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In Collaboration with
Rx Solutions

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Out of Pocket Elasticity:

New Situations Highlight the Importance of Understanding Patient Responses to Cost Burden Sharing

Subtle trends in health insurance plan designs are having a profound impact on patient cost sharing burdens. Resulting distortions to the desired encouragement toward cost effective therapies are driving some patients to abandon needed medications while others, either consciously or not, are gaining access to exceptional health plans at non-competitive costs. Circumstances such as these are developing across the complex US health system and patients are becoming more informed and responding to the often perplexing incentives. It has never been more important for pharmaceutical manufacturers to understand the circumstances these patients face.

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A Delicate Balance

Patient access to pharmaceutical products is controlled through an ongoing balance of powers among payers, patients, physicians, and manufacturers. As each constituency pulls the available levers, a healthy equilibrium can emerge in which patients are effectively motivated to begin and remain adherent to the most cost effective therapies. Unfortunately, in other circumstances, disruptions to the complex interplay of pricing, rebates, formulary plan management, out-of-pocket spending, and coupons can have detrimental consequences for both patient health and manufacturer economic performance.

Recent commercial healthcare insurance trends are tilting the balance, and manufacturers need to look closely at how these trends are affecting patients' behaviors, most importantly the motivation to take the final step of fulfilling a prescription.

Many patients never retrieve and take the therapies that they are prescribed. This is bad for the patients, and bad for the manufacturers who have invested enormous sums to discover, develop, and market the medications. Careful observers of the US healthcare system have long recognized the destructive drop-off in patient care that occurs after the patient leaves his or her physician's office. Many patients never make it to the pharmacy, and some that do abandon the process when they are informed of high out-of-pocket payments.

By increasing out-of-pocket burdens, recent plan design trends are driving higher levels of prescription counter abandonment and lower levels of therapy adherence. Moreover, factors deep within an increasing number of plans are driving a surprising, and costly, level of seasonality to patient out-of-pocket responsibilities. Notably, trends toward higher deductibles paired with a consolidation of medical and pharmacy obligations are prompting unexpected patient incentives. Manufacturers must build a greater understanding of how patients' true out-of-pocket responsibilities influence adherence and they must reevaluate their patient support strategies.

Box 1: Why Tiered Copayments are Tiered

Tiered copayments are a well-established component of pharmacy plan designs. These systems are intended to guide patients toward cost effective therapeutic choices. They also enable benefit managers to obtain manufacturer discounts by facilitating competition for attractive formulary positioning. In the best circumstances, an effective tiered copayment system will encourage patients to adopt generic products where they are available and steer patients to lower out-of-pocket costs when therapeutically similar options exist. They can, however, result in high pharmacy counter abandonment rates and associated poor therapy adherence.

Today, managing the information that is needed to calculate a patient's out-of-pocket cost is complex, and few players possess the full picture. When a patient hands a prescription to the pharmacist, he or she initiates an elaborate sequence of financial communications. Insurance eligibility is confirmed, coverage within the primary payer is tested, and, if appropriate, secondary insurance options are identified. Sources of secondary insurance may include Medicare supplemental programs, a spouse's plan, or manufacturer coupon programs. All of these options are designed to offset a patient's out-of-pocket responsibility, but few patients know exactly how they operate. Moreover, the primary insurance provider often receives no information about secondary coverage.

Abandonment – The Outcome of Out-of-Pocket Elasticity

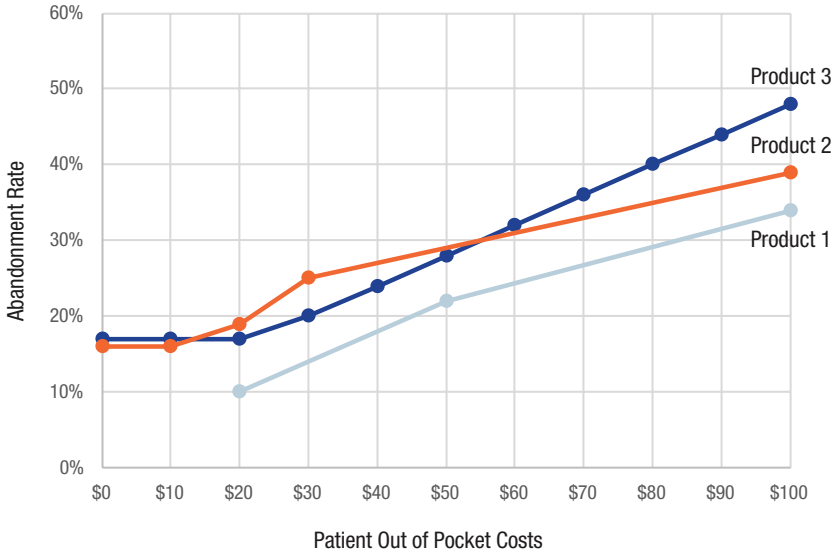
Pharmaceutical reimbursement complexity can make it very hard to understand how copay levels are influencing abandonment rates. Relationships that might be anticipated based on differences in copayments are obscured because some patients rely on secondary coverage and others do not. Instead, it is more important to look at the relationship between the patient's ultimate out-of-pocket costs and the abandonment rate.

In Figure 1 RxSolutions was able to show this relationship using information from some of their programs. In these instances, for the critical range between $30 and $100, every $10 in increased out-of-pocket spending resulted in an abandonment rate increase of 2.5 to 3.5 points.[1]

In Figure 2 we review information from the 2017 Kaiser Family Foundation survey of health coverage. Among the findings, Kaiser reported average copayment levels for products on the second benefit tier at $33 and those on the third tier at $59. Pairing this spread with the abandonment information above, the $26 difference in out-of-pocket costs would be expected to increase pharmacy counter abandonment levels by over seven points if patients relied only on their primary insurance.

Saying this a different way, if 100 patients who do not have access to a secondary means of coverage, have a Tier 3 copayment, approximately 30 will leave the pharmacy without their medication. For 100 patients with Tier 2 copayment, approximately 23 will

Figure 1: Relationship Between Out of Pocket Costs and Abandonment



Source: Rx Sample Solutions

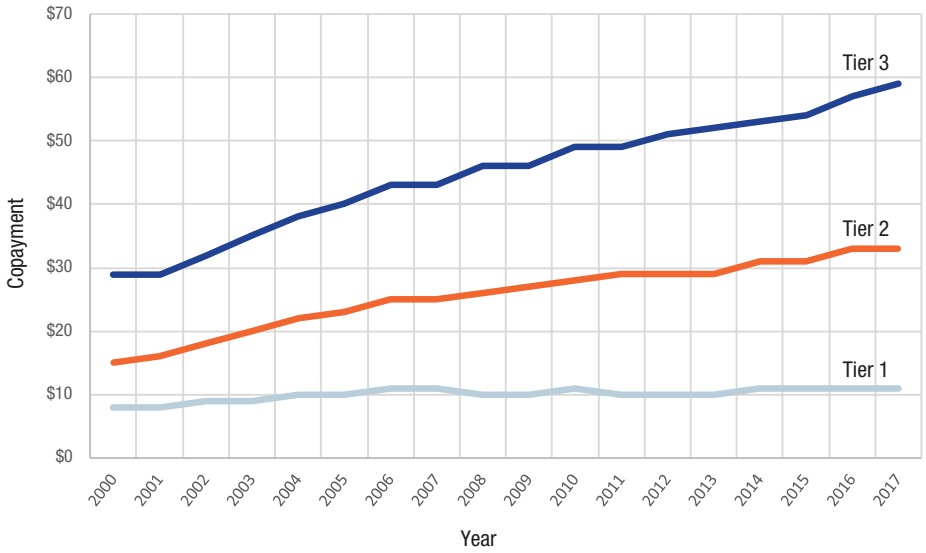
abandon the prescription. For a therapy with 80% gross margins and an annual cost of $4,000, each of those patients represents $3,200 in lost contribution to the manufacturer. More importantly, up to the point where the patient reached the pharmacy counter, the healthcare system had concluded that this was a patient for whom there existed a medical need for the therapy. Extensive reviews of the literature have consistently demonstrated the fundamental role of adherence in achieving the benefits of therapeutic interventions[2,3,4].

Of course, estimating abandonment rate is not as simple as comparing copayment tiers. As stated above, many patients participate in secondary payment arrangements that offset the potential influence of higher patient out-of-pocket costs. Further understanding the out-of-pocket influence requires segmenting patients based on their type of secondary insurance.

First, and most important, patients receiving products or services payable by a Federal health care program cannot benefit from manufacturer copayment couponing. However, patients who participate in other types of coverage such as Medicare Advantage plans may receive offsets to pharmaceutical out-of-pocket costs.

Patients with commercial insurance may benefit from manufacturer couponing programs. Moreover, the greater the patient out-of-pocket responsibilities, the higher the likelihood that manufacturers will offer support - and the more likely patients will access and use these programs.

Figure 2: Average Copayment by Tier



Source: Kaiser Family Foundation, Employer Health Benefits, 2017 Annual Survey

1 Looking specifically at high cost specialty products and using a large database of commercial patients from July 2010 to December 2012, Starner showed a similar, though less steep, relationship between out-of-pocket spending and adherence. Starner, et al. 'Specialty Drug Coupons Lower Out-of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums' Health Affairs, 2017

2 Boswell et al. 'Associating Medication Adherence with Improved Outcomes: A Systematic Literature Review'. The American Journal of Pharmacy Benefits. 2012.

3 Eaddy et al. 'How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review.' Pharmacy and Therapeutics. 2012.

4 Goldman et al. 'Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health'. Journal of the American Medical Association. 2007.

Fast-Moving Disruptions of the Balance

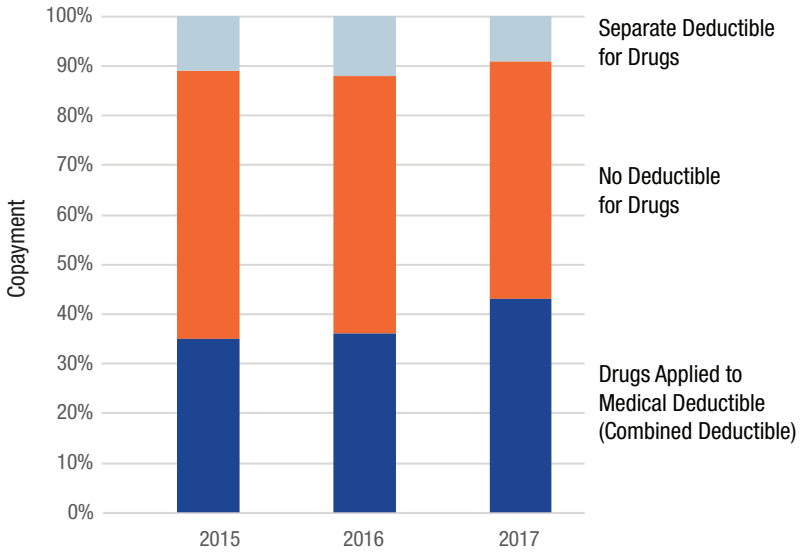
Overall, health plans have been on a steady path of increasing the patient's share of costs. In the background of headline-grabbing increases in premiums, average deductible levels have also been on the rise. The Kaiser Family Foundation reports that almost 30% of all covered workers are now in a high deductible health plan. The family deductible within these plans is often above $4,000. These patients are learning that they must plan annual budgets around substantially higher healthcare spending in the beginning of the year than in the end of the year.

In the past, a patient's insurance coverage for pharmaceuticals was separate from medical benefits. For example, a patient's contribution to copayments for pharmaceuticals was not considered within accumulation of deductible costs. Recently, pharmaceutical and medical deductibles are being combined within high deductible health plans. Figure 3 provides information presented in the *2017 PwC Health & Well-being Touchstone Survey.* It shows over 40% of patients now have combined deductibles.

These trends are particularly important to those patients receiving specialty therapeutic products. These products represent an increasing share of the pharmaceutical market. Before the growth in combined deductibles, many patients were responsible for coinsurance payments that fell in the range of 20-30%, and those costs were excluded from deductable calculations.

Naturally, manufacturers have responded to this system with programs that off-set these high out-of-pocket costs, but it appears they are not getting to everyone. In Figure 4, data are provided showing the average out-of-pocket burden by quarter for two biologic products. Strikingly, the Q1 to Q4 average monthly patient cost varies

Figure 3: Patients with Drugs Applied to Common Deductible



Source: 2017 PWC Health & Well-being Touchstone Survey

Figure 4: Patient Out-of-Pocket Cost by Quarter for Two Biologic Products

Source: This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: SMART US Edition for th eperiod 2016. IMS expressly reserves all rights, including rights of copying, distribution and republication.

by over $25 for one product and by just short of $20 for the other. Combining these observations with the pharmacy counter abandonment rates discussed above suggests that therapy initiation may be thwarted for more than 7% of patients simply because they were prescribed treatment in the first quarter of the year rather than the fourth. Applying an annual cost of therapy of $30,000 and 80% margins, manufacturers are losing $24,000 for every one of these patients.

Box 2: The Low Premiums of a High Deductible Plan Without the High Deductibles

The notion of a high deductible health plan is designed to provide a consumer with an option that addresses catastrophic health events, but does not cover more mundane medical needs. In return for paying directly for routine costs, the consumer is charged substantially lower monthly premiums. Initially the option was most attractive to generally healthy individuals who placed a light burden on the national health system.

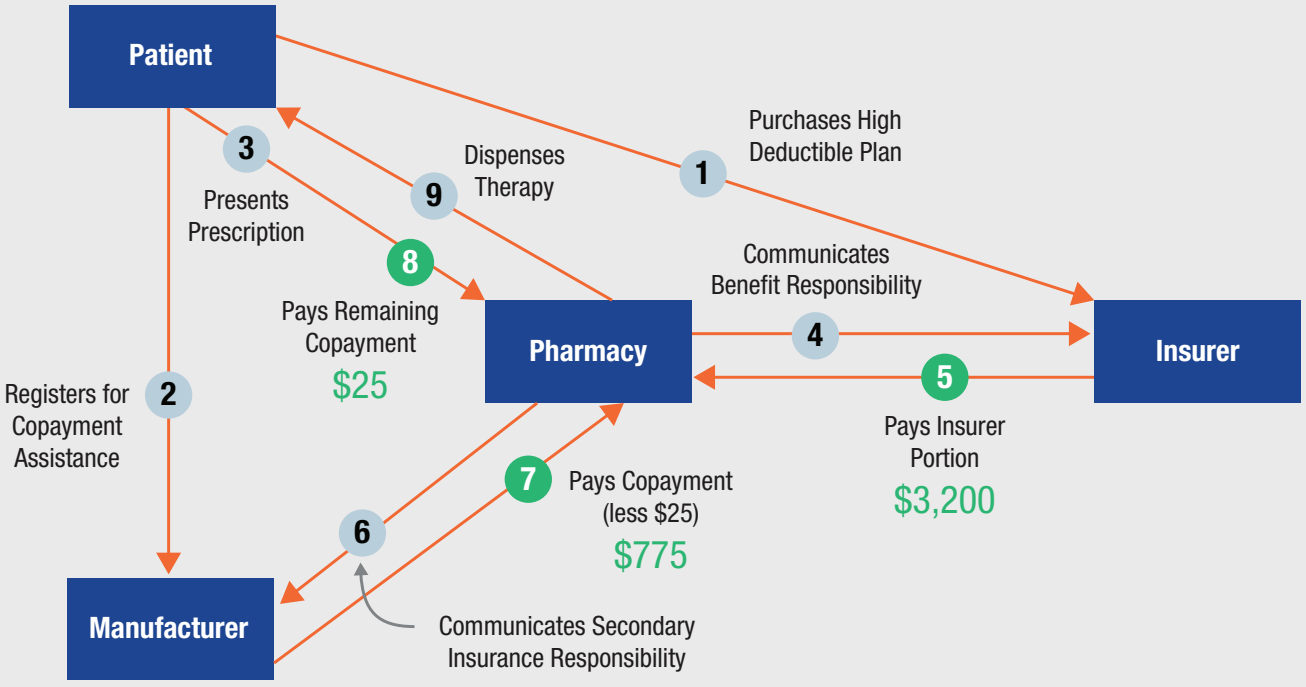
Remarkably, a confluence of new factors is resulting in a situation where some of the highest users of health system resources are gaining access to the low monthly premiums of high deductible plans while bearing little responsibility for the associated out of pocket payments.

Many patients suffering from diseases such as multiple sclerosis, rheumatoid arthritis, and Crohn's disease are young enough to remain on commercial plans, but still represent the high individual patient costs that are more often encountered in Medicare. Being in a commercial plan these patients are not restricted from having their out-of-pocket drug costs offset by manufacturer sponsored couponing programs. For these patients, monthly therapy costs can exceed $4,000. As shown in Figure 5, a series of two-party communications are initiated when such a patient arrives at the pharmacy requesting her first script of the year. If she has a high deductible plan with a combined pharmacy and medical out-of-pocket design and 20% coinsurance for high cost drugs, the patient could be responsible for an $800 payment. However, she likely has a manufacturer coupon assuring that she "pays no more than" $25. In turn, the manufacturer covers $775—but the insurer is not made aware of the source of these funds. Soon, the patient's full deductible is covered. For many patients, these fees quickly exceed the out-of-pocket maximum.

Such a dramatic distortion it truly remarkable, so much so that we questioned whether it represents a theoretical anomaly or if it is really occurring. Given patients' large economic incentives, we concluded they would be anxious to share their knowledge of how to "beat the system" with others. We found confirmation of this hypothesis in several chat rooms dedicated to patients with severe diseases (see Table 1).

Insurers have, of course, taken notice of these distortions. Recently, Blue Cross and Blue Shield of Illinois informed members that copayment support cannot be applied to deductibles. Such "accumulator adjustments" may be the next tool applied in this ever-changing landscape.

Figure 5: Eight Steps to a Dispensed Therapy Reimbursement Example for an $4,000 Prescription with 20% Copayment



Recommended Actions

It is a fairly reasonable assumption that no one in the healthcare system would suggest that the month of first prescription is a medically sound means of guiding product adoption and adherence. Nevertheless, it seems unlikely that payers and manufacturers are going to adjust processes to overcome these emerging distortions. Therefore, manufacturers need to align their patient support programs. Potential actions include the following:

1) Enhance patient support programs to address the increased cost patients experience at the beginning of the year. Quite simply, manufacturers need to provide adequate benefits during the first quarter to stem pharmacy counter abandonment

2) Assure patients receive support when initiating therapy regardless of the time of year. The increased out-of-pocket costs observed in the first quarter result when therapeutics represent a patient's first major medical costs within the year. Newly diagnosed patients on high deductible plans may face a similar burden. Manufacturers need to assure adequate support is provided to overcome the out-of-pocket abandonment elasticity for these patients.

3) Communicate an understanding of the system to patients and physicians. For many patients, the entry into a high deductible plan is new, and certainly, the concept of a combined deductible is unfamiliar to many. Increasingly, such a plan is the only option offered by employers. As shown in Box 2, these systems can have surprising benefits for the patient, but the system is anything but intuitive. Manufacturers will need to step up their already extensive communication programs to assure patients know what to expect from the new plans.

4) Expand awareness of patient economic factors. Changes within US healthcare reimbursement are occurring at an astonishing pace. In 2013, few patients faced a prescription drug deductible of any kind. Now, more than half work within such a plan design. Manufacturers must pair their deep understanding of the patient's therapeutic journey with a similarly robust appreciation for the economic journey. This means knowing where the patient considers cost and understanding how that patient reacts to the demands placed on him or her. Manufacturers must institute regular, deep communication with patients that are designed to learn how they react to today's environment and build understanding that facilitates anticipation of patient response to future changes. This starts by segmenting patients into groups according to their source of primary and secondary insurance. Box 3 provides a high-level depiction of an approach for such a segmentation.

Table 1: Social Media Response to Out-Of-Pocket Incentives

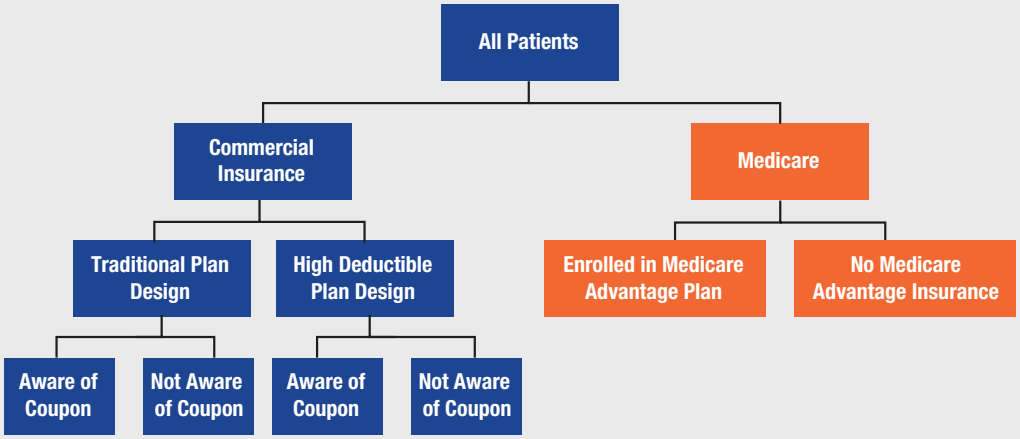
Website	Date	Patient Observation
https://www.reddit.com/r/MultipleSclerosis/comments/3cpqy4/the_benefits_of_tecfidera_and_a_high_deductible/#bottom-comments	July 2015	I'm on Tecfidera, which has a payment-assist program through the manufacturer ***so I don't pay ANYTHING***. So on a monthly basis the charge goes through my insurance - the first month of my plan year Biogen pays my entire deductible ($1,800 this year) then some and they pay co-insurance amount thereafter ($45/month). So pretty much, after my first script is filled I pay peanuts for any doctor's appointments, etc for the rest of my plan year. I just thought I'd share since I'm not sure… **if any of you are scared of high deductible health insurance plans**. I'm kind of stoked about it.
https://www.reddit.com/r/MultipleSclerosis/comments/3cpqy4/the_benefits_of_tecfidera_and_a_high_deductible/#bottom-comments	February 2017	That is how it works for me, I got the copay assistance because my insurance company wanted a 25% copay... I have never paid a dollar for my Tysabri since I started it a year ago. ***How*** **it works, I don't have any idea, I just know that it does, somehow**.
http://www.livingwithpsoriaticarthritis.org	September 2014	The Enbrel copay card is what has kept me on biologic therapy for so long. I have a $4000 deductible so if it wasn't for the card I couldn't afford the medication plus $1200 month premiums for the affordable Obamacare plan! LOL I time it just right **so basically they pay for my entire deductible and OOP**
https://www.reddit.com/r/CrohnsDisease/comments/6pqpcz/insurance_deductible_and_humira_copay_assistance/	July 2017	It is low premium but has a fairly high deductible at $3,000 and prescription aid does not kick in until that deductible is met. The Humira co-pay assistance program, however, will cover something like $9,000 for the first two months. Humira would be 85% covered by this insurance after reaching the deductible, leaving roughly $700 per refill remaining- well below the $1200/month Abbvie assistance limit, **basically leave a low premium, no deductible plan**.
https://www.reddit.com/r/CrohnsDisease/comments/6pqpcz/insurance_deductible_and_humira_copay_assistance/	July 2017	My Entyvio Connect program pays all but $5.00 of the cost of my Entyvio. It also ends up paying my entire $2,000.00 deductible in basically one infusion. Thus, **somehow being on a crazy expensive drug actually ends up saving me a ton of money**.

Box 3: Segment Patients Based on Out-Of-Pocket Economics

Pharmaceutical manufacturers have developed highly sophisticated methods for patient segmentation. Typically, these rely on specification of disease characteristics, level of disease severity, treatment location, and other clinical factors. Steps are also taken to understand at a high level the share of patients that are likely to have insurance that provides access to the product. At times, a perspective will be developed to anticipate the share of patients that will face different copayment levels.

These models need to be extended to better anticipate patients' out-of-pocket responsibilities. For example, as shown in Figure 6, one important separation should be made between patients with commercial insurance vs. those with Medicare (or depending on the product Medicaid). Patients with Medicare coverage are not permitted to use manufacturer coupons, but a large share of them may have Medicare Advantage plans that offset a portion of pharmaceutical out-of-pocket costs. For those patients with commercial insurance, it is a fundamental step to segment patients based on the level of coverage those plans will provide. Given the rapid shift toward high deductible plans, a predecessor step should be added to reflect the breakdown of patients on this dimension. Further, because of the increasing role of manufacturer coupons in supporting patients' cost sharing burden, it is now also very important to anticipate the reach of communication programs designed to make patients aware of the coupon.

Figure 6: Initial Patient Economic Segmentation



About Triangle Insights Group

Headquartered in Research Triangle Park, Triangle Insights Group, LLC is a strategy consulting firm providing guidance on the most critical business issues to leaders in life sciences organizations. The firm's approach combines deep knowledge of the industry across therapeutic areas and functional groups, with a dedication to creativity and disciplined critical thinking. Recommendations from Triangle Insights Group are original, relevant to the industry environment, and supported by rigorous analytics. Clients of Triangle Insights Group include large pharmaceutical companies, emerging biotechnology firms, diagnostics manufacturers, medical device companies, and private equity investors.

For more information about Triangle Insights Group, visit www.triangleinsights.com or call (919) 813-6079.

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Has thirteen years of pharmaceutical and consulting experience. Gautam focuses on providing strategic guidance to clients within life sciences organizations. His recent engagements have involved commercial assessment, indication prioritization, white-space strategy, commercial model design and in-licensing/out-licensing support.

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His previous employers have included GlaxoSmithKline, Boston Consulting Group and Campbell Alliance, where he was a Senior Practice Executive and led business/corporate development efforts for the central region. Gautam received his M.B.A. from the Fuqua School of Business at Duke. He holds an M.S. and a B.S. in Bio-Statistics from UNC-Chapel Hill.

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While at GlaxoSmithKline, Chris's scientific accomplishments led to multiple patent authorships and peer-reviewed publications, as well as discoveries resulting in over $30 million in company cost savings. In business development roles, Chris was responsible for corporate strategy and reviewing in-licensing and out-licensing opportunities. Chris earned an M.B.A. from the University of North Carolina Kenan-Flagler Business School as a member of Beta Gamma Sigma academic honor society. He has an M.S. from the University of Buffalo and a B.S. in Biochemistry from the University of Rochester.

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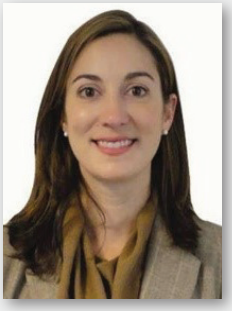
Ben is the chairman of the Life Sciences Sector of the Licensing Executive Society. He has also been a member of the program committee for the BIO International Convention. Prior to the founding of Triangle Insights Group, Ben was the leader of the Business Development Practice at Campbell Alliance and a partner in the Strategy practice at Oliver Wyman (formerly Mercer Management Consulting/Strategic Planning Associates). Ben earned an M.B.A. from the Stanford Graduate School of Business and a B.S. from Duke University.



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His background also includes client-side experience within the pharmaceutical industry. For plasma manufacturer Grifols Therapeutics (previously Talecris), Barrett led market intelligence for the pulmonary franchise including Prolastin-C, an orphan drug indicated for alpha-1 antitrypsin deficiency. Barrett received his M.B.A. from the Tuck School of Business at Dartmouth College. He holds a B.A. from the University of Virginia. He has been a lecturer at several life science industry conferences.