Alpha 1C
STRATEGY, MODELING, MEASUREMENT

&

*jointly present ...*

NavAxxess
HEALTH SOLUTIONS

# Seamlessly Linking Your Access & Co-pay Strategies

A Best Practices Roadmap and Timeline to Ensure Successful and Profitable Market Access

# How to Avoid Inefficiencies

It's about linking your strategies

## Overview

**The Market Access Contracting and Patient Co-pay Program strategies and execution are only loosely linked in most pharma companies. As a result, tremendous inefficiencies can result, costing companies and their brands tens of millions of dollars in wasted spending. This issue can also filter down to patients in the form of inconsistent out of pocket costs which can cause increased abandonment and decreased adherence.**

**It is not uncommon to see that the managed markets team handles rebates and contracting with health plans, while either the business units, or even the marketing department handles patient co-pay programs. The absence of a joint analysis frequently results in excess spending and in contradicting strategies. Everyone knows the old saying about the right hand not knowing what the left hand is doing… Something very close to this is happening every day at most pharma companies and it has to stop.**

**In this white paper we'll explore best in class processes for the market access contracting process and the co-pay program planning process and provide recommendations to ensure a successful, profitable and coordinated market access approach.**

## Managed Markets

### Gaining profitable access for brands

Market access contracting has been a core initiative for many pharma companies for years now. Most companies have a dedicated team focused on structuring their contracts with their accounts across the country. These teams are leading the efforts to contract with health plans and PBMs to gain profitable access positions for their products. Clearly, this is an important effort since it is estimated that more than $125 billion dollars is paid annually on rebates by pharmaceutical companies, a trend that will continue to grow fueled by the increasing number of competitive and very expensive "Specialty Products".

The fact is, in most cases, these internal teams operate in a vacuum where they have very little if any visibility to the outside world (retail, specialty, or buy and bill). They usually start the contracting for each brand and may never even think of how a co-pay program may interact with the contracting strategies. For these teams, co-pay is a distant afterthought at best. If the two departments are not talking to one another, there is a very good chance that there could be a discount overlap causing the brand's spending to be much higher than it needs to be… driving gross to net (GTN) down to unacceptable levels. There have been some unfortunate cases where net profitability has gone negative since rebates and additional co-pay programs exceeded 100% of Gross Margins.

The fact is, in most cases, internal market access teams operate in a vacuum where they have very little if any visibility to the outside world … co-pay is a distant afterthought at best.

# The Market Access Process

## Complexities and limitations

### The "Go To" Market Process

In the pharma industry today, everyone sets up their go to market process essentially the same way. Once management sets the strategy and budget, the managed markets department is tasked with managing the brand's efforts to contract with health plans and PBMs to gain what is hopefully a profitable access formulary position for their products. The average brand would have about 40 contracts and a large brand would have as many as 50+ contracts. Larger companies have multiple brands, so for each brand that is another 50+ contracts. The market access team is in constant contract negotiations with PBM's and health plans, most of which are looking to squeeze out every extra penny of profit they can from the manufacturer.

The above is further complicated by the fact that these market access departments must deal with several channels, i.e., Commercial, Medicare, Medicaid Fee-for-Service, Managed Medicaid, Federal (VA, DHA, etc.), GPOs and so on. Each of these contracts will often have very different rebate levels and related conditions such as varying levels of control, different formulary structures and benefit designs, and so on.

At the same time a large company like Aetna could put out a category for request for proposal (RFP). Internally within the pharma company, there needs to be an analyst who will run the different options and costs to come up with the optimal option based on the circumstances. In their sales pitch, the PBM's will tell you that you'll probably get a certain share if you go to a certain level of discount (low) with them… but there are never any guarantees. During times like these there is probably a negligible chance that the market access team is thinking about co-pay program strategies.

### Thinking about Co-pay

When "co-pay program" discussions come up, the most common practice for the managed markets team is to avoid the conversation altogether as they know it can be a hot point of discussion with health plans and PBMs. In addition, most managed markets teams don't have a solid understanding of how the co-pay programs work or how they can/should be integrated into the planning process. This is exacerbated by the fact that programs are most frequently handled outside of the market access department. Hence, market access team members should be trained on how these programs work, the costs involved, and how to handle objections by the managed care organizations. This will make them much better prepared in their day to day jobs and will save money for pharma brands long term.

A comprehensive analysis supporting both market access and co-pay program impact must be done for maximum efficiency and effectiveness.

Some Pharma companies are starting to link these two business functions, even organizing "market access" departments that now cover both these business areas under one roof, but these combined initiatives are in their infancy and are few and far between.

A comprehensive analysis supporting both market access and co-pay program impact must be done for maximum efficiency and effectiveness.

# Planning Your Process

## A best practices approach

### Market Access Contracting Approach

A best practices approach to market access contracting needs to include pre-contract planning, comprehensive post contract analytics to ensure objectives are being met and a solid understanding of tracking data and how to best leverage it.

### Things to Know Pre-Contract

A comprehensive "pre-contract" approach will help ensure that the market access contracts are structured appropriately. Here are a few questions the market access team should agree on prior to finalizing contracts:

- What is the role of the brand within the company's portfolio and what are the objectives for the brand?
- What is the target level of coverage or formulary position requested by the brand?
- What is the "optimal profitability level" expected for the coverage desired by the brand?
- What level of restrictions (step-edits, prior auths) are acceptable to the brand?
- Will the health plan be able to effectively control the formulary and achieve the market share expectations?
- What is the cost of all rebates and discounts that need to be paid for the required market access?
- What are all other ancillary costs associated with the contract needed to calculate an "NPV" and an "ROI" for the contract (such as COGS, royalties, impact to best price, etc.)?
- What are the costs of market access contracting and co-pay programs at different price points?
- How do market access contracts impact co-pay offers and vice versa?
- For existing products, how is the cost of the current co-pay program impacting the specific health plan?


- Will the absence of a co-pay program hinder access to the drug given the negotiated rebate for a formulary position?
- Will the negotiated formulary position make co-pay assistance unnecessary?
- Will the negotiated formulary position result in an affordable co-pay or will it involve a co-insurance that is too high to be paid by the patient?
- Which is a more focused spend? A rebate delivered through a health plan vs. co-pay subsidy via a co-pay program?
- What does an improved co-pay offer really mean for each brand?

### Things to Consider in Planning Market Access Contracts

- What is value of each contract?
- What is the incremental profit for every dollar of rebate spent?
- Looking at historical actual share (from IQVIA or SHS), what if they go on contract or not? By looking at historical rates, you can determine if signing a contract will impact the market share. Perhaps the market share is already too high, or near to the expected market share level on contract.

- How high or how low will market share go and how fast will the market share shift? A pre-contracting model must "predict" how-high the market share will move if the contract is executed, or how low it's going to get if not contracted. By the same token based on the health plan level of control, market share changes will be faster or slower depending the ability of the health plan to exercise strict control on prescription approvals.

# Measuring Performance

## Effective analysis is critical

### Things to Consider Post-Contract

After the contract has been put in place, it is critical to evaluate results to ensure objectives are being met. Here are some of the key questions to ask "post-contract":

- Is the contract achieving the market share, financial expectations and other criteria established during the "pre-contracting" phase?
- If not, Is the variation due to volume, price, competitive pressures, or other reasons?
- If performance is way-off, should the contract be cancelled or re-negotiated?
- Has the projected profit, NPV and ROI for the contract been met?
- What is the break-even market share?
- Which contracts are performing up to expectations and which ones are not?
- Has the health plan complied by positioning the product at the agreed formulary position and made it accessible to patients at a reasonable out of pocket level?
- Are there any instances where patient utilization is hindered by a very high co-pay or co-insurance?
- How will a proposed price increase impact each market access contract? And how will the patient be impacted from an OOP perspective?

  *Example: A $199 WAC, $239 retail cost, Patient's co-pay offer is PNMT $30 with a $100 cap. What if there is a 10% price increase? What will happen to the patient's OOP cost?*

### Market Access Data

Market access data is critical to evaluating and tracking performance of contracts, however working with the data to understand and track performance has its challenges.

### Key Data Sources to Analyze

**Customer claims data** – actual or projected sales from Aetna and other plans (The plans will have to be paid a certain amount on rebates). When the data comes in from Aetna (as an example), it's not ready to be used by the market access team. The data will have to be "scrubbed", taking many hours before it can become useful for deeper analysis. This scrubbing is often done in house, but outside companies can do the scrubbing for a cost.

**Rx data** - IQvia or Symphony Health Solutions (SHS) provide this information including competitive data. It's not very accurate at the local level, so this is something to keep in mind.

**Health plan & formulary data** - Rx's, doctors, patients, formularies, restrictions, etc. can be seen by accessing audits such as those from DRG-FingerTip or MMIT.

The goal is to match claims data, prescription data (IQVIA, SHS) and Formulary data (MMIT and FingerTip Formulary) for a comprehensive view as this is the only way to track and manage the process.

However, significant challenges arise when trying to marry these data sources as bridge files connecting these databases are not very accurate. Brand names, therapeutic classes, market definitions are different across data sources and this creates significant mapping challenges for the analyst.

Ensuring that sufficient resources exist to map and analyze the data is critical for tracking progress!

# Patient Co-pay Programs

## A best practices approach

### The Importance of Co-pay Programs

Co-pay programs have been out in the Pharma mainstream for almost ten years now. It is uncommon these days for any brand to be in market without having a co-pay program being delivered to patients through several different channels (e.g.: Card, Web, E-Prescribe etc.). These programs are even more important now that the percentage of US households with high deductible health plans (HDHP) has passed the 40% mark. This has created large gaps in what used to be a solid market access approach. Brands can no longer rely solely on the forecasted out of pocket costs since such a large percentage of patients will be impacted by deductibles.

The percentage of US households with high deductible health plans (HDHP) has passed the 40% mark. This has created large gaps in what used to be a solid market access approach.

Co-pay programs are especially important for "lifestyle" brands or "non-life threatening" conditions, and even more prevalent for brands with high WAC prices. When a patient walks up to the pharmacy to fill a script and is told that the cost will be $300… it's quite a shock. This is the reason to have a solid co-pay program to help that patient get on and stay on therapy.

Analytics departments and in some cases operational "Centers of Excellence" have led co-pay program design and execution efforts. However, it is primarily the individual brands making their own decisions on co-pay design and vendors and many times upper management does not even establish high level guidelines for the brands to follow. This can create situations where costs can quickly get out of hand or not be counted at all if some of the costs fall in a corporate budget for which the brand teams are not responsible.

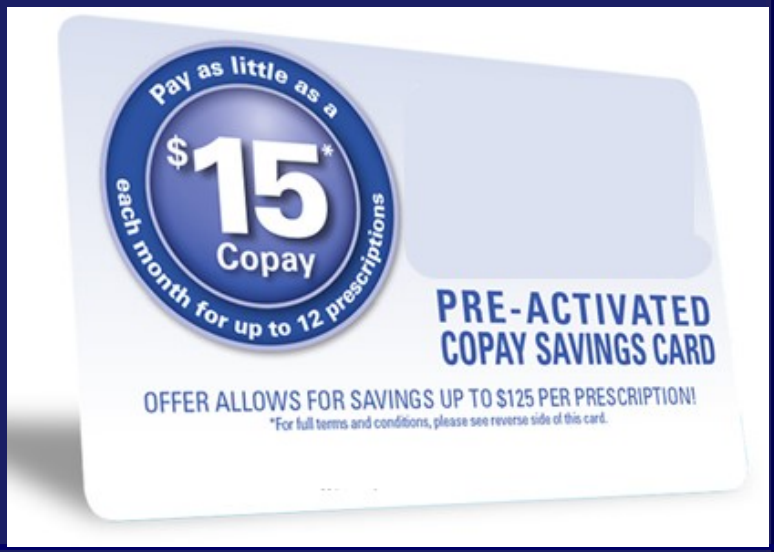
### The Co-pay Optimization Process

Co-pay program optimization requires a solid understanding of the market/competitive situation and past program performance (for established brands) as well as a comprehensive planning and tracking approach. Here are some key steps for best in class co-pay program planning and optimization:

#### Pre-Program Planning

Before the co-pay program can be developed, the team should have a clear understanding of the following:

- **Data** – past history of current programs as well as an understanding of what is happening in the marketplace
- **Brand and program objectives** – what result is needed and what would be considered a success?
  - Incremental volume target
  - Program budget, gross to net (GTN) or margin % that needs to be maintained
  - Increased adherence, trial etc.
- **Impact of HDHP's** (high deductible health plans) on the patient's out of pocket costs




Given the importance and expense of these co-pay efforts, it is important to follow a best in class approach to developing and implementing co-pay programs.

# Planning Your Co-pay Program

## There are many things to consider

### Program Planning Checklist

When planning a co-pay program, the following items should be incorporated:

- Alignment of program structure to the brand's strategic objectives
- Learnings from data analysis (past program performance, competitive information, category trends etc.)
- An understanding of the potential impact of the program on field sales force messaging / execution
- An evaluation of the program's business rules and how the rules selected will impact patients, HCP's, and the bottom line
- An analytical framework to give the brand "situational awareness" on these programs
- A forecast of the expected outcome of the potential offer (s) including running "what if" scenarios to measure impact on incremental volume, adherence, abandonment rates and all other KPI's
- A focus on capturing the abandoning patient = incremental patient = incremental volume
- A qualified 3rd party perspective on the structure of the patient offer
- Measurement criteria and reporting processes to facilitate program tracking and ongoing analysis


In order to face the challenges ahead, your co-pay program planning will need to address how the co-pay program will complement the market access strategy and deliver on brand objectives given where the brand is in its lifecycle.

# The Timeline for Success

## Coordination between the two efforts is key to achieving desired results

### Market Access Planning

### Co-pay Program Planning

*months till launch*

**12**

- Payer list is updated in the market access database
- The Competitive Market Basket is defined for the product
- NCP Dossier is prepared

- RFP to select a co-pay vendor is written
- Vendor presentations are conducted and a co-pay vendor is selected
- Brand and competitive data from clinical trials, market research, brand claims, etc is gathered

**9**

- IQVIA/SHS and MMIT/DRG Finger Tip are contracted for Therapeutic Class
- Bridge Files to connect the databases are created
- Databases are connected and initial reports are made available

- Program objectives are established and analytical forecasting framework is finalized
- Preliminary co-pay strategy including offer options, channels and patient types to include is developed

**6**

- Price is established and market is tested
- Rebates are established for each Segment and tested with Payers

- Co-pay strategy, program budget and objectives are finalized
- Simulations of program offers with different layers of managed care coverage are run

**3**

- Under NDA's start discussion of Formulary Position and Rebates
- Pre-Contract Valuation Analytics are performed
- Cost of Patient Assistance Program is evaluated

- Scenarios and financial planning are completed
- Patient vehicles and quantities are finalized
- Co-pay offers and business rules are finalized
- Co-pay offers for Insured Not Covered (INC) patients are defined

**2**

- Negotiation with Payers begin on Formulary Position and Rebates
- Co-pay program cost is incorporated into Pre-Contract Analytics
- Written contracts are prepared

- Patient educational copy and artwork finalized
- Vendor implementation of program begins
- Educational material, cards and starter kits printed
- Copy for electronic coupons finalized (Relay, ePrescribe, Web)

**1/2**

- Contract Negotiations and Pre-Contract Valuation are continued

- Cards and materials distributed to field and sales force.
- Execution of web offers and electronic coupon delivery tested and finalized

*6 months post launch*

- Post-contract Analytics Valuation is performed
- Non-performer Payers are renegotiated or canceled

- Results evaluated against goals and expectations and adjustments are made as necessary

# So … Where Do You Start?

How should you meld these processes together?

## What Comes First?

If contracting / rebate decisions and related investments are focused on enhancing access and lowering patient cost, and co-pay investment and design/execution are focused on lowering patient OOP costs, the big question is how do these processes meld together and which process / strategy should be done first?

Should either strategy take the lead, or should they be done together at the same time? And who should manage the process?

One thing is certain, the two sides should be linked in analytics, execution, pull through etc. so the teams responsible can see and understand the impact each decision can potentially have on tier coverage, patients, and costs market by market.

There needs to be a clear balance between these two very important areas. Typically, nowadays the market access process comes first and then the co-pay offer design comes later, however, unfortunately most of the time these processes are done independently with little communication between the teams involved.

No matter how large the spending is, pharma employees are often operating in a vacuum without the proper training, data, tools, and visibility into the other side of the equation and this is costing most pharma companies tens of millions of dollars in wasted spend annually.

# Bringing it All Together

## Which combination of market access and co-pay is most efficient?

### Breaking Down the Silos

If a pharma company has invested "heavily" in rebates for formulary position with lower co-pays to start, the co-pay offer should be structured to provide just the remaining level of support needed.

However, today we must also look at the HDHP's to know their impact on the patient's OOP cost at different times of the year. The question remains: which combination of market access/co-pay is the most cost efficient? The answer is that most likely it's a different mix for every brand and a thorough pre-planning, planning and tracking process incorporating the following should be implemented to help ensure success for the brand:

- Train market access teams on co-pay programs and vice versa…. train co-pay teams on market access contracting
- Balance the two initiatives to ensure successful and profitable access. If good access has been achieved, adjust co-pay program structure to provide appropriate support while still achieving profitability goals
- Link planning, analytics, execution and pull through so teams responsible can see and understand the impact each decision has on tier coverage, patients, costs market by market.
- Ensure sufficient analytical resources to properly navigate market access data. Ensure that data from various sources can be properly aligned and mapped
- Understand "formulary cold spots" geographically and consider adjustments to the co-pay program to compensate
- Consider creating one department that oversees both functional areas to help ensure a coordinated effort (i.e. Center of Excellence etc.)
- Implement best in class procedures for both functions as outlined in this white paper. The goal should be to have market access and co-pay programs working closely together for maximum efficiency.

### Working Together

The development of a turn-key solution that addresses both market access rebates and co-pay programs may not come as easily as one would expect as these programs target different audiences with different and often opposing objectives. A rebate program is geared to improving the formulary position of a product so patient out of pocket amounts become affordable. The advantage of a rebate program is that it is fairly focused to the beneficiaries of a specific plan.


On the other hand, co-pay programs are distributed amongst populations which have different health plans, with different formulary positions. So, while the development of a turn-key solution that handles both rebates and co-pays may still be a very difficult proposition, the alternative remains finding an equilibrium point where rebates and co-pay offerings generate the most profitable mix and achieve the desired objectives. Running programs in parallel, using simulation software to run "what if" scenarios and adopting a comprehensive, best in class approach to both sides of the equation as outlined in this white paper will help ensure successful, profitable market access.

# About the Authors

## About Al Kenney and Alpha 1C

### About Al Kenney

Al Kenney has 30 years experience in sales, marketing, and analytics within the pharmaceutical, OTC, food, direct marketing, and software industries. Al's expertise lies in the areas of marketing, sales, business process redesign, data, software application design, program implementation, forecasting, and the analysis and measurement of marketing and sales spending. Al is now applying his knowledge and skills specifically to the pharma and bio-technology industries.

Al is the founder of Alpha 1C, an innovative company focusing on strategic marketing, predictive modeling and measurement. Prior to this, Al spent eight years in the software industry specifically focused on advanced analytics, supply chain, and forecasting. He founded, owned and operated Performance Wave Inc. a software company which also specialized in modeling and forecasting pricing and product assortment for both major consumer goods manufacturers and retailers. Performance Wave was sold in 1999. Later, he served as the General Manager for Demantra Inc., a leading provider of scenario optimization and program measurement software (which is now part of Oracle).

In addition to evaluating thousands of sales and marketing programs across many different industries, Al has analyzed and optimized well over 100+ co-pay incentive programs in over 80+ pharma, bio-pharma, and specialty pharma categories.

### About Alpha 1C

We are marketing, sales, and analytical industry professionals with a deep background in strategy, predictive forecasting, and post event tracking and analysis for sales and marketing programs (with a major focus on co-pay). We have vast experience solving complex problems and providing key insights across more than 20+ core industries. For the last 7 years, we have been focusing our solutions primarily on the Pharmaceutical and Bio-Tech marketplaces.

Alpha 1C provides key insights to brand teams allowing them to make more informed decisions that provide a better ROI. We are known for goals based predictive models which recommend the best options for you based on your stated objectives and budget.

We apply truly innovative thinking and a solid approach to your complex business problems and utilize our easy to use predictive analysis tools so you can quickly identify the information you need to run your business more productively and utilize the most profitable solutions to meet your business goals.

Alpha 1C has unparalleled experience in:

- Strategic Marketing
- Marketing Program Optimization
- Predictive Modeling & Forecasting
- Sales and Marketing Program Measurement and Reporting
- Brand Building

Our work is easily paid for through the efficiencies and insights we bring to your business.

Alpha 1C is headquartered in Sherman, CT and was founded in 2012.

To learn more you can contact Al Kenney at al@alpha1c.com

or call 860-354-7979

# About the Authors

## About David A. Velez and NavAxxess

### About David A. Velez

David has over 40 years' experience in Sales, Marketing and Pharmaceutical Management. A certified Actuary, David spent his initial career developing sophisticated analytical algorithms on Pharmaceutical Consumer Behavior. He obtained an MBA from Columbia University focusing in Marketing, Consumer Behavior and Decision-Making Processes.

David worked 35 years in Merck & Co., Inc. where he had Sales, Marketing and Management Functions. He worked in the international Headquarters of the Company in the areas of Strategic Planning where he developed the first interactive Strategic Planning Models that were implemented worldwide. He then gained experience as Marketing and Sales Director in Argentina, Commercial Director in the Caribbean, and eventually established and became Managing Director of the first operations of Merck in the Former Soviet Union based in Moscow, Russia. Back in the headquarters, David was the founder of the Merck University, and then moved to the US headquarters of the company where he had 15 years' experience in market access.

During his tenure in market access, David was responsible for the Federal Segment and eventually had responsibilities in Medicaid, Medicare and Commercial Segments. He then developed the company-wide Contract Analytics Platform.

In 2012, he was Co-founder and a partner of NavAxxess Health Solutions, a consulting firm dedicated to Market Access Strategy, Segmentation, Account Management, Market Access Training and Contracting Analytics. David has developed state-of-the-art Contract Analytics Platforms focused in Rebate Management and Optimal Market Access.

### About NavAxxess

NavAxxess Health Solutions, LLC was founded in 2012 by a group of highly experienced individuals in the Pharmaceutical Industry and specifically in Market Access. The U.S health care system is the most complex of any industry due to multiple stakeholders with varied roles, incentives and regulations. With the ACA, the soon to be "Trump-Care" and other market-driven reforms, that landscape is constantly changing. The pharmaceutical industry invests heavily in account management and contracted business arrangements with a hope of profitable access and reasonable returns. It is estimated that in 2017, rebates paid to Health Systems exceeded $125 Billion.

Our leadership team has over 100 years' experience managing a wide range of products over the entire health care network and all Market Access' Segments including Commercial Health Plans and PBMs, Medicare, Medicaid FFS and Managed Medicaid, Federal (VA and DoD), and other emerging segments such as IDNs and ACOs. NavAxxess ensures you have the most updated understanding of the market and customer perspective, the right priority by key segment and the strategy, contracting approach and tactics for each to maximize your return. In addition, our team has developed "State-of-the-Art" Market Access Analytics to maximize contract profitability and optimize profitable market access.

To learn more you can contact David A. Velez at DVelez@navaxxess.com

or call 215-422-3120