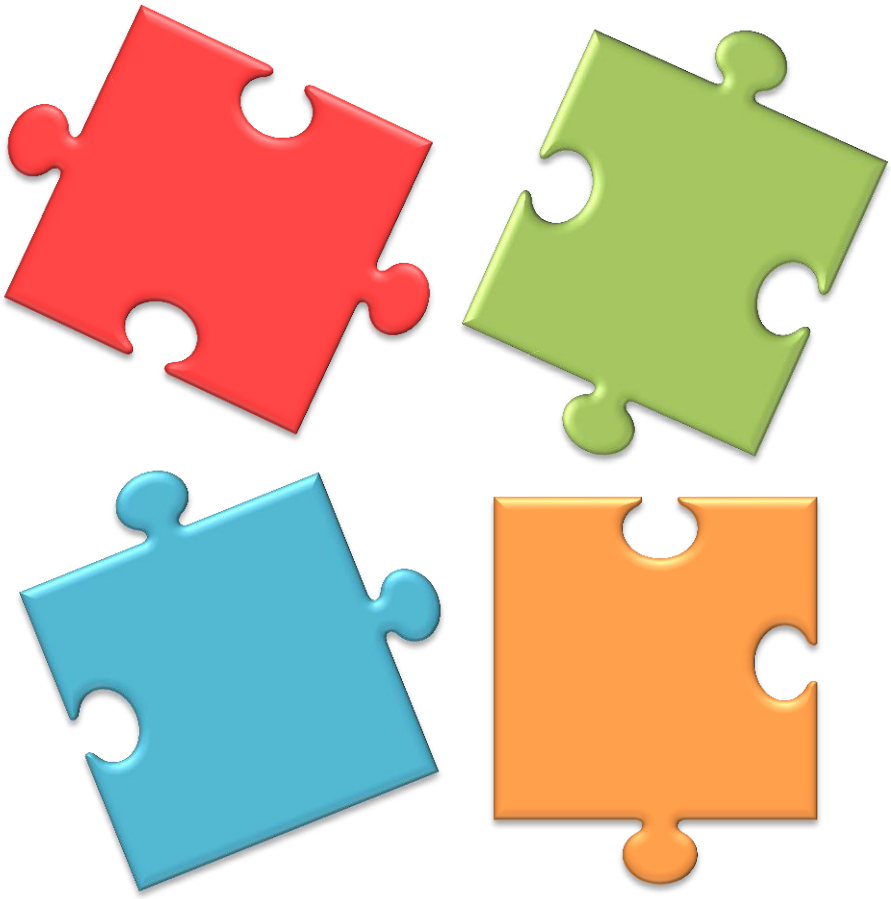


Closing the gap may also lead Pharma companies to look at contracting opportunities through multiple lenses. For example, if analysis indicates that a large Payer struggles to control its formulary at the national level, Pharma may choose to look for opportunities with downstream plans proven to be more effective in formulary compliance. The manufacturer could elect to pursue a less favorable formulary position at the national level (with less rebate at risk) while offering a more aggressive rebates, through carve-out contracts, to a select group of high-control, high-value downstream plans for preferred formulary positioning.

Challenges

A number of Pharmaceutical manufacturers already have pre-deal contract analysis and processes in place today to drive "Go/ No-Go" contracting decisions. The use of control scores in the contract evaluation process should be considered as an addition to current processes, not a replacement. Once models are built and tested, the inclusion of formulary control should supplement other analysis, institutional knowledge, etc. that Pharma currently employs.

Adding another input to the contract review and approval process, focused on formulary control, may present challenges internally. Organizations need to address such challenges openly, allow stakeholders to become comfortable with the analysis, and implement steps that reduce/eliminate potential obstacles, skepticism, etc.



Case Study

Axtria's analysis of Payer Impact on Product Performance demonstrated to a top-tier Pharma client that FFS Medicaid spillover did not yield the indirect impact (spillover) they had anticipated. As a result allocation of resources (personal & non-personal), rebates, etc. were re-evaluated.

Situation:

Top-tier Pharma manufacturer required a better understanding of how managed care formulary elements influence the physician and patient choices for their Primary Care product.

Challenges:

Sales and Marketing/Brand team leadership differed on impact of spillover No formal process in place to measure impact based on Payer control and market influence.

Approach:

Axtria developed an analytical framework and methodology to enable sensitivity analysis that measured the total (direct and indirect) impact of the change of formulary status for a Product. This enabled the Pharma manufacturer to assess 1) the general impact of a product being placed on a lower or higher Tier, 2) the specific impact of different managed care levers (Prior Auth, Step Edits etc.), and 3) the indirect spillover impact of formulary status change on prescribing in other plans.

Results:

- Direct Impact: Managed Care influence was greatest in Medicare Part D, while FFS Medicaid was least impacted by Managed Care
- Spillover (indirect) impact was 9% - 15% of total impact (direct + indirect) across all payers; Managed Medicaid had the highest & FFS Medicaid the lowest indirect (spillover) impact
- MSAs heavily influenced by well established, organized customer groups (IDNs, ACOs, etc.) displayed the highest impact from managed care controls

About the Author:

Michael *is an experienced leader in the Pharmaceutical industry with extensive background and expertise in streamlining operations, developing insightful analytics and building strategies for new and existing markets. He is known for his ability to develop staff and build leaders, deliver results through influencing and collaboration skills, and manage projects across numerous market segments.*

Tel.: +91 123 1234 1234 | Email: michael.diggin@axtria.com

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