PUTNAM ASSOCIATES

INFLECTION POINT

US Managed Markets

Opportunities and Risks in the Emerging *Appropriate Use* Paradigm

Executive Summary

For years, a mutual perception of conflicting interests has persisted between managed care and pharmaceutical companies: coverage restrictions used by managed care to reduce plan spend are viewed as being at odds with pharmaceutical companies' focus on increasing drug revenues. However, Putnam Associates' recent study of managed care organizations (MCOs) uncovered specific therapeutic areas where interests between pharmaceutical companies and MCOs are actually aligned towards increasing the *appropriate use* of branded prescription drugs.

We define *appropriate use* of prescription drugs as finding the right balance of use by preventing both over- and underutilization of drugs. Managed care is undoubtedly focused on perceived drug overuse in categories like GERD, and will continue to increase restrictions within these categories. Conversely, in categories like cardiovascular health and asthma MCOs recognize that prescription drugs are underutilized. Furthermore, they acknowledge there is unrealized pharmacoeconomic value to be captured by increasing *appropriate use* in these categories.

Pharmaceutical companies can develop strategies to target the categories where their interests are aligned with MCOs. They can build on these alignments to shift discussions concerning their products to value delivered and patient outcomes rather than prices and rebates. Focused use of combined resources on these opportunities can yield greater returns, particularly when physician and patient advocacy are harnessed in support of branded product utilization.

About the Study

A recent Putnam Associates survey of 52 managed care decision makers representing ~124 million privately insured lives evaluated their perceptions of branded drug use in 18 therapeutic areas. We examined overutilization, including patient use of therapy where not medically necessary and patient overuse of agents, and underutilization, meaning untreated patients who should be on therapy, and patients who are on therapy but are not compliant.

Striking the Right Balance

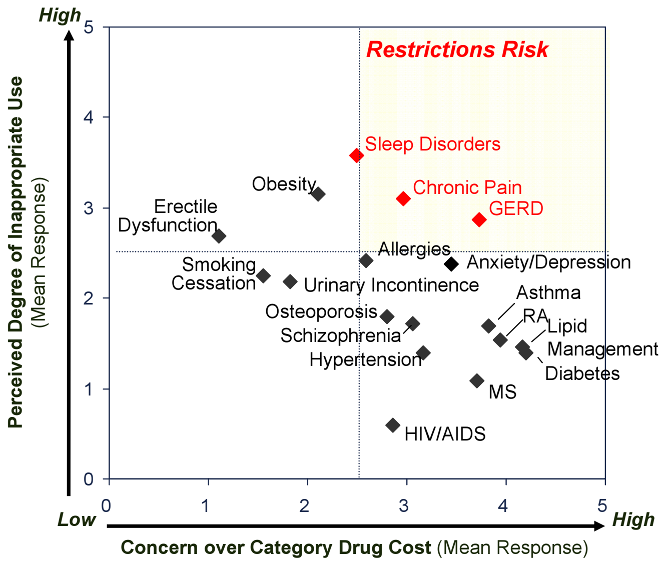
While spending on prescription drugs is rising, pharmaceutical companies are under pressure from an increasingly restrictive managed care environment. Prescription drugs' share of total U.S. health care expenditures is expected to rise from an estimated 10.1% in 2006 to 12.2% over the next 10 years, an increase of ~$300 billion.[1] Furthermore, private health insurers, which accounted for 42% of prescription drug spending last year[2], are expected to pick up a larger share of the bill in coming years. Many worry that restrictions implemented by managed care to curb drug overuse will also decrease the *appropriate use* of branded drugs.

Despite increasing efforts to restrict prescription drug usage, MCOs readily acknowledge not only the existing pharmacoeconomic benefits of drug use across categories, but also the greater potential pharmacoeconomic value than what therapies are currently achieving. On average, MCOs estimate as much as 38% of total potential pharmacoeconomic value is not being captured by available branded drugs (even when branded pricing is accounted for).

Perceived Appropriateness of Drug Use

	Restrictions Risk (Overuse) Categories	Growth Opportunity (Under Use) Categories
Criteria Explored:	• Inappropriate patients on therapy • Patient overuse of agents	• Appropriate patients not on therapy • Patient non-compliance
Drug Categories:	• Sleep Disorders • Chronic Pain • GERD	• Hypertension • Asthma • Lipid Management • Anxiety/Depression • Schizophrenia • Diabetes • Smoking Cessation • HIV/AIDS

Appropriate Use High Concern Categories



Promoting *appropriate use* can allow plans to access the untapped pharmacoeconomic potential, and by engaging MCOs, pharmaceutical companies can help shape their perceptions of current branded drug use in each therapeutic area.

Categories at Risk

Not surprisingly, we found that MCOs perceive considerable overuse of branded drugs across many therapeutic categories. In particular, the majority of MCOs believe there is significant overuse in five categories: sleep disorders, chronic pain, obesity, gastroesophageal reflux disease and erectile dysfunction. Three of these categories – sleep disorders, chronic pain and GERD – also received high ratings for MCO cost concerns. This suggests that pharmaceutical manufacturers can expect increasing MCO restrictions in these categories.

Identifying Win-Win Growth Opportunities

Unexpectedly, our study revealed several therapeutic areas where MCOs perceive significant under use of branded drugs and are interested in increasing *appropriate use*. MCOs have considerable stake in improving clinical and pharmacoeconomic outcomes. They recognize that correcting under use of prescription drugs and non-compliance in specific therapeutic areas can contribute to better patient outcomes and an improved bottom line.

Plans highlight concerns of underutilization in the following categories: hypertension, asthma, lipid management, anxiety/depression, schizophrenia, diabetes, smoking cessation and HIV/AIDS. Promotion of increased *appropriate use* in these categories presents clear market expansion opportunities for many pharmaceutical companies in alignment with managed care's interests.

Cost of Expanding *Appropriate Use*

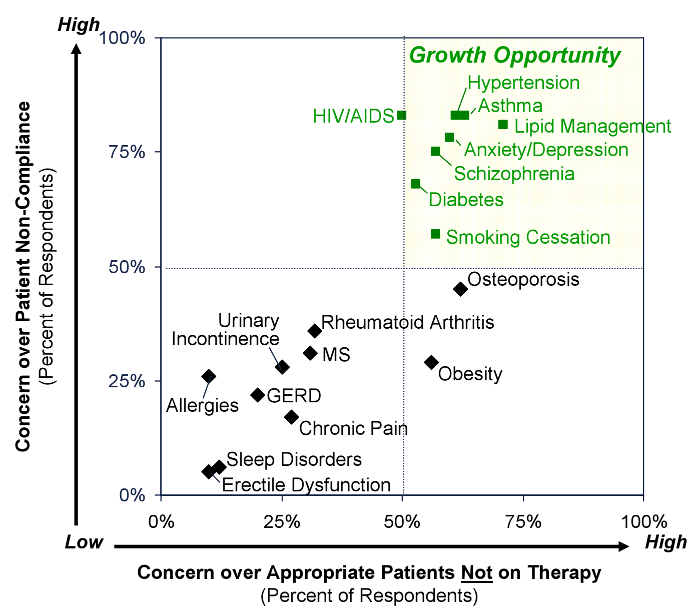
Whether working independently or with managed care, pharmaceutical firms are constantly considering the cost of reaching physicians and patients to impact their prescribing and usage behaviors. The time and money required to get incremental patients on therapy is high. It can cost from hundreds to thousands of dollars to enlist each additional patient depending on the disease and other market factors. Thus, some patient or physician segments will not be worth the investment required to pursue them.

In order to drive market expansion where under-treatment is a concern, pharmaceutical companies will need first to determine what prevents patients from getting the therapy they need by identifying where any breakdowns are occurring in access and compliance. Companies can then evaluate the cost of reaching these patients and getting them on appropriate therapy. In this process, consideration must be given to the cost of working independently versus seeking the coordinated involvement of multiple stakeholders.

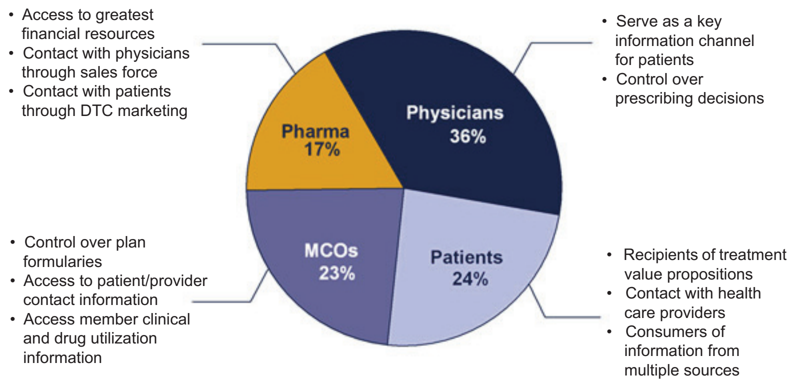
Pursuing Common Goals

MCOs acknowledge that every stakeholder has a role to play in promoting *appropriate use*. When asked to estimate each stakeholder's importance across a 100-point allocation, MCOs assigned pharmaceutical companies the smallest role (17%). The remainder of the burden is shared by doctors (36%), followed by patients (24%) and MCOs (23%). However, expanding awareness and increasing appropriate drug use are expensive tasks, and pharmaceutical firms possess the greatest resources and motivation to change the status quo. This reality positions pharmaceutical companies to identify market expansion potential, assess revenue opportunity, and develop coordinated strategies for realizing this growth.

Appropriate Use Growth Categories



Key Stakeholder Roles and Resources



Pharmaceutical companies can take steps to identify revenue opportunities where market expansion aligns with the interests of other stakeholders. In doing so, they will find themselves better positioned to leverage the resources available through all stakeholders, and thereby reduce the cost of incremental patient acquisition. However, while collaborative efforts between stakeholders provide more efficient use of combined resources, they are often met with skepticism – particularly between managed care and pharmaceutical manufacturers.

We have seen pharma-sponsored proposals for programs around enhancing patient treatment and compliance run into insurmountable barriers before ever making it off the ground. While these manufacturer proposals are focused on patient care – and thus attuned to MCO concerns – they are often presented in categories where the incentives of manufacturer brand teams and MCOs are more likely to be fundamentally misaligned (i.e., where MCOs are more focused on reducing branded drug overuse). Often in these cases, MCOs keep their distance either because of the reality of their conflicting interests with pharmaceutical manufacturers, or because of an inherent distrust of working with manufacturers.

Our analysis leads us to conclude that incentives *are* aligned in particular categories, and suggests opportunities that have not been fully leveraged. With better category targeting and initiative design, greater cooperation between manufacturers and MCOs may yet reshape the dynamic of particular categories – but only in particular categories. One key step both manufacturers and payers will have to take for these initiatives to succeed will be to work cooperatively on goals and *appropriate use* where they can and to "agree to disagree" where they cannot.

Conclusion

Putnam's findings highlight therapeutic categories with potential market expansion opportunities for branded drug manufacturers. They further show unexpected and non-obvious places where interests are aligned between pharmaceutical companies and managed care organizations. Exploring these opportunities may allow pharmaceutical manufacturers to engage MCOs in conversations on a different level than in the past. By pursuing such win-win opportunities, stakeholders can take advantage of pooled resources and lower their individual costs of increasing *appropriate use*. Ultimately, win-win opportunities around *appropriate use* do exist – it is a matter of finding them with the right products, in the right therapeutic areas, and pursuing them with the right strategies.

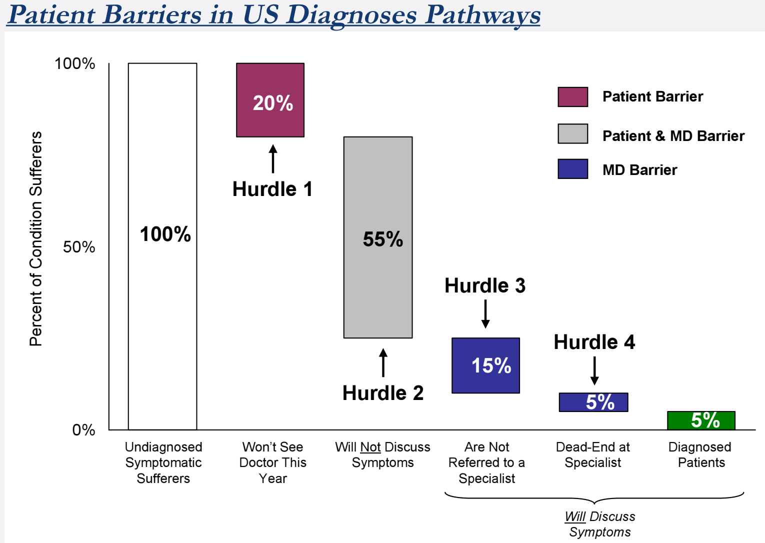
References
[1] Centers for Medicare and Medicaid Services, Office of the Actuary.
[2] Ibid

Expanding *Appropriate Use*: A Case Study

The recent experience of one Putnam Associates client illustrates the financial value and process of increasing *appropriate use*. The company has a product for a widespread chronic condition that is significantly underdiagnosed and is associated with high costs of secondary health complications. Putnam found that low disease awareness was a large barrier, with 90% of undiagnosed patients either unlikely to visit a doctor (20%), discuss key symptoms if they did see a doctor (55%), or be referred to a specialist (15%).

Our analysis determined that detailing primary care physicians would be too costly and likely take longer than marketing directly to appropriate patients. Turning next to patients, we segmented the patient population by co-morbidity. We evaluated each segment by potential revenue, the difficulty of reaching the segment, and patient

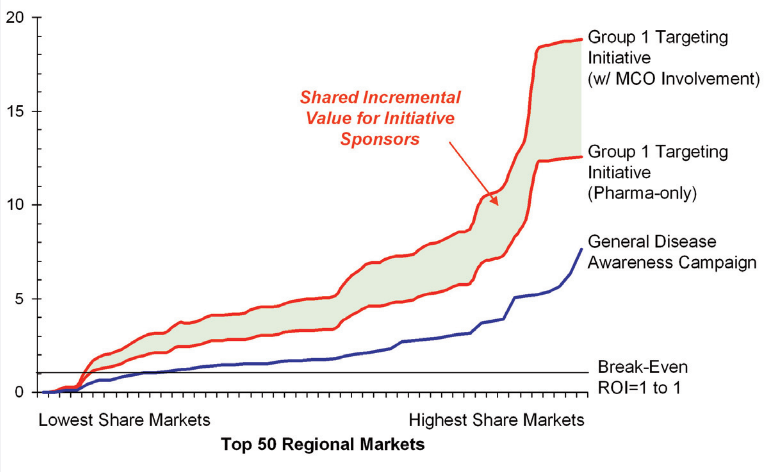
Patient Barriers in US Diagnoses Pathways



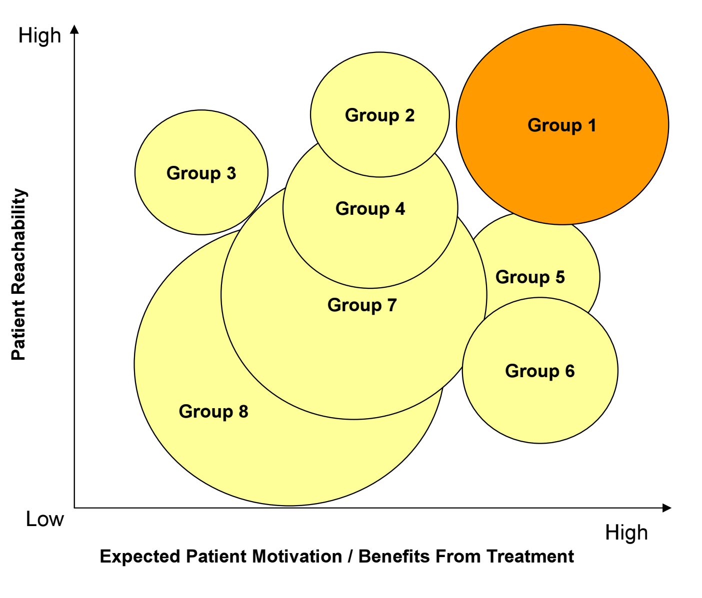
motivation. We found that patients in Group 1 were the best segment to target. They were the most likely to get the greatest health benefits from treatment, and they could be reached most economically. Group 1 was also the third-largest patient segment in terms of having significant overlapping co-morbidity with the targeted condition.

We then benchmarked several disease awareness campaigns for their effectiveness, test-marketing them to people whose demographics were highly comparable to those of the target population. We analyzed the profitability of disease awareness campaigns in each of the top 50 U.S. regional markets, comparing general awareness campaigns to campaigns targeting patients in the previously identified Group 1 segment. Assuming a constant market share for our client's product, we found that launching a general disease awareness campaign would be profitable in 82% of the top 50 U.S. regional markets (i.e., ROI greater than 1), and that a targeted campaign would be profitable in 90%. Furthermore, if our client were to act alone, we identified the ROI opportunity to be as high as 15 to 1 in regional markets where market shares were highest and consumer initiatives were most attractive.

Estimated Gross Profit Returns on Consumer Initiative



Segmentation Mapping: Targeting by Reachability and Motivation/Benefit



However, if our client were to jointly pursue a targeted campaign with MCOs in the designated regions, the expected maximum return to be shared by our client and the MCOs would exceed a unilateral client initiative by as much as 50%.

Based on the study findings, the company piloted a disease awareness campaign to refine its messages and tactics. It targeted Group 1 patients and used a secondary campaign to increase the number of patients going directly to a specialist. Because market leaders are likely to capture more new patients than competitors in a broad market expansion, we recommended that the company target its primary campaign in geographic areas in which it had a high market share. Following the conclusion of Putnam casework, our client's FY2006 annual net product sales growth rate exceeded FY2005 growth by over 60%.

About Putnam

Putnam Associates is a strategy consulting firm focused exclusively on the health care field. For nearly two decades, we have been helping pharmaceutical, biotechnology, medical device and diagnostics companies create strategies that maximize the revenue and profitability of their products throughout their lifecycles.

For more information about Putnam's services or to discuss US Managed Markets issues contact Richard Tinsley, Partner at rtinsley@putassoc.com. Special thanks to Mina Khosravi, Senior Associate Consultant, for her contributions in research and writing for this article.

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