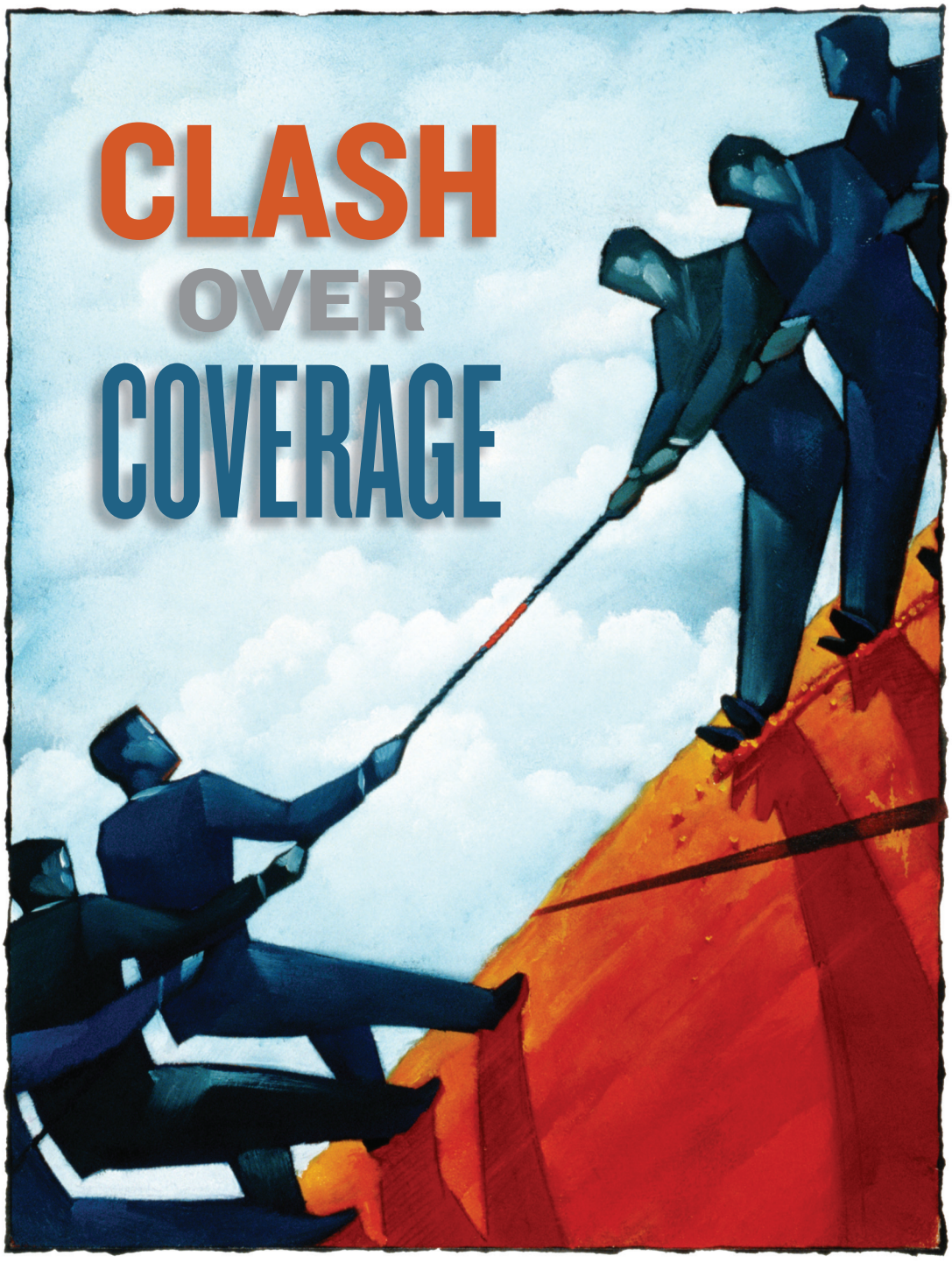

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Manufacturers launching products into ever more powerful managed markets will find that contracting strategy is a tug of war between the product's value proposition and a payer's desire for cost effectiveness. **Kevin O'Leary** and **Gerhard Gallwitz** explain why some managed-care contracts yield better results than others

Due to increased payer management and the anticipated effect of comparative effectiveness research, pharmaceutical manufacturers in the US market are being forced to winnow their development pipelines to those compounds that offer a clear and compelling benefit over existing treatments. Manufacturers are making "no-go" decisions on me-too products to focus their resources on compounds with the potential to be true therapeutic breakthroughs, or at the very least, to offer clear differentiation from what is already on the market. This will create a very different market bereft of nth-to-market entries that served both as solid revenue producers for manufacturers and as competitively priced products attractive to payers.

To the extent that companies have begun to develop only those products that providers and payers will embrace, they've taken the first all-important step toward ensuring that their launches continue to be successful. Assuming that a product has intrinsic value to patients, physicians and payers, there is much that companies can do to improve their success in launching into a managed-market environment, as covered below.

Managed-care organizations (MCOs) already have a substantial effect on US industry performance in general and on new product success in particular. Consider that nearly 90% of all US retail prescriptions are covered by third-party payers (both public and private). Pharmas spend 10-15% of their gross sales on payer rebates and discounts. And according to the 2009 IMS Launch Excellence Study, the success of a newly launched product in the US now has as much to do with managed-care contracts as with prescriber engagement.

Unfortunately, most companies are not yet getting optimal results from their managed-care contracts on new (or established) products. This is not for lack of trying; they've simply not had the information required to understand payer influence, the net value of individual contracts and the reasons some yield better returns than others, as covered below.

Managed care on steroids

As more than 30 million Americans gain health insurance coverage through the Patient Protection and Affordable Care Act (PPACA), the reach and influence of managed care will only intensify. The Congressional Budget Office estimates that half of those newly insured will be covered by Medicaid, with the remainder covered by commercial plans sold through Benefits Exchanges.

The healthcare reform program will encourage MCOs to consolidate in order to realize economies of scale, spread risk across a broader insured pool and increase their leverage in negotiating better deals with providers. As a result, manufacturers will be negotiating fewer contracts. But, each of those contracts—including those with the government—will have an even more pronounced effect on product performance. Failing to get a preferred position with one organization could cause a dip in market share at the national level and a dramatic drop in certain regions where that plan is dominant.

And, with the projected growth of Medicaid, the spillover effect on physician prescribing for patients covered by commercial plans and Part D could be significant, though not uniformly so. Some geographies are bound to be affected more than others, depending upon how dominant the Medicaid plan is in a given state.

Thus, companies with upcoming launches are facing:

- A complex, localized payer environment that requires extensive analysis in order to know where and how to structure contracts.
- Complicated pricing considerations that must take into account their product's degree of differentiation, the likely cost of access, different sales channels, and mandated discounts in government programs, to arrive at a net revenue projection. The days of creating a forecast by arriving at a wholesale price and multiplying it by the number of units that one expects to sell are over.

Consequently, manufacturers need to be more strategic in their contracting, and the most effective strategy will be different for every company, product and portfolio. The following is a broad outline of the work that needs to be done.

Demonstrate compelling value

Companies must first gather insight from payers on what would constitute sufficient value in a new product to warrant favorable coverage and what clinical evidence will convince them of that value. Manufacturers must then create Phase-III trial programs that produce proof of incremental benefit for defined populations that are inadequately treated with existing therapies. This means that trials must be designed with sufficient patient numbers to accommodate possible sub-analyses of specific populations to prove specific or differential value propositions. Understanding unmet needs in

Traits of Excellent Managed-Market Launches

Launches into managed-care environments succeed when they:

Begin with a powerful and pertinent value proposition. This requires that the trial design strike the right balance between regulatory requirements and payer concerns. This is not just a matter of trial size, but of also applying a pragmatic and nimble approach to developing the value proposition across a broad set of criteria.

Engage stakeholders (most significantly payers) effectively and efficiently. Excellent launches are built on in-depth insight on what payers want in every country, gathered in time to genuinely influence how the product's value proposition is developed. Manufacturers can contract judiciously when they have done the analysis to understand the value of individual contracts, considering co-pay structures, the formulary position, the competitive situation and the spillover between programs. And, of course, the companies that can engage stakeholders most effectively are those that have adopted a commercial model that takes into account the mixed payer model at the regional level.

Proceed with an aligned and prepared organization. The best launches evolve from multi-disciplinary teams assembled from Phase IIb onward. In the most successful cases, senior management communicates the values for the launch and sets the guidelines, leaving the detail to the launch team. The launch team works from a common, agreed-upon vision of the product and uses tools to aid decision making, ensure consistency in global/local launch readiness, and performance tracking, both pre- and post-launch. Earlier country involvement in developing the global plan is also a growing best practice, although most companies struggle to mobilize countries much before 12 months pre-launch.

Source: 2009 IMS Launch Excellence Study of 1,388 promoted products launched between 2006 and Q1 2009 in US, Japan, France, Germany, Italy, the UK, Spain and Canada

treatment and what clinical differentiation matters to providers, patients, and payers is also critical in determining a product's launch price and whether it can sustain a premium price. But a lower price cannot stimulate uptake of a product that does not offer equal or incremental benefit over existing treatments.

Assemble the right team

To create an effective launch strategy, a company should bring together all those who will have a hand in the brand's commercial success, including members responsible for brand strategy, managed-care strategy, government and commercial payer contracting, pricing, health outcomes and economic research, account management, payer marketing and market analytics. Ideally, this multi-disciplinary team would begin its planning two years prior to launch—a full year earlier than is typical.

Before a comprehensive launch strategy for managed markets can be developed, the team will need to:

- Understand the product's value proposition to patients and physicians. If physicians are not excited by a new product, payer influence is of little import.
- Measure and understand the influence of all payer types for analogous products in the therapeutic class in question. The results of this analysis could steer the launch strategy dramatically. While payers don't generate demand for a new product, they can inhibit its uptake.
- Using product analogs, measure and understand the effect that a specific position on a managed-care formulary has on the plan's ability to drive share. While this is done routinely at a national level, it now needs to be done regionally to address differences in competitive conditions.
- Understand the influence employer groups have on the price patients will pay for each product, and how that impacts volume and share.
- Identify sites of care, how reimbursement differs in each, and how those incentives will affect utilization of a new product. Does decision making align with price sensitivity, or is the decision maker insulated from cost? The answers to these questions will affect pricing and contracting strategies.
- Devise different strategies for each channel. The approach for commercial payers may be different than for Part D and government customers. Further, a product's status in Medicaid may affect prescriber behavior when treating patients covered by other payers, so the team needs to model potential spillover before landing on an approach to Medicaid.

Determine the optimal price

While this topic warrants its own treatise, the most important point is to incorporate input from payer research into the initial pricing policy. A disconnect between a manufacturer's and payers' expectations about price and discounts can create obstacles to uptake and inhibit success.

Pricing models should incorporate some logic on relevant benefit design options and on how competitive products are positioned on regionally important formularies. Potential value to the payer may still be supplied through rebate and coupon programs, although they may reduce actual net price. Again, product differentiation determines whether the manufacturer or payer is in the driver's seat when it comes to determining formulary access. The overall contracting strategy is driven by this balance of power and negotiating leverage.

Develop a regional contracting strategy

The next step is to develop a regional contracting strategy that segments payers, given the competitor's position and the dollar volume generated by each payment type. In the process, it is important to analyze the regional and local differences in the benefit designs and co-pay structures that are offered by each payer to determine if contracting for a specific tier will produce the gains expected. The analytics described above will play a key role in both targeting payers

Seven Managed Care Pitfalls

The seven most common mistakes manufacturers make when deciding whether to offer a rebate to a payer in exchange for improved formulary access:

1. **The control fallacy**—Payers cannot influence the behavior of the physicians it reimburses. Thus, extending a rebate to the payer has no impact whatsoever on prescription volume and as such is a waste of money.
2. **Ruinous restrictions**—The deal improves the tier status of the drug, resulting in a lower co-pay, but leaves restrictions (e.g., step therapy, prior authorization) unchanged. Such a deal does not provide any relief to hassle-averse physicians.
3. **Looks good on paper**—The deal is struck because it is "too good to pass," regardless of manufacturer's ability to deploy reps to leverage the "win"; like buying half-price tickets to a sports game that you cannot attend.
4. **The patient burden**—Patient assistance is left out. Instead of a rebate, manufacturers can lighten patient burden by offering buy downs, coupons, discounts and free-trial certificates directly.
5. **Spillover**—Ignoring spillover, the "free ride" a drug enjoys from other payers that reimburse physicians who are also reimbursed by the payer in question. Physicians remember that a drug is hassle-free and/or does not incur a high co-pay but do not remember for which payer(s) that holds true.
6. **Final hammer blow**—Credit only the last hammer blow for breaking the stone. Improving drug access through contracting works because of multiple payer deals, with the last one convincing the physician that this is the drug of choice.
7. **One-off mindset**—A "portfolio deal" approach may be more appropriate in instances where the deal can help lower the cost of improving formulary access of other drugs in the portfolio.

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and negotiating with them from a position of strength.

Prior to launch, manufacturers should prepare for plans' Pharmacy and Therapeutics (P&T) Committee reviews, which typically take place within six to nine months after FDA approval. Usually, this is done according to payers' twice-yearly review cycle, although exceptions can be made for exceptional products. A payers' first goal is to make a clinical assessment and decide whether a product is a "may add" or "must add" to the plan's formulary. "May add" products then move into a second stage, which is a financial assessment and contract negotiation.

The P&T review process is a company's opportunity to discuss with a skeptical—but objective—audience such topics as the product's clinical benefits, the pricing rationale in the context of health economics and outcomes research findings, formulary positioning and how the payer might support or restrict the uptake of the product upon launch.

The ongoing challenge for manufacturers is to view payers as customers and to find creative ways to make the arrangement mutually beneficial. For example, the parties could work together to ensure that only appropriate patients receive a drug, consistent with the approved label. Risk-sharing agreements have been elusive in the US market, for a variety of reasons, but will likely become more important down the road. In addition, payers have found it helpful to see the utilization statistics that manufacturers have gathered as a by-product of the contracting process. It can be instructive for a payer to see, for example, that a contracted product in a low-control plan has exactly the same market share as in the high-control plan, creating less of a mutual advantage.

Target key plans by region

Companies can actually identify the plans—and the specific benefit designs—that correlate most closely with market-share movement. They can draw on this knowledge in targeting only those plans/benefit designs that will give them a positive ROI and then in negotiating wisely. Manufacturers should be willing to walk away from a contract that does not make financial sense, though this is difficult to do when the sales force is pleading for a preferred position.

It is then possible to segment and target physicians in a territory based on the payer plans that are reimbursing prescriptions for their patients. Specific "payer messages" related to a product formulary position and associated co-pay levels can be delivered via the sales force to create pull-through demand. A well-integrated pull-through plan is essential to capturing the full potential of a contract, and it is important to set objectives for the sales force consistent with it. Everyone should have a stake in making the most of a contracted position. Still, there is a need for "classical" approaches to building demand and encouraging physician uptake. In the US market, it remains a balancing act.

Monitor for compliance, manage for optimal ROI

With robust information on formulary position, benefit design, and patient co-pay, companies can assess the degree to which MCOs are upholding their contractual obligations. Account executives should keep their customers informed about this performance so both parties get what they bargained for and are not surprised when rebate payments are made.

Ultimately, companies can use this performance information to determine how best to spend their contracting budget in the future; they can home in on those plans/benefit designs that can influence market share and drive business. In the best scenario, companies are rewarded for their years of research, planning, and negotiations with a launch plan that secures market access through regionally-based, managed-care contracts and spurs brand adoption through a synchronized field-sales effort. In those cases where manufacturers are unsuccessful in negotiating the desired formulary tier status or access, the game changes to one of working around payer obstacles with a completely different set of strategies. ■

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Selling in a Third-Tier World

Payers are struggling to balance rising demand against rising costs. Restrictions on access to tier-3 brands are increasing. Here are some suggestions when selling into a third-tier world:

■ Appreciate what healthcare reform really means to your key accounts. One Blues plan representative said, "Pretty much all of our resources…are focused on…how we are going to manage our business in this new post-healthcare reform environment—there's little appetite for anything that doesn't support these imperatives."

■ The brass ring for managed-markets customers is cost-of-care savings through clinical quality improvement (QI). Ask yourself how to expand your brand-service offerings to support healthcare QI, disease management and other medical-management initiatives.

■ Look hard at your value proposition from each major payer's perspective. Your brand is on tier 3, but can you create a "defensible" value proposition for tier 2 access for a subset of the targeted patient population, via in-depth interviews with select plans?

■ Can new technologies and new media increase redemption rates for your co-pay assistance/savings programs among target populations? Data exchange via smart and standard cell phones can link patients with programs at the drop of a text message—just when patients are at critical decision points.

■ Optimize the provider conversation. Field personnel who are less confident with "managed-care speak" are less likely to address and diffuse physician objections around step edits and co-pay levels. Skill development initiatives between POA meetings and real-time information sharing among key account managers and sales personnel will help the sales team resolve these concerns.

■ Share provider feedback with payer customers. Timely and relevant insights you gather through sales and marketing efforts could present opportunities for your account managers to offer added value to a payer's provider-relations activities.

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